

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEETING OF THE
ORTHOPEDICS AND REHABILITATION
DEVICES ADVISORY PANEL
PMA P020033
INDEPENDENCE iBOT 3000 MOBILITY SYSTEM
INDEPENDENCE TECHNOLOGY

Wednesday, November 20, 2002

9:35 a.m.

Walker/Whetstone Room
Gaithersburg Holiday Inn
2 Montgomery Avenue
Gaithersburg, Maryland

C O N T E N T S

AGENDA ITEM:	PAGE
MORNING SESSION:	4
Call to Order	
Dr. Michael J. Yaszemski, Chairperson	8
Open Public Hearing (No Speakers)	9
Sponsor Presentation	
Jim O'Donnell, Vice President, Regulatory Affairs, Independence Technology	11
Susan Eichler-Huston, Manager, Regulatory Affairs	16
Dr. Heikki Uustal, Johnson Rehabilitation Institute, Edison, New Jersey	27
Jean Minkel, PT, Minkel Consulting, New Windsor, New York	54
FDA Presentation	
Robert J. DeLuca (Engineering)	63
Captain Marie A. Schroeder (Clinical)	77
Panel Presentations	
Dr. Joel Myklebust (Preclinical Review)	91
Gary Fenical (Electromagnetic Compatibility)	94
Dr. Kinley Larntz (Statistical Review)	100
Dr. Steve Stiens (Clinical Review)	102
General Panel Discussion	114
AFTERNOON SESSION	
General Panel Discussion (Continued)	151
Vote	258
Adjourn	310

1 P R O C E E D I N G S

2 MR. DEMIAN: Good morning, and welcome.

3 We are ready to begin this meeting of the
4 Orthopedic and Rehabilitation Devices Panel.

5 My name is Hany Demian. I am the
6 Executive Secretary for this panel.

7 I would like to remind everyone that you
8 are requested to sign in on the attendance sheets
9 which are available outside the doors. You may
10 also pick up an agenda and information about
11 today's meeting, including how to find out about
12 future meeting dates through the Advisory Panel
13 phone line and how to obtain meeting minutes or
14 transcripts.

15 I will now read two statements that are
16 required to be read into the record, the
17 Appointment to Temporary Voting Status Statement
18 and the Conflict of Interest Statement.

19 "Appointment to Temporary Voting Status."

20 "Pursuant to the authority granted under
21 the Medical Device Advisory Committee Charter dated
22 October 27, 1990, as amended on August 18, 1999, I
23 appoint the following individuals as voting members
24 of the Orthopedic and Rehabilitation Devices Panel
25 for this meeting on November 20, 2002: Blake

1 Hannaford, Joel Myklebust, Gary Fenical, Kevin
2 McQuade, Ann Buzaid, Steve Stiens, Gary Abrams, and
3 Robert Goldman. For the record, these individuals
4 are Special Government Employees and consultants to
5 this panel or other panels under the Medical Device
6 Advisory Committee. They have undergone the
7 customary conflict of interest interview and have
8 reviewed the material being considered at this
9 meeting."

10 This is signed by the Director for CDRH,
11 Dr. David Feigel.

12 The second statement is the Conflict of
13 Interest.

14 "The following announcement addresses
15 conflict of interest issues associated with this
16 meeting and is made part of the record to preclude
17 even the appearance of any impropriety. To
18 determine if any conflict existed, the Agency
19 reviewed the submitted agenda for this meeting and
20 all financial interests reported by the Committee's
21 participants. The Conflict of Interest statute
22 prohibits Special Government Employees from
23 participating in matters that could affect their or
24 their employer's financial interest. However, the
25 Agency has determined that the participation of

1 certain members and consultants, the need for whose
2 services outweigh the potential conflict of
3 interest involved, is in the best interest of the
4 Government."

5 "Therefore, a waiver has been granted to
6 Dr. John Kirkpatrick for his interest in a firm
7 that could potentially be affected by the panel's
8 recommendations. The waiver involves a
9 stockholding in a parent company of the PMA Sponsor
10 and allows him to participate fully in today's
11 deliberations. His stockholding is valued between
12 \$5,001 to \$25,000. Copies of his waivers may be
13 obtained from the Agency's Freedom of Information
14 Office, Room 12A-15 of the Parklawn Building."

15 "We would like to note for the record that
16 the Agency took into consideration another matter
17 regarding Ms. Ann Buzaid. She reported an interest
18 in a firm at issue, but in matters not related to
19 today's agenda. The Agency has determined
20 therefore that she may participate fully in all
21 discussions."

22 "In the event the discussions involve any
23 other products or firms not already on today's
24 agenda for which an FDA participant has a financial
25 interest, the participant should excuse his or

1 herself from such involvement, and the exclusion
2 will be noted for the record. With respect to all
3 other participants, we ask in the interest of
4 fairness that all persons making statements or
5 presentations disclose any current or previous
6 financial involvement with any firm whose product
7 they may wish to comment upon."

8 Before turning this meeting over to Dr.
9 Michael Yaszemski, I would like to introduce our
10 distinguished panel members who have generously
11 given their time to help FDA in matters being
12 discussed at today's meeting and other FDA staff
13 seated at the table. So we'll just go around the
14 room and ask you to give your name, your
15 affiliation, and your area of interest.

16 Mike?

17 DR. YASZEMSKI: Michael Yaszemski, Mayo
18 Clinic, Rochester, Minnesota. I am an orthopedic
19 surgeon and a chemical engineer.

20 DR. NAIDU: Sanjiv Naidu. I am from Penn
21 State College of Medicine. I am an orthopedic
22 surgeon and into biomaterials.

23 DR. ABRAMS: Gary Abrams, from the
24 University of California San Francisco. I am a
25 neurologist in rehabilitation.

1 DR. HANNAFORD: Blake Hannaford,
2 Department of Electrical Engineering, University of
3 Washington in Seattle. My interests are in
4 robotics.

5 MS. BUZAID: Ann Buzaid, University of
6 Washington Medical Center. I am an occupational
7 therapist.

8 DR. McQUADE: Kevin McQuade. I am a
9 rehabilitation research scientist at the VA Medical
10 Center in Baltimore and Assistant Professor in the
11 Department of Orthopedics and Physical Therapy,
12 University of Maryland. My area is biomechanics.

13 MS. WITTEN: Celia Witten. I am with FDA,
14 Division Director of the reviewing division for
15 this product.

16 MR. HERMAN: Bob Herman, Patient
17 Representative. I am a senior advocacy attorney at
18 the Paralyzed Veterans of America.

19 DR. STIENS: Hi. I'm Steve Stiens, and I
20 am an Associate Professor of Rehabilitation
21 Medicine at the University of Washington. I am a
22 staff physician in spinal cord medicine at the VA
23 Medical Center in Seattle, and I am a paralyzed guy
24 who uses mobility devices.

25 MS. MAHER: Sally Maher. I am Senior

1 Director, Regulatory and Clinical, Smith and Nephew
2 Endoscopy. I am the Industry Representative.

3 MS. RUE: I am Karen Rue. I am a
4 registered nurse and Consumer Representative.

5 DR. GOLDMAN: My name is Robert Goldman.
6 I am an Assistant Professor of Rehab Medicine at
7 University of Pennsylvania and bioengineering
8 training at Drexel University.

9 MR. FENICAL: I am Gary Fenical with Laird
10 Technologies in Delaware Water Gap, Pennsylvania,
11 an electromagnetic compatibility engineering, and
12 my interest is electromagnetic compatibility.

13 DR. MYKLEBUST: I am Joel Myklebust. I am
14 the Associate Director of the National Institute on
15 Disability and Rehabilitation Research, and my
16 background is in biomedical engineering.

17 DR. LARNTZ: I am Kinley Larntz, and I am
18 Professor Emeritus, University of Minnesota. I
19 also work as an independent statistical consultant,
20 and my interest is in statistics.

21 DR. FRIEDMAN: My name is Richard
22 Friedman. I am an orthopedic surgeon. I am
23 Clinical Professor of Orthopedic Surgery at the
24 Medical University of South Carolina in Charleston.
25 I am also an Adjunct Professor of Bioengineering at

1 Clemson University. My interest is in
2 biomaterials, biomechanics, and telegony [phonetic]
3 replacement.

4 DR. KIRKPATRICK: I am John Kirkpatrick.
5 I am an orthopedic surgeon and spine surgeon. I am
6 an Associate Professor at the University of Alabama
7 at Birmingham of both orthopedics and engineering,
8 and I am here as an orthopedic surgeon.

9 DR. FINNEGAN: Maureen Finnegan. I am an
10 orthopedic surgeon at UT Southwestern in Dallas,
11 and adjunct faculty at UT Arlington in Biomedical
12 Engineering.

13 MR. DEMIAN: Thank you.

14 At this time, I would like to turn the
15 meeting over to our chairman, Dr. Michael
16 Yaszemski.

17 DR. YASZEMSKI: Thanks, everybody, and
18 good morning.

19 My name is Dr. Michael Yaszemski, and I
20 will be chairman for this meeting today.

21 Today, we the panel will be making
22 recommendations to the Food and Drug Administration
23 regarding a Pre-Market Approval application for
24 Independence Technology's INDEPENDENCE iBOT 3000
25 Mobility System, intended for individuals who have

1 mobility impairments and the use of at least one
2 upper extremity.

3 I would like to note for the record that
4 the voting members present constitute a quorum as
5 required by 21 CFR Part 14.

6 We will now proceed to the open public
7 hearing session of this meeting.

8 I would ask at this time that all persons
9 addressing the panel come forward and speak clearly
10 into the microphone, as the transcriptionist is
11 dependent on this means of providing an accurate
12 record for this meeting.

13 We are requesting that all persons making
14 statements during the open public hearing session
15 of the meeting disclose whether they have financial
16 interest in any medical device company. Before
17 making your presentation to the panel, please state
18 your name, affiliation, and the nature of your
19 financial interest, if any.

20 Is there anyone at this time wishing to
21 address the panel?

22 [No response.]

23 DR. YASZEMSKI: Seeing that there are no
24 persons wishing to present at this time, we are now
25 going to consider the Pre-Market Approval

1 application for the INDEPENDENCE iBOT 3000 Mobility
2 System.

3 I would like to remind public observers at
4 this meeting that while this portion of the meeting
5 is open to public observation, public attendees may
6 not participate except at the specific request of
7 the panel.

8 We are now ready to begin with the
9 sponsor's presentation which will be followed by
10 the FDA presentation. I would like to ask that
11 each speaker state his or her name and affiliation
12 to the firm in question before beginning the
13 presentation.

14 We are now going to ask the sponsor,
15 Independence Technology, for their presentation.

16 I think Mr. O'Donnell will go first.
17 Thank you.

18 Sponsor Presentation

19 MR. O'DONNELL: Good morning.

20 My name is Jim O'Donnell. I am Vice
21 President of Regulatory Affairs at Independence
22 Technology in Warren, New Jersey.

23 Independence Technology is a small
24 start-up company within the Johnson & Johnson
25 family of companies. The mission of Independence

1 Technology is to develop products using innovative
2 technologies to help meet the needs of people with
3 disabilities.

4 Today we have the pleasure and the
5 privilege to present to you the culmination of more
6 than a decade of research and development by our
7 partner, DEKA Research Corporation of Manchester,
8 New Hampshire.

9 Their efforts have resulted in the
10 INDEPENDENCE iBOT 3000 Mobility System, an advanced
11 mobility system indicated for individuals who have
12 mobility impairments and who have the use of at
13 least one upper extremity.

14 [Slide.]

15 To begin, we will have a short video of
16 the INDEPENDENCE iBOT 3000 Mobility System. Then,
17 Susan Eichler-Huston will present a brief overview
18 of the Mobility System, its functions and key
19 components, and provide a summary of the
20 nonclinical testing performed on the device.

21 Dr. Haikki Uustal will describe the
22 conduct and the results of the pivotal clinical
23 trial.

24 Our presentation will conclude with Jean
25 Minkel presenting the training program used during

1 the clinical study for both clinicians and trial
2 participants. These same training programs will be
3 used when the device is marketed.

4 We also have other Independence Technology
5 and DEKA Research Corporation personnel available
6 to answer any questions that you may have.

7 At this time, we will show a video that
8 provides an introduction to the INDEPENDENCE iBOT
9 3000 Mobility System and its operating functions.

10 [Videotape.]

11 MR. O'DONNELL: Here, you see the device
12 in Standard function. Note that the two front
13 drive wheels are off the ground.

14 Negotiating elevators and doorways is
15 easily performed.

16 Here, you will see a transition from
17 Standard function to 4-Wheel function using the
18 buttons on the user control panel. The seat height
19 is elevated to further the distance between the
20 casters and the ground.

21 This grass-covered slope is easily handled
22 and down the curb on the other side; across the
23 parking lot and up the curb.

24 The driver transitions from 4-Wheel to
25 Balance by using the buttons on the UCP, leaning

1 the seat back, and a slight pull on the joystick
2 moves the driver into Balance.

3 Balance can be used in most ADA-compliant
4 environments, such as sidewalks.

5 Here, the driver transitions from Balance
6 to 4-Wheel using the buttons on the user control
7 panel.

8 Balance is also very useful indoors and
9 can be used for reaching objects.

10 In stair-climbing, the driver transitions
11 in the Stair function, making sure that the front
12 tires are perpendicular to the step, and proceeds
13 down the stairs shifting her weight forward to move
14 the cluster to the next-lower step, then leaning
15 backward to slow the cluster as it reaches that
16 next step.

17 In this case, the driver is using the
18 one-rail stair-climbing technique.

19 On completing stair-climbing, she
20 transitions back into 4-Wheel function.

21 In this segment, she will climb the stairs
22 by backing up to the step, again making sure the
23 tires are perpendicular to the step. Again, this
24 is the one-rail stair-climbing technique. Note
25 that this time, the chair arm with the user control

1 panel is closest to the railing.

2 At the top of the landing, the driver
3 pushes straight back.

4 This segment demonstrates the two-rail
5 stair-climbing technique. Again, you can see that
6 stair-climbing is accomplished by shifting your
7 center of gravity, or leaning.

8 In Stair-Assist, the assistant pulls up
9 and locks the Assist handle. The driver puts the
10 device in Stair function, and the assistant hits
11 the Assist button located on the back of the seat.
12 Here, the assistant shifts the driver's center of
13 gravity by pushing down on the handle; this moves
14 the cluster toward the next-higher step. As the
15 cluster approaches that higher step, the assistant
16 lifts the handle thereby shifting the center of
17 gravity forward and slowing the cluster movement as
18 it approaches the step.

19 Here is the same process going down the
20 steps. The assistant lifts and locks the Assist
21 handle, the driver puts the device in Stair
22 function, the assistant then presses the
23 Stair-Assist button. The device is rolled off the
24 top step, and stair-climbing follows.

25 When stair-climbing is completed, the

1 driver transitions back to 4-Wheel function.

2 I hope that has provided you with an
3 overview of the uses of the device. I would now
4 like to turn the presentation over to Susan
5 Eichler-Huston.

6 DR. YASZEMSKI: Thanks, Mr. O'Donnell.

7 MS. EICHLER-HUSTON: Good morning. My
8 name is Susan Eichler-Huston, and I am the Manager
9 of Regulatory Affairs for Independence Technology.

10 Now that the device has been viewed in
11 several operating functions, we would like to
12 explain the product's characteristics in more
13 detail.

14 [Slide.]

15 The iBOT Mobility System is a
16 battery-operated advanced mobility system designed
17 for both indoor and outdoor use.

18 [Slide.]

19 The iBOT Mobility System is made up of two
20 key components--the seating system and the power
21 base. The seating system includes all the
22 components designed to support a person in a seated
23 position. The power base includes all the
24 components that provide mobility--the wheels,
25 batteries, motors, and computers.

1 [Slide.]

2 The iBOT Mobility System has the following
3 features: seatback, armrest, clothing guards,
4 battery packs, seatback fold latch, brake levers,
5 drive wheels and clusters, front tiedown rings,
6 caster wheels, footrest and footplates, toe guards,
7 calf strap, seat pan, external computer connection,
8 user control panel, assist handle, armrest release
9 latches, battery charger socket, power button, rear
10 tiedown rings, battery cover panel, assist button,
11 and carrying hook.

12 [Slide.]

13 The user control panel is a device in
14 which a person communicates with the iBOT Mobility
15 System. The user control panel contains a
16 joystick, back light button, warning, caution, and
17 go lights, display, drive-setting button, okay
18 button, seat tilt buttons, armrest mounting
19 bracket, seat height buttons, function-select
20 buttons, external computer connection, and
21 alarm/acknowledge and horn button.

22 [Slide.]

23 Currently available wheelchairs are
24 passively stable devices. They are only statically
25 stable when their center of gravity is located

1 somewhere between the wheels. These devices have
2 no sensors or data regarding pitch, which is the
3 inclination of the machine with respect to gravity.

4 The iBOT Mobility System is an actively
5 stabilized device in that it has sensors and
6 gyroscopes that monitor pitch and send that data to
7 the motors to adjust the movement of the device to
8 accommodate that information. This is called the
9 i-Balance technology.

10 The i-Balance technology maintains balance
11 in the forward and backward directions. This means
12 the iBOT Mobility System will keep the seat
13 relatively level when driving straight up or down
14 curbs or inclines.

15 The i-Balance technology is active in four
16 of the five operating functions, with each function
17 using this core technology in a slightly different
18 way.

19 [Slide.]

20 The iBOT Mobility System has five
21 operating functions: Standard, 4-Wheel, Balance,
22 Stair, and Remote.

23 [Slide.]

24 In Standard function, the i-Balance
25 technology is not active. In Standard function,

1 the device operates similar to conventional power
2 chairs. The seat is at the lowest available
3 position in this function. The casters attached to
4 the base of the seat are in contact with the
5 ground, and the front drive wheels are raised off
6 the ground. The casters provide good turning
7 performance in this function.

8 As with currently-marketed power
9 wheelchairs, the use of casters limits the terrain
10 and obstacle performance. Standard function is
11 appropriate for relatively firm indoor and outdoor
12 ADA-compliant environments, obstacles up to
13 one-half inch and inclines up to 5 degrees.

14 [Slide.]

15 In 4-Wheel function, the i-Balance
16 technology is active so the device reacts to
17 changes in pitch caused by changes in terrain,
18 external impacts, and other factors. The device
19 uses both wheel and cluster position to maintain
20 stability.

21 For example, if the user drives the device
22 up a curb, the cluster will rotate in reaction to
23 the change in pitch to maintain a relatively level
24 seat as the wheels drive forward. In this manner,
25 stability is enhanced even during a steep ascent.

1 [Slide.]

2 In 4-Wheel function, the device operates
3 using the four drive wheels. The casters are
4 lifted off the ground. 4-Wheel function provides
5 the user with mobility and flexibility in a wide
6 variety of environments. 4-Wheel function is the
7 4-wheel drive of the iBOT Mobility System, enabling
8 consumers to traverse over soft, uneven terrain
9 such as gravel, sand, dirt, and grass.

10 In 4-Wheel function, the device can also
11 navigate inclines up to 8 degrees, over obstacles
12 up to 4 inches, and through water up to 3 inches
13 deep.

14 [Slide.]

15 As the name suggests, Balance function
16 uses the active i-Balance technology to operate on
17 two points of contact with the ground, mimicking
18 the human balance model. Balance function provides
19 mobility at an elevated height.

20 This is accomplished by the combined
21 weight of the device and the user shifting open the
22 back wheels. The device reacts to a center of
23 gravity change by transitioning up onto two wheels.
24 A brake locks the clusters into its vertical
25 arrangement.

1 In Balance function, the iBOT Mobility
2 System maintains stability by driving the wheels to
3 stay under the user. The seat height can be
4 raised and lowered to facilitate the reaching of
5 objects on shelves or having an eye-level
6 conversation with a standing person.

7 Balance function is appropriate for a
8 variety of indoor and outdoor firm surface with an
9 incline up to 5 degrees and obstacles up to
10 one-half inch.

11 [Slide.]

12 Stair function uses the i-Balance
13 technology to enable the user to ascend or descend
14 commonly-encountered stairs, either by themselves
15 or with an assistant. Stair-climbing is achieved
16 by the rotation of the clusters over the stairs
17 using a closed-loop control algorithm that uses
18 pitch and sensor data to control the clusters
19 motors. The device strives to keep the center of
20 gravity of the system over the ground-contacting
21 wheels.

22 When a user leans either forward or back,
23 or an assistant leans the device, shifting the
24 center of gravity, the device will rotate the
25 clusters in response, which will result in the

1 device climbing down or up one stair, respectively.

2 The user will climb up or down a staircase
3 facing down the stairs, with the direction of the
4 weight shift determining the direction of climbing.
5 When a landing is reached, the user can transition
6 into 4-Wheel function and drive away from the
7 stairs.

8 [Slide.]

9 The joystick is deactivated in Stair
10 function to prevent unintentional deflection of the
11 joystick on the stairs. The user or assistant is
12 the input device during stair-climbing, as they
13 control the rate of climbing and provide stability
14 by holding the stair handrails or the Assist
15 handle.

16 Criteria for staircases are the following.
17 Handrails for independent stair-climbing should
18 extend 6 inches beyond the top of the steps. They
19 need to be strong enough to be pulled on and should
20 be able to be grasped from underneath. The stairs
21 need to have a height of between 5 to 8 inches and
22 a tread of 10 to 17 inches.

23 [Slide.]

24 Landings should be at least 52 inches deep
25 and should not have any obstacles. Stairs

1 themselves should be strong, stable, level, not
2 sloped, and debris-free.

3 [Slide.]

4 Remote function provides the user with a
5 way to operate the iBOT Mobility System when not
6 seated in the device. Remote function is useful
7 for maneuvering the device for transfers, parking
8 the device after a transfer, driving into a vehicle
9 for transport, and other purposes.

10 The user control panel may be removed from
11 its mount on the armrest and operated via 5-foot
12 long retractable cable.

13 Entry into Remote function is only allowed
14 when the seat is folded to prevent use of this
15 function when a user is seated in the device. This
16 is because the device was designed to have an empty
17 seat in this function. Since the device does not
18 have to keep the user stable, it is able to
19 traverse inclines up to 25 degrees--for example, up
20 a ramp to get into the back of an SUV.

21 While this function is very good for steep
22 inclines, it is not appropriate for obstacles or a
23 wide variety of terrain. Remove function is
24 appropriate for firm, even surfaces with obstacles
25 no greater than one inch.

1 [Slide.]

2 The INDEPENDENCE iBOT 3000 Mobility System
3 has been tested to a wide range of nonclinical
4 tests, quantifying the software, mechanical,
5 electrical, performance, anomalous, and
6 environmental device characteristics.

7 [Slide.]

8 The software information includes the
9 software development process, risk management, and
10 comprehensive verification and validation. The
11 documentation describing these activities is
12 consistent with the recommendations of the FDA
13 Guidance for the Content of Pre-Market Submissions
14 for Software Contained in Medical Devices,
15 5-29-1998.

16 [Slide.]

17 To test the mechanical, electrical,
18 environmental, performance and anomalous properties
19 of the iBOT Mobility System, many of the
20 CDRH-recognized consensus standards were used as
21 the basis for testing. The primary standards were
22 the ISO 7176 Series and the ANSI/RESNA WC Series.
23 Additional standards are listed on the slide.

24 [Slide.]

25 All these standards were used to create

1 the test plans and test cases that the Mobility
2 System was tested to. Most of these standards do
3 not contain acceptance criteria. As such, the
4 standard test method was used, and the criteria was
5 generated from the system specifications. For
6 those standards that do contain acceptance
7 criteria, that information was used to generate the
8 requirements.

9 The iBOT Mobility System has unique
10 features that were not envisioned when some of the
11 standards were written. As such, some of the test
12 methods in the standards had to be modified to
13 accommodate these features. This occurred
14 primarily with the ISO 7176 panel of tests.

15 For example, Standard function would be
16 tested as per the standard's test method, but for
17 4-Wheel, Balance, and Stair, modifications to the
18 test method would have to be made to accommodate
19 the i-Balance technology.

20 For reporting purposes, the test data were
21 grouped together either by which standard they are
22 linked to or by similar requirements being tested.
23 There are 36 test reports that contain all of the
24 qualification testing. As is shown in the test
25 reports, the iBOT Mobility System meets the

1 criteria that have been established for this
2 product, and as such, the standard supports the
3 safety and efficacy of the device for its intended
4 use.

5 [Slide.]

6 In the information that FDA has provided
7 to the panel, one of the questions was regarding
8 EMC testing. To address this concern, the
9 following slides summarize some key points of the
10 iBOT Mobility System and the battery charger EMC
11 testing.

12 [Slide.]

13 The CDRH-recognized and international
14 standards were used to create the test plan for the
15 iBOT Mobility System. The primary standard was the
16 ANSI/RESNA WC Section 21, with additional
17 applicable standards listed on this slide.

18 [Slide.]

19 FDA guidance documents regarding EMC
20 testing and labeling were also used. Device and
21 labeling contain the FDA-recommended information
22 and warnings.

23 [Slide.]

24 The iBOT Mobility System was tested for
25 EMC in the five operating functions--Standard,

1 4-Wheel, Balance, Stair, and Remote. The criteria
2 that were set and passed are listed on the slide.

3 [Slide.]

4 For testing while charging batteries,
5 those criteria are listed on this slide.

6 [Slide.]

7 The device has been shown to meet the past
8 criteria, and as such, the iBOT Mobility System and
9 its charger comply with the relevant EMC standards
10 and are safe in their intended use in regard to
11 electromagnetic compatibility.

12 Now, Dr. Heikki Uustal will present the
13 results of the clinical pivotal trial.

14 DR. YASZEMSKI: Thanks, Ms.
15 Eichler-Huston.

16 Dr. Uustal?

17 DR. UUSTAL: Good morning.

18 My name is Haikki Uustal. I am a
19 practicing physiatrist in the Department of
20 Rehabilitation Medicine at the JFK-Johnson Rehab
21 Institute in Edison, New Jersey. I am the
22 principal investigator for the pivotal trial of the
23 INDEPENDENCE iBOT 3000 Mobility System.

24 I have not been compensated directly by
25 Independence Technology; however, JFK-Johnson Rehab

1 Institute has received compensation for the time I
2 have spent on the pivotal trial.

3 Additionally, Independence Technology has
4 paid for my travel arrangements.

5 I am pleased to present to you the results
6 of the pivotal trial demonstrating the safety and
7 effectiveness of the INDEPENDENCE iBOT 3000
8 Mobility System.

9 [Slide.]

10 A team of investigators participated in
11 the trial. My role in the trial was to provide all
12 medical input to assure the adequacy of the
13 training programs, to discuss the subjects' study
14 participation with their personal physician, if
15 needed, to review the device usage data, to review
16 any potential adverse events, and to work with the
17 sponsor in preparing the report presented in the
18 PMA.

19 I was not involved in the evaluation or
20 training of study subjects, as these
21 responsibilities would be performed by therapists
22 should the device be commercialized.

23 Dr. Lei Lin's role in the trial was
24 limited to providing medical review and input for
25 the rest of the team in the event I was not

1 immediately available.

2 The remaining investigators were
3 therapists responsible for the evaluation and
4 training of subjects. Other than Jean Minkel and
5 Sandy Salerno, all therapists are currently
6 employed full-time as therapists and participated
7 in the trial on a part-time basis--Jean Minkel as a
8 consultant to Independence Technology, and shortly,
9 she will present to you the training programs for
10 the device; Sandy Salerno as an Independence
11 Technology employee and would participate only when
12 a subject was scheduled to come to the test site
13 and another therapist was not available.

14 [Slide.]

15 Jean, Sandy, and I comprised the steering
16 committee for the trial. The responsibility of the
17 steering committee was to approve the protocol,
18 review all data collected during the trial, and
19 approve the study report.

20 [Slide.]

21 The pivotal trial was a single-center,
22 prospective, balanced, open-label evaluation that
23 utilized study participants as their own control.
24 The study was conducted at a research facility in
25 Manchester, New Hampshire.

1 The objectives of the pivotal trial were:

2 1) to demonstrate that people with a variety of
3 mobility skills using different configuration of
4 the iBOT were able to safely and effectively use
5 the product in real world environments; 2) to
6 demonstrate that subjects will have improvements in
7 both objective and subjective measures of
8 functional activities in a real world environment
9 when using the iBOT compared to their current
10 device.

11 [Slide.]

12 The primary inclusion criteria are
13 presented here. We did have three types of current
14 wheelchair users. A skilled manual wheelchair user
15 is a subject who routinely propels faster than
16 walking speed and is able to travel in a wheelie
17 position for 10 feet. A slow manual wheelchair
18 user is a subject who self-propels at walking speed
19 or slower, or is unable to travel in a wheelie
20 position for 10 feet. A power wheelchair user uses
21 a powered device; this would include the use of a
22 scooter.

23 [Slide.]

24 The primary exclusion criteria are
25 presented on the next few slides. Items that I

1 would especially like to highlight are: a weight
2 limit of 250 pounds--this was the maximum payload
3 in all the tests listed earlier by Susan; subjects
4 need the use of at least one upper extremity
5 sufficient to operate the joystick and push the
6 buttons on the user control panel; subjects who
7 require the use of tilt or reclining were excluded,
8 as well as an active decubitus ulcer or an history
9 of decubitus ulceration if they were unable to use
10 their own cushion in the study.

11 [Slide.]

12 Finally, the present of cardiac,
13 pulmonary, or fracture risks could eliminate some
14 subjects or restrict the use of the device
15 functions.

16 [Slide.]

17 A total of 20 subjects was required to
18 complete the study. The pilot phase of the trial
19 consisted of two subjects; these were both skilled
20 manual wheelchair users. Following completion of
21 the pilot trial, the remaining 18 subjects were
22 enrolled.

23 To ensure a broad range of current
24 wheelchair users were included, these 18 subjects
25 were equally divided among skilled manual

1 wheelchair users, slow manual wheelchair users, and
2 power wheelchair users.

3 Potential subjects who showed an interest
4 in participating in the trial were approached to
5 undergo a telephone screening to determining if
6 there was a possibility they would qualify for the
7 study. Subjects who were successful with the
8 telephone screening were then put into a queue to
9 be brought to the test site for further evaluation
10 and possible study participation.

11 [Slide.]

12 I'll use the next two slides to present
13 the trial design. The four columns with the purple
14 background are the four times a subject would go to
15 the test site. The first time a subject went to
16 the test site was for assessment. Informed consent
17 would be obtained, and the clinician would check
18 inclusion/exclusion criteria to assure the subject
19 met the requirements. A mat assessment would also
20 be performed. The functional capacity evaluation
21 is a formal driving assessment in which the
22 candidate must demonstrate operation of the four
23 main driving functions--Standard, 4-Wheel, Balance,
24 and Stair; the clinician observes the candidate's
25 performance and makes a decision regarding the

1 potential this candidate demonstrates to become a
2 safe and effective driver following thorough
3 driving instructions. Of course, adverse event
4 monitoring occurred at assessment and throughout
5 the trial. Also at the assessment,
6 subject-specific functional scale data would be
7 obtained. This data was the secondary efficacy
8 variable, which I will discuss in more detail
9 shortly.

10 [Slide.]

11 After the assessment, the subject would be
12 brought back to the test site for training in the
13 iBOT. In the study, training was done on two
14 separate days. Each of these two sessions would
15 last about half a day. Two half-day sessions were
16 chosen to assure that neither the subject nor the
17 clinician would become too fatigued.

18 The first day of training would include
19 all device functions except Stair function. The
20 subject would then go home with the device with
21 Stair function turned off and use the iBOT as their
22 mobility device.

23 Approximately 3 days later, the subject
24 would return for Stair function training. They
25 would then go home with their device for

1 approximately 11 more days. During the total of 2
2 weeks in the iBOT, subjects were contacted daily to
3 find out about their daily activities and to
4 download data from the iBOT.

5 After a total of 2 weeks in the device,
6 they would return to the test site. At that time,
7 subject-specific functional scale data, the
8 secondary efficacy variable, would be obtained and
9 community driving test data, the primary efficacy
10 variable, would be obtained.

11 Daily mobility activity data would also be
12 collected for 2 weeks when the subjects used their
13 own device. Half the subjects used the iBOT, then
14 their own device, and half used their own device,
15 then the iBOT.

16 [Slide.]

17 A total of 29 subjects entered the trial.
18 As per the protocol design, 20 subjects completed
19 the trial. In two cases, it was determined at
20 assessment the subject was not a candidate for the
21 iBOT. One of these subjects had poor dexterity and
22 had too much difficulty opening and closing the UCP
23 for the daily downloads; the other subject had
24 impaired vision due to brain surgery and hence had
25 difficulty visually scanning the surrounding

1 environment. This presented a potential safety
2 concern.

3 In two cases, the subject voluntarily
4 withdrew from the study prior to training--one due
5 to an injury suffered in an auto accident which
6 occurred between assessment and day one training,
7 and one because he had difficulty transferring from
8 the iBOT into and out of his van.

9 In four cases, the sponsor ended the
10 subjects' participation in the study prior to
11 training. Two of these four ended because the
12 required number of subjects for the study had been
13 obtained; one because it was determined that stairs
14 in his home were not appropriate for the iBOT, and
15 one was ended due to a potential conflict of
16 interest. One subject did voluntarily withdraw
17 after the first day of training because the
18 hallways of his home were too narrow to comfortably
19 operate the device.

20 [Slide.]

21 The subject demographics show the study
22 sample consisted predominantly of men and
23 predominantly spinal cord injury. The subjects
24 covered a broad range of ages and weights.

25 There was an excellent distribution of

1 stair-climbing qualifications, with eight subjects
2 attaining solo stair-climbing with both one and two
3 rails. An additional four subjects also qualified
4 as solo stair-climbers with either two rails or
5 both one and two rails. These four subjects also
6 chose to have an assistant trained. And there were
7 eight subjects who only qualified for Stair-Assist
8 climbing. Hence, a total of 12 stair assistants
9 were qualified in the study.

10 [Slide.]

11 Moving to an analysis of the safety of the
12 device, the protocol defined a serious adverse
13 event as being associated with the use of a device
14 and requiring treatment outside of the test site or
15 home. There were no serious adverse events in this
16 trial for either the iBOT or the subject's own
17 device.

18 [Slide.]

19 An adverse event was similarly defined as
20 being caused by or associated with the use of a
21 device but which required treatment at the test
22 site or at home. We did have one such event during
23 assessment. A subject pinched his mid forearm
24 between the UCP and the armrest, resulting in a
25 small bruise. A bandage was placed over the bruise

1 to prevent any additional injury. Pinch points are
2 covered in both the labeling of the device and
3 device training.

4 There was another bruise that did not
5 require medical attention. Although this did not
6 meet the definition of an adverse event in our
7 protocol, I have included it here, because you may
8 interpret such a bruise as an adverse event.

9 [Slide.]

10 We defined the category of "Other Medical
11 Events" as events which were likely not caused or
12 associated with the device which required medical
13 attention. We had four such occurrences, all when
14 the subjects were in their own device.

15 [Slide.]

16 We also identified five events which did
17 not require medical attention, but which could have
18 required medical attention should the event recur.
19 All five events were falls. As recorded in the
20 iBOT daily download data and confirmed through a
21 discussion with the subjects, there were three
22 falls while in the iBOT. Subjects self-reported
23 two falls while in their own device.

24 Subject 11 was in Standard function when
25 he attempted to squeeze between his scooter and a

1 pole in his carport. The front wheels of the
2 device rode up on top of the scooter, tilting the
3 device backward, resulting in a backward fall.

4 Subject 12 wanted to demonstrate to a
5 friend that by leaning far forward and moving his
6 center of gravity forward of the wheelbase of the
7 device, he could lift the rear wheels off the
8 ground. In this case, the subject continued
9 leaning far forward, and the device was unable to
10 get his center of gravity back within the
11 wheelbase. Rather than let this out-of-control
12 situation continue, the device is designed to shut
13 down once the device moves 10 feet and is unable to
14 get the driver's center of gravity back within the
15 wheelbase. The device intentionally shuts down
16 rather than continuing in an out-of-control
17 situation. When the device shut down, the rear
18 wheels were off the ground; this resulted in the
19 device tipping backward.

20 Subject 27 was driving to work in Balance
21 function. The driver struck a curb at an angle,
22 and the right wheel of the device attempted to
23 climb the curb. This caused lateral instability,
24 and the device fell laterally. In this case, the
25 subject had a slight bruise on his leg which did

1 not require any treatment.

2 In all three of these falls in the iBOT,
3 the device was put in an upright position, the
4 subject cycled power, and used Recovery mode to
5 resume driving the device.

6 When in their own device, Subject 3
7 encountered a metal edge on the carpeting in a
8 department store, causing the subject to fall
9 backward. Subject 11 encountered a soft patch of
10 grass in the yard, causing his device to tilt over
11 sideways.

12 [Slide.]

13 This slide presents a summary of all
14 safety-related events observed in the study.

15 [Slide.]

16 The safety of the iBOT is established
17 because there were no serious adverse events; there
18 was one adverse event requiring a bandage to
19 protect the pinch point site; and the rate of falls
20 in the iBOT was similar to the rate of falls in the
21 subjects' own device.

22 [Slide.]

23 To establish the efficacy of the device,
24 we created a community driving test. This test
25 consisted of 15 tasks that wheelchair users

1 encounter in everyday life. Fourteen of these 15
2 tasks were out in the real world, one we created.

3 After completing 2 weeks in the iBOT, the
4 subjects would return to the testing center and go
5 through the test in both the iBOT and their own
6 device; hence, the subjects served as their own
7 control for the efficacy evaluation.

8 [Slide.]

9 To score subjects on the various tasks, we
10 utilized this 7-point rating scale. When the
11 subject was performing the task, the clinician
12 would make one of three determinations--that the
13 subject was unable to do the task or that the
14 subject could do the task with assistance or that
15 the subject could do the task independently.

16 Please note that this is a very objective
17 observation--the task cannot be performed; it can
18 be performed with assistance; or it can be
19 performed independently.

20 For tasks that were done with the
21 assistant, the clinician would ask the assistant
22 how much exertion was required--maximum, moderate,
23 or minimum. The identical question would be given
24 to the subject if the subject performed the task
25 independently. Please note that this rating is

1 very subjective.

2 When we compare the subject performance in
3 their own device and the subject performance in the
4 iBOT, we are looking for changes in independence,
5 changes from one set of scores to another set of
6 scores.

7 While performing the community driving
8 test, the clinician did not provide any instruction
9 or hints, nor did the clinician advise which device
10 function should be used to perform the task.
11 Hence, it is possible that for some tasks, one
12 subject might choose Standard function, another
13 choose 4-Wheel function, and another choose
14 Balance. However, for most tasks, only one
15 function was utilized by all subjects.

16 [Slide.]

17 So, what were the 15 tasks and the
18 results?

19 There were four tasks that would be
20 performed primarily in Standard
21 function--negotiating an elevator, negotiating a
22 sidewalk, crossing a street with curb cuts, and
23 driving up an incline. This picture shows the
24 sidewalk and the curb cut tasks. This is an
25 example where subjects might choose Standard,

1 4-Wheel, or Balance.

2 Looking at the data, we have the
3 following. On the left side, we have each of the
4 20 subjects grouped according to pilot trial,
5 manual skilled subjects, manual slow subjects, and
6 power subjects. For each subject and task, I have
7 presented the score in the iBOT, the score in their
8 own device, and the difference in the two scores.
9 Where the difference is blank, there was no
10 difference in scores. Where the difference was an
11 increase in independence level, the difference is
12 highlighted in green. Where the difference was not
13 an improvement in independence level but was an
14 improvement in exertion level, the difference is
15 highlighted in gold.

16 This method of data presentation allows
17 you to quickly look at and interpret the results
18 both within and between subject groups.

19 Here, we see that power chair users saw no
20 difference between their device and the iBOT. This
21 is an expected result because in standard function,
22 the iBOT is very similar to power chairs. You see
23 manual skilled users show some slight benefit, and
24 manual slow users showed a greater benefit. But we
25 would probably see the same results with any power

1 chair.

2 So these results simply show that in
3 Standard function, this device is like any other
4 power chair. I will point out that for each of
5 these tasks in the iBOT, every subject was able to
6 perform the task independently, with minimal
7 effort.

8 We had one task where Balance function was
9 utilized--retrieving a book off a high shelf. The
10 data shows that in the iBOT, all 20 subjects were
11 able to perform this task independently with
12 minimal exertion. We do see that in their own
13 device, many people were able to perform this task
14 with assistance. They would accomplish the task by
15 asking someone else, like the clinician, "Can you
16 please get that book for me?" Clinicians always
17 like to help out, so they were able to retrieve the
18 book with minimal exertion and hand it to the
19 subject.

20 We did have one subject who did not ask
21 for help and was unable to retrieve the book.

22 The Balance results are statistically
23 significant with a P value less than .001.

24 [Slide.]

25 We had a total of six tasks that were

1 performed in 4-Wheel function. The top picture
2 shows the one-step exit. The negotiation of uneven
3 terrain was the one task we created. The Belgian
4 blocks shown here vary in height from three-quarter
5 inch to two-and-a-half inches.

6 The first thing I would like to point out
7 with these data is that with two exceptions, all 20
8 subjects were able to perform all these tasks
9 independently with minimal exertion when using the
10 iBOT.

11 Subject 2 did not climb down the curb in
12 the iBOT. When he came upon the curb to climb
13 down, he observed a curb cut farther down the
14 sidewalk and decided it was easier for him to
15 simply use the curb cut.

16 On approaching the one-step exit pictured
17 here, Subject 4 decided the height of the step
18 exceeded the 4-inch maximum. The subject decided
19 Stair function should be used to traverse the
20 one-step exit. With the aid of their assistant,
21 the subject traversed the one-step exit with
22 minimal exertion by the assistant, resulting in the
23 assigned score of 3.

24 In their own device, the subject performed
25 the task independently with maximal exertion.

1 The data show here that all subjects in
2 all subject groups showed increased independence
3 using 4-Wheel function. These 4-Wheel results were
4 statistically significant with P value less than
5 .008.

6 [Slide.]

7 There were four tasks in the community
8 driving test that evaluated stair-climbing. The
9 picture shows the interior stairs that subjects
10 went down. I would like to point out that none of
11 the four sets of stairs could be traversed using
12 the 2-rail stair technique, either because only one
13 rail was present or, as shown here, the two rails
14 were too far apart to do 2-rail climbing. Hence,
15 only subjects qualified in the one-rail climbing
16 technique have the potential to climb these stairs
17 independently.

18 Subject numbers that are not highlighted
19 qualified for one-rail stair-climbing. All these
20 subjects traversed all stairs independently.

21 Subject numbers that are highlighted are
22 subjects who did not qualify for one-rail climbing.
23 These subjects required an assistant. The data
24 show that all these subjects successfully traversed
25 all stairs in the iBOT with the aid of their

1 assistant. Hence, every subject in the study
2 successfully climbed stairs in the iBOT.

3 Subject 26 could traverse all stairs in
4 her own device. When going down stairs, she would
5 be seated in her chair with her back toward the
6 flight of stairs and her assistant behind the
7 chair. The assistant would then slowly go down the
8 steps, dropping her wheelchair one step at a time.
9 To go up stairs, the assistant removed the 81-pound
10 subject from her wheelchair and carried her and her
11 chair up the stairs. As you can see from the data,
12 this was done with maximal effort on the
13 assistant's part.

14 Subject 13 could go down the stairs
15 independently in his own chair with less effort
16 than when going down stairs in the iBOT. He would
17 simply go down the stairs backward by falling off
18 the first step and grabbing onto the rail to stop
19 from falling off the next step. He would repeat
20 this controlled fall process for every step. He
21 explained that he first used this technique when a
22 fire alarm went off in the building and, with the
23 elevators not functioning, he had to get down the
24 stairs.

25 Following that experience, he decided he

1 would practice that technique until he became an
2 expert at it, and as you can see from his score, he
3 is an expert using that technique.

4 The stair-climbing results are
5 statistically significant with a P value less than
6 .001.

7 In summary, the data from the 15 tasks in
8 the community driving test provide statistically
9 significant evidence that the iBOT is effective in
10 each of its functions.

11 The primary efficacy variable consisted of
12 the driving test.

13 [Slide.]

14 We also had a secondary efficacy variable,
15 which we called "subject-specific functional data."
16 When the subjects entered the trial, we asked them
17 to identify three activities which they had
18 difficulty doing in their own device. We asked
19 them to assign a score for that activity using the
20 same scoring scale we used in the community driving
21 test. Following their 2 weeks in the iBOT, we
22 asked them to rate the difficulty of those specific
23 activities when using the iBOT. This data shows a
24 statistically significant improvement with a P
25 value less than .001 in independence when using the

1 iBOT.

2 However, we recognize this is of limited
3 value when showing device efficacy for two reasons.
4 First, subject chose tasks specific to themselves.
5 Hence, it is questionable whether this data should
6 be pooled over all subjects. Second, we asked them
7 to identify activities they had difficulty doing.
8 Hence, by definition, scores in their own device
9 should be low, with nowhere to go but up when using
10 the iBOT.

11 In spite of these limitations for
12 statistically drawing conclusions, we believe this
13 data does provide additional data to demonstrate
14 the efficacy of the iBOT.

15 [Slide.]

16 One of the features of the device is that
17 it records usage data which can later be downloaded
18 for review. During the clinical trial, these data
19 were downloaded on a daily basis. Highlighted data
20 in the Totals column show the total distance
21 traveled in hours of iBOT usage in each function.

22 For example, subjects were in Balance
23 function for a total of 138 hours and traveled a
24 distance of 84.3 kilometers. This slide also shows
25 how the data were split for the 2 training days,

1 the 11 real world days, and the test day.

2 Since subjects were also out in the real
3 world on training days and the test day, it is
4 recognized that the real world numbers are
5 underestimated, and the numbers for training days
6 and test days are overestimated.

7 One item that jumps out in this data is
8 that of the 31-1/2 total hours in Stair function,
9 only 4 hours were in the real world, compared to
10 23.6 hours in training. I think this speaks more
11 about the extensive stair training subjects were
12 given than it does about lack of use of the Stair
13 function in the real world.

14 We see here that Stair function was
15 entered 141 times in the real world, or about 7
16 times per subject. When one considers how much the
17 real world is ADA-compliant with ramps and
18 elevators, this result is not surprising.

19 I have also highlighted the total of five
20 controller failures which occurred in the trial. A
21 controller failure is important, because that
22 indicates the iBOT has decided to shut down. With
23 each of the three falls, a controller failure
24 occurred. You will recall that in one fall, the
25 subject was leaning forward and had traveled 10

1 feet without his center of gravity being returned
2 to within the wheelbase of the device. Rather than
3 continue in the out-of-control situation, the
4 device shut down, which caused the fall to occur.

5 With the remaining two falls, when the
6 fall occurred, the device shut down rather than
7 continued to be powered-up in an out-of-control
8 situation. In those cases, the fall caused the
9 device to shut down.

10 The fourth controller failure occurred
11 when the subject wanted to climb stairs with their
12 assistant. The subject intended to instruct the
13 device to go into Stair-Climb function. Instead,
14 the subject inadvertently instructed the device to
15 go into Balance function. In both Stair function
16 and Balance function, the process is initiated by
17 the subject leaning back. The subject was leaned
18 back by the assistant, and the chair went into
19 Balance. The assistant wanted the device to climb
20 to the step and kept pushing on the Assist handle
21 to bring the device down onto the first step.

22 The device, which was in Balance function,
23 responded to the assistant's force by attempting to
24 move backward to keep the subject upright and in a
25 safe position. However, the step prohibited the

1 device from rolling backward. The device responded
2 by doing an automatic transition to 4-wheel drive
3 to get the subject to a safe position with all four
4 wheels on the ground. This resulted in the device
5 rear wheels resting on the first step.

6 During an auto-transition to 4-Wheel, if
7 the pitch angle exceeds 15 degrees, a controller
8 failure is declared, and the device will shut down.

9 The device was moved off the step, and the
10 device was powered-up and functional.

11 The final controller failure occurred on
12 the final day of use in the device. The subject
13 was unable to transport the device to the test site
14 in order to complete participation in the study.

15 An Independence Technology representative went to
16 the subject's home to transport the device to the
17 test site.

18 When the device was placed in the van, the
19 footrest was placed under the seat in the van.
20 After arriving at the test site, the device was
21 powered up to remove it from the van. The footrest
22 of the device was caught under the seat, and the
23 device was pitched more than 35 degrees at
24 start-up. Hence, a controller failure was
25 declared, and the device shut down. After freeing

1 the footrest, the device was powered-up and
2 functional.

3 As designed and as shown in the clinical
4 trial, a controller failure is not a device failure
5 but rather a device success. When a situation
6 occurs which can put the safety of the driver at
7 risk, the device is designed to shut down.

8 In summary, the data logger results show
9 extensive use of the device in all operating
10 functions.

11 [Slide.]

12 Daily during the study, we asked subjects
13 if they encountered any accessibility problems that
14 day. These data show that while the total count of
15 accessibility problems is similar in the iBOT and
16 their own device, the nature of those problems is
17 very different.

18 In their own devices, subjects had
19 difficulty going places. In the iBOT, subjects had
20 difficulty maneuvering, and the high seat height
21 limits accessibility.

22 Difficulty maneuvering is not surprising
23 given that 70 percent of subjects were manual
24 wheelchair users. The high seat height result is
25 not surprising because this device has a higher

1 seat height than currently-marketed devices.

2 [Slide.]

3 At the end of the study participation, we
4 also asked subjects to compare the iBOT and their
5 own device with regard to maneuvering in the home
6 and community. Use of the iBOT decreased
7 maneuvering ability in the home and increased
8 maneuvering ability in the community. This shows
9 the greatest benefit to the iBOT is in the
10 community, an expected result given the functions
11 of Balance, 4-Wheel, and Stair.

12 [Slide.]

13 We also monitored device or component
14 replacements in the trial, and there were a similar
15 number in each group.

16 [Slide.]

17 In conclusion, the safety of the device is
18 established because there were no serious adverse
19 events. There was one adverse event requiring a
20 bandage to protect a pinch-point site. And the
21 rate of falls in the iBOT was similar to the rate
22 of falls in subjects' own device.

23 The efficacy of the iBOT has been
24 established by providing statistically significant
25 improvement in subjects' level of independence.

1 Additionally, the data logger analysis shows
2 extensive use of the device in all device
3 functions.

4 Jean Minkel will now summarize the
5 training program.

6 DR. YASZEMSKI: Thanks, Dr. Uustal.

7 Ms. Minkel?

8 MS. MINKEL: Good morning.

9 My name is Jean Minkel. I am President of
10 Minkel Consulting in New Windsor, New York. We are
11 an independent consulting firm which specializes in
12 the area of assistive technology.

13 In addition to the consulting arrangement
14 with Independence Technology, I own a very small
15 number of shares of Johnson & Johnson common stock.

16 Additionally, Independence Technology has
17 paid for my travel arrangements.

18 I have been a consultant to Independence
19 Technology and the INDEPENDENCE iBOT 3000 Mobility
20 System program since 1995.

21 [Slide.]

22 I would like to give you an overview of
23 the training programs to be utilized in the planned
24 distribution in the device. These training
25 programs are nearly identical to the training

1 programs utilized for the pivotal trial.

2 [Slide.]

3 The training programs are targeted toward
4 two groups of people. One group is consumers who
5 will use the device. The other group is clinicians
6 who will deliver the device to consumers.

7 [Slide.]

8 The training program for clinicians can be
9 separated into four phases: consumer training
10 program, assessment training, delivery training,
11 observed performance.

12 This training program takes approximately
13 4 days to complete. As you can see here, the first
14 phase of clinician training is to treat them as a
15 consumer and have them experience the consumer
16 training program.

17 [Slide.]

18 The consumer will visit a clinic to go
19 through the assessment process. During the
20 assessment process, a potential consumer is
21 provided an orientation and limited training in
22 each function. The consumer must demonstrate
23 operation of the four main driving
24 functions--Standard, 4-Wheel, Balance, and Stair.

25 The clinician observes the candidate's

1 performance and makes a decision regarding the
2 potential this consumer demonstrates to become a
3 safe and effective driver following completion of
4 the full driver training program.

5 Based on the candidate's performance, the
6 iBOT can be individually configured by activating
7 and deactivating certain functions. At a minimum,
8 a potential consumer needs to successfully complete
9 the Standard and 4-Wheel function evaluations.

10 For persons who are unable to demonstrate
11 the potential to safely operate stair-climbing
12 alone, then an assistant must be identified and
13 also assessed before a final recommendation for
14 Stair-Assist can be made.

15 For persons with limitations in the visual
16 or perceptual skills needed to operate Balance
17 function, this function can be deactivated to
18 prevent unsafe usage.

19 Assuming the consumer has the potential to
20 become a safe and effective driver, he or she is
21 provided a user manual to read prior to returning
22 to the clinic for the driver training program.

23 The user manual contains a description of
24 the Mobility System, including all of its features,
25 how to operate the device in all of its functions,

1 information on warnings and cautions, and how to
2 respond to the safety system present in the device.

3 The manual also describes how to transport
4 the device as well as routine service and
5 maintenance.

6 After reading the user manual, the
7 consumer would return to the clinic for driver
8 training.

9 [Slide.]

10 The driver training program given to all
11 clinicians by Independence Technology, and to all
12 consumers by clinicians, consists of information
13 about the intended uses and limitations of each
14 function, detailed driving instruction in each
15 function, application of these driving skills in
16 indoor and outdoor environments.

17 At this point, the consumer is provided
18 the User Quick Reference Cards you saw in the
19 labeling. The cards contain tips on the operating
20 functions and the system's cautions and warnings.
21 These cards can easily be placed under the seat of
22 the iBOT.

23 The program also includes specific
24 training on the iBOT safety system. This includes
25 viewing the safe usage videos.

1 Finally, the training concludes with the
2 safe and effective driver's test.

3 [Slide.]

4 That is the training program for consumers
5 and the first phase of training for the clinician.
6 During Phase 2, the clinician will receive
7 instruction on how to conduct an assessment of a
8 person with a disability who is interested in
9 purchasing an iBOT.

10 The clinician is first shown how to
11 perform a center of gravity calibration for a
12 prospective consumer. This calibration is
13 necessary to utilize the device's functions where
14 i-Balance technology is active. The clinician is
15 trained in how to orient and evaluate a prospective
16 consumer.

17 The training of the clinician stresses the
18 concept "Begin with the end in mind." The criteria
19 which characterize a safe and effective driver are
20 stressed. Each therapist is taught to analyze the
21 physical, cognitive, and perceptual skills needed
22 in order to successfully pass the driver's test.
23 Each function is presented, and the clinicians are
24 asked to analyze the functional requirements to use
25 that function safely.

1 [Slide.]

2 You will recall that I mentioned consumers
3 must demonstrate the potential to operate the
4 device in each function. We call this the
5 Functional Capacity Evaluation or FCE.

6 During the clinician training, the
7 criteria for successful completion of each section
8 of the FCE is carefully reviewed. Clinicians are
9 encouraged to be conservative and to always share
10 with the consumer the results of the testing.
11 Using the results of the testing, the clinician can
12 recommend a specific configuration including speed
13 and operating functions. The consumer must agree
14 to this recommendation before the ordering process
15 can continue.

16 If recommended, an iBOT will be
17 manufactured to the specific configuration ordered
18 by the clinician and delivered to the clinic. The
19 consumer will return to the clinic for driver
20 training in his or her own iBOT.

21 [Slide.]

22 The assessment process I have just
23 described is outlined in the Assessment Guidebook
24 presented in your labeling. Interactions with the
25 device, such as calculating the center of gravity

1 or setting device configuration, are performed with
2 a software program called the Medical Interface.
3 The manual for the Medical Interface is also
4 presented in your labeling.

5 Both the Assessment Guidebook and the
6 Medical Interface manual are reference documents
7 the clinician can use when performing an
8 assessment.

9 [Slide.]

10 The third phase of clinician training
11 prepares the clinician to deliver a correctly
12 configured iBOT to the consumer and to administer
13 the driver training program. Similar to the
14 Medical Interface software used in the assessment,
15 the delivery interface software is utilized during
16 the delivery to properly set the center of gravity
17 in the device configuration. Clinicians are
18 provided a Delivery Interface manual for reference.

19 Clinicians are also provided a Delivery
20 Guidebook. The Delivery Guidebook presents the
21 driver training program in great detail. This is
22 the same driver training that the clinicians
23 themselves had to complete in the first phase of
24 their training.

25 [Slide.]

1 You will recall the driver training
2 program consists of these primary activities. The
3 Guidebook is designed to cover all the material
4 which is presented to the driver during training
5 for safe and effective use of the iBOT.

6 [Slide.]

7 The training is divided into four modules
8 covering different functions of the device. Each
9 module contains classroom and practice sessions and
10 provides necessary instruction to deliver the
11 material. The presentation of the safety systems
12 is presented within each module. Instruction on
13 the driver's test is provided as well as
14 information on care and maintenance of the device.

15 Throughout this phase of training,
16 clinicians are encouraged to ask themselves: Is
17 this person understanding and demonstrating the
18 knowledge and skills needed to safely operate the
19 product?

20 If there is a doubt, the clinician will
21 inform the consumer of the need for further
22 training prior to independent use of an activated
23 function.

24 [Slide.]

25 The final phase of the clinician training

1 is observed performance. Each clinician will be
2 observed by an Independence Technology
3 representative during an actual assessment and
4 driver training sessions. These observations are
5 designed to ensure the assessment and training
6 materials are being implemented as designed.

7 The clinician will be provided feedback
8 regarding their performance. Hopefully, the
9 clinician will demonstrate the skill to be an
10 iBOT-qualified clinician. Clinicians who do not
11 satisfactorily implement the programs as instructed
12 will continue to be observed, required to attend
13 further training, or be informed that they have not
14 earned the qualification.

15 For iBOT-qualified clinicians, an
16 Independence Technology representative will most
17 often be present during the consumer's deliver
18 training program, thereby providing an opportunity
19 for continued observance.

20 [Slide.]

21 In light of the successful usage of the
22 iBOT in real world environments by study
23 participants who were trained by qualified
24 clinicians, the data show that both the driver
25 training program and the clinician training program

1 are adequate to assure safe and effective use of
2 the iBOT.

3 That concludes the Independence Technology
4 presentation, and we thank you for your attention
5 during our presentation.

6 DR. YASZEMSKI: Thanks very much, Ms.
7 Minkel.

8 We are now going to move to the FDA
9 presentations, and first, we will have the lead
10 scientific review from Mr. DeLuca.

11 Mr. DeLuca?

12 FDA Presentation

13 MR. DeLUCA: Good morning, Mr. chairman
14 and members of the Committee. My name is Robert
15 DeLuca. I am a Scientific Reviewer in the
16 Restorative Devices Branch which is located in the
17 Food and Drug Administration's Office of Device
18 Evaluation.

19 I am the lead reviewer of this Pre-Market
20 Approval application for the INDEPENDENCE iBOT 3000
21 Mobility System which was submitted to FDA by
22 Independence Technology, a Johnson & Johnson
23 company.

24 [Slide.]

25 I would like to identify the members of

1 the CDRH Review Team for this PMA application and
2 acknowledge their efforts.

3 The members of the team include myself--I
4 am an electrical engineer and biomedical engineer,
5 and I served as the leader of the review team, and
6 I reviewed the device description, engineering, and
7 nonclinical testing aspects of the proposed device.

8 Captain Marie Schroeder is a physical
9 therapist in the Center's Office of Device
10 Evaluation. She served as the clinical reviewer
11 for the PMA device.

12 Phyllis Silverman is a statistician in the
13 Center's Office of Surveillance and Biometrics.
14 She served as the statistical reviewer for the
15 device application.

16 Laurel Mendelson is a rehabilitation
17 engineer in the Center's Office of Health and
18 Industry Programs. She served as the reviewer of
19 the device's patient labeling and human factors
20 issues.

21 Donald Witters is an engineer in the
22 Center's Office of Science and Technology. He
23 served as the reviewer of the applicant's
24 electromagnetic compatibility test report.

25 Joseph Jorgens is an engineer in the

1 office of Science and Technology. He served as the
2 reviewer of the application's software
3 documentation.

4 And finally, William Defibaugh is an
5 engineer in the Center's Office of Compliance. He
6 served as the reviewer of the application's
7 manufacturing aspects.

8 [Slide.]

9 There will be two presentations from FDA.
10 First, I will be discussing the nonclinical aspects
11 of the device. This will include a brief
12 introduction, a description of the device, a
13 summary of the nonclinical or qualification testing
14 that was performed, and the documentation relating
15 to that for this device.

16 Please note that in this presentation, I
17 may refer to the device as "iBOT" for short.

18 Immediately following my presentation,
19 Captain Schroeder will discuss the clinical aspects
20 of the iBOT Mobility System. This will include a
21 description of the pivotal study, user assessments,
22 and a summary of the safety and effectiveness data
23 reported in the PMA application.

24 The sponsor has already done a nice job of
25 describing the device, so to avoid unnecessary

1 repetition, I will move quickly through some of
2 these slides, and I will attempt to focus on some
3 of the aspects of the device that haven't already
4 been addressed.

5 [Slide.]

6 The sponsor has discussed the fact that
7 the device has multiple operating functions and
8 that it uses a multitude of sensors and gyroscopes
9 and microprocessors and motors to dynamically
10 control the stability and mobility of the iBOT
11 system. Note that the device does not have
12 anti-tip bars, so that is one distinguishing point
13 from conventional power chairs, but it does rely on
14 the i-Balance technology for dynamic stabilization
15 in four of the five operating functions.

16 Another unusual characteristic of the
17 device is that it utilizes nickel cadmium batteries
18 as the power source, and finally, the fact that it
19 does have five operating functions makes it
20 distinct from other powered mobility systems.

21 [Slide.]

22 Just to reiterate, the five functions are:
23 Standard, 4-Wheel, Balance, Stair, and Remote. I
24 will briefly describe each one.

25 [Slide.]

1 The Standard function is, as the sponsor
2 noted previously, quite similar to conventional
3 powered wheelchairs in functionality. The casters
4 contact the ground, and this is useful for
5 providing good turning performance and is suitable
6 for use on firm, level surfaces such as indoors,
7 sidewalks, and paved surfaces.

8 In this function and only in this
9 function, dynamic stabilization is not used. It is
10 suitable for inclines up to 5 degrees, obstacles up
11 to one-half inch. It has a range of 9.3 miles, and
12 I should note that the maximum speed is adjustable
13 depending on the clinician's selection of the
14 template. So if the Slow template is selected, you
15 end up with a maximum speed of 1.8 miles an hour;
16 if the fastest template is selected, you get 5.7
17 miles per hour. And there is an in-between
18 template as well that can be selected.

19 [Slide.]

20 Four-Wheel function is not similar to
21 conventional powered wheelchairs. In this
22 function, it utilizes four driven wheels, but no
23 casters contact the ground. The casters are
24 elevated so that ground clearance is maintained.
25 It is useful for performing on loose terrain and

1 outdoor conditions such as dirt, grass, gravel, and
2 for traversing small curbs and obstacles.

3 Dynamic stabilization is used. It works
4 on inclines or is suitable for inclines up to 8
5 degrees, obstacles up to 4 inches, which includes
6 smaller curbs. The maximum speed is 2.0 to 3.4
7 miles per hour depending on the template selection,
8 and the range is 7.4 miles.

9 [Slide.]

10 In Balance function, only one pair of
11 drive wheels makes contact with the ground, and
12 this was observed in the video that we saw earlier.
13 It is useful for providing mobility at an elevated
14 height. It enables eye-level conversation. It can
15 be turned on or off by the clinician depending on
16 the capabilities of the individual user. It is
17 useful for turning in very confined spaces in that
18 it can pivot basically on a point.

19 It does use dynamic stabilization. It is
20 suitable for inclines up to 5 degrees, traversing
21 obstacles up to one-half inch. It has a maximum
22 speed range of 2.2 to 3.2 miles per hour, and the
23 overall range on a single battery charge for this
24 function is up to 12.4 miles.

25 [Slide.]

1 In Stair function, the available settings
2 that the sponsor noted were assist or solo,
3 depending on the capabilities of the individual
4 user. It can be used with either one or two stair
5 rails.

6 It uses dynamic stabilization. It has a
7 stair geometry that is suitable for Stair function
8 anywhere from 10 to 17 inches, and the riser height
9 is anywhere from 5 to 8 inches.

10 [Slide.]

11 The fifth and final function is Remote
12 function. As the sponsor pointed out, this is an
13 unoccupied function in which the seat back is
14 folded down to enable use of the function. It is
15 useful to moving the device before and after
16 transfers.

17 Mobility of the device is achieved by
18 using a tethered user control panel and by moving
19 or deflecting the joystick while holding down the
20 Okay button on the user control panel. Because of
21 the fact that you need to operate both the joystick
22 and hold the button, two hands are needed.
23 Therefore, some individuals may need the help of an
24 assistant.

25 This function also uses dynamic

1 stabilization. It is suitable for inclines up to
2 25 degrees, a maximum speed of 0.25 miles per hour,
3 and can traverse obstacles up to one inch.

4 [Slide.]

5 The battery and battery charger have some
6 unique characteristics in that nickel cadmium cells
7 are used. The capacity of the batteries when fully
8 charged is 10 amp hours. The time to fully charge
9 them is 6 hours, and if the user chooses to achieve
10 something less than a full charge, 80 percent
11 charge can be done in only 4 hours.

12 [Slide.]

13 Briefly to touch on some of the human
14 factors and user controls, there is a user control
15 panel located either on the right or the left side
16 of the armrest. It extends forward from the
17 armrest and can be easily configured for either
18 right-handed or left-handed use. It includes a
19 joystick and LCD displays which show alert
20 conditions and icons that reflect the particular
21 operating function that is currently in use or that
22 can be selected. It has LED status indicators that
23 indicate a normal condition or a fault condition or
24 an alert condition. It contains an enunciator or
25 horn that is used to either alert the user to an

1 alert condition or to alert other individuals
2 nearby.

3 And finally, there are command buttons
4 that are used to select the particular function or
5 to change the seat angle or seat height.

6 Finally, there is power button that the
7 user controls. That is located on the right side
8 only. So for individuals who may be restricted to
9 only left-handed functionality, that may present
10 some difficulties for those individuals. That
11 would be assessed by the clinicians during the
12 assessment procedure.

13 For Assist function, there is an Assist
14 button on the back of the seat and an Assist handle
15 that the assistant uses to provide leverage for
16 assisted stair-climbing.

17 [Slide.]

18 The PMA sponsor has provided documentation
19 regarding numerous nonclinical tests conducted to
20 evaluate the system level performance of the iBOT
21 device. The sponsor refers to these as
22 "qualification tests." Any of these tests were
23 conducted in accordance with FDA-recognized
24 standards as well as other voluntary international
25 standards.

1 These include standards developed
2 specifically for mobility devices such as the
3 ANSI/RESNA Series and the ISO Series, as well as
4 the more widely applicable standard regarding
5 electromagnetic compatibility, electrical safety,
6 flammability, biocompatibility, environmental
7 performance, and many others.

8 When necessary, for example, to evaluate
9 unique features of the iBOT System, these standards
10 were supplemented by the sponsor's own test methods
11 and acceptance criteria.

12 [Slide.]

13 The sponsor has compiled the qualification
14 testing documentation into the following 36 test
15 reports. They are presented on this slide and the
16 following slide. I would just like to point out a
17 few of the more important tests.

18 Static and dynamic stability; braking
19 performance; speed, acceleration and deceleration
20 performance; obstacle climbing ability;
21 flammability resistance; electromagnetic
22 compatibility are all tests that were performed in
23 addition to the other ones you see here.

24 [Slide.]

25 In addition, they looked at electrical

1 safety, general device safety, operation the user
2 control panel, environmental tests such as exposure
3 to altitude, exposure to sunlight, et cetera.

4 [Slide.]

5 These comprehensive system-level tests
6 were performed to evaluate the performance of the
7 iBOT System across its range of operating functions
8 and configurations. The tests represented both
9 normal and worst-case conditions. The results
10 documented in each of these test reports
11 demonstrate that the device met all of the
12 established pass/fail criteria.

13 Note also that FDA is currently working
14 with the sponsor to obtain clarification regarding
15 electromagnetic compatibility test methodologies
16 and results.

17 [Slide.]

18 In terms of the device dimensional
19 specifications, a few that I would like to point
20 out are that the maximum payload is 250 pounds; the
21 overall system weight is roughly 250 pounds; and
22 the seat and backrests can be configured for a
23 variety of dimensions. Also of note is that the
24 device is supplied with a particular type of
25 cushion, but the seatpan and backrest will

1 accommodate other third party-developed cushions.

2 [Slide.]

3 Additional specifications with regard to
4 the dimensions of the device include the fact that
5 the seat height is adjustable in 4-Wheel and
6 Balance functions of a range of several inches, as
7 are the armrest and footrest distances to
8 accommodate individual's needs.

9 Also of note is the wheelbase. In
10 Standard function, it is the greatest because the
11 casters are contacting the ground, whereas in
12 4-Wheel function, it is significantly reduced
13 because the casters are no longer touching the
14 ground, but all four drive-wheels are.

15 Therefore, looking just at the numbers,
16 you would expect that 4-Wheel function might be
17 somewhat less stable, but because of the fact that
18 i-Balance technology is being employed, that
19 enhances the stability of the device.

20 [Slide.]

21 In terms of performance specifications, I
22 would like to point out briefly that the maximum
23 speed is adjustable according to the clinician's
24 set template. In Standard function, the speed is
25 anywhere from 1.8 to 5.7 miles an hour in the

1 forward direction, and in reverse, it is 1.0 mile
2 an hour. Similarly, there is a range of adjustment
3 on the 4-Wheel and Balance function speeds, whereas
4 with Remote function, the speed is set at 0.25
5 miles an hour in both forward and reverse,
6 independent of the template that is set.

7 [Slide.]

8 In addition, depending on the particular
9 function and use, the braking distance varies over
10 a range of roughly 5 to 10 feet, and the driving
11 range, as I noted earlier on the slides, ranges
12 depending on the particular function that is being
13 used.

14 [Slide.]

15 Additional performance specifications
16 include obstacle heights that vary depending on the
17 particular function, with 4-Wheel function being
18 most appropriate for obstacles of heights up to 4
19 inches, the maximum surface slope again being
20 dependent on the particular function.

21 And an additional point which I haven't
22 raised to this point is that the noise emissions
23 from the device were measured with roughly a 44 db
24 ambient noise level, so when the device is
25 stationary, the noise is quite low, and when it is

1 being driven, when the motors are turning, the
2 noise level is increased above ambient; however,
3 these are significantly lower than levels which
4 would be necessary to cause any type of hearing
5 damage. It is quite a ways below that level.

6 [Slide.]

7 Finally, electromagnetic compatibility.
8 This has been an issue of continued interest to the
9 Center. The Agency has become aware of a number of
10 adverse interactions between medical devices and
11 other sources of electromagnetic energy, such as
12 handheld radios, cellphones, and the like.

13 The sponsor has provided testing and
14 labeling regarding EMC. A little later, when it is
15 time for the panel to address FDA's questions,
16 please note that there will be a specific panel
17 question asking for your opinions on the EMC
18 testing that was provided in the PMA as well as the
19 labeling for the iBOT Mobility system.

20 This concludes my presentation.

21 Marie Schroeder will now discuss the
22 clinical aspects of the iBOT Mobility Device.

23 Thank you.

24 DR. YASZEMSKI: Thanks very much, Mr.
25 DeLuca.

1 Captain Schroeder.

2 CAPTAIN SCHROEDER: Good morning.

3 Welcome.

4 My name is Marie Schroeder, and I did the
5 clinical review for this PMA, and I would like to
6 welcome you to the panel meeting.

7 [Slide.]

8 The sponsor has done an excellent job of
9 providing an overview of the pivotal trial. I
10 would like to give you an overview to set the stage
11 for the panel questions later today and provide a
12 little bit of additional information that could not
13 be done during the sponsor's presentation and
14 highlight a few items that the sponsor has
15 presented.

16 Therefore, I will be discussing a little
17 bit of the background of the PMA, review the
18 Indications for use, discuss the assessments and
19 training, and then briefly summarize again the
20 pivotal trial, discussing the safety analysis,
21 effectiveness analysis, and some human factors.

22 [Slide.]

23 This is an original Pre-Market Approval
24 application. It was granted expedited review
25 status, and the sponsor also conducted some pilot

1 studies, one in 1999 and one in 2002, that dealt
2 with assessing the early versions of the iBOT as
3 well as the early versions of the training and
4 assessment tools.

5 The sponsor used the experiences from
6 these pilot studies to initiate revisions to both
7 device and to the training materials and processes.

8 [Slide.]

9 The pivotal study was conducted from
10 February until May of 2002, and this was the only
11 study in the PMA that assessed the actual marketing
12 version of the iBOT and the marketing versions of
13 the assessment and training methods and materials.

14 [Slide.]

15 The Indications for Use as stated in the
16 PMA are the INDEPENDENCE iBOT 3000 Mobility System
17 is a powered mobility device for individuals who
18 have mobility impairments and the use of at least
19 one upper extremity.

20 It is to provide indoor and outdoor
21 mobility in confined spaces at an elevated height.
22 It is to be used to climb curbs, to ascend and
23 descend stairs, to traverse obstacles, travel over
24 a wide variety of terrain and negotiate uneven and
25 inclined surfaces.

1 [Slide.]

2 The device label will bear the
3 prescription labeling, and clinician certification
4 will be required.

5 And now I would like to summarize the
6 pivotal trial.

7 [Slide.]

8 First, I would like to discuss the
9 assessments and training, and again, since the
10 sponsor has already covered these, I will just
11 briefly remind you of what was involved and note
12 that what was used in the pivotal trial is what
13 they intend to use for the marketing version.

14 [Slide.]

15 Clinician certification is basically four
16 steps--learning to drive and operate the iBOT by
17 themselves as a user would be trained. Then, they
18 learn to assess the driver; the learn to deliver
19 the iBOT training to the user; and then, they go
20 through an observation in the field where they go
21 through the whole process with the potential user.

22 [Slide.]

23 This slide and the next are just a
24 reminder of the materials that are used in each
25 step of the clinician certification process.

1 [Slide.]

2 I will note that, under Number 3, the
3 clinician observation test videos have not been
4 provided to date but will be provided in an
5 amendment.

6 [Slide.]

7 User assessment and training basically
8 involved five steps starting with the screening
9 mailings to the users, the clinic assessment to
10 decide whether they seem to be a good candidate.
11 Then, materials were delivered prior to receipt of
12 the device and final training, and finally, the
13 actual clinic training and assessment.

14 [Slide.]

15 Again, this slide and the next are just
16 reminders of the materials that were used for each
17 step.

18 [Slide.]

19 There will be panel questions, one about
20 the clinician certification process and one about
21 the user training and assessment later today, so
22 again you can use this as a reminder of what is
23 involved.

24 [Slide.]

25 We will also have two panel questions

1 regarding the safety and effectiveness of the
2 product, so I will start the discussion by
3 reviewing again the safety results.

4 [Slide.]

5 As noted under the adverse events by the
6 sponsor, there were two minor bruises and five
7 falls. Out of the falls, three were with the iBOT,
8 and two were experienced with the user's own
9 device. In only one case did one of the falls from
10 the iBOT result in a minor bruise.

11 There were four other adverse events that
12 occurred that were not related to the iBOT. They
13 occurred during use of the users' own mobility
14 devices.

15 [Slide.]

16 There were some device failures that
17 required replacement of either the device or the
18 components. Twelve of the 20 subjects experienced
19 a total of 22 events that resulted in replacement
20 of the device or one or more components. Nine of
21 these events occurred with the user's own devices
22 and 13 with the iBOT. None of the device failures
23 resulted in injury to the subjects.

24 [Slide.]

25 This slide is just a listing of the

1 replacements needed for the iBOT. The very first
2 one, you can see there were three cases where the
3 sponsor actually replaced the entire device, and
4 the rest were component replacements.

5 [Slide.]

6 The three cases where the entire device
7 was replaced, it was decided that instead of
8 replacing the component, it would be more
9 convenient for the study to actually replace the
10 whole device. These are the three problems that
11 initiated those device replacements--a bent charger
12 port pin; seat height was unable to be adjusted;
13 the user control panel back light failed to
14 function during stair-climbing.

15 [Slide.]

16 And this list is again the replacements to
17 the own mobility devices, so you can see there were
18 a number of other replacements. The majority for
19 both iBOT and the own device replacements were
20 mechanical; there were a few related to power and
21 modem cables and modems with the iBOT.

22 [Slide.]

23 I would like to just discuss under safety
24 as well a subset of what the sponsor refers to as
25 data logger distribution data, which I identified

1 as computerized alert and failure identification
2 data, this particular subset. We were concerned
3 that some of these incidents that were identified
4 through the computerized program could be a
5 potential case where a user could get hurt,
6 especially depending on where the event occurred.

7 However, the sponsor has already discussed
8 in detail the controller failure cases, the five
9 cases, and the other alert cases, they have
10 clarified that none of them has resulted in injury
11 to users.

12 So in this case, each of these cases, the
13 device actually responded as it was intended, and
14 there were no injuries to the users.

15 I would also like to mention that we asked
16 the sponsor to clarify whether it appeared that any
17 of the patient's medical condition actually
18 contributed to any of these failure conditions or
19 alert conditions. They clarified that after
20 reviewing the data, it seemed that possibly two
21 patients' conditions may have contributed to the
22 problem.

23 In one case, a subject had a C6/C7 spinal
24 cord injury and a right below-knee amputation. He
25 had a large body build, but he had poor tone and

1 muscle control of his trunk, and he used large
2 trunk movements to achieve a functional trunk
3 position. This is the subject who had been trying
4 to cause the rear wheels to lift off the ground,
5 which is not recommended, by leaning his trunk far
6 forward. As the device started to travel forward to
7 get the wheels under the subject's center of mass,
8 the subject could not lean backward to attempt to
9 regain control, and therefore, his medical
10 condition may have contributed to the controller
11 failure which shut down and caused the fall.

12 There was another subject in which case
13 there was a C6 spinal cord injury, and the patient
14 lacked finger flexion, so grip was difficult. This
15 particular subject had attempted to avoid a hazard,
16 and he turned too far to the right and struck a
17 curb and fell laterally. It is possible that if he
18 had had better grip, this might not have occurred,
19 but again, just to indicate that there were two
20 cases where medical condition may have had an
21 impact on the outcome.

22 [Slide.]

23 I would like to briefly review for your
24 discussion for the effectiveness question this
25 afternoon, there were a number of effectiveness

1 analyses performed. The primary outcome measure
2 was the community driving test, and the secondary
3 outcome measure was the subject-specific function
4 scale.

5 [Slide.]

6 The sponsor did a very nice job of going
7 through the actual score results. I just wanted to
8 highlight again the test limitations that were
9 already mentioned. This test did not test the
10 two-rail technique; it only tested the one-rail
11 stair-climbing technique. The Balance function was
12 tested by one task which was retrieving a book from
13 a high shelf. The Remote function was not tested.
14 And speed templates that were assigned to the
15 subjects which were utilized during the real world
16 use and during the test, the vast majority--18
17 subjects out of the 20--used the medium speed; only
18 two subjects used the fast speed template.

19 [Slide.]

20 I would also like to clarify that, just
21 looking at the scores of the community driving
22 test, it appears that 10 users were solo or
23 independent stair-climbers. The data, however, and
24 the demographic analysis of the PMA indicated that
25 there were 12 solo or independent stair-climbers.

1 The discrepancy was that the community driving test
2 limitation was one-rail stair-climbing, not two.

3 Two of the 12 independent users were
4 independent only with the two-rail technique, and
5 when they passed their driving test, they were
6 cleared as a two-rail user. However, during the
7 community driving test, they could not be tested
8 and had to use an assistant for that. So that is a
9 discrepancy in those numbers.

10 [Slide.]

11 Also of note is that four of the subjects
12 who were independent also decided to bring and
13 train assistants for stair-climbing in anticipation
14 that some of the stairs that they will encounter in
15 their environment would require assistance.

16 [Slide.]

17 And this is just a reminder of some of the
18 limitations of the subject-specific function scale,
19 but again, while there are limitations to this
20 data, it does provide some additional insight on
21 both limitations and benefits of the iBOT as
22 compared to users own chairs for mobility devices.

23 [Slide.]

24 There were a number of other methods of
25 data collected to provide additional insight to the

1 use of the iBOT and the user's own mobility
2 devices. The data logger distributions also
3 include effectiveness data as discussed by the
4 sponsor, the device failures and replacements that
5 I just mentioned, the accessibility problems that
6 were discussed earlier today by the sponsor,
7 mechanical and operational difficulties, which I
8 will briefly go over in a minute, and home and
9 community maneuvering summary which was provided by
10 the sponsor.

11 Before I go on to the next slide, I just
12 wanted to clarify--for the data logger
13 distributions, this included some of the distance
14 and time data regarding how much time was spent
15 totally in the iBOT versus how much time was spent
16 in each function, and if you look at the balance
17 information, the community driving test really only
18 tested one Balance function, so I thought it was
19 helpful that they had this additional data to show
20 time and distance traveled in the Balance function
21 from the data logger distributions.

22 I did ask for clarification about
23 individual subject use of the Balance function, and
24 it was clarified that seven subjects used the
25 Balance function for less than 2 hours total during

1 the 2-week testing and usage period of the iBOT.
2 One of these subjects used it for only 0.7 hours,
3 so for less than an hour. It is not clear how much
4 of that time for these low users was actually done
5 in testing, whether they actually used it in the
6 real world or not, or most of it or all of it was
7 done in the testing situation.

8 However, they also clarified that 13 of
9 the subjects used it for greater than 2 hours, and
10 in fact, one patient used the Balance function for
11 18.4 hours.

12 Also, regarding the Remote function, which
13 was not tested by the community driving test, data
14 logger distributions report a total of 5.9 total
15 hours for the Remote hour meter. However, if you
16 look at the individual data, the sponsor clarified
17 that only one subject actually used this function;
18 the other subjects had no time reported for the
19 Remote function.

20 [Slide.]

21 This is just a chart to remind you of the
22 mechanical and operational difficulties that was
23 provided in the PMA. The majority of the areas of
24 difficulty were similar. The main differences
25 between the mechanical and operational difficulties

1 for the iBOT versus the users' own chairs existed
2 with the batteries, the user control panels, and
3 the user techniques.

4 Since the vast majority of the users' own
5 devices were not powered, we would expect, of
6 course, to have more battery difficulties with the
7 iBOT when comparing both groups.

8 The user techniques, the sponsor went back
9 and itemized the specific techniques and looked at
10 them, and in fact most of these should become less
11 of a problem as the user becomes comfortable with
12 the device.

13 [Slide.]

14 And I will just briefly mention a few of
15 the human factors that were identified during this
16 2-week iBOT usage period and testing period. And
17 of course, the first one I listed was that one of
18 the subjects identified a problem with disabling
19 the joystick. There is a method to disable it,
20 especially when you are in the Balance function, so
21 that if you are in a crowded room, for instance,
22 and someone bumps the joystick, you won't go flying
23 across the room. However, if you touch any one of
24 the buttons on the control, you can reawaken the
25 joystick. And someone, another person, had bumped

1 one of these buttons, and the joystick was bumped,
2 and the user was not expecting it--but of course,
3 there was no injury involved in that case.

4 Another, the sponsor already mentioned.
5 There are a number of pinch points. One patient
6 received a bruise in the study, and the user manual
7 and the training do emphasize the areas of
8 potential pinch points.

9 [Slide.]

10 There were some cases where it was noted
11 that the user control panel was difficult to detach
12 from the armrest, and the user may get hurt or
13 might not be able to detach to use the Remote
14 function. And the user control panel display can
15 be difficult to see due to glare, and also, when
16 operating the joystick, your hand is obstructing
17 the display. So that was somewhat of a problem.

18 In conclusion, I would just like to remind
19 you that we will be having the panel questions
20 later today. I hope this information will be
21 helpful in setting the stage for your deliberations
22 and discussion of these questions.

23 I would really like to thank the sponsor
24 this morning for their cooperation. It was a lot
25 easier planning for this panel meeting when there

1 is cooperation and sharing of information on the
2 presentations.

3 So thank you so much for your time, and I
4 am available for any questions later on.

5 DR. YASZEMSKI: Thank you very much,
6 Captain Schroeder.

7 This concludes the presentations by both
8 sponsor and FDA.

9 We are going to move now to our panel
10 presentations. These will be a preclinical
11 evaluation by Dr. Myklebust; an electromagnetic
12 compatibility presentation by Mr. Fenical; a
13 clinical presentation by Dr. Stiens; and a
14 statistical presentation by Dr. Larntz.

15 We'll start with the preclinical review by
16 Dr. Myklebust.

17 Panel Presentations

18 DR. MYKLEBUST: I focused primarily on
19 Volumes 10 to 13, which present the results of the
20 36 test reports that have been described in both of
21 the earlier presentations. And I tried to focus on
22 four kinds of considerations. One was to look at
23 the overall plan of the test procedures, these nine
24 clinical test procedures; look at how the system
25 performed in standard mode compared with other

1 available systems; looking at the enhanced modes
2 and how they performed on these tests in those
3 cases; and then, I wanted to look particularly at
4 the internally-generated tested aspects for which
5 there is no apparently available standard.

6 Basically, in terms of the overall plan,
7 my view was that this is a very comprehensive and
8 thorough evaluation, certainly with respect to all
9 of the available standards and in fact, in a number
10 of cases seemed to be a more rigorous evaluation
11 than might be routinely required.

12 I might have liked to have seen a little
13 more discussion of how the internally-generated
14 tests were developed and how the pass/fail criteria
15 were developed, but having said that, it appears to
16 be a very thoughtful consideration of all these
17 other aspects, and the tests seem to be
18 well-thought-out, and I don't have a quarrel with
19 the criteria that were utilized.

20 I think another strength in this regard is
21 that they apparently involved some well-known and
22 well-respected experts in the area of the
23 wheelchair standards that were used in the testing
24 process which adds some additional confidence, I
25 think, to the quality of this testing.

1 In the Standard mode, I was looking
2 particularly at some of the tests that involve what
3 I think are arguably the most critical evaluations
4 in terms of safety and so forth, and I think this
5 is borne out by the adverse events that were
6 described in the clinical portion. This comes down
7 to the stability question, particularly the static
8 and dynamic stability tests.

9 In the Standard mode, the device performs
10 as well as or better than most of the
11 commercially-available systems that I have seen,
12 and particularly in the Dynamic mode, it seems to
13 be significantly better.

14 This actually carries over into the
15 enhanced modes. It performs quite well in these
16 modes as well.

17 Looking at these internally-generated
18 standards, there is a wide range of things that
19 were evaluated, and again, although I think it
20 would be interesting to hear a little bit more
21 about how these particular areas were chosen and
22 how the tests were developed, it certainly appears
23 to be a comprehensive evaluation of a number of
24 other aspects that are important, including things
25 like stability under impact, which is I think

1 particularly interesting in the Balance mode,
2 looking at the crack traversal evaluations, and so
3 forth.

4 DR. YASZEMSKI: Thanks very much, Dr.
5 Myklebust.

6 We're going to continue now, Mr. Fenical,
7 with your electromagnetic compatibility review.

8 MR. FENICAL: Thank you.

9 I reviewed the--I'll just use "EMC"
10 instead of "electromagnetic compatibility," if
11 that's okay with everybody--I reviewed the EMC
12 report supplied and found that it used recognized
13 standards, standards that do deal specifically for
14 devices such as this, so I found that to be
15 appropriate.

16 The functions tested were as shown, the
17 five functions--Standard, 4-Wheel, Balance, Remote,
18 and Stair. However, I will say that the report was
19 quite vague about how it was tested in these
20 functions. It showed that it was tested and did
21 pass the requirements, but there were no
22 descriptions of how and no photographs or
23 schematics or drawings or anything of just how
24 these tests were performed. I would be very
25 interested to see how a test such as stair-climbing

1 was performed in an EMC laboratory environment.

2 I just have a slide here in front of me of
3 the devices tested, and it shows that four
4 different devices were tested at various times for
5 various parts of the test.

6 Maybe I should go back and say what
7 actually was tested from an electromagnetic
8 compatibility point of view. It was tested for
9 electromagnetic radiated emissions--that is,
10 electromagnetic energy being emitted from the chair
11 that might interfere with other devices.

12 It was tested for immunity against
13 electrostatic discharge. I think we are all
14 familiar with that--walking up to something and
15 creating an ESD event that might upset the devices.

16 Electromagnetic immunity to radiated RF
17 fields such as fields that might come from things
18 such as mobile phones, GPS receivers, and so on and
19 so forth.

20 Additionally, for the charter, it was
21 tested for immunity to electrical fast transients,
22 which are switching transients on the power line
23 that might upset the device; and electromagnetic
24 compatibility for surge, which would involve things
25 such as lightning surge on the lines or surge from

1 large switching transients.

2 So the range of tests was applicable to
3 this type of device.

4 As for radiated emissions, all units
5 passed except that one unit failed at 180 megahertz
6 by 6.2 db. That was the worst-case failure.
7 Failure analysis as reported in the test report was
8 inclusive, but was particular to that specific
9 machine; no other machine had any failure.

10 I researched that frequency, and that is
11 Channel 4. So worst case is that that might
12 interfere with "Days of Our Lives" or something
13 like that--which the FCC would not like. But the
14 failure had no potential safety issues for the
15 chair; that was an emissions failure.

16 For electrostatic discharge, all units
17 passed all tests in excess of the requirements in
18 all modes.

19 For radiated RF fields, all units passed
20 all tests in excess of the requirement of 20 volts
21 per meter in all modes tested. However, they did
22 test above the required 20 volts per meter, and it
23 was reported in the test report, so I should
24 probably bring it to light--there were some
25 failures in excess of the 20 volt per meter

1 requirement.

2 Let me jus quickly go through them. I
3 won't identify the machine numbers.

4 One in Balance mode at 448 megahertz had a
5 gyro fault, and that frequency range is radio
6 location, such as GPS. The chance of fields being
7 high in that frequency range are low because it
8 would be something such as a GPS receiver. Nothing
9 near the device should be transmitting at that
10 frequency.

11 In Balance function between 829 to 1,000
12 megahertz, there was a Power Source B fault. Again
13 I might say the report did not say what these
14 faults really were. It just said they had this
15 fault. So an explanation of what the fault is
16 would be good. But that is aerospace navigation,
17 amateur broadcasting, and others. And again, I
18 think there is a very low possibility of anybody
19 transmitting near this device in those frequency
20 ranges.

21 In Balance function at 374 and 380
22 megahertz was a gyro alarm. That is a mobile
23 satellite communication.

24 And then, in all except Balance and Charge
25 modes-- these next three failures were all except

1 Balance and Charge modes--378 megahertz, gyro
2 fault, mobile satellite communication again. At 40
3 megahertz, it stopped forward motion, and that is a
4 space research channel, communications between
5 Earth stations and satellites.

6 At 376 megahertz, a gyro fault, and again,
7 mobile satellite communication.

8 So the faults that did show up, again in
9 excess of the requirements, present a very low risk
10 of fields really being out there in the real world
11 that might get near the device.

12 For transient burst, and surge in Charge
13 mode--actually, on the charger--all units passed
14 all tests in excess of the requirements.

15 For labeling, I reviewed all of the
16 labeling proposed, and they appeared to be in
17 accordance with the current guidelines and
18 standards.

19 In conclusion, my opinion is that the iBOT
20 3000 Mobility System meets its EMC requirements and
21 EMI labeling requirements. However, in Tab 6 of--I
22 think this is called the Summary of EMC Review
23 Findings--on the last page of Tab 6 of the report
24 by CDRH, there are five recommendations that I
25 concur with. And I noticed in the presentation, it

1 says "FDA is currently working with the sponsor to
2 obtain clarification regarding electromagnetic
3 compatibility test methods and results." So if
4 that is currently going on, that should be covering
5 these issues.

6 But the issues are: a clear summary of
7 all EMC testing, emissions and immunity of the iBOT
8 device with the test results and data to support
9 their claims for immunity to EMI; a brief
10 explanation of how each EMC test was performed and
11 how the testing for each mode addresses the risk
12 for EMI and demonstrates EMC to be to the claimed
13 levels; reference to the appropriate EMC testing
14 standards, such as CDRH-recognized ANSI/RESNA,
15 WC/Volume 2 1998 Standard, Section 21; the
16 pass/fail criteria for each of the EMC tests--how
17 were these qualified and measured--and
18 justifications for each criterion.

19 In addition, if there are any deviations
20 from the reference standards or modifications to
21 the device under test, these must be explained and
22 justified.

23 So again, my final conclusion is that I
24 believe it meets its requirements, but these things
25 need to be addressed, and it appears that they are

1 being addressed.

2 Thank you.

3 DR. YASZEMSKI: Thanks very much, Mr.
4 Fenical.

5 Dr. Larntz, would you present your
6 statistical review now?

7 DR. LARNTZ: Yes. This is easy
8 statistically. It is a small study--only 18
9 subjects. How do you get significance done with
10 that? You get significance there if everything
11 works just like it should. Isn't that amazing?

12 I thought it was very cute that they even
13 explained away the small number of cases where they
14 missed by a point. Amazing.

15 So statistically, there is no problem
16 here. The study does show that the device does
17 work, does improve for patients.

18 I have a couple comments, small
19 comments--and by the way the sponsor's presentation
20 was excellent. Everyone has said that, and I'll
21 say it.

22 It would be nice to see the device.
23 Sorry--I'm a statistician, but I like concrete
24 things. It's a minor point. Maybe you've got one
25 someplace.

1 We have to be very careful in extending
2 the results of this pivotal study. There is
3 clearly a need to qualify individuals for this
4 device, and you clearly talked about that. I just
5 want to make sure we understand that that is
6 absolutely necessary. And in that qualification--
7 you exclude a few individuals from the pivotal
8 study because they would not qualify. That has to
9 be carried out for sure in the real world. And I
10 think you are planning to do that, but I just want
11 to make sure that is clear.

12 The other thing which I thought would be
13 interesting, but I know the pivotal study was
14 finished in May of this year, it would be nice to
15 know what those devices are doing now and what the
16 people are doing with them now. It would be nice
17 to have a longer-term follow-up, and I think the
18 agency might want to request that and find out for
19 these 20 people or whatever who had devices how
20 many are sitting in the corner now, not being used,
21 how many are being used regularly, and so on, just
22 for long-term follow-up.

23 Other than that, as we say in statistics,
24 this effect is so big, it is a slam-bang effect.
25 There is no need for a statistician to see the

1 effect--and that's too bad, because we like to be
2 employed.

3 Thank you.

4 DR. YASZEMSKI: Thanks very much, Dr.
5 Larntz.

6 Dr. Stiens, would you present for us your
7 clinical review?

8 DR. STIENS: Sure, I'd be happy to.

9 I'd like to direct everyone's attention to
10 a diagram that I circulated and will also project
11 up there through a transparency.

12 I come at this from a variety of realms,
13 being a consumer; I am a clinician. And I hope I
14 won't bore the group by being a little redundant in
15 some of the parts of my presentation that I will
16 come about with.

17 I want to make it clear that as a
18 clinician, I am a physiatrist, and many of the
19 people in the room know what that is, but some may
20 not. It means I am a rehabilitation physician. I
21 work with a group of clinicians in concert to meet
22 patient-centered needs that would come under our
23 noses as a result of their various conditions and
24 impairments.

25 Now, with that information from a patient,

1 their diagnosis and so on, I want to also mention
2 that we tend to use a variety of assessments of
3 patients that go beyond diagnosis. These have been
4 defined by the World Health Organization in the
5 past as impairments, disabilities, and handicaps.
6 That has since been revised to impairments,
7 activity limitations, and limitations in
8 participation.

9 So when I view effectiveness and so on, I
10 see things in that realm.

11 I want to give a few general comments, and
12 I want to read them from my notes made last night.
13 I want to preface that by saying that I did receive
14 all of the volumes in a big box and went through
15 those, and I had a variety of comments on those,
16 but many of them have been covered previously, so I
17 won't bore you with all my notes from those.

18 From my standpoint, the size and weight
19 are comparable to other power wheelchairs, and that
20 is encouraging to me as a consumer and a clinician.
21 And I thought it offered effective mobility in what
22 I term the intermediate environment.

23 Now, they are working up to projecting the
24 diagram, but you guys should have the low-tech
25 version on your laps, and I am going to go through

1 that diagram with you to help you kind of
2 understand how I conceptualize this device within
3 the environment.

4 And this diagram, I might mention, came
5 from a National Center for Rehabilitation Research
6 symposium here in town a number of years ago, but
7 essentially, it puts the person in contact with the
8 immediate environment, which is all that they are
9 wearing and the mobility device that they would
10 choose to carry with them.

11 Then, you take that unit, the person and
12 their mobility device--and those who are listening
13 should realize that I am sitting here in a mobility
14 device, wheelchair-presenting--and then you take
15 that unit and put it into the intermediate
16 environment.

17 The intermediate environment has a roof on
18 it here, and it is a little space, and what I want
19 to point out is that the intermediate environment
20 is an environment that the person has chosen to
21 tune for their own specific needs. So this
22 wheelchair and that person need to interact with
23 that environment, and we have had a few examples of
24 that interaction come up already this morning.

25 So the intermediate environment might be

1 their office or their home that they have chosen to
2 adapt to the extent they can for their needs. And
3 I might add that there might be a variety of other
4 characters within that environment. We have twins
5 at home, so they explore and intrude into all
6 environments that they can.

7 And then, outside is the community
8 environment. I am now sitting in the community
9 environment, and I have been back and forth to
10 community facilities and so on that have allowed me
11 to hang out here.

12 Then, beyond that is the natural
13 environment, and the natural environment, coming
14 from the Northwest and visiting National Parks and
15 so on to the extent that I can, is the unaffected,
16 unmodified space that is celebrated and protected
17 by our Government as well. So there is that
18 interaction between the natural environment and the
19 person and their mobility device that occurs. So
20 if you take that out of the home, we have
21 accomplished that politically, and if you put them
22 in the natural environment, there are good and bad
23 aspects of that interaction, but you need to
24 consider that.

25 Now, with that information, I want to go

1 on and give my comments.

2 The 4-Wheel drive function I thought
3 certainly expanded user capability over
4 conventional manual and powered mobility that I was
5 aware of, and it certainly increased the
6 effectiveness of the person within the natural
7 environment from the descriptions of the testing
8 that I received.

9 I thought that the capacity for balancing
10 on two wheels in the intermediate environment and
11 the community environment was impressive--I was
12 impressed by that--and I was actually surprised
13 that there weren't problems with that, reviewing
14 the description of what the tolerance for barriers
15 was. I have read it all the way from a half-inch
16 to an inch. I was impressed with the challenges to
17 stability of the device, and I was reassured by the
18 fact that there were no significant safety risks
19 associated with the interaction between the person
20 and the community and intermediate environments in
21 that regard.

22 I also thought the Balance mode produces a
23 precarious state that could lead to falls and
24 injuries. I was concerned with that. I was
25 encouraged that that didn't happen. I wondered

1 about the effect on participation that would result
2 from such a situation that the person indeed can be
3 raised up to interact with people, and that has
4 been mentioned as an advantage. I am wondering
5 about the risks and benefits of that.

6 It seems to me that the consumers in the
7 trials that have been presented have been able to
8 make good judgments about when to use that
9 capability and when not to, and I would look
10 forward in the future to see if well-chosen
11 consumers and trained consumers would be able to
12 make that judgment.

13 The mechanism for descending stairs I
14 thought was successfully intuitive for going down
15 stairs. I was concerned about the intuitive
16 challenge of going upstairs backward, and I see the
17 interaction between the person and the device in
18 the immediate environment and the stairways which
19 are pictured in the presentation, mainly in the
20 community environment. That requires a fair amount
21 of judgment.

22 I would look ahead to future assessments
23 of that and look forward to the tapes that were
24 described as assessment tapes in that regard to
25 allow people to make some virtual decisions that

1 they might learn from without having to be
2 challenged with the real situation during a
3 training environment.

4 I wanted to point out an aspect of the
5 interdisciplinary team. We include on the
6 interdisciplinary team physical therapists,
7 occupational therapists, psychologists, sometimes
8 rehabilitation engineers if it is indicated, and
9 these people make judgments with patients in a
10 person-centered mode for their future, and they
11 also provide education.

12 And occupational therapists--we will hear
13 from one today--do this as well as physical
14 therapists, and they do spot people using various
15 mobility devices. It is not common, and I don't
16 know of a situation where a physical therapist
17 would be spotting a person weighing up to 250
18 pounds in a device that weighed 250 pounds on
19 stairs. I do know that there are challenges to
20 nurses' backs and therapists' backs, but I see this
21 as kind of a challenge in the training aspect of
22 this device, and I look forward to some solutions
23 in that regard. I don't think that that is going
24 to be a major pitfall, but it is something that we
25 have to consider.

1 I could talk for a long time, as I have,
2 but I am going to make some comments on the five
3 questions that were presented to us here in our
4 binders.

5 One is clinical certification. Training
6 in the use of the iBOT chair requires skills of
7 occupational therapists as well as physical
8 therapists. I thought assessment for eligibility
9 and indications for the wheelchair can be carried
10 out by a physiatrist with physical medicine
11 rehabilitation, board certification or other
12 trained physicians familiar with the diagnosis, the
13 impairments, activity limitations, and
14 participation limitations of the patient.

15 The development of prescription in
16 training and use of the iBOT wheelchair should be
17 an interdisciplinary process, looking that over and
18 so on. It seems to me that it would be difficult
19 for any one individual, as I understand it, with
20 qualifications to fully bring a patient through
21 that process.

22 And I thought training methodology should
23 include knowledge acquisition as well as hands-on
24 use, and I was very pleased to hear that the
25 clinician was put in the consumer role through that

1 training process--I thought that was important and
2 successful from what I read--and bring them through
3 all the anticipated environments that the patient
4 would anticipate using the chair in.

5 Then, I have no comments on the
6 electromagnetic capability. That was addressed.

7 On device safety, I thought that the risks
8 of the precarious situation that a person could be
9 put in this device were ones that clinicians have
10 not been faced with previously, so this is kind of
11 a new situation for clinicians to judge, although
12 many of our patients came to their disability as a
13 result of risk-taking. That further needs
14 assessment as part of the interdisciplinary team
15 and through the clinician. But I was impressed
16 that when there were challenges to safety in the
17 testing thus far--for instance, when the subject
18 was thrown from the chair and when the chair had
19 fallen over and there was ground contact and
20 bruises--that subjects did reasonably well with
21 that, although I wasn't impressed that testing thus
22 far ruled out safety that would prevent the product
23 from going to market in my estimation.

24 Then, finally, device effectiveness--I
25 will conclude with that and bring you through the

1 diagram.

2 The first area of effectiveness that I
3 consider as a clinician with the interdisciplinary
4 team is the interface between the person and the
5 immediate environment. It seems like this product
6 has the capability for individualization for skin
7 needs and stabilization of the body and posture for
8 controlling the chair.

9 It seems like the armrest was effective
10 for the one limb that is required to control this
11 chair, but I would direct everybody to what is
12 called the linked segment model, where you look at
13 the limb as connected to all the segments--the
14 trunk has already been brought up--so with the
15 linked segment model, you can either work up from
16 the device to the cortex of the person, or you can
17 go from the cortex down. But I would suggest that
18 they need a functioning neuromuscular and
19 perceptual system that goes all the way from the
20 cortex through the coordination of the upper
21 extremity and stability of the trunk and controls
22 the shoulder, elbow, and hand in controlling the
23 device.

24 We have had a limited assessment of the
25 diagnostic groups in our patient population, and

1 those people demonstrate some of the mechanical
2 challenges, but they demonstrate few or none of the
3 perceptual and neuromuscular orchestration
4 challenges that other subjects might present once
5 this chair became a product that would be presented
6 to a variety of consumers. And that variety of
7 consumers includes, of course, people who have had
8 stroke, who are represented in the much larger
9 numbers in the patient populations that exist out
10 there, and that is going to be a conundrum that the
11 clinician has once a device comes out. So that is
12 something that we have to prepare for.

13 Moving on from the immediate environment
14 to the intermediate environment, some of the issues
15 have been addressed there, and I would just suggest
16 that we need a continued focus on outcomes within
17 the intermediate environment, both negative and
18 positive.

19 And then, finally, community
20 environment--you got a hint of that from the video.
21 I think that the demonstration of effectiveness in
22 that regard was pretty successful.

23 Finally, the natural environment was not
24 fully addressed, and that is something that we need
25 to advise consumers on, advise clinicians on in the

1 assessment process.

2 The specific recommendations--inclines
3 were discussed, and inclines that might be present
4 in the community environment and limitations in
5 that regard with respect to barriers in the 2-wheel
6 or Balance mode and 4-Wheel mode, but the consumer
7 mainly learns this information, as a clinician, I
8 feel, from interacting with the environment, and it
9 is a different experience when you are in a manual
10 wheelchair or a powered wheelchair with supervision
11 than when you would be in a Balance mode or
12 otherwise, or 4-Wheel drive, so to speak.

13 Those areas need to be addressed carefully
14 in the assessment and need to be prescribed and
15 limited through an agreement with the consumer who
16 would receive the prescription, because as a
17 clinician, I have to kind of act on the first rule
18 of medicine which is "Do no harm," so when these
19 potential options are presented, I have to judge
20 those with patients and to some extent make an act
21 of faith in certain aspects of patients'
22 capabilities and judgments within the variety of
23 environments I described, and consideration of this
24 variety of issues would be welcome in further
25 development of materials for the device and in

1 testing.

2 I think I'll conclude and respond to some
3 of the other people's presentations in open
4 discussion. I really appreciated all the patience
5 you offered me for the presentation.

6 DR. YASZEMSKI: Thanks very much, Dr.
7 Stiens.

8 The next thing on our agenda is a general
9 panel discussion which is going to aim at answering
10 FDA's questions to us. With FDA's approval, I
11 would like to suggest that we proceed as follows.

12 Let's take a 5-minute break, come back in
13 5 minutes and begin with Question 3, which
14 discusses EMC.

15 Let's take a break now.

16 [Break.]

17 General Panel Discussion

18 DR. YASZEMSKI: Mr. DeLuca, do you want to
19 read it, or shall I?

20 MR. DeLUCA: Your choice.

21 DR. YASZEMSKI: You can read it; go ahead.

22 MR. DeLUCA: Question Number 1, which is
23 not necessarily in the same order as in your panel
24 packs, is regarding EMC.

25 The question is: "Are the electromagnetic

1 compatibility (EMC) testing and labeling--for
2 example, regarding the use of cell
3 phones--sufficient to mitigate the risks in a
4 changing electromagnetic environment over which the
5 user has limited control? If not, what additional
6 measures are recommended?"

7 DR. YASZEMSKI: Thanks very much.

8 What I'd like to suggest that we do here
9 is offer everyone on the panel a chance to give
10 their opinions as an answer to this question, and
11 if you have nothing to say for a particular
12 question, just pass on, and we'll go to the next
13 person.

14 What I'd like to do is, Mr. Fenical, since
15 you gave the overview, I'd like to start with Dr.
16 Goldman next to you, go clockwise, and then you'll
17 have the last word after you have heard what
18 everybody else has to say.

19 Dr. Goldman, do you have any comments on
20 this question?

21 DR. GOLDMAN: I have no questions on this
22 one.

23 DR. YASZEMSKI: Thanks.

24 Ms. Rue, comments on this question?

25 MS. RUE: No comments.

1 DR. YASZEMSKI: Ms. Maher?

2 MS. MAHER: No, thank you.

3 DR. YASZEMSKI: Dr. Stiens?

4 DR. STIENS: I would just add to that
5 weather--the electromagnetic radiation of heat and
6 light--and others who would consider this question,
7 please consider that in the form of weather and
8 whether they feel the device has been sufficiently
9 weathered for release knowing that some people
10 would be in a variety of environments, intense heat
11 and otherwise, using the device.

12 DR. YASZEMSKI: Thank you.

13 Mr. Herman?

14 MR. HERMAN: One of the most certain ways
15 to avoid problems with electromagnetic interference
16 is to turn your chair off when you are not using
17 it. Yet I noticed in the materials provided to me
18 that the On/Off button is not located on the UCP
19 but is rather down on the base. Now, maybe I read
20 that wrong, but I wondered--that is an issue. If
21 the user can't reach the On/Off button, how can
22 they turn the chair on and off?

23 I would be interested from the sponsor to
24 know whether I read that wrong or if it is possible
25 to have an On/Off button on the UCP.

1 DR. YASZEMSKI: Members of the sponsor,
2 can somebody address that?

3 MS. MINKEL: Yes, you are correct. The
4 power to the entire system is located on the power
5 base. The joystick can be deactivated using a
6 sleep function that is on the user control panel.

7 MR. HERMAN: Is that the equivalent of
8 turning it off, as I would do--

9 MS. MINKEL: No, no. It does not
10 eliminate the transfer of power.

11 MR. HERMAN: Okay.

12 DR. YASZEMSKI: Thanks.

13 Ms. Witten, you are always welcome to
14 comment. Have you any comments at this time?
15 Otherwise, we'll end with you and ask if we have
16 answered your question.

17 MS. WITTEN: Yes--has everyone had a
18 chance to comment at this point?

19 DR. YASZEMSKI: No. Then I'll come back
20 to you after we're done.

21 Dr. McQuade?

22 DR. McQUADE: No comment.

23 DR. YASZEMSKI: Ms. Buzaid?

24 MS. BUZAID: I have no comment.

25 DR. YASZEMSKI: Dr. Hannaford?

1 DR. HANNAFORD: Just a brief comment that
2 there may be users--Mr. Fenical mentioned that, for
3 example, at very high, above standard fields in
4 amateur radio bands, there was a test event. So I
5 am just suggesting that labeling or other sorts of
6 information be available.

7 For example, if a user of this device is
8 an amateur radio operator, they may be fiddling
9 around with their transmitter and actually expose
10 to those fields at very high levels. Or, suppose
11 they are an engineer at a broadcasting station.
12 And both of those classes of users would be able to
13 understand the technical info, so maybe there is a
14 website or something that they could be referred to
15 in the labeling where a technically knowledgeable
16 person who happens to be fooling around with
17 radio-frequency energy could check what potential
18 impacts there might be on their wheelchair--excuse
19 me--mobility device.

20 DR. YASZEMSKI: Thanks, Dr. Hannaford.

21 Dr. Abrams?

22 DR. ABRAMS: No comment.

23 DR. YASZEMSKI: Dr. Naidu?

24 DR. NAIDU: I have a few comments. I will
25 base most of my comments on Mr. Fenical's review of

1 the device.

2 It appears that this device seems to have
3 passed in just about everything as far as the EMC
4 criteria. There appears to be immunity against
5 electrostatic discharge. There appears to be
6 immunity to mobile phones. There appears to
7 immunity against switching transient power line.

8 It appears that for general uses, this has
9 passed EMC compatibility by all requirements, and
10 I'm not so sure if there is any special labeling
11 that is needed other than maybe what Dr. Hannaford
12 suggest, that something be posted on the website.

13 So I think that this has passed
14 everything, but of course, my commentary is
15 dependent on Mr. Fenical's review.

16 Thank you.

17 DR. YASZEMSKI: Thank you.

18 I have only one question. I'm not sure,
19 Ms. Minkel, if we got an answer to Mr. Herman's
20 question--how does the person turn it off if he or
21 she needs to? What step do they need to take to
22 disconnect power?

23 MS. MINKEL: One needs to be in Standard
24 function and reach down on the power base and
25 operate the On/Off button to remove power.

1 DR. YASZEMSKI: Thanks very much.

2 Mr. Demian?

3 MR. DEMIAN: No comments.

4 DR. YASZEMSKI: Dr. Finnegan?

5 DR. FINNEGAN: One comment and one

6 question.

7 The comment is to thank Mr. Fenical for a

8 wonderful review that made it very easy to

9 understand.

10 And my question is both to Mr. Fenical and

11 the sponsors, and that is in the most recent

12 Forbes, there is a suggestion that use of most of

13 these bands--there is a huge number of bands out

14 there, and most of them are going to be used with

15 different types of wireless technology over the

16 next decade. Is this a shifting of sands, and do

17 these requirements need to be reviewed on a regular

18 basis?

19 MR. FENICAL: Shall we answer it now?

20 DR. YASZEMSKI: Go ahead, Mr. Fenical.

21 MR. FENICAL: Okay. You are exactly

22 right. Wireless technology is expanding

23 exponentially out there, and I think, as one of the

24 committee members who actually worked on the

25 standard, committees are constantly looking at and

1 reviewing new technology and trying to write
2 standards to anticipate the effects of the changing
3 technology.

4 So, yes, it is something that needs to be
5 looked at, but I think it is effectively looked at
6 as effectively as these committees can be.

7 DR. YASZEMSKI: Thanks very much.

8 Dr. Kirkpatrick?

9 DR. KIRKPATRICK: No questions on this
10 issue.

11 DR. YASZEMSKI: I'm sorry, Dr. Finnegan.
12 Are you done?

13 DR. FINNEGAN: I think the sponsor wants
14 to respond.

15 DR. YASZEMSKI: Go ahead, please.

16 MR. ROLLINGER: I'd like to say a similar
17 thing there. This is Dennis Rollinger, CEO of
18 Radiometrics Corporation.

19 The reason for stepping up is that I am
20 currently the committee person and the technical
21 advisor on electromagnetic compatibility for ISO
22 7176. I am currently the EMC Chair for the
23 ANSI/RESNA WC document, Version 21.

24 I represent a laboratory that is the first
25 laboratory to be accredited through AALA, the

1 American Association of Laboratory Accreditors, for
2 doing testing to 7176 and also for doing testing to
3 ANSI/RESNA WC 21.

4 Right now, I believe we still might be the
5 only laboratory accredited through AALA for doing
6 those types of tests.

7 As a committee member, I also want to
8 amplify what Gary is saying. The standards move,
9 and it takes a while to get the standards out, and
10 I think an important thing to say at this point is
11 that DEKA and J&J on the iBOT have been involved in
12 those advances. We are testing beyond the
13 standard, we are testing beyond the frequency
14 range. The wireless communications that you are
15 talking about, the expansion of communications into
16 the microwave end of the frequency range, the
17 current standards do not cover those frequencies;
18 however, the iBOT has been tested to them.

19 So I just need to make sure that everyone
20 is aware that we have taken those things into point
21 when we did the testing on the iBOT.

22 DR. YASZEMSKI: Thanks very much for that
23 clarification.

24 Dr. Kirkpatrick, you have no questions?

25 DR. KIRKPATRICK: No questions on this

1 issue.

2 DR. YASZEMSKI: Thank you.

3 Dr. Friedman?

4 DR. FRIEDMAN: No questions.

5 DR. YASZEMSKI: Dr. Larntz?

6 DR. LARNTZ: No questions.

7 DR. YASZEMSKI: Dr. Myklebust?

8 DR. MYKLEBUST: No questions.

9 DR. YASZEMSKI: Mr. Fenical, you have the
10 last say. Anything to add or expand?

11 MR. FENICAL: Yes, one thing. The
12 question was brought up about usage by amateur
13 radio operators or people working in broadcast, or
14 in research or in satellite communications.

15 Current labeling requires the device to
16 state that it meets 20 volts per meter. People
17 working in these environments should have some idea
18 of the relative field strength of the environments.
19 If not, they should find it out. Somebody who
20 needs a device like this that is going into an
21 exceptional electromagnetic environment has the
22 basic knowledge that this device has met 20 volts
23 per meter and is deemed safe at that range, and if
24 they are going into a higher level, I think it
25 would be up to them to find out what that level is

1 and then just deal with it accordingly.

2 DR. YASZEMSKI: Thanks very much.

3 I think that to FDA, a summary of our
4 discussion would be that the sponsor has met the
5 requirements for testing for EMC. There were some
6 questions that we had regarding temperature and
7 amateur radio bands and perhaps access to this
8 information for those technical users who might
9 desire it. But in summary, the sponsor has
10 adequately addressed this.

11 FDA, have we adequately addressed your
12 question on this issue?

13 MS. WITTEN: Yes. Thanks.

14 DR. YASZEMSKI: You're welcome.

15 We have 10 minutes before lunch. Can we
16 start another question, and I'll just say that
17 we'll halt our discussion in the middle of it at
18 12:30 and break for lunch, but let's use the next
19 10 minutes.

20 Let's go to the question on clinical
21 certification, and I'll ask Mr. DeLuca to read it.

22 MR. DeLUCA: Thank you.

23 "Clinician certification. The sponsor
24 proposes that clinicians obtain certification in
25 order to be able to assess and train prospective

1 iBOT users. Is the proposed clinician
2 certification process adequate for assuring that
3 clinicians can identify appropriate users and train
4 them to use the iBOT in a safe and effective
5 manner?"

6 DR. YASZEMSKI: Thank you.

7 For this one, I would like, Mr. Herman, to
8 start with you and go clockwise, so Dr. Stiens, you
9 can give a summary after you have given your
10 clinical review.

11 Mr. Herman?

12 MR. HERMAN: Well, I don't have
13 substantive comments on the form and substance of
14 the training as much as I have concerns about the
15 power a clinician can have over the desire and
16 power of a consumer to purchase and use an iBOT
17 wheelchair by the simple act of saying one is
18 qualified or one is not qualified to use such a
19 device--although I understand that there are a lot
20 of issues, and the consumer needs to be able to use
21 the device safely.

22 But I wonder if anybody could help me
23 understand or comment on how the prescription
24 process would work and what kinds of limitations on
25 a consumer to make his or her own choices about

1 purchasing such a device and using it--and I hope,
2 Mr. Chairman, this is the right time to ask this.

3 DR. YASZEMSKI: That's quite all right.
4 Would you like a member of the sponsor's group to
5 answer that question?

6 MR. HERMAN: That would be great.

7 DR. YASZEMSKI: Can someone from the
8 sponsor's group address that?

9 Ms. Minkel?

10 MS. MINKEL: It is anticipated that much
11 like current power mobility, or manual mobility for
12 that matter, that is seeking third party payment
13 reimbursement, those are often needing a
14 physician's agreement, signature, sign-off, in
15 addition to a letter of justification.

16 We anticipate that this process would be
17 very much the same with a formal assessment process
18 having an outcome with specific device
19 configuration that would need consensus with other
20 team members including the physician. So the
21 physician's signature would be required as a part
22 of the purchase process of this prescriptive
23 device.

24 MR. HERMAN: A follow-up?

25 DR. YASZEMSKI: Please do.

1 MR. HERMAN: If a person is paying for it
2 privately, would the same sort of prescription be
3 needed from a physician and the same kind of
4 training? Would that be a requirement before one
5 could actually take possession of it?

6 MS. MINKEL: Yes. My understanding as a
7 prescriptive device is that it would require a
8 physician's signature, and from the sponsor's
9 perspective, the training is consistent regardless
10 of who the payer is.

11 MR. HERMAN: Okay. The clinician, of
12 course, would be the one to do the training of the
13 user and I assume to calibrate the device according
14 to the individual's center of gravity. Would the
15 same clinician also be responsible for measuring
16 the device to the person--the seat width, the seat
17 depth, the back height, whether it is a J-back or a
18 J-cushion or a footrest measurement--that sort of
19 thing?

20 MS. MINKEL: Again, consistent with
21 today's practice, you usually partner--I as a
22 clinician will partner with the company's
23 representative, so we do that collaboratively, so
24 that I am sure that what I am measuring, they can
25 provide. So it would be a joint effort with the

1 Independence Technology representative and the
2 clinician.

3 MR. HERMAN: Okay. Thank you.

4 DR. YASZEMSKI: Thanks very much, Mr.
5 Herman.

6 Ms. Witten, I'm going to pass you by
7 unless you have something to say, but I'll ask you
8 every time.

9 MS. WITTEN: Nothing to add.

10 DR. YASZEMSKI: Dr. McQuade?

11 DR. Just to follow up on what you just
12 said, does this mean that the certification process
13 for the clinician does not render the clinician
14 independent assessor, that they always have to have
15 a sponsor member there with them? That's what I
16 read from what you just said.

17 MR. O'DONNELL: This is Jim O'Donnell with
18 Independence Technology.

19 We intend to have a company representative
20 there during the course of device delivery, not
21 necessarily at assessment or when the decision is
22 made as to whether or not an individual is
23 appropriate for the device, but yes at device
24 delivery.

25 DR. McQUADE: So the question about the

1 measurement for the device size, then, would be
2 made independently by the clinician.

3 MS. MINKEL: Could be.

4 DR. McQUADE: Could be.

5 MS. MINKEL: Could be. And I'll speak
6 from my own personal experience. I have been
7 recommending chairs for people for 20 years and
8 feel pretty comfortable about knowing what the
9 tradeoffs are and how to do the product match to
10 person.

11 There are certain clinicians who would
12 say, "This is new to me; I'd really like to have a
13 representative with me so that we can do this
14 together."

15 DR. McQUADE: Thank you.

16 The other question I had was on precisely
17 "the clinician"--is it required for certification
18 that the clinician be a licensed occupational or
19 physical therapist, or could they be a nurse, could
20 they be a physical therapy assistant? What does it
21 mean by "clinician"?

22 MS. MINKEL: Again I will defer to the
23 sponsor. One clarification is that because the
24 assessment process is equivalent to evaluation by
25 the Practice Acts for Occupational Therapy and

1 Physical Therapy, it would not be inclusive of the
2 assistant level because that is outside of their
3 Practice Act.

4 Physicians--certainly if there were an
5 interested physician, I can't imagine that they
6 wouldn't be welcomed into the certification
7 process.

8 DR. McQUADE: Is the assessment itself
9 reimbursable as an ICV Code physical therapy
10 evaluation?

11 MS. MINKEL: Currently, there are physical
12 therapy and occupational therapy CPT Codes as well
13 as new activity being submitted to the AMA
14 regarding those assessment activities.

15 DR. YASZEMSKI: Mr. O'Donnell, do you want
16 to comment on Dr. McQuade's question?

17 MR. O'DONNELL: To respond to your
18 question about just physical therapists and
19 occupational therapists, I would term it a
20 "licensed health care provider" would be
21 appropriate.

22 DR. YASZEMSKI: Thank you.

23 Dr. McQuade, additional comments?

24 DR. McQUADE: That's it right now. Thank
25 you.

1 DR. YASZEMSKI: Ms. Buzaid?

2 MS. BUZAID: Does the certification
3 require any updates, and how frequent would those
4 be?

5 DR. YASZEMSKI: Ms. Minkel?

6 MS. MINKEL: Not at this time. While the
7 device is stable, it would be qualified, and then
8 continued observation by the representative during
9 delivery.

10 MS. BUZAID: How many wheelchairs or
11 mobility devices would you anticipate that a
12 certified person would do per year in order to
13 maintain the certification?

14 MS. MINKEL: The expectation is that
15 persons who are routinely involved in wheelchair
16 recommendations would be the most likely to be
17 attracted to this kind of process, and the company
18 is well aware of those kinds of facilities that
19 specialize in assistive technology recommendations.

20 Beyond that, I'm not sure that that level
21 of detail has been confirmed at this point.

22 MR. O'DONNELL: No--and again, by having
23 the company representative present during delivery,
24 we get to observe the performance so that if we
25 felt that a clinician was not following the

1 instructions that they had been provided, indeed,
2 we would take some kind of corrective action there.

3 MS. BUZAID: So do you determine that
4 after you receive the clinician's recommendation,
5 or do you determine that by observation?

6 MR. O'DONNELL: By observation during the
7 delivery of the device.

8 MS. BUZAID: So it is after the device is
9 recommended?

10 MR. O'DONNELL: That's correct; not yet
11 delivered, but during the process of delivery.

12 DR. YASZEMSKI: Thanks very much.

13 For the transcriptionist, that entire
14 conversation was between Ms. Buzaid and Mr.
15 O'Donnell.

16 Further questions?

17 MS. BUZAID: No, not right now.

18 DR. YASZEMSKI: Dr. Hannaford?

19 DR. HANNAFORD: No comments on this
20 question. Thank you.

21 DR. YASZEMSKI: Dr. Abrams?

22 DR. ABRAMS: In answer to the question, I
23 guess my answer would be I'm not sure. I think the
24 clinician certification process has been very well
25 thought out, but the studies thus far--patient

1 selection is really the critical issue here in
2 terms of my perspective in terms of safety, and not
3 many difficult patients were either--or, if they
4 were screened in or screened out, it is not really
5 discernible from looking at the data.

6 I believe Ms. Minkel talked about
7 assessing physical, cognitive and functional
8 skills, but that is really broad. Take cognitive
9 skills, for example. Are there certain absolute
10 cut-offs for cognitive skills? What are you doing
11 to assess cognitive skills? It is just not really
12 clear from the application.

13 DR. YASZEMSKI: Dr. Abrams, may I ask you
14 to expand for FDA's perspective--what could the
15 sponsor add that would make you feel that they had
16 dealt with the certification issue thoroughly?

17 DR. ABRAMS: I think they could possibly
18 add some standard cognitive testing that is
19 well-recognized in terms of both ability to learn,
20 memory skills, executive functioning--the kinds of
21 things that are used to assess cognitive
22 competence. I don't want to restrict the clinician
23 by having a menu of testing to have gone through,
24 but it is tough to answer this question from the
25 information that I see there.

1 DR. YASZEMSKI: Thanks, Dr. Abrams.

2 Dr. Naidu?

3 DR. NAIDU: Yes. My thoughts are pretty
4 much along the wavelength that Dr. Abrams
5 expressed. He expressed about cognitive abilities.
6 In one of the slides presented, the one on
7 computerized alert and failure identification data,
8 one of the failures was because of lack of better
9 grip.

10 This device is dependent on use of the
11 upper extremity. Is there anywhere in the protocol
12 to optimize this upper extremity function? Is the
13 patient going to be evaluated by an upper extremity
14 specialist--because this is a difficult population.
15 Like Dr. Abrams stated, you guys screened fairly
16 reasonable people, but when it gets to optimizing
17 function of the patient, is an upper extremity
18 specialist going to be required? Is that going to
19 be a part of the process? This is just a question
20 that I'm throwing out.

21 DR. YASZEMSKI: Ms. Minkel?

22 MS. MINKEL: With regard to actually both
23 of your comments, the assessment, functional
24 capacity evaluation, is a demonstration by the
25 intended user on a whole series of specific tasks.

1 From the cognitive perspective, access to several
2 of the functions, for example, Balance function, is
3 a multiple-sequence application, and during the
4 assessment process, it became very evident to a
5 clinician as to when somebody had those sequencing
6 skills and when they did not. That is where that
7 identification of the potential for someone to
8 learn becomes very evident.

9 From a physical perspective, the
10 stair-climbing has very specific physical
11 requirements to be able to control the device and
12 operate the function.

13 In our current clinical practice with
14 regard to power mobility capabilities, it is
15 performance-based, and there are no standards. And
16 when you look at how can somebody get around, it is
17 putting somebody in the device and watching them
18 get around. And we formalize that even much more
19 than what is currently used for standard power
20 mobility recommendations.

21 DR. YASZEMSKI: Dr. Abrams?

22 DR. ABRAMS: I appreciate that, as I think
23 Dr. Naidu does. It is interesting, though, as
24 these devices become more and more complex to use,
25 these kinds of questions come up. I think it's a

1 very good point about the upper extremity function.
2 Basically what you are saying is that tit is a
3 judgment in kind of an observational sort of task
4 is what you are going to use as criteria.

5 MS. MINKEL: Well, we have provided a very
6 structured functional capacity evaluation. That is
7 one thing that is different. This assessment, at
8 the end of the assessment, each clinician will
9 observe the performance of a potential candidate on
10 a set number of skills that were individually
11 chosen to demonstrate the capability of that user
12 to perform those skills, to tease out the upper
13 extremity functioning, the cognitive functioning,
14 the perceptual functioning.

15 DR. ABRAMS: One follow-up question. How
16 are you going to handle kids, or are they going to
17 be excluded?

18 MR. O'DONNELL: They are excluded at the
19 present time.

20 DR. ABRAMS: Excluded; so there will be a
21 minimum age that this will be indicated for?

22 MR. O'DONNELL: To answer your question,
23 yes, there is an age requirement, but it is really
24 more size-related, whether or not the individual
25 can be fit to the device and a proper center of

1 gravity obtained.

2

3 DR. YASZEMSKI: I have no questions.

4 Dr. Finnegan?

5 DR. FINNEGAN: I actually have two

6 questions related to this.

7 This is so time-intensive and

8 skill-intensive that this is going to create a

9 funnel and probably a lot of the public who could

10 use this are going to have a long time getting to

11 it.

12 The country has a number of local areas

13 that have very skilled people already in chair

14 assessment. Two questions on that part of the

15 question--are you considering doing an intensive

16 training program for people who are already skilled

17 at doing power chairs; and then, are you going to

18 do a "train the trainer" type of assessment so that

19 those people can go across the country and perhaps

20 diffuse this training process so it is not such a

21 funnel? That is number one.

22 Number two is that I think in reality, you

23 are going to be shutting off the Balance and the

24 stairs for a huge number of patients, and

25 particularly because so much of this country is

1 rural, the 4-Wheel component is incredibly--what is
2 the word I want--appealing to a lot of people,
3 particularly adolescents and college students who
4 are trying to get around campuses, or in Texas,
5 because you want to go to the ranch or go outside
6 at the ranch.

7 So my question is is there consideration
8 of an iBOT "junior" or an "iBOOT" or something that
9 only has the 4-Wheel and the Remote, and would this
10 require less intensive training.

11 DR. YASZEMSKI: Ms. Minkel?

12 MS. MINKEL: Let me address your first
13 question first, with regard to targeting those
14 persons with experience. Absolutely, that is the
15 plan. It is premature at this time to know whether
16 we will pursue the "train the trainer" approach. I
17 think we want to control the message for right now.
18 And I actually defer to the sponsor with regard to
19 future model adaptations.

20 MR. O'DONNELL: There are a number of
21 things that we are looking at that could occur down
22 the road, but until we go through the entire
23 research and development process and the extensive
24 testing that you have seen here, I think it would
25 be premature to comment as to whether or not those

1 products will come to fruition.

2 DR. FINNEGAN: If you just did the 4-Wheel
3 and the Remote, would that require the same type of
4 clinician certification?

5 MS. MINKEL: You would need a large
6 percentage of it, because as soon as you go into
7 4-Wheel, you have activated the i-Balance, and
8 that's really where the clinician needs to be aware
9 of what the whole sum of skills needs to be.

10 DR. YASZEMSKI: Thank you.

11 Dr. Finnegan, any additional questions?

12 DR. FINNEGAN: No.

13 DR. YASZEMSKI: Dr. Kirkpatrick?

14 DR. KIRKPATRICK: The first is point of
15 clarification. When you say "clinician," what your
16 real target is is physical therapists and
17 occupational therapists who are licensed in their
18 State; is that correct?

19 MS. MINKEL: Correct.

20 DR. KIRKPATRICK: Thank you.

21 As far as the certification issues of the
22 trainers and all that, as I understand it, in your
23 study, the trainers had a device to use with the
24 prospective client first, and measurements were
25 made, and those things were sent off to the company

1 to get the actual study device for that client; is
2 that correct?

3 MS. MINKEL: Yes.

4 DR. KIRKPATRICK: Is that what you propose
5 to do for actually marketing the device?

6 MS. MINKEL: Yes. There will be a
7 demonstration device used in the assessment
8 process.

9 DR. KIRKPATRICK: So a demonstration
10 device will actually be used for the patient that I
11 write for this mobility device to be evaluated for
12 it; correct?

13 MS. MINKEL: Yes.

14 DR. KIRKPATRICK: Okay. Thanks.

15 DR. YASZEMSKI: Thanks, Dr. Kirkpatrick.
16 Dr. Friedman?

17 DR. FRIEDMAN: I have a comment and a
18 question. The first one regards clinical judgment.
19 I think you have to allow the physician and the
20 clinician the freedom to make that decision. I
21 think you know when someone can and when someone
22 cannot. I mean, if I'm going to put a total
23 shoulder arthroplasty in somebody, I have to make
24 the judgment that they are able to participate in
25 the rehab program and have a good outcome, and if

1 not, I don't do that procedure.

2 So I think that cognitive testing and all
3 will bog us down, and I don't think it is going to
4 be very productive.

5 My question is this is a five-function
6 device--is there a middle ground where there might
7 be some patients who can manage with four of the
8 functions, but for example, the Stair function
9 seems to be the most difficult and the most
10 challenging. Might there be some who can use this
11 to get over, say, 4-inch curbs and can Balance but
12 who might not have the cognitive or physical skills
13 to do the Stairs, yet we are going to give it to
14 them and say "You can do the four, but not the
15 fifth one, not the stairs," for example?

16 MS. MINDEL: The device is programmable to
17 match the functional needs of the person, and with
18 regard to Stair, that is where Stair-Assist is
19 absolutely essential. And we have identified that
20 the assistant needs to be assessed and trained as
21 well as the occupant.

22 DR. FRIEDMAN: Thank you.

23 DR. YASZEMSKI: Thank you, Dr. Friedman.

24 Dr. Larntz?

25 DR. LARNTZ: No additional comments.

1 DR. YASZEMSKI: Dr. Myklebust?

2 DR. MYKLEBUST: No questions.

3 DR. YASZEMSKI: Mr. Fenical?

4 MR. FENICAL: No, I have nothing.

5 DR. YASZEMSKI: Dr. Goldman?

6 DR. GOLDMAN: Thank you.

7 First off, I am very delighted to be on
8 this panel with respect to a hugely innovative
9 product such as this.

10 With regard to specific questions that I
11 have about this, as I reviewed this, it was helpful
12 for me to think about this as driving a car, with a
13 process of driver's ed and maybe a learner's
14 permit, something like that.

15 But to be able to assess both the patient
16 assessment and the clinician assessment process, my
17 first question is are the exact materials used for
18 the pivotal trial what we reviewed. I just want
19 you to answer that question before I ask my next
20 question.

21 MS. MINKEL: Yes.

22 DR. GOLDMAN: Okay; simple.

23 MR. O'DONNELL: Well, I just want to point
24 out that the labeling that you reviewed is the
25 final proposed labeling. There were some learnings

1 that we had from the pivotal trial, such as the
2 individual who was leaning forward, and we added
3 that to the training program.

4 So I would call it nearly identical, but
5 we did learn some things during the clinical trial,
6 and we made a couple of minor modifications to the
7 labeling.

8 DR. GOLDMAN: Okay. My second question is
9 since the medical interface--and there was another
10 type of interface that was designed for the
11 professional--each of those was approximately 150
12 to 200 pages, I think, and involved a good bit of
13 technical information, physics, that might not be
14 considered to be standard knowledge in physical or
15 occupational therapy. Was there any thought to a
16 formal certification process like a test or a
17 didactic regime, such as one with--understanding
18 that this is truly a new classification, an
19 advanced mobility system.

20 MS. MINKEL: There was the observed
21 performance across the spectrum, so when we
22 observed the performance of potential clinicians to
23 participate in the trial, it involved the use of
24 the MI to determine the calibration, it included
25 using the FCE, it included delivering the delivery

1 training.

2 We had clinicians out of our potential
3 pool who were not successful. They could not
4 demonstrate either the knowledge or the skill to
5 represent the complexity of the device comfortably
6 and therefore did not participate in our study. So
7 we did have excluded clinicians in our training
8 process.

9 DR. GOLDMAN: I just want to make one more
10 comment before I pass it on. For the pivotal
11 trial, usually, there is an investigators' meeting
12 and then there is an intense hands-on process
13 involving the entire team. When the device is
14 actually in the marketplace, the same peer
15 environment, so to speak, may not be present, and
16 that this may be considered.

17 MS. MINKEL: Yes, absolutely.

18 DR. YASZEMSKI: Thanks, Dr. Goldman.

19 Ms. Rue?

20 MS. RUE: No further questions.

21 DR. YASZEMSKI: Thanks.

22 Ms. Maher?

23 MS. MAHER: No further questions.

24 DR. YASZEMSKI: Dr. Stiens, we'll end with
25 you.

1 DR. STIENS: Well, with lunch looming,
2 there are a variety of things we could discuss, and
3 I'll try to limit it to some of the things that
4 have been brought up, a number of which were issues
5 on my mind.

6 The first thing I want to say as a
7 rehabilitation physician who practices in an
8 interdisciplinary mode and decisionmaking is
9 carried out in that interdisciplinary mode--it is
10 not signing off on a driving assessment form that
11 may occur at night and just putting it in the mail;
12 we do sign off on a variety of things, including
13 home care and so on, but that's not without
14 supervision and a relationship with the clinicians
15 and the patients who are part of the treatment
16 process. So for me as a physiatrist, working with
17 an interdisciplinary team to place our patient or
18 my patient into a device such as this and
19 projecting them into society--and the inoculation
20 issue and so on was brought up, that metaphor, so I
21 would say "inject" them into society--is indeed a
22 very serious process. And for me, it is as potent
23 and carries as much medical responsibility as
24 injecting an immunization into a patient or
25 referring the patient to an orthopedic surgeon for

1 a shoulder replacement and then following them up
2 after those decisions have been made with the
3 surgeon and so on for rehabilitation that the
4 patient would need to carry out and go back into
5 the field.

6 So my viewpoint would be that the
7 clinician decision would include a physician in
8 that process. It may be as simple as the physician
9 knowing that patient, having a medical relationship
10 with that patient and referring the patient to an
11 occupational therapist, knowing that therapist--or
12 physical therapist, whoever would be certified--and
13 then signing off, as it often is for me when I
14 clear a person for driving after they have gone
15 through an evaluation with a therapist that I know
16 and so on. Or maybe it is as complicated as my
17 seeing that patient and screening them for this
18 nebulous assessment called "judgment" that
19 physicians are still in the--the weight of the
20 responsibility is on our shoulders in that regard;
21 there is no big test for that.

22 We want to preserve opportunities for
23 patients within society, so we want to have success
24 with opportunities that they would take into this
25 complex environment.

1 So I would suggest that the assessment
2 program that has been proposed, which I went
3 through, is adequate, but the medical side of that
4 would be a requirement and that the medical
5 clinician might be required to go through at least
6 a part of that. And I don't know exactly how that
7 could be worked out, but it would seem to me that
8 that would be very helpful.

9 The analogous situation that I would
10 propose there is approved devices that are beneath
11 the skin that various clinicians adjust and control
12 from the outside, and one of those that
13 physiatrists tend to get the responsibility for is
14 devices that release various medications, for
15 instance, for spasticity, into the subarachnoid
16 space. And we are in charge of referring to some
17 extent for that, and surgeons put that tin, but we
18 refill the tank and assess the patient on an
19 ongoing basis.

20 And judgment varies in patients, and
21 ongoing connection with the patient who might have
22 this device I think is a conundrum that we need to
23 work out. As you know, there is an aftermarket
24 that is even beyond the closet--the closet was
25 brought up--and patients sell devices; they might

1 share devices with family members, and family
2 members might choose to try the devices. So I am
3 very glad to know that there is that password as a
4 key to the device.

5 So my question, then, to you is with those
6 challenges, the first being the challenge of the
7 physician's awareness of the complexity of the
8 device, what role had you guys thought the
9 clinician might take, the medical clinician, in
10 this prescriptive process?

11 DR. YASZEMSKI: Ms. Minkel?

12 MS. MINKEL: I think again, consistent
13 with other comments, in targeting those clinicians
14 and, really, facilities that are currently involved
15 in specific equipment recommendation that there is
16 an interdisciplinary team relationship there. And
17 certainly, I think, to your point of at minimum,
18 the physician has to know the client to whom I am
19 referring, and that is built into the system
20 because very often, I will need a referral for the
21 assessment, so the physician needs to know, needs
22 to provide the paperwork to let me start the
23 demonstration device assessment.

24 So there are some connections in there
25 with regard to patient care. Certainly

1 philosophically, we are totally brought into the
2 interdisciplinary approach and model. There is a
3 recognition that in all parts of the country, in
4 all places, that team may not be as strong as it is
5 in other places, but we are certainly going to
6 target the team approach facilities as our launch
7 effort.

8 DR. YASZEMSKI: Thank you.

9 FDA, our discussion brought up issues of
10 cognitive and physical skills, and it would appear
11 that the evaluation which will be done by our
12 clinicians who will prescribe this seems to cover
13 most of those, but we also thought that the
14 clinician team should include both the therapist
15 and the physician and would make a recommendation
16 that this is a very realistic goal for
17 interdisciplinary care.

18 Have we answered your questions on this
19 issue in this question?

20 MS. WITTEN: Yes. Thanks.

21 DR. YASZEMSKI: Thanks so much.

22 We're going to break for lunch now. It's
23 10 minutes to one. Let's resume at 10 minutes to
24 two, with Question 2 on user training.

25 Thanks, everybody.

1 [Whereupon, at 12:54 p.m., the proceedings
2 were recessed, to reconvene at 1:52 p.m. this same
3 day.]

1 DR. YASZEMSKI: Okay. We'll read it
2 again.

3 "The sponsor proposes a number of
4 procedures to assess and train potential users.
5 Are these user assessments and training procedures
6 adequate for assuring safe and effective use?"

7 So the question we ended with was are they
8 training the clinicians well enough; now we are
9 going to ask are they also training the users of
10 the device well enough.

11 DR. STIENS: Okay. The users of the
12 device are going to be screened to some extent by
13 clinicians before they come to training, so I think
14 the question that we are answering is with the
15 variety of potential users coming through the
16 system, is this curriculum sufficient as a general
17 curriculum to meet their individual needs.

18 And going over that, my answer is that it
19 seems to be, but I think what we need to stress in
20 the curriculum--there is a portion of the
21 curriculum where they discuss various learning
22 styles of various consumers--we should also add
23 into that that the curriculum would be
24 person-centered and based in such a way that it met
25 individual consumers' learning styles as well as

1 their person-centered goals.

2 An example of that would be we have had
3 the situation pointed out that one consumer might
4 be from a rural area, for instance, and would
5 picture the device on their cornfield, so to speak,
6 or on their stairs; that indeed, these
7 person-centered goals would be eked out, and the
8 training condition would include addressing their
9 person-centered goals for chosen environments for
10 the use of the device.

11 So that might include adding in some
12 requirements for assessment of them using the
13 device in the field possibly--a cornfield in some
14 situations, or someone's own stairs in another--to
15 really target some education in the environment
16 where they would be most likely to use the device.
17 And that would eke out potential--some
18 potential--environmental hazards or barriers that
19 might contribute to problems with use of the device
20 and also might snuff out some potential ideas that
21 consumers had about the device that would not come
22 to fruition. The device might not meet that goal
23 in their particular situation.

24 DR. YASZEMSKI: Thanks very much, Dr.
25 Stiens.

1 Mr. Herman?

2 MR. HERMAN: I think that the assessment
3 and training procedures are adequate for assuring
4 safe and effective use of the iBOT, and I would
5 just add that I think it is important not to set
6 the bar too high.

7 Not every danger can b accounted for, and
8 not every risk can be ameliorated, and I would hate
9 to--if that were the standard by which
10 mobility-impaired people lived their lives, we
11 would never leave the house. So, while that is not
12 particularly helpful to the FDA because it is more
13 of an amorphous kind of suggestion, I would
14 encourage the sponsor to not be shy to say we don't
15 need to be doing this, or we don't need to be doing
16 that. There are not enough people who are getting
17 this device because the bar has been set too high
18 for user training.

19 And one other comment which is a
20 combination of a labeling issue as well as a user
21 training issue. It is not uncommon for people to
22 let other people use their wheelchairs, to borrow
23 them. I have a friend who is using a friend's
24 unused power chair in order to figure out whether
25 or not a power chair is right for him.

1 Now, it is one thing for me to let someone
2 borrow my power chair, but an iBOT is carefully
3 calibrated to the user, and if someone for whom it
4 was not intended tried to use it on steps, I think
5 the results could be disastrous. So I suggest that
6 that labeling be included to the extent that it
7 recommends that it is for the user only and that
8 the user be trained in that respect.

9 DR. YASZEMSKI: Thank you very much.

10 Dr. McQuade?

11 DR. MCQUADE: I think the user training
12 documentation was well thought out and adequate.

13 I had one question. Although I concur
14 that getting into a direct environmental assessment
15 for each person and their cornfield would be nice,
16 it might be cost-prohibitive. Who is going to pay
17 for that, sending people out to do field
18 assessments?

19 The other question I had about user
20 training--is it all done on an "easy street" kind
21 of environment, or what is the environment that it
22 is done on?

23 DR. YASZEMSKI: Would a member of the
24 sponsor like to answer that?

25 MS. MINKEL: Yes. I clearly identified

1 that "easy street" was very convenient but not very
2 practical once the product is distributed.

3 DR. McQUADE: Do all the panel members
4 know what "easy street" is?

5 DR. STIENS: You should explain that for
6 everybody so they understand that that is a
7 product.

8 MS. MINKEL: Sure. There is a basically a
9 therapeutic built environment that is available
10 particularly for rehab-type facilities that
11 introduce indoors community-based mobility barriers
12 or challenges.

13 Actually, for a bulk of the user training
14 in the pivotal trial, we used lots of the outer
15 "easy street" environment and tried to identify
16 things that would easily be replicated in another
17 facility--bathroom environments, curb cuts,
18 sidewalks, grassy terrain--to identify things that
19 could be located in a typical clinical-type
20 environment and built the program around that so
21 that it was not built around a specific "easy
22 street" environment.

23 DR. McQUADE: So the difficulty is
24 standardizing user training because it is
25 environment-specific to that.

1 MS. MINKEL: We did find, though, in
2 several environmental observations in a previous
3 study where we were conducting a study in multiple
4 sites that when you specify things like a curb up
5 to 4 inches, you can pretty much walk around the
6 block and find the area or the curb cut that is
7 ADA-compliant. They were very easily-identified
8 locations, and we specifically wanted the program
9 to be easily transferrable.

10 DR. McQUADE: Just a suggestion--there are
11 some tools now that are becoming available. For
12 example, at our university, we have adapted the
13 FIM--which I notice in your document, you have
14 tried for a while--again, not specific to
15 wheelchair users--but we have modified that--we
16 call it the FIM/WC for "wheelchair"--so there might
17 be some tools out there that you could use that
18 would help as a kind of standardized environmental
19 assessment.

20 MS. MINKEL: Excellent.

21 DR. YASZEMSKI: Thanks, Dr. McQuade.

22 Ms. Buzaid?

23 MS. BUZAID: I would also like to say that
24 the materials were very well-designed.

25 My questions are more around the actual

1 training time it takes and how reimbursable that is
2 as a clinician. I also wonder if you ever
3 considered rolling that into the cost of the
4 wheelchair.

5 MS. MINKEL: Let me address the structure
6 of the training program to identify time
7 variability. The module set-up is particularly
8 designed so that if you can only do it in
9 hour-and-a-half, 2-hour segments, you can turn off
10 functions that you have not trained in yet. So a
11 freestanding module will allow someone once they
12 have completed those functional activities to use
13 the device.

14 That approach allowed for multiple
15 outpatient visits, if you will. You could do the
16 whole package if someone has traveled long
17 distances, is coming into town for the training,
18 and wants to take it home. So we were sensitive to
19 that.

20 With regard to the reimbursement, there is
21 limited--although I will tell you--as I put on a
22 different hat--Jean Minkel Consultants has been
23 working on CPT coding, and we specifically have an
24 application in with the AMA on assistive technology
25 assessment coding to add to what is currently

1 available but to make it more specific to a user
2 and a device assessment. So we are hopeful that
3 there will be future activity.

4 MS. BUZAID: This is just a comment. In
5 my State, we have had difficulty getting
6 reimbursement for training. The expectation of the
7 funding sources has been that the training occurs
8 before the device is delivered.

9 MS. MINKEL: I think what we are in a
10 position to discuss is the iBOT is
11 functionally--multiple functions, for starters--and
12 in some ways is analogous to prosthetic training;
13 that people are understanding that you need the
14 device in order to them progress with the training.

15 So that, yes, this is a payor source
16 question, but I think there is an understanding
17 that, you know, it is like delivering five chairs
18 in one day when you look at what the intended uses
19 are and the limitations, and we have to provide
20 time to let somebody synthesize that information.

21 MS. BUZAID: The other question I have is
22 actually related to attendant training, and I'm
23 hoping I can ask that at this point.

24 DR. YASZEMSKI: Yes, go ahead.

25 MS. BUZAID: It is my experience that a

1 lot of our patients have multiple attendants and
2 change attendants frequently. Will it be the
3 expectation that the user will change the
4 attendants who follow, or is the user expected to
5 return to the clinic for further training?

6 MS. MINKEL: The expectation is that only
7 a trained assistant will operate the device. So if
8 you know that you have multiple attendants, you can
9 bring multiple attendants in for the initial
10 training. When there is turnover, we would expect
11 that new attendants to come in and gain the
12 training.

13 It is a sophisticated skill and technique
14 that is difficult, I think, for the occupant to be
15 able to provide the feedback to the attendant to
16 know how to modify what they are doing to be
17 successful. So it is an expectation that someone
18 would come back for training if they were in a new
19 position that required Stair-Assist.

20 MS. BUZAID: Thank you.

21 DR. YASZEMSKI: Thank you.

22 Dr. Hannaford?

23 DR. HANNAFORD: First of all, I hope
24 people will forgive me if I missed something in the
25 20 volumes, but I have a very brief question. Are

1 we confident in the training of the users for
2 assessing a flight of stairs prior to using it in
3 Stair mode?

4 I did see in the user manual a diagram of
5 the stair dimensions that are recommended, and for
6 me as an engineer, it would be easy to measure the
7 stairs and verify that they meet those
8 requirements, but I am not sure that that would be
9 true for a lot of otherwise cognitively functional
10 patients. The thought came to mind of a plastic or
11 cardboard template that they could put against the
12 stairs and verify it.

13 I would just like to hear a little more
14 about that.

15 MS. MINKEL: We recognize your concern
16 equally. The module related to stair-climbing is a
17 half-day unto itself, and a significant amount of
18 that time is spent around stair geometries, both in
19 the ability to visually inspect and in addition to
20 kind of a rig, the wheel of the chair is used as a
21 reference, because you have a 12-inch wheel, so you
22 can give people a visual orientation as to where
23 the riser is and where the tread length is.

24 We spend time on specific exercises on
25 varied geometries so that people can anticipate

1 what the response of the device would be.

2 At the end of that training, almost ad
3 nauseam, because they have now tried 10 different
4 sets of stairs, in our driver test, we actually
5 have unacceptable stairs as part of the route, and
6 that is one of the tests is to see does somebody
7 just barrel up as if every stair is absolutely
8 fine, or is there the assessment of the environment
9 to determine whether the stair qualifies or not.

10 DR. HANNAFORD: Thank you.

11 DR. YASZEMSKI: Thank you, Dr. Hannaford.

12 Dr. Abrams?

13 DR. ABRAMS: Yes, I have several comments.
14 First of all, in answer to the question, I think
15 based on the data that we have seen today, the user
16 training does seem adequate.

17 The only caveats I would have would be,
18 again, I think this is a relatively able group and
19 maybe not the toughest customers that you would
20 have to deal with. And I guess the two adverse
21 events that were worth talking about were with two
22 of the people who were less able. So that is just
23 something to keep in mind.

24 I also would like to echo the idea of some
25 real life situation cornfield testing if that could

1 be incorporated into the user training, because of
2 the unusual environments that I know some of the
3 people that I deal with might want to use this
4 device in.

5 Likewise, I would like to echo the idea
6 about not setting the bar too high; I think that's
7 an important thing to remember.

8 DR. YASZEMSKI: Thanks, Dr. Abrams.

9 Dr. Naidu?

10 DR. NAIDU: I think the sponsor does a
11 very adequate job, an excellent job, in having a
12 systematic approach to training. I just have a few
13 questions with regard to the study itself.

14 In the additional effectiveness data, the
15 Balance mode was used on average only about 2
16 hours. Is that because of lack of training, or is
17 that because the task that was asked was just to
18 reach up with the--the limited task was basically
19 to get the book off the shelf--is that because of
20 that single task, or is that because of lack of
21 training?

22 MS. MINKEL: Could you just tell me which
23 page you are referring to in terms of where the
24 2-hour data is coming from?

25 DR. NAIDU: I got that from the FDA

1 presentation. On average, the longest Balance
2 hours was 18.4, but the average was 2 hours. Is
3 that because the task that was tested was just
4 retrieving a book off the high shelf, because it
5 was a single task, or is that because--

6 DR. YASZEMSKI: Dr. Naidu, may I ask
7 Captain Schroeder to comment on that?

8 DR. NAIDU: Yes.

9 DR. YASZEMSKI: Captain Schroeder?

10 CAPTAIN SCHROEDER: That was a
11 clarification on the data logger distribution data
12 that I reported that I got from the sponsor. So in
13 looking at the community driving test, there was
14 only one task, which was reaching up to get
15 something off a high shelf. So as a clinician, I
16 was interested in whether they had other usability
17 data in the real world or otherwise, so they
18 pointed out the data logger time and distance data.
19 And then, if you look at individual patients, there
20 were those several patients who had less than 2
21 hours of use, and there were 13 patients who had
22 more usage.

23 They did not have a more specific
24 breakdown as to how much of that time was used in
25 the training session versus the real world session.

1 DR. NAIDU: Thank you.

2 DR. YASZEMSKI: Thanks, Captain Schroeder.

3 No comments from me.

4 Dr. Finnegan?

5 DR. FINNEGAN: I'd like to follow up on
6 Ms. Buzaid's question, because attendant changes in
7 the real world happen on a regular basis, and
8 particularly for people traveling long distances,
9 having an attendant come in is going to be a
10 challenge.

11 Have you considered using distance
12 learning capabilities for training, or at least
13 assessing whether an attendant has the capability
14 to learn that at a distance rather than coming into
15 your service?

16 And secondly, as a follow-up to that, what
17 are you going to do for a help desk for these
18 people, because when they get home, they are going
19 to find themselves stuck in the cornfield, and
20 would you have that web-based?

21 DR. YASZEMSKI: Ms. Minkel?

22 MS. MINKEL: With regard to your second
23 question, yes, there is an 800 number to call in;
24 there will also be a website for people to refer
25 to.

1 I also think there are opportunities for
2 client use for access to somebody to go into their
3 home to do the training. That may be a feasible
4 option, too. So I think there is a lot of
5 flexibility when it comes to that assessment
6 training.

7 DR. FINNEGAN: Actually, the question
8 about distance learning had to do with
9 telecommunications.

10 MS. MINKEL: One of the challenges--and I
11 will speak now as a clinician who was involved in
12 the training--I would need to have both visual,
13 because it is observing the person's--really, body
14 mechanics is what it comes down to. It is
15 certainly a possible way to go, and I know it is
16 being used increasingly.

17 DR. YASZEMSKI: Thanks, Dr. Finnegan.

18 Dr. Kirkpatrick?

19 DR. KIRKPATRICK: I think the training
20 procedures are adequate.

21 DR. YASZEMSKI: Thank you.

22 Dr. Friedman?

23 DR. FRIEDMAN: I think they are adequate,
24 and I have one comment or question.

25 If I buy a car today, and a problem

1 develops 2 years from now, there is some registry
2 that is kept, and I am notified to go back to the
3 dealer and get it fixed. is there some kind of
4 registry or recall process for these types of
5 things so if, 2 years down the road, a problem
6 develops or something changes with it, you can
7 contact these people and deal with it?

8 DR. YASZEMSKI: Ms. Minkel, Mr. O'Donnell?

9 MR. O'DONNELL: Yes. We have every
10 customer identified, and if indeed something needed
11 to be done, that could be done. We need to
12 maintain those records as part of potential recalls
13 for FDA and so on.

14 DR. FRIEDMAN: You said you can, or you
15 plan to, or you will--because for example, I know
16 that when we put in a joint prosthesis, we don't
17 keep any records, and if something is discovered
18 that is a problem, we do not have the ability to
19 notify people. We do much better with our cars
20 than we do with the implants we put into people.

21 MR. O'DONNELL: If there were a potential
22 problem with a device where a device needed to be
23 recalled and repaired, then, yes, most definitely,
24 we would be contacting them.

25 DR. FRIEDMAN: Thank you.

1 DR. YASZEMSKI: Thanks, Dr. Friedman.

2 Dr. Larntz?

3 DR. LARNTZ: No comments on training.

4 DR. YASZEMSKI: Thanks, Dr. Larntz.

5 Dr. Myklebust?

6 DR. MYKLEBUST: No comments.

7 DR. YASZEMSKI: Thank you.

8 Dr. Goldman?

9 DR. GOLDMAN: Yes. Frankly, there was an
10 issue of a little bit of concern to me. The only
11 way I have to assess the safety of the device is to
12 look at the pivotal trial, and that is the only way
13 I can do this. I keep thinking in my mind as I go
14 through this that this is a 500-pound instrument
15 going up and down stairs at a 45-degree angle, and
16 you are thinking about the people who are coming
17 down the stairs from the top and going up the
18 stairs from the bottom. So it is not only an issue
19 of the person and their mobility, which is of
20 paramount importance to them and to all of us in
21 society, but of everyone else around them. And it
22 comes to the issue of judgment.

23 As I reviewed these insignificant, really
24 minuscule adverse events, I need to check on a
25 couple things or mention a couple things. The

1 first one--the subject who wanted to show off to
2 his nurse that they could get the back wheels off
3 the ground--this was a guy who was a C6/7
4 tetraplegic--I assume it was complete--who did not
5 have good trunk control. He went forward, and the
6 back wheels came up in front of the center of
7 gravity, and the thing shot forward with the back
8 wheels still up, and then the thing shut down after
9 10 feet.

10 So I am thinking about that incident.
11 Maybe he had a bruise, maybe he didn't--I
12 forget--but that is one of them. And the other was
13 a much more innocent one, where the C6
14 tetraplegic--I assume it was complete--who had
15 absent finger flexors had a problem with a rapid
16 response that the machine took care of, which gets
17 back to the issue of it is not the device--the
18 device is incredible--it is the human being on top
19 of the device, which gets back to the issue of
20 judgment.

21 And my question is is it adequate to have
22 2 days of intensive manual and then an assessment
23 on a particular set of skills that don't include a
24 real world assessment that might include the
25 cornfield, it might include the environment where

1 they live. I am wondering if there should be more
2 of a period of breaking in in a real world
3 environment, especially as regard to judgment,
4 because I understand that these folks went through
5 this training. They went through the training, and
6 they obviously demonstrated excellent judgment, but
7 when they got home, this guy wanted to lift his
8 back wheels up--and you only need a couple of them,
9 and you have liability lawsuits.

10 So I just wanted you all to speak to that
11 a little bit.

12 MS. MINKEL: You are absolutely right, but
13 it is back to that faith issue, and there is a
14 level of judgment that a clinician needs to bring
15 with regard to the balance between risk and reward.
16 I feel that training is incredibly focused on
17 potential challenges, right down to showing them a
18 videotape that I make the equivalent to the
19 16-year-old who is taking driver's ed, and you show
20 them the crash and burn, what happens if you go 75
21 miles and hour with a 6-pack of beer in your
22 system.

23 We do the same thing, everything short of
24 observing their everyday driving. We don't hide
25 anything in terms of the device's possible

1 response. And once somebody has completed the
2 test, very similar to the 16-year-old in the
3 driving exam, you make a judgment as to whether
4 this person can use the device safely in a real
5 world environment.

6 DR. GOLDMAN: And in a real world
7 environment as far as automobiles are concerned,
8 there are accidents; there is no question that
9 there are. So I guess that was my comment.

10 DR. YASZEMSKI: Thanks, Dr. Goldman.

11 Ms. Rue?

12 MS. RUE: I have a comment, and it is not
13 directly on user training, but it is some follow-up
14 after that, if I can comment on it at this point.

15 DR. YASZEMSKI: Go ahead.

16 MS. RUE: Obviously, you do a very good
17 job of evaluating center of gravity and functional
18 capacity, but the way life evolves, some people's
19 center of gravity does change because of change in
20 mass issues as well as functional capacity. Is
21 there any method of reevaluating these patients at
22 any point in time as life progresses, or is that up
23 to individual self-reporting?

24 MS. MINKEL: At the moment, it is up to
25 individual self-reporting with the clinical caveat

1 that many of us are working in an interdisciplinary
2 team--and again, I'll speak for myself as a
3 clinician--when working with somebody whose medical
4 condition may predict a change in function. Take
5 multiple sclerosis, for example. It is my clinical
6 advice that I would have that person come back on a
7 regular basis to be sure that what I saw at
8 assessment and training is what I am seeing several
9 months later.

10 With regard to changes in center of
11 gravity, we do inform people that it is a 20-pound
12 window, gain or lose, and that the device's
13 performance is just not as enhanced if you go
14 outside that window--but it doesn't all of a sudden
15 not work anymore.

16 And again, we put that right up front in
17 the training, and let people know to come on back,
18 we can customize it to your smaller or larger
19 frame, depending on which way you go.

20 MS. RUE: So it would just be an issue of
21 if they were cognizant enough of calling, coming in
22 and getting it reconfigured.

23 MS. MINKEL: Absolutely.

24 MS. RUE: Thank you.

25 DR. YASZEMSKI: Thank you.

1 Ms. Maher?

2 MS. MAHER: No comments on the user
3 training. I think the sponsor has done an
4 excellent job.

5 I would like to comment briefly on some
6 other things that I have heard as we have been
7 going around. One is that we should not actually
8 be looking at what new devices the company can come
9 up with or should be coming up with. That is
10 within the company's purview.

11 The other is that reimbursement and CPT
12 Codes are really not part of this discussion. That
13 is handled by other areas of the Government and
14 insurance, and I don't think it should be discussed
15 here.

16 DR. YASZEMSKI: Thank you.

17 We're going to move on after we ask FDA if
18 we have adequately answered your question.

19 MS. WITTEN: I have a little follow-on
20 question if that's okay.

21 DR. YASZEMSKI: Yes, go ahead.

22 MS. WITTEN: In view of the short
23 discussion this morning about pediatrics and what
24 age limit was proposed for this device, the
25 indication proposed by the sponsor does not include

1 a specific age limitation, so I am wondering if
2 anybody on the panel wants to comment on the
3 procedures in place for the sponsor to assess and
4 train potential users in particular with respect to
5 younger age groups.

6 DR. YASZEMSKI: Does anyone on the panel
7 want to offer an answer to Ms. Witten's question?

8 Ms. Rue?

9 MS. RUE: I would just like to comment.
10 You mentioned that it was on body weight, and there
11 are some very large little children that don't have
12 the discerning to be able to manipulate. So I don't
13 know that just body weight, in my opinion, is just
14 something that is qualified.

15 DR. YASZEMSKI: Thank you.

16 Do other panel members wish to comment?

17 Dr. Kirkpatrick?

18 DR. KIRKPATRICK: I would suggest that the
19 labeling and instruction be limited to 18 and
20 above, because learning styles and educational
21 techniques are completely different at different
22 stages of development. Typically, at 18 and above,
23 you can use exactly what they have proposed, and I
24 think it is an excellent fit.

25 In addition, those under 18 are likely to

1 take risks that those over 18 generally do not. I
2 don't think it is fair to eliminate those between
3 18 and 25 for the same reason, because I think the
4 device does offer a great deal of benefit for those
5 within that age range. But I think if you try to
6 teach an 8- or 10-year-old using the same
7 techniques, you are going to have significant
8 challenges.

9 I would add the caveat that if they wish
10 to provide a different training style or make
11 modifications that would be appropriate for
12 age-related learning differences, I think that
13 would be admirable.

14 DR. YASZEMSKI: Thank you, Dr.
15 Kirkpatrick.

16 Dr. Finnegan.

17 DR. FINNEGAN: I'm wondering if my
18 esteemed colleague would consider using something
19 similar to the graduated driver's license, because
20 I do think this has a major ability enhancement for
21 adolescents, and whether in fact the sponsors would
22 consider shutting off the Balance and Stair and
23 having them go for 6 months with the 4-Wheel drive
24 and the Remote, seeing how they perform, and then
25 perhaps adding Balance for 6 months and seeing how

1 they perform and then adding Stairs. In that way,
2 you could start at a younger, perhaps 15-year-old,
3 age group similar to driving and move it up.

4 DR. YASZEMSKI: Thank you.

5 Dr. Goldman, I'm going to ask you for your
6 comments and then ask sponsors to respond if they
7 would like to.

8 Dr. Goldman?

9 DR. GOLDMAN: Is it okay at this point to
10 talk about post-market studies?

11 DR. YASZEMSKI: I think if it relates to
12 user, because we are going to have a question that
13 relates specifically to that.

14 DR. GOLDMAN: Yes. The issue of judgment
15 in someone who is not quite mature is a germane
16 one. I am wondering if one way to approach the
17 able and pediatric user, especially the teen user,
18 would be to do an assessment based on a post-market
19 study and see if the user interface needs
20 significant tweaking.

21 DR. YASZEMSKI: Thank you.

22 Mr. O'Donnell or Ms. Minkel, would you
23 like to comment on any of these--and may I ask
24 you--perhaps we can year from you--do you have
25 either an age or a weight that you think would be

1 appropriate, and if so, how would you say it to
2 potential clinicians who are thinking about this
3 for their patients?

4 MS. MINKEL: The driving analogy is one
5 that I have always used in my head, and I think
6 the graduated driver's license is a great model.
7 So the concept that at 18, somehow there is a magic
8 flip of the switch--there are adolescents who could
9 get great benefit. So while I would respect and
10 understand why, I would like to see a little bit
11 more open window if someone of the size can
12 demonstrate the judgment and the skill equivalent
13 to driving an automobile could still be open to be
14 recommended for the device.

15 DR. YASZEMSKI: And may I ask what is the
16 size--is it based upon a weight, a height, a
17 weight-height combination?

18 MS. MINKEL: It is actually to be seated
19 on the seat frame. We have a 16-wide, 16-deep, the
20 height of the foot pedals, to get the foot pedals
21 up high enough--generally, it is an adolescent.
22 You can't put a little kid in it; they just don't
23 fit. And calibration has some body weight
24 involvement.

25 DR. YASZEMSKI: Thank you.

1 Mr. O'Donnell, anything else?

2 MR. O'DONNELL: I was just going to add
3 the last comment made by Jean, that it is not so
4 much weight as the device being able to calculate a
5 center of gravity for you. If your center of
6 gravity is being calibrated, and the device is
7 unable to fit you, then you would not be eligible
8 for the device. So it is not weight--it is a
9 combination of weight, size--

10 DR. YASZEMSKI: And that is something you
11 do experimentally--you put someone on and assess
12 whether the device is capable of calibrating?

13 MR. O'DONNELL: That is correct.

14 MS. MINKEL: That is the very first thing
15 you do in assessment.

16 DR. YASZEMSKI: Okay.

17 Ms. Witten, has the further discussion
18 adequately addressed the question?

19 MS. WITTEN: Yes. Thank you.

20 DR. YASZEMSKI: Thank you very much.

21 May we move on, Mr. DeLuca, to the next
22 question?

23 MR. DeLUCA: Question 4 is on device
24 safety.

25 "The sponsor conducted a clinical trial

1 that compared 2 weeks of iBOT usage to 2 weeks of
2 subjects' own mobility devices usage. The sponsor
3 provided safety data that included summaries of
4 injuries, physical device failures--for example,
5 device and component replacements--and other
6 events--for example, falls, intentional device
7 actions such as system shutdown--that could place
8 the user at risk of injury due to user error and/or
9 device design limitations. Given these data, has
10 reasonable assurance of device safety been
11 demonstrated?"

12 DR. YASZEMSKI: Thank you, Mr. DeLuca.

13 Dr. Naidu, this is a device safety
14 question. We'll start with Dr. Naidu this time and
15 go counter-clockwise.

16 May we have comments from you, please?

17 DR. NAIDU: Yes. The adverse events that
18 were reported were very minor--bruises,
19 falls--nothing harmful, and the device failures
20 were comparable to the own device.

21 The only question that I have is from the
22 presentation by Captain Marie Schroeder and the
23 slide with the computerized alert and failure
24 identification data. If you could answer as to
25 what the total count, the number of controller

1 alerts, stair--the counts were pretty high--there
2 were 80 of them. The cluster motor was hot in 89
3 instances.

4 I'm not sure I understand that data.

5 DR. YASZEMSKI: Mr. O'Donnell?

6 MR. O'DONNELL: Okay, I'll just clarify
7 some of the data.

8 The first item you mentioned was which
9 parameter?

10 DR. NAIDU: Controller alert stair and the
11 cluster motor being hot. This is the computerized
12 alert and failure identification data.

13 MR. O'DONNELL: Okay. The controller
14 alert stair I believe you said was 80.

15 DR. NAIDU: Yes.

16 MR. O'DONNELL: That is correct. Much of
17 that is during training, on training days. There
18 were 32 such controller alerts which occurred when
19 the individual was out in the real world. The
20 controller alert, the count for that, the device
21 will add to that count or accumulate if, when, for
22 example, going down the stairs, they may be leaning
23 forward a little too much, and the device will stop
24 and say "I'm going to wait until you bring this
25 device back to center," or back to neutral. So the

1 device will stop a potentially unsafe situation,
2 and that adds to the controller alert stair count.

3 Other examples might be that if the
4 subject goes into Stair and leans the seat back and
5 then doesn't begin stair-climbing or does not climb
6 any steps, then you could get a count to occur.

7 In effect, these are safety features; they
8 are not failures, the counts that were shown. They
9 are really ways to protect the subject. I think
10 that sometimes we have chosen some wrong words by
11 calling them things like a "controller failure"
12 when in retrospect, we probably should have called
13 them a "controller success" because they stopped
14 the individual from getting into an unsafe
15 situation.

16 DR. NAIDU: Thank you. That really
17 clarifies a lot of issues, and in my opinion, I
18 think this is a very safe device.

19 DR. YASZEMSKI: Thanks, Dr. Naidu.
20 Dr. Abrams?

21 DR. ABRAMS: On the basis of what we have
22 seen in the presentation, I would agree; I believe
23 this is a safe device. I think my colleagues'
24 analogies about operation of an automobile are very
25 germane here. This is a device that can be misused

1 and can be placed in unsafe situations, and in that
2 case, it is not going to be safe, but I'm not sure
3 that is the problem with the device. It is going
4 to require excellent training.

5 The other comment I'd like to make about
6 safety was the Stair-Climb. The pivotal study, if
7 I read it correctly, only had a few hours of people
8 actually using the Stair-Climb mode. I think I
9 heard that correctly--it was something like 3-1/2
10 hours total.

11 I'm not sure that I can make a decision
12 about whether it is safe on Stair-Climbing in terms
13 of looking at the pivotal study just because it
14 wasn't used very much. It would be nice to see
15 some more data long that line.

16 And the final thing I just want to say in
17 terms of the safety is the way the pivotal study
18 was stratified was by device use. It would be
19 interesting to know--I'm not sure if you have any
20 data--in terms of it you had stratified the study
21 by the body mechanics or by the use of one arm, the
22 use of two good arms, use of one good arm, and so
23 on and so forth. It would be interesting to see
24 whether things worked out the same way, but I know
25 that's potentially a large study which I know you

1 wouldn't want to think about. But it would be
2 interesting to know about things such as those.

3 DR. YASZEMSKI: Thanks, Dr. Abrams.
4 Dr. Hannaford?

5 DR. HANNAFORD: I'll just preface my
6 remarks by first thanking the sponsor and the FDA.
7 There is a lot of information here and a lot of
8 well-done engineering and studies. My remarks are
9 fairly long because, as an engineering, I felt that
10 my expertise was best spent on the engineering and
11 safety issues of the device, and not the clinical
12 side, since that is outside of my expertise.

13 And again, to think about it most
14 effectively, that took written form, so I will read
15 my remarks.

16 I reviewed the detailed information
17 consisting of 20 volumes. I received them on the
18 6th of November, and since that time, I have spent
19 about 14 hours reviewing them. In view of the
20 limited time available and my own expertise and the
21 request of the FDA, I am limiting my own review to
22 the software and control systems of the iBOT.
23 Similarly, I am focusing my review on only one of
24 the questions--this question--device safety, and
25 has reasonable assurance of device safety been

1 demonstrated.

2 Although the question seems to limit the
3 terms to the clinical trial experience, I am
4 interpreting it a little more broadly to include
5 safety issues which might be evident in the
6 software and control system hardware documentation.

7 Although I was specifically tasked with a
8 software review, in this type of complex system,
9 software and hardware failures are potentially
10 tightly coupled to each other, and safety cannot be
11 assured without considering them as they work
12 together.

13 Due to the constraints of available time,
14 I have limited my review to the embedded control
15 software inside the iBOT, primarily the power-based
16 processors and related testing. Although there is
17 potential for danger due to errors in the physician
18 interface, the technician interface, and other
19 software components, I selected software and
20 hardware to review based on what appear to be the
21 most critical safety risks, namely, the loss of
22 control or balanced in enhanced Balance and
23 Stair-Climbing modes.

24 I have used exclusively the 20 binders
25 sent to me by the FDA, and I don't have any other

1 knowledge of the device. The bulk of my time was
2 spent on Volumes 3, 4, 11, and 14.

3 On design issues, and first, the concept
4 of risk and level of risk, the iBOT is a
5 breakthrough product which has major potential to
6 benefit the lives of a significant portion of
7 mobility-impaired people and, in turn, society as a
8 whole. I concur with the FDA's belief that the
9 device represents a breakthrough technology with a
10 clear, clinically meaningful advantage over
11 existing technologies.

12 However, in performing an expedited
13 review, we must recognize that this technology also
14 carries significant new risks to the user and to
15 others. The public interest is not served if this
16 technology is released before these risks are made
17 as small as reasonably practical.

18 The overall engineering of the iBOT and
19 the care taken to make sure it is safe are
20 impressive and mostly well-documented. As a
21 touchstone, the triple-redundant computer system
22 and serial bus used in the iBOT bears a remarkable
23 similarity with an exception discussed below to the
24 fly-by-wire control system used in the Boeing 777
25 aircraft, the most modern one in Boeing's fleet.

1 It is remarkable that the declining cost
2 of information technology makes this level of
3 sophistication available to a single-user consumer
4 product. It is also necessary, in my view, since
5 the vendor and the FDA have classified the risk
6 level for loss of balance on stairs as catastrophic
7 according to the Risk Management Plan in Volume 3.

8 The risk is highest for Stair-Climbing
9 mode. Clearly, a loss of control on stairs could
10 result in the user and chair being pitched down a
11 flight of stairs. This is also a very significant
12 risk to other users of the stairs who might be
13 below the iBOT user. In a crowded facility like a
14 school, theater, or sports arena, this could cause
15 a domino effect and injure a large number of
16 people.

17 ADA requirements have reduced the need for
18 stair-climbing in public facilities, so the risks
19 have to be balanced against the real benefit.

20 The following are my concerns after
21 reviewing the software, hardware, and testing
22 documentation.

23 The first is multiple-redundant processors
24 running a single code. Three processors are
25 provided for the power-based controller to guard

1 against processor failure. A vote is performed,
2 and a processor which disagrees with the other two
3 is presumed to be faulty and is shut down by the
4 two which agree. As mentioned above, this method
5 is also used in the Boeing 777. The key difference
6 in the 777 is that each of the three processors
7 runs different software written by three different
8 software teams to the same specification. This
9 very expensive method reduces the risk that a
10 single software bug will crash or create erroneous
11 output on all three processors simultaneously.

12 Even though the power-based software has
13 been carefully developed and tested, it is
14 extraordinarily difficult to guarantee that no bugs
15 remain. Even successful use in the field for years
16 cannot eliminate this possibility. As in the
17 failure of the Arion-5 rocket booster, which used
18 proven software from the Arion-4 and failed due to
19 a bug in that software, that bug never caused a
20 problem because the Arion-4 never went quite as
21 fast as the Arion-5; so the Arion-5 happened to go
22 a little bit faster and caused this software bug
23 and exploded.

24 I recognize that having three separate
25 software development teams is expensive, and it

1 still does not guarantee a safe system.
2 furthermore, the consequences of flight control
3 failure are even more catastrophic than iBOT
4 failure. In a fly-by-wire control system, there
5 are serious safety risks almost 100 percent of the
6 time the system is in use. In contrast with a
7 powered wheelchair, there is a large percentage of
8 time in any user's day exclusive of Balance and
9 Stair-Climbing modes where a software crash or bug
10 would be detected and logged and thereby discovered
11 and fixed without risk to the user.

12 For these reasons, I think the lack of
13 independently-written software versions in the
14 three processors is not a barrier to approval.

15 However, I feel that the classification in
16 the Risk Management Plan should be modified. As
17 far as I can tell, the 50-page Hazard Analysis
18 Table, at pages 3-71 through 3-120, lists only one
19 possible software failure, which is Number G9.02 on
20 the last page of that table. The report lists the
21 possibility of this cause as "improbable" and the
22 severity as "critical." And if you refer to the
23 Residual Risk Chart which defines these terms and
24 trades them off against the likelihood, I
25 believe--and that is as given on page 3-70--I

1 believe the possibility should be increased from
2 "improbable" to "remote"--and these are obviously
3 generic words, but they are listed in a certain
4 order in that table--and the severity increased to
5 "catastrophic" because a software bug causing all
6 three processors to crash simultaneously is
7 possible and would cause a user to lose control on
8 the stairs.

9 This does not change the approval
10 rating--that is, the failure mode risk should still
11 be classified ALARP, or "As low as reasonably
12 practical," according to that table, but the margin
13 of safety should be considered less, and
14 consequently, the level of vigilance increased.

15 So these are the best I can interpret the
16 guidelines in the methodology that is described for
17 evaluating software risk.

18 The next thing is of much lower concern,
19 and that is the use of MATHLAB and SimuLink block
20 diagrams in the documentation of the control
21 system. The second issue is software development
22 methodology for the control system.

23 The control system is documented in
24 detail, which reveals extensive, careful
25 engineering. One troublesome detail is the use of

1 what appear to be block diagrams created with the
2 SimuLink software package from MathWorks. SimuLink
3 is an excellent program, and it is an industry
4 standard. Indeed, I would have some concerns if
5 iBOT designers did not use SimuLink or an
6 equivalent tool to model the system. However, the
7 documentation refers to the control system itself
8 and not to the system model, or a model of the
9 control system.

10 What is the exact relationship between
11 these block diagrams and the embedded controller?

12 Did you use a product such as RealTime
13 Workshop Embedded Coder to automatically generate
14 code from the block diagrams?

15 If so, this needs to be carefully
16 documented, and we should have evidence that the
17 generated code is correct. If not, and the code
18 was generated by hand based on these block
19 diagrams, what is the assurance that the generated
20 code is the same as the simulation?

21 Finally, many but not all of these block
22 diagrams, such as 5-27, page 3-283, convey no more
23 information than a table listing inputs and outputs
24 would. Such a table would be significantly easier
25 to read and should be derived directly from the

1 actual embedded code.

2 I am assuming that the system was fully
3 modeled and simulated in parallel with controlled
4 software development. What were the results of
5 this simulation? How well does it match real
6 performance of the system?

7 It is possible that this information is
8 covered somewhere in the documentation which I have
9 not been able to find in the available time, and I
10 will leave it to the FDA staff to decide if this
11 has been addressed in sufficient detail. Rather
12 than a clearly-identified safety issue, to me, this
13 is an area that should be more carefully
14 documented.

15 Next, 4.4, controller coupled to battery
16 voltage. This is not a safety issue. The system
17 design would be more modular and robust if
18 power-based controller output was the desired motor
19 current or torque, usually directly proportional to
20 each other, and the power amplifier
21 micro-controller determined the duty cycle required
22 based on current or torque feedback.

23 Adjusting duty cycle based on battery
24 voltage, which is what is described on page 3-328,
25 does not compensate for other factors such as motor

1 inductance, back EMF, and temperature-induced
2 resistance change.

3 Assuming that those factors are not
4 necessary to compensate for and that battery
5 voltage change is the only important variable which
6 needs to be measured to get adequate torque
7 control, locating this compensation in the
8 power-based controller seems to unnecessarily
9 intermingle two separable functions. This coupling
10 could complicate system requalification in response
11 to possible future modifications to the motors,
12 battery, or power amplifiers by requiring
13 reanalysis of the control algorithms.

14 So again, this is just a flag or an issue
15 that might happen in future revision.

16 Now on to testing, because as I implied,
17 there really isn't any methodology that can prove
18 that software is safe at all.

19 Clinical and nonclinical testing seems to
20 be adequate for most of the modes of operation.
21 With 18 subjects--I'll note here that I am still
22 unsure if it was exactly 18 or 20 who made it all
23 the way through the clinical trial; I read that
24 there were 20 and that two dropped, but the numbers
25 I saw this morning implied that the two dropped

1 before the 20--it doesn't matter that much to what
2 I am going to say--those numbers are within 10
3 percent--using the iBOT for 2 weeks, there were
4 three falls reported with the iBOT. Two falls were
5 reported with 2 weeks' use of the patients' own
6 devices. Although I don't believe the sample size
7 is adequate to determine the significance of this
8 number of falls, we should also note that the users
9 had extensive prior experience with their usual
10 devices and only basic training with their iBOTs.
11 And I will also leave statistical issues to the
12 judgment of Dr. Larntz, which I agree with.

13 Although Balance mode would seem to raise
14 safety concerns, it has the advantage that since
15 its function is to keep upright on a normal
16 surface, it is relatively compatible with existing
17 wheelchair standards for dynamic and static
18 stability, since those devices can also tip over
19 under certain circumstances. The stability results
20 of nonclinical testing of this mode were very good.

21 However, a concern remains that of
22 necessity, the Balance mode and to some extent the
23 4-Wheel enhanced mode generate displacements of the
24 chair in the front-back direction in order to
25 maintain balance.

1 We are not given much information about
2 the magnitude of these displacements. There is the
3 safety feature which disables the chair if a
4 runaway displacement of 10 feet or more is
5 detected. Ten feet is a very long distance in an
6 environment like a kitchen or an office. Are users
7 likely to run into obstacles during balance
8 recovery? What are the typical displacements
9 during normal operation?

10 My remaining concern is with
11 Stair-Climbing mode, especially solo Stair-Climbing
12 mode. The review notes that in an earlier clinical
13 trial of spring 2001, a user was thrown from their
14 chair on the stairs, causing injury to the user.
15 Suspension of that portion of the trial and
16 revisions to the software resulted.

17 So the rest of my comments are on the solo
18 Stair-Climbing mode and to some extent Assisted
19 mode. Nonclinical testing, the Stair-Climbing
20 Report, Volume 11, page 232--this report describes
21 testing Stair-Climbing function subject to several
22 variables, including stair strand, geometric
23 variations, climbing rate, et cetera. Although
24 comprehensive, these tests are primarily focused on
25 performance metrics and not reliability or safety.

1 The summary of results on page 11-237
2 notes that the device failed one of the geometric
3 variations--that is, long treads--until software
4 was corrected. We are not told whether this
5 failure resulted in an unsafe condition or a safe
6 state which would not ascend or descend the stairs.

7 The geometric variations tested included
8 5-inch and 8-inch risers and 10-inch and 17-inch
9 runs. The latter, that is, the 17-inch runs,
10 exposed the software problem. Are run and rise
11 variations tested independently? There are really
12 four combinations of the two runs and rises. Did
13 you test all four? In view of the software failure
14 for a 17-inch run, wouldn't it be good to test all
15 four, that is, the long-and-high and short-and-low,
16 and so forth? Wouldn't it be good to test all four
17 combinations? Maybe they were, but that wasn't
18 quite clear to me in the report--even if those are
19 infrequently found in the outside world, some of
20 those extremes.

21 And then, what was the surface material of
22 the stairs? The user manual lists many stair
23 surfaces, including secured carpet. Were they
24 tested? Aren't there some types of secured carpet
25 that would be dangerous, such as shag carpet? I

1 don't know.

2 Except for the lack of carpet surface
3 testing, this testing seems okay as far as it does
4 but does not do much to address safety because
5 there are so many variations of stair types and
6 user behavior out there.

7 Next, the Fault Insertion Test Report,
8 Volume 11-269. This report describes insertion of
9 electrical and software faults into the system to
10 make sure expected but safe behavior occurs. Under
11 A-415-Z1, Power Based Processor Hardware Faults, on
12 page 11-293, faults in Stair mode seem to be only
13 tested while sitting on the stairs. What about
14 climbing and descending? Since climbing and
15 descending somewhat stress the system mechanically
16 and thermally, it seems a relatively likely time
17 for a sensor failure--relatively, not a likely time
18 but a relatively likely time.

19 And then, clinical testing, Volume 14,
20 Appendix A. Eighteen subjects--perhaps 20--used
21 the iBOT for 2 weeks. Results were compared with 2
22 weeks for their own use. About half the subjects
23 were allowed or configured to use solo
24 Stair-Climbing mode.

25 One concern is the mix of male and female

1 subjects. While I realize there may be more male
2 wheelchair uses in this population, we have in this
3 trial the fact that we have only one female subject
4 who used the device in solo mode on stairs. She
5 did well. Do we have enough data to decide that
6 solo Stair-Climbing mode is safe for female users?
7 Women may have less upper body strength; they may
8 also have different mass distributions, even if
9 they have the same center of gravity.

10 Again, I don't think that higher-order
11 mass distribution other than center of gravity is a
12 crucial issue for the engineering, but it might be.

13 Finally, the device has a terrific logging
14 facility, so we have a wealth of data on how the
15 device was actually used in the trial. Table
16 M--this table tells us important things about
17 stair-climbing and also drives the need for more
18 data. In trying to decide if this trial validates
19 the safety of stair-climbing, we have to look
20 carefully at how much stair-climbing was actually
21 performed.

22 We have three log entry types to
23 use--stair hour meter, stair entry count, and
24 controller stair alert count. Using this, we see
25 that of 1,440 total hours in the active wheelchair

1 functions, we have only 4 total hours of real world
2 stair-climbing use. This works out to only 13
3 minutes per subject.

4 During this time, we have 32 controller
5 alerts in Stair-Climbing mode. Although there were
6 five times as many Stair mode entries during
7 training, there were fewer controller alerts. So
8 there were 770 entries to Stair mode in training
9 versus 141 in actual use, and there were 24
10 controller alerts versus 32 in actual use. And
11 your clarification was useful just now on what a
12 controller alert means, but my interpretation still
13 is that the controller alert happens when they are
14 going outside of some envelope, perhaps toward the
15 edge of the safe region of operation, even though
16 still in it.

17 So we are seeing users in the field going
18 to the edge of the safe envelope much more
19 frequently than they are during the training phase
20 as a percentage of the number of entries they are
21 making to Stair-Climbing mode.

22 There seems to be something different when
23 Stair-Climbing is used outside of the lab. Note
24 that one subject reported "Difficult time climbing
25 stairs as smooth as in training."

1 Similarly, out of 1,055 entries to
2 Stair-Climbing mode, only 141--which is seven or
3 eight per subject--were real world use. Thus, we
4 have each subject doing an average of eight
5 stair-climbs at about 1.6 minutes per stair-climb
6 during their 2 weeks. And 1.6 minutes is 96
7 seconds. The testers in the nonclinical testing,
8 which I assume are experts on the chair, averaged
9 about 2 seconds per step according to the data in
10 the report. That works out to 48 steps per
11 stair-climb. And most flights of stairs are a lot
12 less than 48 steps.

13 So my point in this is that the users are
14 negotiating stairs significantly slower than these
15 experts in the nonclinical testing.

16 We also know that about half the subjects
17 were restricted by their initial medical evaluation
18 to Assisted mode. That leaves about eight solo
19 stair-climbs with about nine subjects, or 72 total
20 stair-climbs of total data. What kind of stairs
21 did they climb? We don't get the statistics broken
22 down according to how many controller alerts
23 occurred in assisted Stair-Climbing mode or solo
24 Stair-Climbing modes. And how many carpeted stairs
25 were climbed?

1 I would be a lot more comfortable with
2 data from more solo stair-climbs by end-users in
3 their real environments, as well as more
4 documentation of the types of stairs they used.
5 Were they frequently negotiating little flights of
6 three levels, or were they climbing long flights?

7 And data logging could be enhanced to
8 measure the number of stairs climbed in solo versus
9 assisted modes, what climbing rates were achieved,
10 and whether controller alerts were in solo or
11 assisted modes. Stair counts are not
12 straightforward to get from the cluster odometer
13 data.

14 Finally, just a small comment on the user
15 manual. It says to avoid stairs with "flared
16 handrails"; I don't know what a "flared handrail"
17 is, but I assume it is something that is covered in
18 training.

19 That's my analysis. I have a page or two
20 of very small typos and things like that.

21 DR. YASZEMSKI: Thank you. Thanks very
22 much for that complete description, Dr. Hannaford.

23 Ms. Buzaid?

24 MS. BUZAID: I am not an engineer, so my
25 remarks will be slightly more anecdotal. Thank

1 you for that, by the way.

2 I am a clinician, and I have about 15
3 years of experience mainly in evaluation and
4 training for power wheelchairs. My concern with
5 the study centered around that in the study, most
6 of the patients had been manual wheelchair users
7 and not previous power wheelchair users.

8 I realize that this is a breakthrough kind
9 of device, and perhaps it is identifying a
10 different population of patients than were
11 identified prior by the power wheelchair market.
12 But some of the concerns that I have regarding
13 safety are around the typical behavior of someone
14 who has a power device and what typically happens
15 to them after it has been delivered--and I guess I
16 need a point of clarification as to whether or not
17 I can discuss that now.

18 DR. YASZEMSKI: Go ahead.

19 MS. BUZOID: As was brought up earlier,
20 often, patients' weight changes, for example. I
21 don't quite understand whether the powered device
22 will alert the patient when it needs to be
23 recelebrated because of a weight change.

24 DR. YASZEMSKI: Would sponsor respond?

25 MS. MINKEL: There is no loop back to the

1 consumer from a detection point of view. The
2 consumer will feel a change in the performance
3 mostly around the transitions into and out of
4 Balance if the calibration is changed from where it
5 was delivered.

6 MS. BUZAID: Just to clarify, they might
7 not know until they have a problem?

8 MS. MINKEL: It's not a problem. The
9 distance traveled or the bump that they will feel
10 as they are coming out of Balance down onto
11 4-Wheel, when it is a properly-calibrated device,
12 it is a nice, smooth transition; it may have a
13 bumpier landing. But the function of the device
14 doesn't change.

15 MS. BUZAID: One of the other things that
16 tends to happen is that patients change their
17 seating systems, and I also was not clear on
18 whether the back of the mobility device needed to
19 be the back that is on the iBOT.

20 MS. MINKEL: Yes.

21 MS. BUZAID: It does; so there is no
22 aftermarket putting on a different-style back. And
23 a variety of different seats can be put on the
24 chair?

25 MS. MINKEL: Correct.

1 MS. BUZAID: They all just have to fit the
2 parameter of the seat.

3 MS. MINKEL: Right.

4 MS. BUZAID: Okay. Being an occupational
5 therapist, I am a little concerned about the fine
6 motor aspects of the actual control box. Sometimes
7 people slide those fore and aft and move them into
8 midline, and sometimes in sunlight, they can't see
9 because the light doesn't show exactly where they
10 are. In the material that I have reviewed, I just
11 couldn't see the control box well enough. I am
12 assuming that with the therapist doing the testing
13 beforehand, they are going to have ruled all these
14 things out, but I was concerned in the test that
15 the quadriplegic did have a difficult time
16 differentiating the buttons.

17 Do you know what the reason was for that
18 specific individual when he pressed the wrong
19 button--

20 MS. MINKEL: He didn't actually press the
21 wrong button. He couldn't respond to the joystick
22 quickly enough because he didn't have grasp. So he
23 was using a modified hold on the joystick, and when
24 he went to change his direction of travel, he
25 couldn't grab the stick like you or I would grab

1 the stick. It wasn't a button issue.

2 MS. BUZAID: So are you recommending any
3 other accessories be put on that box to help people
4 like that, or is this device pretty much going to
5 go out as it is?

6 MS. MINKEL: Pretty much it is going to go
7 out as is. We have found that the use of a
8 touch-tone telephone is a real good indicator as to
9 whether you will be able to accurately use our
10 buttons.

11 MS. BUZAID: So anyone who needed a
12 modified joystick or a modified On/Off button or
13 anything like that would be disqualified from use.

14 MS. MINKEL: [Nodding head.]

15 MS. BUZAID: Thank you.

16 DR. YASZEMSKI: Thank you.

17 Dr. McQuade?

18 DR. McQUADE: It's pretty hard to follow
19 Dr. Hannaford's dissertation. I hope he hasn't set
20 a precedent here.

21 A couple of just clarification questions.
22 I pulled this out from reading the volumes, but I'm
23 not sure I got it exactly right. When you
24 disengage the auto brakes for moving, is there a
25 way that the disc can become automatically

1 reengaged in case the user forgets to reengage it?

2 MS. MINKEL: The brake levers will not
3 automatically reengage, but there is on the user
4 control panel both a yellow alert and an icon to
5 inform the user that the brake levers are not
6 engaged.

7 DR. McQUADE: Okay. I read 3 meters
8 braking distance needed for traveling in Balance
9 mode. Did I read that correctly? That's an awful
10 long way. When do you have 3 meters before you hit
11 something?

12 MS. MINKEL: That is under a worst-case
13 situation, going at the top speed. What happens
14 is, just as if you were out running, and you needed
15 to stop, your feet have to stay underneath you, so
16 we need that distance for the wheels to stay
17 underneath the rider. With a smaller traveling
18 speed, it is a much shorter braking distance.

19 Basically, that's part of our training--we
20 show people what the braking distances are at
21 various speeds so they recognize that their
22 personal space is bigger when they are riding
23 around in Balance, particularly at top speeds. It
24 is really an application of if you are going to the
25 mall, and you are tooling down, you keep an eye out

1 in front of you. If you are in your kitchen, you
2 want to be going at much slower speeds so that you
3 can roll to a stop.

4 DR. McQUADE: Okay. And I want to kind of
5 reinforce the same point as has been made twice
6 here in terms of understanding the most significant
7 features as being calibration and balance
8 adjustment. You talked about using the body
9 weight, but the center of gravity is a kinematic
10 variable, not a kinetic variable, so it is all a
11 distribution problem, so it is not based on their
12 weight. And things like Ann said about changing
13 seats, or someone can change their weight and not
14 change their center of gravity--it's just the way
15 it is distributed. A large man with big arms can
16 reach forward and change his center of gravity.

17 How sensitive is the center of gravity
18 calculation to these kinds of fluctuations?

19 MS. MINKEL: For each individual--as I
20 said, the very first thing we do in assessment is
21 to use the medical interface to calibrate the
22 device to this user. If you are outside of our
23 operating envelope, the medical interface will
24 inform me as a clinician that you are not in our
25 operating envelope.

1 In some cases, I can adjust parameters of
2 the seat to see if I can move you into our
3 envelope, and in other cases, we are sorry, but
4 your body doesn't fit our machine, and that ends
5 the assessment right then and there.

6 If you fit in our envelope, where you will
7 see the device will respond to changes in center of
8 gravity--you had mentioned reaching forward--that's
9 exactly what happens--you reach forward in Balance,
10 the wheels are going to roll underneath you. That
11 is all built into our training program so that
12 people know what the device's reaction is going to
13 be to various changes of center of gravity that can
14 be predicted.

15 DR. McQUADE: But only in response to
16 pitch. What about lateral?

17 MS. MINKEL: Lateral stability is the same
18 as current mobility devices, and again, in the
19 training, we illustrate to people through
20 driving--up and down, forward, aft, you're fine;
21 make a sharp turn here, you're not going to be so
22 fine. So it's built in.

23 DR. McQUADE: In I think it was Study
24 Number 3, where you had a kind of a snapshot
25 assessment of the 98 manual wheelchair users--or, a

1 combination, manual wheelchair, power users--a kind
2 of single-visit test, you reported that 99 percent
3 were evaluated as prospective users. I would
4 imagine that if it was truly a random sample of 100
5 people, getting 99 to be qualified is hard to
6 believe. But then, you reported that only a little
7 bit over half would be considered independent users
8 without the need for assistance, which makes the
9 point that this is a really difficult device to
10 use. And I'm not sure the category of these
11 users--you identify a whole group that you think
12 are appropriate, almost all of them, which is
13 interesting--but not that many percentages could be
14 used as--

15 MS. MINKEL: Let me just clarify one
16 thing. The 99 percent recommendation was after
17 people had completed a telephone screen. So we had
18 many more calls come in that didn't make it through
19 the telephone screen; they either couldn't operate
20 a push-button telephone, or they weren't able to
21 sit in a standard chair. So we had questions that
22 we could ask, really to be honest, to save somebody
23 from coming into the assessment only to find out
24 they weren't going to fit in the device.

25 DR. McQUADE: Does that seem reasonable

1 that--do you think that of the percentage of people
2 who make it past that--this percentage that you
3 gave actually was 57 percent would be considered
4 independent users--is that what you expect, or is
5 it--

6 MS. MINKEL: Independent in all five
7 functions.

8 DR. McQUADE: Okay.

9 MS. MINKEL: I think that's not bad,
10 because what that is excluding are those folks who
11 aren't physically capable of doing stair-climbing
12 independently, and that probably is the most
13 physically demanding in terms of grip, rotation,
14 coordination. That's probably a real number.

15 DR. McQUADE: Okay. Thank you.

16 DR. YASZEMSKI: Thanks, Dr. McQuade.

17 Mr. Herman?

18 MR. HERMAN: I have two safety concerns.
19 It bothers me that the i-Balance technology is not
20 enabled in the Standard function, and the device
21 does not have anti-tips. Given the
22 unpredictability of many curb cuts, I'm real glad I
23 have anti-tips, and I have used them many times.
24 So I wonder, given that, can you honestly recommend
25 the use of Standard function in anywhere other than

1 the most controlled, flat environments?

2 MS. MINKEL: That is where we recommend
3 it--in most controlled, flat environments. Our
4 experience is we wanted to provide an easier turn
5 capability, which is what the casters provide
6 you--so, in your office, to go from your table to
7 your filing cabinet. Four-wheel uses wheel torque
8 to turn, and to be honest with you, it's pretty
9 deadly on carpeting. So the casters are really
10 designed to give you an improved turning in that
11 firm, flat environment. As soon as you go outside,
12 most people opt to go into 4-Wheel because they can
13 maximize their stability over those unpredictable
14 terrains.

15 MR. HERMAN: So you would probably
16 recommend 4-Wheel even to go up a ramp in a
17 minivan?

18 MS. MINKEL: Yes.

19 MR. HERMAN: Okay. The second concern has
20 to do with the batteries. Are nickel cadmium
21 batteries like sealed gel cell batteries in that
22 they don't leak, and they don't have to be removed
23 by an air carrier?

24 MS. MINKEL: That's correct, yes.

25 MR. HERMAN: Okay, thank you.

1 DR. YASZEMSKI: Thanks, Mr. Herman.

2 Dr. Stiens?

3 DR. STIENS: I'd like to open by asking a
4 question of the FDA representation here about their
5 definition for device safety. Kind of going back
6 to my diagram, the device is this thing that sits
7 under the person, and with it off and sitting there
8 in transit and so on, maybe on an airplane, for
9 instance, I am absolutely convinced that it is
10 safe, and that is an absolute.

11 Then, of course, I am discussing a
12 relationship between the device and safety with
13 patients, and I'm kind of making a personal
14 decision with someone, and a lot of people have
15 their own definitions of safety as well. So from a
16 clinician's standpoint, I'd kind of like to know
17 what definition the FDA has for this, because if
18 and when it hits the market, clinicians will need
19 to know what safety is when they are counseling
20 patients.

21 DR. YASZEMSKI: Dr. Witten, do you have
22 enlightenment for us?

23 MS. WITTEN: I'll just give you some
24 general enlightenment. I know there is a formal
25 definition that you will read later, at the time of

1 the vote, but in general, let me just say that how
2 we look at safety is we look at safety of a device
3 not just, as you say, the device itself when it is
4 turned off, that it is not going to do anything,
5 but the device for the intended users, the patient
6 population who are going to receive it, in the
7 context of what they are supposed to be doing with
8 it. So I would refer you to the Indications for
9 Use of the sponsor, that we looked at it for
10 individuals who have mobility impairments in the
11 use of at least one upper extremity to provide
12 indoor and outdoor mobility in confined spaces, at
13 an elevated height, to climb curbs, ascend and
14 descend stairs, traverse obstacles, travel over a
15 wide variety of terrain, and negotiate uneven
16 inclined surfaces.

17 So when we are asking about safety, we are
18 asking about safety for that population and for
19 that use.

20 DR. STIENS: I just wanted to reiterate as
21 a point of clarification, I guess, that the
22 environment is quite varied, and the environment
23 would differ for each of the users, and there has
24 been an effort to provide environmental simulation
25 in the training for subjects--actually, in

1 patients--at this point, when a person is receiving
2 the device, he is a patient, and there is an
3 implied relationship and a formal relationship with
4 his clinicians in that regard, that their judgment
5 is part of this device safety equation with them in
6 the device and functioning within the environment.

7 With that in mind, I just have a few
8 questions that are more specific. One is on the
9 test videos. I did not get a chance to review the
10 actual videos. Do those test videos exist where
11 you have the stairs that people would decide yea or
12 nay on? Are those done?

13 DR. YASZEMSKI: Ms. Minkel?

14 MS. MINKEL: We have what we call "safe
15 usage" videos, and within that tape, we demonstrate
16 in the context of a lab what the device's response
17 will be to poor judgment and technique involving
18 stairs. So, you see the device heading down.

19 DR. STIENS: I see. Those are the
20 training videos. So you see the device
21 successfully go down the stairs; is that what
22 you're saying?

23 MS. MINKEL: Unsuccessfully.

24 DR. STIENS: Unsuccessfully. So you see a
25 fall with the device. Is there a person driving it

1 in that video?

2 MS. MINKEL: In a couple of cases, we have
3 the infamous test dummy.

4 DR. STIENS: Okay. That's helpful. And I
5 think that is good to have.

6 What I pictured when you talked about some
7 testing videos was some stairs that would be
8 clearly unsafe to use the device on pictured in the
9 video. Is that a video that you guys imagined
10 making? I thought there were some that were in the
11 making.

12 MS. MINKEL: We have still photos that we
13 use as part of the training.

14 DR. STIENS: Okay.

15 MS. MINKEL: We also have stair "jigs"--is
16 the best I can describe them--where we can take a
17 standard therapy set of stairs and add a piece that
18 makes it a long tread or a short riser or a short
19 tread, so that every person who goes through
20 training sees the orientation of the wheels on the
21 range of steps that are allowed and feels the
22 device performance on each of those corners of
23 short tread, long tread, high rise, low rise. And
24 then, in the course of our test, we introduce a set
25 of stairs that is outside of that range to be sure

1 the person uses those measurement techniques to
2 decide not to climb those stairs.

3 DR. STIENS: Okay. And this is kind of on
4 the bridge from visual learning to experiential
5 learning, so when those jigs are placed--and I am a
6 clinician imagining wood steps moved around in the
7 therapy environment, and I have experienced falls
8 in the therapy environment from attempting too high
9 a curb, for instance--so these jigs are things that
10 they could put up against stairs, and the patient
11 could try the chair on those jigs and experience an
12 unsuccessful stair attempted ascension?

13 MS. MINKEL: Yes.

14 DR. STIENS: Okay. The other thing that I
15 lack discovering from the data is what I would call
16 a kind of uninformed user challenge to the device
17 that engineers often apply before a device might be
18 used by somebody who was uninitiated with the
19 device--in other words, getting into the device and
20 trying to find bugs soon.

21 One way is to use natural history to find
22 bugs, and we have kind of done that with the very
23 limited pivotal trial that has been carried out.
24 But if someone, preferably an engineer--or a very
25 experienced stunt man--would get into the device

1 and try to find these bugs soon, I was wondering if
2 you could report to me about those kinds of
3 investigations and how they turned out. Do you
4 have any background on that?

5 MS. MINKEL: We have a few people who fit
6 that description and are crazy enough to actually
7 say, "What if I do"--blank--what is going to be the
8 device's response.

9 DR. YASZEMSKI: Thanks. Please tell us
10 who you are.

11 MR. AMBROGI: Sure. I'm Mike Ambrogi with
12 DEKA Research.

13 It turns out that the majority of our--we
14 call them "anomalies"--are found by the engineers
15 in this type of accelerated testing. With every
16 software release, there is a significant amount of
17 driving that takes place from the engineering team,
18 the test team, and even before the software
19 release, the controls group or the software group
20 that is working on the changes are doing an
21 extensive amount of testing.

22 In addition, we have built what we call
23 our durability proving grounds. We have an
24 accelerated life track in a facility that has a
25 number of obstacles and stairs and puddles and sand

1 and gravel, and we run extensive tests in the
2 proving grounds also, just to find these types of
3 bugs and these types of anomalies. Again, that's
4 our biggest source of this type of thing. So we
5 are clearly not relying on the clinical trial to
6 surface these types of issues; they are to be found
7 internally, prior to release.

8 DR. STIENS: I am real excited about the
9 device as the potential for users. But at the same
10 time, I am fearful about bugs or glitches that
11 could occur at the interface of the user and the
12 device and the environment.

13 To use the car analogy, for instance, when
14 I am driving my car, there are only certain gears I
15 can put an automatic transmission car in in certain
16 situations--I can't put it in reverse driving
17 forward on the freeway, and so on--and there is an
18 infinite number--well, not an infinite
19 number--there is a large number of buttons and
20 conditions that a user can put the device in, and
21 when you permutate that with the infinite number of
22 environmental situations that the user could be in,
23 I wanted to feel confident that you guys had tested
24 it in that way.

25 For instance, if you were to put the

1 device on the stairs and press a variety of buttons
2 at different steps in the stair descension process,
3 has that happened, to know that no matter what
4 button you push during the course of the stair
5 descension, the device itself--and we are just
6 talking about that--would not precipitate a
7 malfunction that would cause a problem?

8 MR. AMBROGI: Right. We have done
9 extensive work in that area, and in addition, the
10 controllers themselves have some preventive
11 measures to deal with that machine environment
12 interface. So for instance, if you are in Balance
13 mode, and your encounter with the environment is
14 particularly challenging, there is a transition
15 into 4-Wheel mode that is accomplished to basically
16 catch the user.

17 So it is that machine-environment
18 interface which is the most unknown, but we have
19 put a number of controllers in place to deal with
20 that. Also, on the stairs, there are some safety
21 mechanisms where, if there is a detection that what
22 is happening on the stairs is beyond the bounds of
23 what the controller would like to see, we have what
24 we call a cluster safety lock which will lock the
25 clusters and put the user down on the stairs and

1 allow them a chance to slowly transition back up.

2 So there are a number of those types of
3 things.

4 DR. STIENS: Okay. That's helpful to me.

5 So that's the stair answer.

6 The other condition that I am particularly
7 concerned with is the Balance mode. You list
8 barriers that are one-half inch to one inch--is
9 that correct--because I heard two numbers there.

10 MR. AMBROGI: I believe in Balance mode it
11 is half-an-inch. Now, we actually test to an
12 inch-and-a-half in our standardized qualification
13 test to allow some margin for people in recognizing
14 what is a half-inch barrier.

15 DR. STIENS: Okay. But you know, if you
16 are riding along--for instance, me--you bring me up
17 a few feet, and I'm riding on two wheels, and I'm
18 skipping across the pavement and interacting
19 successfully with a colleague face-to-face and
20 carrying a briefcase that is less than 20 pounds,
21 am I going to be safe if I hit a crack in the
22 pavement that is 2 inches high?

23 MR. AMBROGI: Again, that's where this
24 auto transition comes into play. If you were to
25 encounter an obstacle which Balance mode itself

1 cannot handle, that's when we do transition down to
2 four wheels, and in most cases, we can catch the
3 user that way.

4 DR. STIENS: And if I were traveling at
5 the fastest speed because I was late for my
6 meeting, and that was 5.1 miles per hour; is that
7 approximately--

8 MR. AMBROGI: Not in Balance mode. And
9 again, the Balance mode top speed is also limited
10 based on seat height, so we do take that into
11 account--the higher the seat height, the more we
12 cap that top speed, for just that reason.

13 DR. STIENS: Okay. Let's say I'm really
14 tall--I'm way up there--and I'm holding my
15 briefcase on my shoulder. What is the fastest
16 speed I could be going in Balance mode?

17 MR. AMBROGI: In Balance mode, with
18 maximum seat height?

19 DR. STIENS: Yes.

20 MR. AMBROGI: That's a good question.
21 Somewhere around 2-1/2 miles an hour.

22 DR. STIENS: Two and a half miles an hour.
23 So if I encountered a big barrier--let's just say I
24 ran into a curb--

25 MR. AMBROGI: You ran into a curb at full

1 speed. We have done those tests.

2 DR. STIENS: Good.

3 MR. AMBROGI: We have done a lot of those
4 tests, and what happens is you will auto-transition
5 into four wheels and, typically, catch yourself.

6 DR. STIENS: Okay. And I know you went
7 over the specifics of what is in the actual
8 device--and the panel will forgive me for putting
9 scenarios together--but is there a seatbelt on this
10 thing?

11 MR. AMBROGI: Yes, there is.

12 DR. STIENS: Okay. So it's a waist
13 restraint, and it is recommended that you should
14 wear that?

15 MS. MINKEL: Yes.

16 MR. AMBROGI: Yes.

17 DR. STIENS: Okay. The other thing--and
18 I'll get simpler here--is the NICAD batteries. The
19 NICAD batteries are heavy, and they have a memory--

20 DR. YASZEMSKI: Excuse me, Dr. Stiens.
21 Could you talk into the mike so the
22 transcriptionist can hear you, please?

23 DR. STIENS: --oh, I'm sorry--the NICAD
24 batteries have a memory, and your charge does leave
25 you a pretty large range when you are in the drive

1 mode, but when I went through your description of
2 stairs and enough power to get down the stairs and
3 all that, it made me concerned about range and the
4 issue of getting out of places you might get. It
5 made me think of air in the tanks when you go scuba
6 diving, actually. So I was wondering if you could
7 comment on the NICAD batteries and range and the
8 experience the user would get about the safety
9 issue of being able to make it down stairs if they
10 might have gone up, or the safety issue of the user
11 making a decision to traverse a distance with the
12 chair and having enough power to get back.

13 Thanks.

14 MS. MINKEL: Let me speak to that. Again,
15 it is a gas gauge question.

16 DR. STIENS: Yes.

17 MS. MINKEL: In the training, we let folks
18 know different functions are efficiently different
19 in terms of the power consumption. Interestingly
20 enough, Balance is the most energy-efficient. You
21 can travel the longest distance in Balance with
22 very little trouble. Four-wheel uses a lot of
23 energy. So we suggest to people, particularly if
24 you are going out to your natural
25 environment--because now you can--

1 DR. STIENS: Yes.

2 MS. MINKEL: --you may want to head back
3 before that needle is at the halfway point so that
4 you don't end up being stranded.

5 With regard to Stair, there is a very
6 prescribed feedback loop to the user with regard to
7 the amount of battery power left and whether we
8 caution you that you are getting close to the
9 barrier by which we don't think you have enough
10 power to complete the set of stairs, and then, if
11 you are at that power, we don't even let you get
12 into Stair. You can't get into Stair function if
13 we don't think you have enough power to complete
14 the set of stairs.

15 DR. STIENS: And when you say "the set," I
16 know there was a number in those 17 volumes or so--

17 MS. MINKEL: Twenty percent.

18 DR. STIENS: How many stairs?

19 MS. MINKEL: The calculations are based on
20 a flight of 20 steps.

21 DR. STIENS: Twenty, okay. That's helpful
22 to know.

23 And the other thing I wanted to ask about
24 is just for the sake of safety and avoidance of
25 being stranded, is there any convenient way for the

1 consumer to have an extra battery or anything like
2 that for getting out of situations they may get
3 into?

4 MS. MINKEL: The best that we can tell is
5 people got really good at figuring out what their
6 daily profile was like. A good example was a
7 gentleman who used the iBOT as his personal
8 transportation to and from work, and then at work
9 was tooling around and at home was tooling around.
10 He made the request to have two chargers, which was
11 perfectly reasonable. He left a charger at work,
12 so when he was going to be sitting at his desk for
13 a while, he used the charger and filled up the tank
14 to be sure that he had a full evening ahead.

15 The practicality of carrying around an
16 extra battery--if it were in your van, that would
17 probably be fine--but keeping it on you while you
18 are tooling around is not very practical.

19 DR. STIENS: Yes, sure.

20 MS. MINKEL: So we foresee people
21 identifying their usage profile and either making
22 charging changes or, for that matter maybe having a
23 second set of batteries that they swap out over a
24 weekend.

25 DR. STIENS: That's helpful. Thank you

1 very much.

2 DR. YASZEMSKI: Thanks, Dr. Stiens.

3 Ms. Maher?

4 MS. MAHER: No other comments.

5 DR. YASZEMSKI: Thank you.

6 Ms. Rue?

7 MS. RUE: No comments.

8 DR. YASZEMSKI: Dr. Goldman?

9 DR. GOLDMAN: Yes, just very briefly. On
10 the center of gravity issue, let's say you have an
11 EK or AK amputation and you have a prosthesis which
12 is variable weight and/or you have a long leg brace
13 and/or you are walkaholic, like me, and you have a
14 25-pound briefcase. Does that change the center of
15 gravity?

16 MS. MINKEL: Within a 20-pound
17 differential, our envelope can accommodate that.

18 DR. GOLDMAN: Okay.

19 MS. MINKEL: So you can put your briefcase
20 on your lap, or we have the carrying hook on the
21 back specifically designed for that.

22 DR. GOLDMAN: And that's reflected in the
23 training, the 20-pound--

24 MS. MINKEL: Yes.

25 DR. GOLDMAN: Okay. The other question is

1 concerning wound care. I noticed that in
2 transitioning from one mode to the other, the
3 device seems to go into a tilt-and-space
4 configuration. I know it wouldn't be used for
5 that.

6 Also--this is the last comment--Rojo or
7 J-cushion are actually manufacturers' trademark
8 terms--were both of those used in the pivotal
9 trial, and they could fit the seatpan?

10 MS. MINKEL: Yes.

11 DR. GOLDMAN: Okay. That's it.

12 Thank you.

13 DR. YASZEMSKI: Thanks, Dr. Goldman.

14 Dr. Myklebust?

15 DR. MYKLEBUST: My reading of the
16 discussion that we have been having is that other
17 than the potential for some software problems,
18 which I think Dr. Hannaford dealt with very well,
19 all of the safety issues that we have been talking
20 about revolve around the user, back to the
21 questions about user training and so forth.

22 In the discussion of the clinical trials,
23 I was struck by a couple of examples. One was the
24 person who had somehow figured out how to drive his
25 conventional powered chair down the stairs.

1 MS. MINKEL: It was a manual chair.

2 DR. MYKLEBUST: Manual?

3 MS. MINKEL: A manual chair, yes.

4 DR. MYKLEBUST: Okay. That's a little
5 different, I guess. But also, the person who, when
6 confronted with the threshold, refused to go over
7 it because they perceived that it wasn't safe.

8 I think that I am left, at least, with the
9 conclusion that the device itself is safe, and
10 there may be issues around the user, but at a
11 certain point, if you do as well as you can in
12 training and helping them understand what the risks
13 are, there is a point beyond which I'm not sure
14 that you can get.

15 DR. YASZEMSKI: Thanks.

16 Dr. Larntz?

17 DR. LARNTZ: I believe the device is safe,
18 certainly safe for the population that was done in
19 the pivotal trial. There is clear indication that
20 even in that group, it got tried out a bit, and
21 basically, nothing bad happened, and that was very
22 nice.

23 I do worry when you go outside--and I
24 mentioned this in my comments--that group of
25 patients--your youngest was 27, by the way, in the

1 pivotal trial, and I think your oldest was 67,
2 something like that, 60-something--anyway, when you
3 go outside those bounds, I wonder what my
4 22-year-old would do--yes, well, you know. And I'm
5 not sure on the other end if you had a problem of
6 speed or not.

7 But at any rate, for the population that
8 you studied, I think it is certainly safe, and I'm
9 sure it is safe outside an envelope of that as
10 well.

11 DR. YASZEMSKI: Thanks, Dr. Larntz.

12 Dr. Friedman?

13 DR. FRIEDMAN: I think the sponsor has
14 done an excellent job of demonstrating safety.
15 Again it comes down to operator error and things
16 like that, but those are issues we can't control.
17 We have already discussed the fact that there is
18 adequate training for the clinician and proper
19 training for the user, and I think the device
20 itself, there is reasonable assurance that it is
21 safe.

22 DR. YASZEMSKI: Thank you, Dr. Friedman.

23 Dr. Kirkpatrick?

24 DR. KIRKPATRICK: Ditto.

25 DR. YASZEMSKI: Thank you, Dr.

1 Kirkpatrick.

2 Dr. Finnegan?

3 DR. FINNEGAN: I have two small points.

4 One is on your computerized alert. The cluster
5 motor got hot 89 times, and this was in people who
6 weren't doing a lot of the Balance and Stairs. What
7 is going to happen when you give it to the
8 22-year-old who is going to do a lot of Balance and
9 Stairs?

10 MR. O'DONNELL: Okay. It did happen 89
11 times; 88 of those were during training, with the
12 extensive use of the device. There was one in the
13 real world.

14 DR. FINNEGAN: And what causes it to get
15 hot, and are you going to do something about it, or
16 wait and see if this is important?

17 MS. MINDEL: Actually, what happens is it
18 alerts the user that it is hot--so, stop what you
19 are doing, let it cool down, and you can continue
20 on your way. It's a little like the indicator
21 light in your car.

22 DR. FINNEGAN: All right. And then, over
23 the next 5 years, the number of young users who are
24 also incredibly software- and hardware-smart is
25 going to increase. Is this stuff locked down so

1 they can't fiddle with it, because if they can,
2 they will, and even if they can't, they will.

3 MS. MINKEL: At the moment, I feel pretty
4 confident that it's locked down in the sense that
5 the external computer connection is customized, so
6 you aren't just putting it into a USB port. And
7 the program at the other end is very customized.
8 So it would be a pretty savvy person--

9 DR. FINNEGAN: In 5 years, someone will do
10 it--I guarantee you.

11 DR. YASZEMSKI: Thank you.

12 We have had an extensive discussion on
13 safety, FDA. Dr. Witten, have we adequately
14 addressed the questions posed?

15 MS. WITTEN: Yes, thank you.

16 DR. YASZEMSKI: Thank you very much.

17 We're going to move on to Question Number
18 5 now.

19 While Mr. DeLuca is putting that up, we're
20 going to turn around the other way, and I'm going
21 to ask Dr. Finnegan to start this time with
22 Question 5, and we'll go in that direction.

23 Mr. DeLuca?

24 MR. DeLUCA: Thank you.

25 Question 5 is with regard to device

1 effectiveness.

2 "The sponsor conducted a clinical trial
3 that compared 2 weeks of iBOT usage to 2 weeks of
4 subjects' own mobility devices usage. The
5 following data were included in support of
6 effectiveness of the iBOT: Primary and secondary
7 outcome measures. These included community driving
8 scores which were primary, and subject-specific
9 function scale, which was secondary. In addition,
10 there were additional effectiveness data, which
11 included data logger distribution--for example,
12 computerized usage data as well as computerized
13 alert and failure action counts; device
14 failures--for example, those requiring component or
15 device replacements; daily activity logs, including
16 accessibility problems, mechanical or operational
17 difficulties, and subjective evaluation of home and
18 community maneuvering."

19 "The primary and secondary outcome
20 measures identified in item (a) yielded
21 statistically significant results in favor of the
22 iBOT. In light of the results of the primary and
23 secondary outcome measures and the additional data
24 collected, as noted in item (b) above, has
25 reasonable assurance of device effectiveness been

1 demonstrated?"

2 DR. YASZEMSKI: Thanks, Mr. DeLuca.

3 Dr. Finnegan?

4 DR. FINNEGAN: To quote Dr. Larntz, in
5 this patient population, I do believe that the
6 device effectiveness has been demonstrated. I
7 think that, to use the diagram we were presented
8 with, this can be translatable for intermediate
9 environment and probably community environment.

10 I do agree with most of the members of the
11 panel who have suggested that this needs to be
12 customized when you get to more complex
13 environments for the individual patients, and I
14 would ask the sponsors if they would consider
15 somehow bringing that into their assessment and
16 follow-up.

17 My other question has to do with the data
18 logger distributions, which I think actually did
19 give you useful information. And as we are
20 comparing this to an automobile, and you get to
21 bring your automobile in at 6 months and 12 months,
22 was there any consideration to doing that with
23 these and then assessing what the data logger
24 distribution information is?

25 DR. YASZEMSKI: Thanks.

1 Sponsors, maintenance schedule. Is there
2 a proposed maintenance schedule? Do you have to
3 get it back to the shop to get looked at every now
4 and then?

5 MS. MINKEL: Yes, and one of the uses of
6 that external communication port is we can do that
7 remotely using the telephone line to look at usage
8 and also alert folks as to when the serviceman is
9 going to come out and visit you.

10 DR. YASZEMSKI: How many hours, may I ask,
11 on the oldest one, and has it needed a routine
12 tuneup yet?

13 MS. MINKEL: The oldest one is hard to
14 define--

15 DR. YASZEMSKI: The one with the most
16 hours on it.

17 MR. O'DONNELL: The clinical units are not
18 out in the field. Each subject used the device for
19 2 weeks and then returned it. So there has
20 certainly been mileage accumulated on these
21 experimental units over time with testing and so
22 on.

23 Did we have an estimate of total--probably
24 about 20,000 hours of use over about 50 machines,
25 whatever that quick math works out to be.

1 DR. YASZEMSKI: And when you talk to the
2 users--I'm paraphrasing, if you'll permit me, Dr.
3 Finnegan, a question--do you have a recommendation
4 that they tune up every 6 months, every year?

5 MS. MINKEL: Yes.

6 MR. O'DONNELL: Yes, there is a
7 maintenance schedule.

8 DR. YASZEMSKI: There is a maintenance
9 schedule. Okay, great. Thanks.

10 Sorry, Dr. Finnegan. Anything else?

11 DR. FINNEGAN: No.

12 DR. YASZEMSKI: Dr. Kirkpatrick?

13 DR. KIRKPATRICK: I do have a few comments
14 with regard to effectiveness. To make it truly
15 relevant to my patient population in Alabama, many
16 of whom have fallen out of deer stands, I'm
17 wondering if you will offer this with mud tires and
18 camouflage paint.

19 [Laughter.]

20 Actually, that's just to get everybody
21 smiling because it has been a long day.

22 Now, I do have some true questions about
23 this. First of all, to really help me understand
24 effectiveness, I need to clearly understand if the
25 patients who were in the trial with the device had

1 their other wheelchair of choice with them at the
2 same time, or did you keep their wheelchair while
3 you gave them the iBOT?

4 MR. O'DONNELL: No, we did not keep it.

5 DR. KIRKPATRICK: Do you have any data on
6 how often people used their conventional device as
7 opposed to the iBOT during the 2-week trial?

8 MR. O'DONNELL: Not during the time that
9 they had the iBOT. We just have data on the iBOT
10 usage.

11 DR. KIRKPATRICK: So we don't know if, in
12 many instances, they may have chosen to use their
13 own wheelchair in preference to the iBOT during the
14 trial.

15 MS. MINKEL: We have the daily download.
16 So if a person chose not to use the iBOT, we would
17 have picked that up on the next day because the
18 data logger was downloaded on a daily basis.

19 DR. KIRKPATRICK: But the data logger
20 doesn't tell you whether they used the bathroom
21 using their old chair or using the iBOT.

22 MS. MINKEL: No.

23 DR. KIRKPATRICK: So I see that as a
24 potential void in really determining effectiveness;
25 and that answers the question of are there any

1 crossovers. Okay.

2 The second question I would ask--unless he
3 has a further response--was that a further response
4 to that question?

5 MS. MINKEL: Yes. In our daily download,
6 in addition to the device downloading, we did have
7 verbal communication on a daily basis between study
8 staff and the subjects, and we asked things like,
9 "Were there places that you couldn't go?" It was
10 based on a person's verbal report of their day.

11 DR. KIRKPATRICK: Did your daily
12 questioning ask, "Did you ever choose to use your
13 other wheelchair in preference to the iBOT?"?

14 MS. MINKEL: We didn't ask that specific
15 question.

16 DR. KIRKPATRICK: Thank you.
17 Have you polled the people who have been
18 in the study and asked them if they want to have
19 one?

20 MR. O'DONNELL: Often, they indicated that
21 they didn't want to return it. Did we have a
22 formal question where we asked each and every
23 one--no, we did not.

24 DR. KIRKPATRICK: So you don't know how
25 many truly would like to have one at this point?

1 MR. O'DONNELL: Not through an organized
2 data collection, but perhaps through anecdotally
3 indicating it.

4 DR. KIRKPATRICK: Do you have any record
5 of how many have called the company asking, "When
6 is it going to be approved?"?

7 MR. O'DONNELL: There have been many
8 people who have shown interest in this device over
9 the many years of its development.

10 DR. KIRKPATRICK: Right, but you can't say
11 how many out of the ones that have actually used it
12 still want it.

13 MR. O'DONNELL: It would be guesswork.

14 DR. KIRKPATRICK: Okay, thanks.

15 And the third thing is we have heard about
16 multiple parts and replacements that have had to
17 occur during the short study time. We have talked
18 about durability and that sort of thing. You have
19 mentioned that you will have a service schedule.
20 What is your target durability lifespan?

21 Obviously, if your service schedule is
22 every 6 months, this 2-week trial is well outside
23 that realm because you had to replace something on
24 almost each one, it looked like.

25 So where are we with durability once you

1 get to market? Do you have any concept of where
2 you--obviously, you have refined some designs, and
3 some of the durability of components has improved,
4 I would imagine, even since the trial has been
5 done. What is your current--the engineers have
6 been hacking around with it still, I'm sure--what
7 is--

8 MR. O'DONNELL: Approximately 5 years.

9 DR. KIRKPATRICK: --what is your current
10 feeling of how long the device itself will last,
11 and how long between minor breakdowns are you
12 experiencing at this point?

13 MR. O'DONNELL: For how long the device
14 would last with the maintenance schedule, we are
15 targeting 5 years for that.

16 The second part of your question was--

17 DR. KIRKPATRICK: If you are targeting 5
18 years, and you have as many parts replaced as you
19 do now, you're talking about replacing the whole
20 thing within that 5 years. So how have you
21 improved the durability of the individual parts
22 now, or have you, and do you have any measure of
23 that?

24 DR. KIRKPATRICK: I'll defer to one of the
25 engineers.

1 MR. AMBROGI: Mike Ambrogi from DEKA
2 Research.

3 With respect to the 5-year life, the
4 5-year life is an ultimate service life of the
5 device which has been determined both analytically
6 with some empirical results.

7 We did a number of sort of lifetime test
8 studies which included multiple transitions. For
9 instance, one activity of the device that stresses
10 most of the actuators is a transition from 4-Wheel
11 to Balance, raise the seat and back down. We did
12 that 20,000 times and kept a log of what type of
13 service events had to happen during that period of
14 time.

15 So we have done a number of long-term
16 durability tests including driving around this
17 proving grounds that I mentioned. As a result, the
18 clinical trial--you are right--since the clinical
19 trial, we have made some incremental improvements
20 to those types of things that have failed in the
21 trial.

22 Right now, we don't have a specific
23 estimate for what we think the targeted number of
24 unscheduled service events is going to be. That's
25 a hard thing to determine a priori before we get

1 real field data.

2 DR. KIRKPATRICK: Thank you.

3 DR. YASZEMSKI: Thank you.

4 Dr. Friedman?

5 DR. FRIEDMAN: I have one question on the
6 software updates. Can they be done--does it
7 download over the modem, or is it something that
8 has to be brought in?

9 MR. AMBROGI: At this time, we are not
10 capable of doing a--the process for doing a
11 software upgrade over the modem is not a validated
12 procedure, so any software upgrade would have to be
13 done locally.

14 DR. FRIEDMAN: Okay. I am pretty
15 satisfied that effectiveness has been demonstrated.

16 Thank you.

17 DR. YASZEMSKI: Thank you, Dr. Friedman.

18 Dr. Larntz?

19 DR. LARNTZ: The device is clearly
20 effective; there is no question about that. It
21 does things that the other devices, alternative
22 devices, cannot do. We could see that.

23 I am disappointed--and that's just me--I
24 disappoint easily--that you didn't allow your study
25 participants--and maybe you couldn't have--to

1 continue using the devices so we could have seen
2 some long-term data.

3 Thank you.

4 DR. YASZEMSKI: Thank you, Dr. Larntz.

5 Dr. Myklebust?

6 DR. MYKLEBUST: I don't have anything
7 else.

8 DR. YASZEMSKI: Thank you.

9 Dr. Goldman?

10 DR. GOLDMAN: To me, the effectiveness is
11 really terrific. But I would make sure that the
12 outcomes which were demonstrated for community
13 driving scores--it is really community ambulation.
14 The in-house scores appear to be, in terms of the
15 subjects polled, it seemed from what I recall that
16 they would prefer their own devices at home, where
17 you have a lot more tight ratios and harder steps
18 and things like that. But for community driving
19 and community ambulation, it is remarkable.

20 DR. YASZEMSKI: Thanks, Dr. Goldman.

21 Ms. Rue?

22 MS. RUE: I don't have anything else.

23 DR. YASZEMSKI: Thank you.

24 Ms. Maher?

25 MS. MAHER: I don't have anything else.

1 DR. YASZEMSKI: Thanks, Ms. Maher.

2 Dr. Stiens?

3 DR. STIENS: The answer to Question 5 was
4 really the easiest for me, because it was clear
5 that in the various realms that are outlined here,
6 the device is effective.

7 I wanted to just reiterate a bit, though,
8 on that. In the intermediate environment, there
9 has been a hint that customizability of that
10 interface with the user may be limited to some
11 extent in this product as compared to other
12 products that may exist on the market.

13 In the major patient population that your
14 trial studies have been done in, in SEI, insensate
15 skin puts us most at risk and leads to bed rest and
16 so on. So that is something that needs to be
17 considered.

18 The nooks and crannies and so on that were
19 identified with respect to pinching and so on, I
20 went over in the studies, and none of them was
21 alarming to me, but I wanted to just comment that
22 it would be helpful to continue to follow those as
23 a way of refining such a device.

24 Then, moving on to the intermediate
25 environment, the device itself does solve a lot of

1 problems in those spaces, namely, reaching and so
2 on. And then, in the community environment,
3 indeed, I was convinced that limitations in
4 participation were--barriers were knocked down by
5 the device, and that was encouraging to me.

6 I was wondering if you could just comment
7 on a few of the major device failures during the
8 testing that required replacement of parts, and if
9 you have modified or refined your prototypes or the
10 devices that you propose to put on the market as a
11 result, because I indeed was struck by, at the
12 device level, the reliability of the device. It
13 just didn't seem to be what other wheelchairs might
14 be.

15 DR. YASZEMSKI: Sponsor?

16 MR. AMBROGI: Yes. Let me address the
17 failures that we had, and let me find the list
18 first.

19 A number of the failures were related to,
20 for instance, the model cables and the modem card.
21 That accounted for six or seven of these failures.
22 We didn't invent or design the modem cards as
23 standard connection. We found that the connection
24 to the modem card was perhaps not as robust as we
25 would like, and we have since that time implemented

1 a more robust connection.

2 We had two failures related to the armrest
3 and structural failure of the armrest. The
4 armrests that were used for the clinical trial were
5 particularly a soft-tooled armrest; and now we have
6 production material which is significantly
7 stronger.

8 So in a number of cases, we have made
9 improvements since the trial and proven that those
10 particular parts are as good or better in most
11 cases than the parts that they replaced.

12 DR. STIENS: Okay. Hearing that, I want
13 to just reiterate that the connection between the
14 cortex and the hand is kind of a critical interface
15 for orchestration of the device. And as far as the
16 parts that failed and so on, were there any parts
17 that supported the device or ran the device that
18 failed that could in any way reflect on safety
19 risks?

20 MR. AMBROGI: No. None of the failures
21 represented a safety risk.

22 DR. STIENS: Okay. Thank you.

23 DR. YASZEMSKI: Thanks, Dr. Stiens.

24 Mr. Herman?

25 MR. HERMAN: Just a couple of concerns

1 about the effectiveness of the device for everyday
2 usage, as an everyday, all-around power chair.

3 One of the things that makes my chair so
4 effective for me is that I can charge it
5 independently because the charging port is in the
6 joystick box. On the iBOT, the charging port is on
7 the base, I believe, down on the right-hand side.
8 Does it have to be there? Is it because the UCP
9 has so much in it already? Is there any chance
10 that that could somehow be changed?

11 MR. AMBROGI: The charger port is located
12 on the power base, and a lot of that was an attempt
13 to contain the voltages associated with charging
14 the batteries to the power base and not bring them
15 up to the user control panel.

16 It is certainly possible you could do
17 something different in the future, but there are no
18 plans to do that in the immediate future.

19 MR. HERMAN: Okay. Another thing that
20 makes my chair effective for me is that I use solid
21 inserts in the tires rather than air bladders, so I
22 don't have to worry about them. Is that an option
23 with the iBOT?

24 MR. AMBROGI: Right now, that is not.

25 MR. HERMAN: Okay. Many of us drive from

1 our wheelchairs, and we use a device called an
2 Easy-Lock, which is a two-part device. One part
3 attaches to the floor of the van; another part is a
4 bracket which attaches to the bottom of the
5 wheelchair. Do you foresee that being adaptable
6 for the iBOT?

7 MR. AMBROGI: We are familiar with the
8 Easy-Lock, but at this time, it is not adaptable to
9 the device we plan to market, so you will not be
10 able to drive from the iBOT with the intended
11 device.

12 MR. HERMAN: Okay. And the last thing is
13 in the 4-Wheel function, the literature notes that
14 the device can climb a curb up to 4 inches. In the
15 Stair-Climbing function, it can climb a riser of 5
16 to 8 inches. Can you use the Stair function to go
17 up a curb?

18 DR. YASZEMSKI: Ms. Minkel?

19 MS. MINKEL: Again, stair-climbing relies
20 on the user's input in changing the center of
21 gravity. So the short answer to your question is
22 if the curb you want to go up to has something that
23 you can hold onto, you could conceivably use
24 Stair-Climbing to climb that curb--or your
25 assistant.

1 MR. HERMAN: Thank you.

2 DR. YASZEMSKI: Thanks, Mr. Herman.

3 Dr. McQuade?

4 DR. McQUADE: While I think the 2-week
5 clinical trial has a couple of flaws in
6 it--specifically, I think there is an order effect
7 in testing in that all the testing was done in
8 their own device first and then in the iBOT, so
9 there was a learning effect that could take place--

10 MS. MINKEL: No, that's not true.

11 DR. McQUADE: Was that not the case?

12 MS. MINKEL: No.

13 DR. McQUADE: I thought that was.

14 MR. O'DONNELL: It was half-and-half.

15 DR. McQUADE: Okay, I stand corrected--and
16 I would have liked to have seen some other outcome
17 measures--I think the face validity of the device
18 and overall efficacy has been well-established.

19 DR. YASZEMSKI: Thanks, Mr. McQuade.

20 Ms. Buzaid?

21 MS. BUZAID: I think the effectiveness of
22 the device has been established given that the
23 training takes place.

24 DR. YASZEMSKI: Thank you.

25 Dr. Hannaford?

1 DR. HANNAFORD: From my point of view, it
2 is clearly very effective.

3 DR. YASZEMSKI: Thank you.

4 Dr. Abrams?

5 DR. ABRAMS: I think the device does what
6 it says it will do.

7 I am a little disappointed that people
8 didn't use it more for stair-climbing. I'm not
9 quite sure I understand that--whether they all
10 lived in ranch houses--why they wouldn't use that
11 feature. It seems like such an attractive feature.
12 But I guess we don't know exactly why at this
13 point.

14 DR. YASZEMSKI: Thanks, Dr. Abrams.

15 Dr. Naidu?

16 DR. NAIDU: Based on the study presented,
17 the device is effective.

18 DR. YASZEMSKI: Thanks very much.

19 We'll ask FDA--Dr. Witten, have we
20 adequately discussed this issue and addressed your
21 questions?

22 MS. WITTEN: Yes. Thank you.

23 DR. YASZEMSKI: Thanks very much. Let's
24 move on to Question Number 6, and we're going to
25 change order again as Mr. DeLuca puts it up and

1 reads it, and Dr. Naidu is going to start us off.

2 Mr. DeLuca?

3 MR. DeLUCA: The final question has to do
4 with post-market data collection.

5 "This PMA study was conducted with 18
6 subjects, most of whom had a spinal cord injury,
7 and allowed for 2 weeks of iBOT usage. If you
8 recommend that this device is approvable, are there
9 any data that should be collected during the
10 post-market period? For instance, post-market data
11 could be collected for the following purposes:
12 Clarifying labeling, for example, to better define
13 the user populations best suited for this device,
14 to better define long-term usage trends or
15 profiles, and to better define adverse event rates;
16 in addition, it could be used to refine assessment
17 and training procedures for clinicians and iBOT
18 users."

19 DR. YASZEMSKI: Thanks very much, Mr.
20 DeLuca.

21 MS. WITTEN: Let me just say, Dr.
22 Yaszemski, you could decide if you wanted to
23 consider this during the vote, or discuss it right
24 now.

25 DR. YASZEMSKI: How about if we do

1 this--is there anybody on the panel who wishes to
2 make a comment on this prior to our discussing it
3 as part of the voting process? If so, identify
4 yourself and offer a comment.

5 Dr. Kirkpatrick?

6 DR. KIRKPATRICK: My concern is that if I
7 don't discuss it now, we can't introduce it with
8 the vote, or--

9 DR. YASZEMSKI: No; you could. You could
10 discuss it as a condition to the vote. But if you
11 have a comment to make now, please make it.

12 DR. KIRKPATRICK: Okay. My comment would
13 be on post-market surveillance. I think that the
14 term of the study was relatively short. People
15 were very enthusiastic about it, so some things may
16 not all be borne out in a 2-week trial.

17 There seem to be a number of opportunities
18 for additional data acquisition. One part of it is
19 does the data logger record falls or tips with the
20 device.

21 MR. O'DONNELL: Yes, it does. That's the
22 controller--

23 DR. KIRKPATRICK: So you would get that
24 feedback automatically every time you get it
25 serviced.

1 I would suggest--and this may be something
2 that we want to put in the vote; I don't know if it
3 has to or not--but I would suggest that any device
4 servicing be accompanied by a questionnaire to the
5 patient indicating whether that device failure or
6 device service need was associated with any injury
7 no matter how small, whether it be a bruise, a
8 scratch, a broken bone, anything.

9 And you have already addressed the
10 maintenance schedule with the telephone hook-up
11 that I was wondering about.

12 So if that could be made as a condition, I
13 would suggest that as part of the post-market
14 surveillance.

15 And then, as far as indications for the
16 use, I am not comfortable expanding it very far
17 beyond what has already been stated. I think that
18 if you try to expand it to some neuromuscular
19 conditions, you're going to have a lot of control
20 problems. You might be able to get it to
21 rheumatoids, but you may not, because they don't
22 have hand control very well, and they may have
23 balanced problems.

24 So I think as to the current thing, and I
25 would limit it to the people that they have

1 actually studied.

2 DR. YASZEMSKI: Thanks, Dr. Kirkpatrick.

3 Dr. Stiens?

4 DR. STIENS: I just have kind of a
5 spectrum of inquiry areas that might be considered,
6 kind of going from the user out. One is the
7 diagnostic group. Traditional medical science is
8 based on diagnosis, although your indication is
9 based on an impairment; it is based on mobility
10 problems, and actually, some might be so specific
11 as to say that indeed this is a disability or what
12 is now termed an "activity limitation"--in other
13 words, mobility problems. It is not an
14 organ-specific but a person-specific limitation
15 that you have asked for an indication on, although
16 medical tradition has required diagnosis. You have
17 a lot of spinal cord-injured people in there, which
18 is really unrepresentative of the constellation of
19 citizens in the United States with mobility
20 impairments. So there is going to be a push for
21 using this with impairments that exist outside of
22 the diagnosis that the testing that has been done
23 on.

24 So I view the prospective studies as an
25 ongoing clinical trial, in a sense.

1 Then, there is the effect on the person,
2 and weight gain has been discussed. What we are
3 trying to do is protect health. So for
4 effectiveness, I like to see a person have a free
5 life, but the way we put it in rehab medicine, it
6 is "life to years and years to life." So I like to
7 see years to life as well.

8 So I have another set of people who I have
9 ergometers for, so weight gain is an issue, and I
10 would like to know what happens with that.

11 Then, the power function, I am concerned
12 about the NICADs and the memory. Indeed, if people
13 constantly recharge them, there is a chance of a
14 shorter memory, so I am wondering about your power
15 source, prospectively.

16 And then, moving on to the environment, I
17 would like to know about any problems that people
18 would have in their intermediate environment and
19 anything that they recognize in the community
20 environment that represents a hazard or problem
21 with the device, because that could feed back into
22 our anticipation of these individuals in the
23 community environment, and that could affect
24 regulation in other ways.

25 And finally, report of any incidences in

1 the natural environment, like people being
2 stranded. That would be helpful. The other thing
3 I think about is communication devices as they
4 relate to this chair, and I wonder about requesting
5 that people have a cell phone or something in that
6 situation.

7 So I just want to leave that out for
8 debate for further discussion.

9 Thanks.

10 DR. YASZEMSKI: Thanks, Dr. Stiens.

11 Any other panel member?

12 Dr. Hannaford?

13 DR. HANNAFORD: Yes. Following up on my
14 early comments, I just want to reinforce that
15 vigilance on the safety of stair-climbing in
16 descending mode is really the one sort of remaining
17 concern that I think several of us have and I
18 certainly have.

19 I think the most appropriate thing is for
20 the FDA engineers to work with the sponsor on
21 exactly what data collection should be done to
22 implement that vigilance, and what attributes that
23 type of data collection should have include a very
24 short latency. That is, I wouldn't want to see
25 them go out in the field for a year before anyone

1 analyzes what is happening on the stairs.

2 There might be things in these logs that
3 could be caught before somebody unfortunately would
4 actually fall down the stairs, especially if that
5 data is collected--the trial worked out to
6 something like 72 stair-climbs, if my calculations
7 were correct, in real world use. So it would be
8 great to know what happens in the next 72
9 stair-climbs and maybe the next 144 stair-climbs,
10 but not waiting for a year or 6 months or whatever,
11 because that might be too long.

12 I think that's it.

13 DR. YASZEMSKI: Thank you.

14 Ms. Maher?

15 MS. MAHER: I just want to remind that
16 panel as we are thinking of post-market
17 surveillance that this company is regulated by the
18 Quality System Regulations, and as such, they have
19 to evaluate complaints, they have to file medical
20 device reports for adverse event report, and when
21 they are doing their servicing, which they will
22 have to be doing under their--they already stated
23 that they have a service period, and they will be
24 downloading the log--they will be evaluating all
25 the events they find at that point as well to

1 determine if they need to do corrective actions;
2 that all gets documented in their files, and if
3 there were an adverse event such that it needed to
4 be reported to the FDA.

5 So there is already a built-in mechanism
6 for information to come into the company which they
7 are required to act on to improve the product if
8 they have to and to report to the agency if there
9 are adverse events.

10 DR. HANNAFORD: Can I follow that up?

11 DR. YASZEMSKI: Yes, Dr. Hannaford.

12 DR. HANNAFORD: I'm just pointing out that
13 hopefully, we can catch something before there is
14 an adverse event.

15 DR. YASZEMSKI: Thank you.

16 Dr. Abrams?

17 DR. ABRAMS: A clarification. So you are
18 saying that Dr. Kirkpatrick's suggestion is
19 actually incorporated into the FDA policy already?

20 MS. MAHER: Well, into our regulations
21 that we have to comply with. When we are doing
22 repair or looking at products that have been
23 repaired, we have to evaluate what happened to
24 cause it to need repair and evaluate whether that--

25 DR. ABRAMS: And a questionnaire has to go

1 out in terms of--

2 MS. MAHER: No, not necessarily a
3 questionnaire. That's an added condition.

4 DR. ABRAMS: Okay.

5 DR. YASZEMSKI: Dr. Hannaford?

6 DR. HANNAFORD: Just one more point about
7 that. Based on the trial, the rate of repairs is
8 rather high, so the data would come in quickly.
9 But supposing these measures that we have just
10 heard about dramatically increase the reliability
11 of the iBOT, and now the users are going for months
12 at a time without a service call. Are you still
13 going to be reading the logs, or are we still going
14 to see what is happening in the logs?

15 MS. MAHER: Maybe the sponsor can discuss
16 what their service period will be.

17 DR. YASZEMSKI: Mr. O'Donnell?

18 MR. O'DONNELL: In accordance with the
19 maintenance schedule; so that, for example, at the
20 first 6-month period, if we haven't heard from you,
21 you will get a service wrench appear on your device
22 to have the device serviced. So that would be the
23 longest period of time after you get the
24 device--there would be some kind of interaction
25 with us at 6 months. Now, it is dependent upon you

1 to contact us.

2 DR. YASZEMSKI: Any other comments?

3 Dr. Goldman?

4 DR. GOLDMAN: In 10 seconds--I didn't have
5 a chance to enter this. I noticed that in the
6 high-tetraplegics, those were the cases of two out
7 of three falls. It may be that that is another
8 disorder-specific issue that needs to be looked at
9 after marketing.

10 DR. YASZEMSKI: Thank you.

11 Other comments?

12 [No response.]

13 DR. YASZEMSKI: Dr. Witten, have we
14 adequately discussed this question from the FDA's
15 perspective?

16 MS. WITTEN: Yes, thanks.

17 DR. YASZEMSKI: You're welcome.

18 Thank you. That concludes discussion of
19 the questions that the FDA has posed to the panel.
20 We are now going to proceed to another open public
21 hearing session.

22 I would ask at this time that all persons
23 who wish to address the panel come to the mike,
24 identify themselves, and do so.

25 Is there anyone who would like to address

1 the panel at this time?

2 [No response.]

3 DR. YASZEMSKI: Seeing no one, what we'll
4 do now is ask the sponsors, Independence
5 Technology, if they have any final comments.

6 Before the panel proceeds to vote, we are going to
7 ask you for your comments, and then we're going to
8 take a break and come back and vote.

9 Mr. O'Donnell?

10 MR. O'DONNELL: No, we do not.

11 DR. YASZEMSKI: Thank you very much.

12 We're going to break for 5 minutes, and
13 then we'll come back and go through the voting
14 process.

15 [Break.]

16 Vote

17 DR. YASZEMSKI: Thanks, everybody.

18 At this time, I'm going to ask Mr. Demian
19 to read the voting instructions for the panel, and
20 then I am going to call on Dr. Stiens for a motion.

21 MR. DEMIAN: Thank you, Dr. Yaszemski.

22 I will now provide you with the panel
23 recommendation options for the Pre-Market Approval
24 Applications.

25 The Medical Device Amendments to the

1 Federal Food, Drug, and Cosmetic Act require that
2 the Food and Drug Administration obtain a
3 recommendation from an outside expert advisory
4 panel on designated medical device Pre-Market
5 Approval Applications that are filed with the
6 Agency.

7 The PMA must stand on its own merits, and
8 their recommendations must be supported by safety
9 and effectiveness data in the application or by
10 applicable publicly-available information.

11 Safety is defined in the Act as
12 "reasonable assurance, based on valid scientific
13 evidence, that the probable benefits to health
14 under the conditions of use outweigh any probable
15 risks."

16 Effectiveness is defined as "reasonable
17 assurance that in a significant portion of the
18 population, the use of the device for its intended
19 uses and conditions of use, when labeled, will
20 provide clinically significant results."

21 Your recommendation options for the vote
22 are as follows:

23 1) Approval. There are no conditions
24 attached.

25 2) Approvable with conditions. You may

1 recommend that the PMA be found approvable subject
2 to specified conditions such as a resolution of
3 clearly-identified deficiencies which have been
4 cited by you, the panel, or FDA staff. All
5 conditions are discussed by the panel and listed by
6 the panel chair and then voted on one-by-one. For
7 example, you may specify what type of follow-up
8 information the panel or FDA should evaluate prior
9 to or after approval. Panel follow-up is usually
10 done through homework assignments by one or two
11 panel primary reviewers, or by other specified
12 members of this panel.

13 Formal discussion of the application at a
14 future panel meeting is not usually required.

15 If you recommend post-approval
16 requirements to be imposed as a condition of
17 approval, then your recommendations should address
18 the following points: The purpose of the
19 requirement; the number of subjects to be
20 evaluated; and the types of reports that should be
21 submitted.

22 3) Not approvable. Of the five reasons of
23 the Act specified for denial of approval, the
24 following three reasons are applicable to your
25 panel deliberations: The data do not provide

1 reasonable assurance that the device is safe under
2 the conditions prescribed, recommended, or
3 suggested in the proposed labeling; reasonable
4 assurance has not been given that the device is
5 effective under the conditions as prescribed,
6 recommended, or suggested in the labeling; and,
7 based on a fair evaluation of all material facts in
8 your discussions, you believe the proposed labeling
9 to be false and misleading.

10 If you recommend that the application is
11 not approvable for any of these stated reasons,
12 then we ask that you identify the measures that you
13 think are necessary for the application to be
14 placed in approvable form.

15 Traditionally, the consumer, industry, and
16 patient representatives do not vote, and Dr.
17 Yaszemski as chairman only votes in the case of a
18 tie.

19 Dr. Yaszemski?

20 DR. YASZEMSKI: Thank you, Mr. Demian.

21 Before beginning the voting process, I
22 would like to mention for both the panel's benefit
23 and for the record that the votes taken are votes
24 in favor of or against the motion made by the
25 panel. Votes are not for or against the product.

1 I would also like to mention the voting
2 sequence. I'm going to call on Dr. Stiens in a
3 moment to make a motion. After he makes his
4 motion, I will ask if there is a second. Then, if
5 any of the panel members feel that the motion
6 perhaps could be modified and wish to introduce a
7 condition, they may introduce it, we'll take a
8 second, and we'll vote individually on that
9 condition. We will continue that process until
10 everyone is comfortable that all conditions that
11 are concerns to them have been brought up and voted
12 upon.

13 We will then read the final motion, with
14 any conditions, and then vote on that motion as a
15 whole, and that will complete our voting process.

16 Dr. Stiens, do you have a motion?

17 DR. STIENS: I wanted to make a few
18 comments and then make a motion.

19 As you have heard in the public record,
20 there has been a lot of deliberation and
21 consideration about the voting process, and I have
22 made an effort to integrate a bit of that in my
23 motion, and I would like to make the motion now.

24 I would move that the device be approved
25 with conditions, and I would like to propose a

1 couple of conditions for that. One is that for
2 dispensing the device, a physician diagnosis and
3 prescription be required for dispensing the device;
4 and the other being that stair-climbing be
5 prospectively evaluated in training and field use
6 of the device as a way of ongoing assessment of
7 this feature of the device, reducing the potential
8 risk to the consumer that might come from a
9 malfunction that would come out of further
10 evaluation of that capability.

11 DR. YASZEMSKI: Is there a second to this
12 motion?

13 May I ask one thing--please repeat your
14 first condition.

15 DR. STIENS: My first condition is that
16 physician diagnosis and prescription be required
17 for dispensing the device.

18 DR. YASZEMSKI: Thank you.

19 Would anybody like to second this motion?

20 DR. FRIEDMAN: May I ask a question?

21 DR. YASZEMSKI: Go ahead.

22 DR. FRIEDMAN: Does that have to be a
23 condition? I thought that this was a device that
24 has to be dispensed only with a prescription by a
25 physician.

1 DR. YASZEMSKI: FDA, clarification. Does
2 physician prescription occur without its specific
3 statement as condition--will it occur anyway if we
4 don't make it a condition?

5 MS. WITTEN: I think the sponsor is
6 proposing to market the product as prescription
7 use, so in that case, it would need a prescription.

8 Now, who would do that prescribing, we
9 would generally leave to the States that regulate
10 medical practice to see who they are licensing to
11 do that prescription.

12 DR. YASZEMSKI: So, Dr. Friedman, that
13 could be anybody licensed by the State, and if we
14 would specifically want to suggest the requirement
15 that a physician make that prescription, then, I
16 think we would have to include it as a condition.

17 Is there a second for the motion?

18 DR. GOLDMAN: I have a question.

19 DR. YASZEMSKI: Go ahead.

20 DR. GOLDMAN: How would it be possible to
21 introduce the idea of trying to limit the approval
22 to the approximate dataset that was examined in the
23 trial--in other words, from 18 to wherever and--

24 DR. YASZEMSKI: I would ask you to
25 introduce that as a condition if we get a second

1 for the motion. We are not going to vote as soon
2 as we get a second.

3 DR. FRIEDMAN: I'll second the motion.

4 DR. YASZEMSKI: There is a second for the
5 motion.

6 Now I'll ask, Dr. Goldman, would anybody
7 like to introduce a motion to introduce a
8 condition.

9 DR. GOLDMAN: Yes.

10 DR. YASZEMSKI: Dr. Goldman.

11 DR. GOLDMAN: I'd like to introduce a
12 motion that the approval of the device be limited
13 to the approximate dataset that was examined during
14 the trial.

15 DR. YASZEMSKI: And that is--specified by
16 age?

17 DR. GOLDMAN: Specified by age, 18 and
18 older; the disorder content involved in the
19 trial--and the disorders that were included in the
20 trial, understanding that that is very limited.

21 I feel more strongly about the age than
22 the disorder type.

23 DR. YASZEMSKI: Okay. So there is a
24 motion now to limit the prescription to age greater
25 than or equal to 18, and disorder type that was

1 included in the trial.

2 Is that an accurate statement of your
3 motion?

4 DR. GOLDMAN: I would like to restate that
5 as age.

6 DR. YASZEMSKI: As age.

7 There is a motion to include a condition
8 of age greater than or equal to 18.

9 Is there a second for that motion?

10 [Pause.]

11 DR. GOLDMAN: What about discussion?

12 DR. YASZEMSKI: I think if we don't get a
13 second, we aren't even going to discuss it. I
14 think that's the order. It will fail.

15 If somebody feels that they want to
16 discuss it, they should probably second it first
17 and then discuss it, and then we can vote on it.
18 If there is not a second, it won't carry toward
19 discussion.

20 Wold anybody like to limit the age to 18
21 or greater?

22 [No response.]

23 DR. YASZEMSKI: I see no second.

24 Are there other conditions that someone
25 would like to raise?

1 Dr. Hannaford?

2 DR. HANNAFORD: I move that data logging
3 on stair-climbing should be enhanced to measure the
4 number of stairs climbed in solo versus assisted
5 modes, what climbing rates were achieved, and
6 whether controller alerts were in solo or assisted
7 modes; and that the sponsor should work with the
8 FDA engineers to define a reporting schedule for
9 this data that is appropriate to the level of
10 vigilance required for these potential hazards.

11 DR. YASZEMSKI: So this is a motion to
12 have data logging in both solo and assisted
13 Stair-Climbing modes, and a schedule as agreed
14 between FDA and sponsor for the frequency of
15 reporting of that data.

16 Is that an accurate statement?

17 DR. HANNAFORD: Yes.

18 DR. YASZEMSKI: Would someone like to
19 second that?

20 DR. ABRAMS: I'd like to clarify. Is that
21 post-marketing or prior to approval in your motion?

22 DR. HANNAFORD: Post-marketing.

23 DR. YASZEMSKI: Post-marketing.

24 Is there a second for that?

25 DR. ABRAMS: Second.

1 DR. YASZEMSKI: Is there any discussion on
2 that?

3 Mr. Herman?

4 MR. HERMAN: I would just ask Sally if the
5 post-marketing approval reporting regime that you
6 described would already take that into account so
7 as to make any other unnecessary or superfluous.

8 MS. MAHER: Well, the first question I
9 would have--and I don't think any of us here can
10 answer that question--is whether this machine and
11 the control system could even calculate those
12 requirements that you just suggested as to assist
13 versus not assist on the stairs and the rate. I
14 don't know whether it can or not, so I think that
15 that is a discussion that would be better left to
16 the FDA to just deal with the sponsor going forward
17 and putting it as a strict restriction in that
18 manner, or ask the sponsor if the machine would be
19 capable of even doing something like that.

20 The second, back to your question--when
21 the sponsor is downloading the information, all the
22 information that is in the machine at the time will
23 be downloaded--that is my understanding, anyway,
24 from reading all of their documents--would be
25 downloaded to their system, and they would be able

1 to evaluate all the information that is there and
2 determine what has been happening with the machine
3 and how much stair-climbing it has done.

4 DR. YASZEMSKI: Any further discussion on
5 whether to include this as a condition of approval?

6 Dr. Kirkpatrick?

7 DR. KIRKPATRICK: I'm confused. Is this
8 just a clarification of one way to do the
9 prospective post-market evaluation on
10 stair-climbing that was already part of our
11 original motion?

12 DR. YASZEMSKI: That's up for discussion.

13 Dr. Hannaford, is this in addition to the
14 prospective stair-climbing evaluation that is
15 already being included as a condition?

16 DR. HANNAFORD: I'm not sure I understood
17 exactly what was proposed in the first prospective
18 stair-climbing study, but my requests for
19 additional logging information probably aren't,
20 because they are not data that are logged right
21 now, although--

22 DR. YASZEMSKI: My understanding, if I
23 may, of the initial condition--and I'll ask Dr.
24 Stiens if I say this correctly--is that a condition
25 of approval would be that the assessment of a

1 prospective patient's ability to use Stair-Climbing
2 be evaluated in their home environment, in the
3 field.

4 Is that accurate, Dr. Stiens?

5 DR. STIENS: What I said was that there
6 would be assessment during the training process of
7 people's stair-climbing capabilities, and a formal
8 recording and reporting of any untoward events. In
9 addition, there would be some assessment in the
10 field of patients doing that activity and some
11 reporting of any untoward events. I did not
12 specify a specific number of trials or time for
13 that, and I would be very interested in our
14 defining that in some way, maybe in general terms,
15 because I feel that this is to some extent not
16 fully evaluated in the clinical trials that we had
17 to review.

18 DR. YASZEMSKI: Thank you.

19 So, Dr. Kirkpatrick, I'll indicate that to
20 mean that Dr. Hannaford's condition is in addition
21 to.

22 DR. KIRKPATRICK: Yes, it's a separate
23 issue.

24 DR. YASZEMSKI: A separate issue.

25 DR. HANNAFORD: It is in addition, because

1 I am trying to complement Dr. Stiens' idea on the
2 engineering side, to make sure the engineering data
3 is also collected.

4 DR. YASZEMSKI: Thank you.

5 Dr. Finnegan?

6 DR. FINNEGAN: Point of clarification from
7 Dr. Hannaford.

8 Do you want this done on a more frequent
9 basis than the regular maintenance schedule, which
10 sounds like it will have fairly significant
11 intervals?

12 DR. HANNAFORD: Yes.

13 DR. YASZEMSKI: What interval would you
14 recommend, Dr. Hannaford?

15 DR. HANNAFORD: I would like to see the
16 interval--first, I think that the FDA engineers and
17 staff probably have better expertise than I do on
18 the specific interval for this kind of reporting.

19 On the other hand, because the device can
20 communicate over the telephone, it shouldn't be
21 extremely burdensome for collecting data more
22 frequently than service intervals. This may be
23 moot, because if the repair history is similar to
24 the trial, repairs will be quite frequent; but
25 hopefully, repairs will not be quite frequent, and

1 I am concerned that 6 months is too long a time.

2 DR. YASZEMSKI: Dr. Abrams?

3 DR. ABRAMS: Once again, a point of
4 clarification for Dr. Stiens. Are you proposing
5 additional studies prior to approval in your
6 motion, and if so, what are the parameters of the
7 studies that you are proposing, or are you going to
8 leave that to--

9 DR. STIENS: In my motion, I am proposing
10 that with approval, and subjects coming for
11 evaluation in preparation to use the device, that a
12 specific protocol for data acquisition derive data
13 from these subjects during their training period
14 and in the field. And then, I am also hearing that
15 we would derive some data or download some data
16 from their chairs and so on about their
17 stair-climbing after they are using it.

18 DR. ABRAMS: So this would be a
19 post-marketing approval.

20 DR. STIENS: That's right, and that's what
21 I am proposing, but I would invite any refinements
22 to that dataset that we would like to have, because
23 I feel from what I have read that the clinical
24 studies thus far have not provided enough data on
25 the Stair-Climbing aspect of this device to know

1 that indeed, in larger populations over longer
2 periods of time, this condition is as safe as it
3 could be, training and device included.

4 DR. YASZEMSKI: And if I may summarize, I
5 think these two are related enough that perhaps
6 yours, Dr. Hannaford, could be considered an
7 addition to the one already proposed by Dr. Stiens.

8 I'll ask, then, if in summary, yours is
9 that after the patient has their device, we would
10 like for the Stair-Climbing mode an interval
11 reporting of their use of the Stair-Climbing mode,
12 the data that the device itself logs during
13 Stair-Climbing being reported to FDA for review by
14 FDA's engineers on a more frequent basis than the
15 every-six-month checks. And you are comfortable
16 letting that interval, which will be shorter than 6
17 months, be worked out between FDA and the sponsors.
18 Is that accurate?

19 DR. HANNAFORD: That's accurate. I guess
20 I would ask for one other piece of information in
21 the same mode that you just suggested, which is if
22 there are any incidences of software problems which
23 cause all three of these processors to crash
24 simultaneously, even if they have no adverse effect
25 on the patient such as in Standard mode or

1 something like that, then that data should be part
2 of that collection.

3 DR. YASZEMSKI: So data-logging at more
4 frequent than maintenance intervals.

5 DR. HANNAFORD: That's right.

6 DR. YASZEMSKI: Is there any further
7 discussion on this motion--and if there is not, I
8 will restate it, and we'll vote on it.

9 Ms. Maher?

10 MS. MAHER: I would just like to make one
11 sort of general comment, that as we are adding on
12 conditions of approval, we need to take into
13 account that the FDA and the sponsor clearly know
14 best how the machine operates and what data it is
15 capable of, so I wouldn't want there to be a strict
16 restriction on exactly what they are looking for.

17 The other thing I would caution is that we
18 try not to add too much cost and too much time to
19 the setting up and the training of the users more
20 than is actually necessary for the users to have,
21 because--and the PTs and the OTs on the panel are
22 more able to talk to this than I am--but that adds
23 to the cost and their time that they can take to
24 get patients into these wheelchairs and may or may
25 not influence their decision to even offer these

1 wheelchairs, or these mobility devices, to
2 patients.

3 So I think we need to be very careful what
4 we are requesting and what we are looking at as we
5 are moving forward.

6 DR. YASZEMSKI: Thanks, Ms. Maher.

7 Dr. Myklebust?

8 DR. MYKLEBUST: In the same regard, I'm
9 not clear as to whether we are saying that this
10 would be a permanent part of surveillance of this
11 device, or are we saying that we are trying to
12 learn something, and there is some endpoint to
13 this.

14 DR. YASZEMSKI: I think, if I paraphrase
15 Dr. Hannaford correctly, he is specifically leaving
16 that interval up to the sponsor and FDA to work
17 out. We are just going to make a recommendation
18 that it would be good for FDA to be seeing this
19 data, and at what interval and for how long, we
20 would leave up to them.

21 Is that accurate, Dr. Hannaford?

22 DR. HANNAFORD: Yes.

23 DR. YASZEMSKI: Dr. Stiens?

24 DR. STIENS: I just wanted to respond to
25 some of the ideas that have been proposed.

1 One way of correcting the data that might
2 come about would be for the FDA to receive copies
3 of the therapists' notes. Both the objective and
4 subjective information in those notes I think would
5 be helpful to the FDA as they monitor this device's
6 use in the field. And the acquisition of the data
7 might be at one-month intervals, for instance, as
8 far as its delivery to the FDA. I would leave
9 that, though, to the FDA to decide. But our
10 purpose, I think, in this condition is to get
11 immediate--or as immediate as possible--feedback
12 about any undetected problems that may exist in
13 this device or consumer's use of it.

14 DR. YASZEMSKI: Thank you.

15 Would anyone care to discuss it further?
16 Otherwise, I'm going to summarize and call for a
17 vote.

18 This is a motion to add a condition that
19 data logging, specifically, the data for
20 Stair-Climbing, but in addition, other data that
21 the device can download, be delivered from the
22 sponsor to FDA at an interval and for a length of
23 time mutually agreeable to the two of them.

24 I'll call for a vote. And a point of
25 order, Mr. Demian--we poll each voting member

1 individually, or can we call for a hand vote on
2 these conditions?

3 MR. DEMIAN: We should go around the room
4 so we can record who said what.

5 DR. YASZEMSKI: Okay. We're going to
6 start, Dr. Stiens, voting on this condition only.

7 Yes or no?

8 DR. STIENS: Yes.

9 DR. YASZEMSKI: Mr. Herman?

10 MR. HERMAN: No.

11 MR. DEMIAN: He doesn't vote.

12 DR. YASZEMSKI: Okay. Thank you.

13 Actually, that's important--I should have asked
14 your opinion. That tells us your input on
15 it--thank you--and I'm sorry I didn't recognize you
16 as a nonvoting member.

17 As I go around to voting members, Mr.
18 Demian, can you identify and call them out for me
19 so I don't do that again?

20 Mr. DEMIAN: It is everyone except the
21 industry rep, the consumer rep, and the patient
22 rep--and you don't vote except in the case of a
23 tie.

24 DR. YASZEMSKI: Thank you.

25 Dr. McQuade?

1 DR. McQUADE: Yes.

2 DR. YASZEMSKI: Ms. Buzaid?

3 MS. BUZAID: Yes.

4 DR. YASZEMSKI: Dr. Hannaford?

5 DR. HANNAFORD: Yes.

6 DR. YASZEMSKI: Dr. Abrams?

7 DR. ABRAMS: Yes.

8 DR. YASZEMSKI: Dr. Naidu?

9 DR. NAIDU: Yes.

10 DR. YASZEMSKI: Dr. Finnegan?

11 DR. FINNEGAN: Yes.

12 DR. YASZEMSKI: Dr. Kirkpatrick?

13 DR. KIRKPATRICK: Yes.

14 DR. YASZEMSKI: Dr. Friedman?

15 DR. FRIEDMAN: Yes.

16 DR. YASZEMSKI: Dr. Larntz?

17 DR. LARNTZ: No.

18 DR. YASZEMSKI: Dr. Myklebust?

19 DR. MYKLEBUST: Yes.

20 DR. YASZEMSKI: Dr. Goldman?

21 DR. GOLDMAN: Yes.

22 DR. YASZEMSKI: The motion carries.

23 The next order is would anyone like to

24 introduce an additional condition to the motion put

25 forth by Dr. Stiens.

1 Dr. Kirkpatrick?

2 DR. KIRKPATRICK: Would it be in order to
3 add a condition for post-market surveillance?

4 DR. YASZEMSKI: You may make any condition
5 you want, and we'll look for a seconder and discuss
6 it.

7 DR. KIRKPATRICK: I would propose a
8 condition which would be that post-market
9 surveillance includes an injury questionnaire with
10 each servicing visit, not with each servicing
11 call--in other words, not phone calls from the
12 patient asking about what they can do. If they can
13 fix it themselves, fine. But any time the company
14 representative has to actually physically put hands
15 on the device, this questionnaire would go with
16 three simple questions: Was this component failure
17 associated with any injury? What was the injury?
18 What treatment was needed?

19 Reporting of this would be with each
20 positive response, and a comprehensive report
21 annually.

22 DR. YASZEMSKI: Is there a second to this
23 motion?

24 DR. FINNEGAN: Second.

25 DR. YASZEMSKI: It has been seconded by

1 Dr. Finnegan.

2 Discussion?

3 Dr. Larntz?

4 DR. LARNTZ: I think it is very important
5 that if we do collect data, we do it in a
6 comparative manner. That is a principle of
7 statistics that I have to invoke. It sounds like
8 we are only reporting instances of failure, and we
9 are not clear about what the universe is that that
10 failure is coming from.

11 If I were doing this, I would think about
12 looking at whether individuals had some AE during a
13 year, let's say, and wanting to relate that to
14 basic characteristics of the patient. We have
15 not--and I think we probably will not--put many
16 conditions on the patient population for these
17 devices, but it may not be effective for certain
18 groups, and the way we find out about that is by
19 having the company record demographics such as they
20 have, gender, age, medical condition, weight, or
21 other demographics, and then relating these things
22 for devices that fail or have events with AEs
23 versus those that do not.

24 So we have to have some comparative
25 information. Just summarizing the report, saying

1 there were failures, I don't think is very useful.

2 DR. YASZEMSKI: Thanks, Dr. Larntz.

3 MS. WITTEN: May I ask a question?

4 DR. YASZEMSKI: Yes, Dr. Witten.

5 MS. WITTEN: What is most helpful to us is
6 if perhaps you could tell us the objective of the
7 particular data that you are suggesting collecting,
8 because I think that would help us figure out the
9 best way to do it.

10 DR. YASZEMSKI: Dr. Kirkpatrick?

11 DR. KIRKPATRICK: The objective to this
12 information was to answer a couple of issues. One
13 is there were multiple component failures that in 2
14 weeks did not result in any adverse events. We
15 don't know if an additional 2 weeks would have
16 caused somebody to fall out of their chair and
17 break a leg.

18 So this seemed to be a reasonable way to
19 at least get the numerator of that aspect, and I
20 recognize we do not include the denominator.

21 I also felt it was a very streamlined way
22 that the company would not have a significant added
23 cost or hassle factor in starting a whole new study
24 to collect this information. They are going to be
25 there; they simply add on their service record,

1 "Did you get hurt with this incident?" and they
2 have that. If it is positive, then, when that
3 service report gets to the company, they simply
4 indicate to the FDA that Person X had a bruise when
5 Component Z failed.

6 DR. YASZEMSKI: Dr. Kirkpatrick, may I ask
7 do you think there should be a time limit to that,
8 or should that be open-ended? Should that be
9 forever, or would there be a certain amount of time
10 after which we would know enough and could
11 discontinue it?

12 DR. KIRKPATRICK: I would certainly be
13 open to a friendly amendment to limit it to the
14 main issue that I'm trying to address, which is a
15 learning curve and the initial service period,
16 which would probably be between 6 months and a
17 year.

18 DR. YASZEMSKI: Thank you.

19 Dr. Abrams, you had a comment?

20 DR. ABRAMS: I had the same question about
21 the time.

22 DR. YASZEMSKI: Dr. Goldman?

23 DR. GOLDMAN: I'd like to introduce--are
24 we going on to other--

25 DR. YASZEMSKI: No. This is still

1 discussion of Dr. Kirkpatrick's motion. If you
2 have another, we'll come to it.

3 DR. NAIDU: Can I just ask a question?
4 Isn't it built into the system, just like Sally
5 suggested, the adverse outcomes and injury? Isn't
6 that built into the industry standard?

7 DR. YASZEMSKI: Can it be that somebody
8 hurts himself, gets cared for by a physician, and
9 the company never hears about it?

10 MS. MAHER: Absolutely, it can be.

11 DR. NAIDU: Thank you.

12 DR. YASZEMSKI: Dr. Hannaford?

13 DR. HANNAFORD: Just a clarification. If
14 we do collect the data logging information, that
15 does provide a denominator, as you say, or an
16 amount of time that the device has been used, so
17 that the injury data could then be formulated as a
18 rate per hours of use or something.

19 DR. YASZEMSKI: Thank you.

20 Dr. Finnegan?

21 DR. FINNEGAN: Dr. Goldman brought up a
22 point earlier to try to narrow the scope of people
23 that this is available to, and while I don't agree
24 with that concept, I do think he has a point in
25 that we don't know what is going to happen when you

1 not only increase the length of time, but you
2 increase the people who are using this. And I
3 think this proposition will allow you to proactive
4 pick out if there are in fact age groups or disease
5 processes or--I'll change my language; I'm an
6 orthoped, so you know we're pretty
7 simple-minded--impairment capabilities that in fact
8 may or may not be able to handle the device.

9 DR. YASZEMSKI: Thank you, Dr. Finnegan.

10 Mr. Herman?

11 DR. LARNTZ: Excuse me--that's if we
12 collect that data. I didn't hear that that was
13 going to be collected. Are we going to have a
14 record of every implant, of age--we haven't asked
15 that of the company, I don't think--age, medical
16 impairment, gender, weight, those kinds of
17 demographics. I don't think we have asked them to
18 collect that.

19 DR. FINNEGAN: But they're going to know
20 who--if you collect a whole bunch of a specific
21 injury like fractured femurs, then, you can go back
22 and look and see if it is a disease
23 process--because they are going to know who they
24 sold it to, and it is a single-user device.

25 DR. LARNTZ: I don't know that they are

1 going to have that record. We're going to have to
2 do it for the whole population of devices put in.

3 DR. KIRKPATRICK: Wouldn't a prescription
4 also include the diagnosis?

5 DR. YASZEMSKI: Mr. Herman?

6 MR. HERMAN: I think the motion is unduly
7 burdensome and paternalistic and not likely to lead
8 to any greater increase in safety that couldn't
9 already be achieved by cooperation between FDA and
10 the manufacturer.

11 DR. YASZEMSKI: Thank you.

12 Is there further discussion?

13 Dr. Kirkpatrick?

14 DR. KIRKPATRICK: Just in answer to that
15 comment, as a patient advocate--and I understand
16 you are indeed a patient as well as a
17 representative on this panel--but my patients have
18 been made victims of companies not cooperating with
19 the FDA, so I do think they need another watchdog.

20 DR. YASZEMSKI: Ms. Maher?

21 MS. MAHER: I think I'll come out
22 somewhere in between. I think that the concept of
23 looking at data is always useful. I think when the
24 companies are doing their service checks, they will
25 be getting that data in, and as part of their due

1 diligence and part of their evaluation of
2 complaints or service records to determine if there
3 are actually complaints, they would be asking those
4 questions in many cases, especially if it were
5 something that looked like it could have caused an
6 injury. Some of them clearly wouldn't ever have
7 caused an injury.

8 I think it sometimes may be difficult with
9 the simplistic questions that you have suggested
10 asking to actually get an answer that would be
11 useful, so I think again that may be something that
12 the Agency and the company can work out to make
13 sure that the information you need--and again, I'm
14 going to go back to something I brought up earlier.
15 We need to make sure--I heard you say that a time
16 limit for the first service warranty may be
17 enough--we need to try not to be overly burdensome
18 to the company. Because it will limit it, it will
19 be overly burdensome to both the patients, who may
20 not want to answer those kinds of questions, and to
21 the company.

22 I think we also need to be cognizant of
23 the HIPAA requirements that are going to be coming
24 into play with patient confidentiality in April.

25 DR. YASZEMSKI: Thanks.

1 Dr. Friedman?

2 DR. FRIEDMAN: I'd like to avoid getting
3 into a quagmire, which I think we are getting into
4 here, at the same time, not reinventing the wheel.

5 FDA has been through this many times, so
6 that if we ask for some post-market surveillance,
7 they know how and what to do. I think the basic
8 principle that I am hearing is that everybody
9 agrees that we would like to vote to approve this,
10 and if so, there should be some post-market
11 surveillance regarding safety.

12 I think we all agree that efficacy is
13 there, effectiveness is there. We are all
14 concerned about safety, though, and what happens
15 beyond the 2 weeks.

16 So maybe we could just simplify it and say
17 that we would like to see continued monitoring of
18 safety for--we can agree--6 months or a year, and
19 leave it up to the FDA and the sponsor to work out
20 what is a reasonable way to do that since they have
21 a lot of experience with that and have done it
22 before.

23 DR. YASZEMSKI: Thank you.

24 Now, from a procedural perspective, this
25 is the discussion of a motion. And Dr.

1 Kirkpatrick, this is your motion. If you like the
2 restatement of your motion by Dr. Friedman, you are
3 free to adopt it; otherwise, we will continue to
4 discuss and then vote on your motion as stands.

5 DR. KIRKPATRICK: May I ask the FDA
6 representatives to comment on what they would
7 presume would be their post-market surveillance
8 methods?

9 DR. YASZEMSKI: We can ask them and see
10 what Dr. Witten says.

11 Dr. Witten, comments?

12 MS. WITTEN: Well, let me just clarify.
13 There are some things that are done no matter what,
14 as Ms. Maher pointed out, and the sponsors have an
15 obligation to continue to learn about the product
16 through the MDR adverse event reporting system and
17 report adverse events to us.

18 So there are some things that the sponsor
19 has an obligation to do even if we just issued a
20 straight approval order. Then, there are other
21 things--and to what extent those would or wouldn't
22 capture some of the things you have been talking
23 about, like learning curve, refining patient
24 selection, would really probably depend on what we
25 ended up having reported to us in the MDR system.

1 If there is some systematic prospective
2 evaluation of the device that you think we should
3 do to look at some of these things, be able to
4 quantify incidents or look at specific aspects of
5 patient selection or certain specific safety
6 events--or, I don't want to call them safety
7 events--but safety pre-events, that is, some
8 indication that there might be something that could
9 be modified to prevent a safety event, which is
10 what Dr. Hannaford is alluding to, if you have some
11 specific suggestions along those lines, those are
12 the kinds of things that just approving the
13 product, it wouldn't be in our normal course of
14 events--those aren't simply just automatic. Those
15 are things that we need to discuss with the sponsor
16 specifically. And it is those kinds of things
17 beyond adverse event reporting, which will take
18 place currently, and their obligations under the
19 Quality Systems regulations that we are interested
20 in your recommendations on.

21 So I would say the most useful thing for
22 us would not be so much exactly how to capture the
23 information, but what specific kinds of questions
24 you think it would be helpful to answer in the
25 post-market period, because you are right, and as

1 has been said, we have a lot of experience working
2 those details out with the sponsor, but it is the
3 questions and the issues.

4 DR. YASZEMSKI: Thank you, Dr. Witten.

5 Dr. Kirkpatrick, would you care to vote as
6 is, or would you care to modify the condition at
7 all?

8 DR. KIRKPATRICK: I would like to follow
9 up to what she has said and comment that since the
10 sentiment of my motion has been clear, and the FDA
11 does indeed have established practices to detect
12 that information, I will withdraw the motion.

13 DR. YASZEMSKI: Thank you, Dr.
14 Kirkpatrick, and Dr. Witten, thank you for that
15 clarification.

16 Other motions?

17 MS. BUZAID: Could I ask for a
18 clarification?

19 DR. YASZEMSKI: Yes.

20 MS. BUZAID: Are we saying that we are
21 approving this with a certified occupational
22 therapist or a physical therapist who has been
23 trained by the company? Is that as part of this
24 approval process already?

25 DR. YASZEMSKI: I believe that was in the

1 company's description.

2 MS. BUZAID: And that the training would
3 occur for the patient?

4 DR. YASZEMSKI: The training occurs for
5 the patient, yes.

6 MS. BUZAID: I would like to make a motion
7 that the certification be updated as changes occur
8 to the device, as well as possibly annually.

9 DR. YASZEMSKI: And how updated? I'm not
10 sure I understand--that a person who already has
11 the device be recertified as changes occur?

12 MS. BUZAID: I'm talking about the
13 therapist. My fear is that the therapist will not
14 do this very frequently, and their skills won't
15 remain current.

16 DR. YASZEMSKI: May I ask for a
17 clarification from the company--is such an
18 update--Mr. O'Donnell, as changes occur in the
19 device, would those who describe this device and
20 provide the user training, in your vision, would
21 they need further training, and how? Please
22 address if you can.

23 MR. O'DONNELL: Certainly any changes in
24 the device which did require training would. I
25 can't say every change--it may change some little

1 thing that doesn't require going out and
2 retraining--but certainly any changes in how the
3 device might be used, how the device functions,
4 things like that, then, yes, we would need to
5 update the training for the clinicians.

6 DR. YASZEMSKI: Thank you.

7 Ms. Buzaid, would you state your motion,
8 if you would, so we can understand exactly what it
9 is, and ask for a second?

10 MS. BUZOID: I have to say I was just a
11 little bit confused, because to me, it is kind of a
12 timing thing, too. I don't know what the timing
13 would be when the company is made aware that there
14 is a need for more training, perhaps as some of the
15 follow-up studies occur, or they actually alter the
16 configuration of the device. I don't know what the
17 timing is that the clinicians would be trained
18 afterward.

19 DR. FRIEDMAN: But it is in their best
20 interest to make sure the people who are teaching
21 the patients are kept up-to-date. Otherwise the
22 patients aren't going to be using the product
23 properly and all those issues. So I would assume
24 that they are going to keep their field people
25 updating the clinicians, who are going to update

1 the patients. That's a natural; otherwise the
2 system is going to break down.

3 DR. YASZEMSKI: Okay. Again from a
4 protocol perspective, if you are going to introduce
5 the motion, we'll ask for a second.

6 Your motion, then, is for a requirement
7 that at some interval, update of training for
8 everyone who can prescribe this occurs--because I
9 think that would include any licensed OT, PT, or
10 physician who cares to do this, and I want to be
11 certain I state it right.

12 MS. BUZAID: That's correct.

13 DR. YASZEMSKI: And make the company
14 responsible to provide training to any person who
15 desires to write a prescription for this product at
16 intervals to be determined by the company and FDA
17 on an as-needed basis.

18 MS. BUZAID: Yes.

19 DR. STIENS: I second that motion.

20 DR. YASZEMSKI: There is a second.

21 Is there discussion of that motion?

22 [No response.]

23 DR. YASZEMSKI: Okay. Seeing no
24 discussion, we'll vote.

25 Dr. Stiens?

1 DR. STIENS: Yes.

2 DR. YASZEMSKI: Dr. McQuade?

3 DR. McQUADE: Yes.

4 DR. YASZEMSKI: Ms. Buzaid?

5 MS. BUZAID: Yes.

6 DR. YASZEMSKI: Dr. Hannaford?

7 DR. HANNAFORD: Yes.

8 DR. YASZEMSKI: Dr. Abrams?

9 DR. ABRAMS: No.

10 DR. YASZEMSKI: Dr. Naidu?

11 DR. NAIDU: No.

12 DR. YASZEMSKI: Dr. Finnegan?

13 DR. FINNEGAN: Yes.

14 DR. YASZEMSKI: Dr. Kirkpatrick?

15 DR. KIRKPATRICK: I hate to ask this, but
16 would you please read the motion as it stands?

17 DR. YASZEMSKI: The motion is to require
18 as a condition of approval that the company at some
19 interval to be negotiated between the company and
20 FDA provide continued update and training for those
21 people, those licensed therapists and physicians,
22 who choose to write a prescription for this device.

23 DR. KIRKPATRICK: Yes is my answer.

24 DR. YASZEMSKI: Dr. Friedman?

25 DR. FRIEDMAN: No.

1 DR. YASZEMSKI: Dr. Larntz?

2 DR. LARNTZ: No.

3 DR. YASZEMSKI: Dr. Myklebust?

4 DR. MYKLEBUST: No.

5 DR. YASZEMSKI: Dr. Goldman?

6 DR. GOLDMAN: Yes.

7 DR. YASZEMSKI: The vote is 7-to-5, and
8 that motion passes.

9 DR. STIENS: I would like to reintroduce a
10 motion on age limitation on the device and suggest
11 that the age be 16, the age when we currently clear
12 people for driving.

13 DR. YASZEMSKI: Greater than or equal to
14 16?

15 DR. STIENS: Yes, equal to or greater
16 than 16, yes.

17 DR. FRIEDMAN: In South Carolina, the
18 driving age is 15, so can we adjust it per State.

19 DR. STIENS: Let's adjust it for 15.

20 DR. YASZEMSKI: Okay. We have a motion to
21 put as a condition of approval that this be
22 restricted for prescription to persons of age
23 greater than or equal to 15.

24 Is there a second to that motion?

25 DR. FRIEDMAN: Second.

1 DR. YASZEMSKI: Is there discussion?

2 Mr. Herman?

3 Mr. HERMAN: In the space of half an hour,
4 we have moved from 18 to 16 to 15, which seems to
5 prove my point that age is too arbitrary a dividing
6 line that would not provide for any real increase
7 in safety. I think the judgment can be left to the
8 clinician to determine who can use it safely and
9 whether or not that person could even fit into the
10 chair within the parameters and limitations that
11 the chair has as it is.

12 DR. YASZEMSKI: Thank you.

13 Is there further discussion?

14 Dr. Abrams?

15 DR. ABRAMS: Yes, I would like to agree
16 with Mr. Herman on that. The therapist already has
17 tremendous responsibility in terms of making a
18 whole bunch of judgments, and I think age is just a
19 very arbitrary barrier to put up on them at this
20 particular point.

21 DR. YASZEMSKI: Is there further
22 discussion?

23 Dr. Goldman?

24 DR. GOLDMAN: I think there has to be a
25 limit somewhere. I think that the vast benefits

1 and efficacy of this device have to be balanced
2 with the issues of judgment, and I think that in
3 the future this could be changed, and I guess that
4 could be something that maybe the FDA should speak
5 to. Since the issues of post-market surveillance
6 are nebulous and difficult to define, I think that
7 for the moment, I would rather err on the side of
8 safety.

9 DR. YASZEMSKI: Thank you.

10 Is there further discussion?

11 DR. STIENS: I want to say as a consumer
12 as well as a scientist that I feel the same way.
13 We are doing an expedited review, and we have data
14 on a limited number of subjects with primarily one
15 diagnosis, and all of them have been adults, and
16 none of them has been adolescent. I think this
17 restriction is a reasonable one at this step, and
18 it certainly is something that can be reevaluated
19 in the future.

20 DR. YASZEMSKI: Is there further
21 discussion?

22 Dr. Naidu?

23 DR. NAIDU: You are already giving a
24 prescription. This is a physician diagnosis; the
25 physician writes the prescription. It's enough

1 burden on the physician. I don't think you need to
2 define an age.

3 DR. YASZEMSKI: Thank you.

4 Is there further discussion?

5 DR. FRIEDMAN: I would agree. You can
6 find a 19-year-old who may not be mature enough to
7 handle this, and there may be a 16- or 17-year-old
8 who is. I would like not to tie the hands of the
9 clinician. Leave it up to their judgment to decide
10 who is an appropriate candidate or not. A
11 physician is not going to prescribe this for a 15-
12 or 16- or 17- or 18-year-old if they don't feel it
13 is appropriate and they can handle what is
14 involved.

15 DR. YASZEMSKI: Dr. Goldman?

16 DR. GOLDMAN: Yes. The issue is one of
17 subtlety. I think there are many cognitive exams
18 that really don't lend themselves well to this
19 task. There are also issues of more detailed
20 formal disability driving evaluations, which may
21 lend themselves to this task. However, neither of
22 these are attached to the approval.

23 So again, to make it simple, admittedly,
24 it is--I really hate to not be able to prescribe it
25 to anyone who may do it. I think that a physician

1 prescribing this device may not have access to
2 detailed cognitive evaluations that would be able
3 to assure safety.

4 DR. YASZEMSKI: Thank you.

5 Dr. Myklebust?

6 DR. MYKLEBUST: Just a question. If we do
7 this, what would be involved in the future with
8 additional information and having this changed to
9 something else?

10 DR. YASZEMSKI: The FDA and the sponsor
11 would work together and may or may not ask for our
12 opinion again.

13 DR. LARNTZ: So they are going to have to
14 be collecting age and whatever else we decide in
15 addition. I heard they are not going to be doing
16 that, we are not requiring that.

17 DR. YASZEMSKI: Dr. Kirkpatrick?

18 DR. KIRKPATRICK: I'd like to call the
19 question on that motion.

20 DR. YASZEMSKI: Okay. We're going to call
21 for a vote.

22 Dr. Stiens?

23 DR. STIENS: Yes.

24 DR. YASZEMSKI: Dr. McQuade?

25 DR. McQUADE: No.

1 DR. YASZEMSKI: Ms. Buzaid?

2 MS. BUZAID: No.

3 DR. YASZEMSKI: Dr. Hannaford?

4 DR. HANNAFORD: No.

5 DR. YASZEMSKI: Dr. Abrams?

6 DR. ABRAMS: No.

7 DR. YASZEMSKI: Dr. Naidu?

8 DR. NAIDU: No.

9 DR. YASZEMSKI: Dr. Finnegan?

10 DR. FINNEGAN: No.

11 DR. YASZEMSKI: Dr. Kirkpatrick?

12 DR. KIRKPATRICK: No.

13 DR. YASZEMSKI: Dr. Friedman?

14 DR. FRIEDMAN: No.

15 DR. YASZEMSKI: Dr. Larntz?

16 DR. LARNTZ: No.

17 DR. YASZEMSKI: Dr. Myklebust?

18 DR. MYKLEBUST: No.

19 DR. YASZEMSKI: Dr. Goldman?

20 DR. GOLDMAN: Yes.

21 DR. YASZEMSKI: The motion does not pass.

22 We now have the motion as it stands, which

23 is a motion for approval with four conditions.

24 Is there any motion for additional

25 conditions? If there are, we will discuss them; if

1 not, we are going to repeat the motion for approval
2 with four conditions and vote on it.

3 Dr. Myklebust?

4 DR. MYKLEBUST: With some trepidation in a
5 room with a majority of physicians, given all of
6 the required training, and now, we are asking for
7 additional certification of the clinicians and so
8 forth, I'm not clear what we gain by requiring
9 physician prescription as opposed to the usual
10 legislation and practice and rules in various
11 locations.

12 DR. YASZEMSKI: Thank you. So noted.

13 I am going to read the motion as it
14 stands. This is a motion for approval with
15 conditions. Those conditions are four.

16 Number one, that it require such diagnosis
17 and prescription by a physician in addition to the
18 therapist who prescribes it; number two, that there
19 is user training specifically with respect to the
20 Stair-Climbing function, both at the test site and
21 in the home environment of the patient; number
22 three, that the data-logging be reported,
23 specifically again for Stair-Climbing but also for
24 the other modes, to the FDA at an interval and for
25 a length as mutually agreed upon between FDA and

1 the sponsor; and number four, that as improvements
2 are made and changes in the provider training
3 occur, those changes be communicated from the
4 company to the cadre of clinicians who prescribe
5 this device.

6 That's the motion, and we're going to go
7 around and vote on it.

8 Is there any further discussion?

9 DR. FRIEDMAN: Can I ask a question?

10 DR. YASZEMSKI: Go ahead.

11 DR. FRIEDMAN: How do you define a
12 physician?

13 DR. YASZEMSKI: A physician is going to
14 be--I guess I don't know if I am going to define
15 that--I guess it would be an M.D. or a D.O. as
16 licensed by the State medical board.

17 Dr. Finnegan?

18 DR. FINNEGAN: I was going to say anyone
19 who is licensed by their State medical board has to
20 be considered a physician.

21 DR. FRIEDMAN: I was just going to make
22 sure that we aren't narrowing it down to just
23 M.D.s.

24 DR. YASZEMSKI: No. I believe a person
25 licensed to practice medicine by the State medical

1 board would be my definition of that.

2 Okay, we're going to vote.

3 Dr. Stiens, you are first.

4 DR. STIENS: Yes.

5 DR. YASZEMSKI: Dr. McQuade?

6 DR. McQUADE: Yes.

7 DR. YASZEMSKI: Ms. Buzaid?

8 MS. BUZAID: Yes.

9 DR. YASZEMSKI: Dr. Hannaford?

10 DR. HANNAFORD: Yes.

11 DR. YASZEMSKI: Dr. Abrams?

12 DR. ABRAMS: Yes.

13 DR. YASZEMSKI: Dr. Naidu?

14 DR. NAIDU: Yes.

15 DR. YASZEMSKI: Dr. Finnegan?

16 DR. FINNEGAN: Yes.

17 DR. YASZEMSKI: Dr. Kirkpatrick?

18 DR. KIRKPATRICK: Yes.

19 DR. YASZEMSKI: Dr. Friedman?

20 DR. FRIEDMAN: Yes.

21 DR. YASZEMSKI: Dr. Larntz?

22 DR. LARNTZ: Yes.

23 DR. YASZEMSKI: Dr. Myklebust?

24 DR. MYKLEBUST: Yes.

25 DR. YASZEMSKI: Dr. Goldman?

1 DR. GOLDMAN: Yes.

2 DR. YASZEMSKI: The vote is unanimous.

3 The motion passes.

4 Mr. Demian?

5 MR. DEMIAN: Before you turn it back over,
6 can we please poll the panelists and ask them why
7 they voted the way they did?

8 DR. YASZEMSKI: Thank you.

9 I'll tell the panel that the poll--and I
10 thank Mr. Demian for reminding me--the poll is
11 extremely useful to FDA to hear plus or minus--and
12 I know they have heard a very detailed discussion
13 today--why we voted how we did and what our
14 thoughts were about our votes.

15 So we'll go around one more time.

16 Dr. Stiens?

17 DR. STIENS: You have had a sense of the
18 depth and breadth of my experience as a clinician
19 and as a consumer, and I kind of rooted out those
20 concerns, and I appreciate people's patience in
21 doing that.

22 I believe from the data presented and the
23 people involved in continued surveillance of this
24 device that consumers and clinicians, including the
25 physician, can make the decision to take the risks

1 associated with the device and reap the benefits,
2 which are clear, at this stage in our offering the
3 device, and that any data that would turn up would
4 be helpful in refining the process of delivery of
5 the device and the device capabilities itself.

6 DR. YASZEMSKI: Thank you, Dr. Stiens.

7 Dr. Goldman?

8 DR. GOLDMAN: On balance, the device is
9 revolutionary, and I think it deserves to be out
10 there.

11 On the other hand, I have concerns that it
12 will be misused by people with poor judgment, even
13 those who do not show up on routine, customary, and
14 exhaustive trials with learning.

15 On balance, I suspect the FDA will collect
16 post-market data routinely that will uncover that
17 if it does occur.

18 So on balance, my vote is yes.

19 DR. YASZEMSKI: Thank you.

20 Dr. Myklebust?

21 DR. MYKLEBUST: I think it has been
22 demonstrated to be a safe and effective device and
23 that normal surveillance methods will bring to
24 light additional engineering problems which can be
25 dealt with in the normal design process.

1 DR. YASZEMSKI: Thank you.

2 Dr. Larntz?

3 DR. LARNTZ: I believe this is a
4 highly-effective device, and I believe the company
5 itself will determine the appropriate patient
6 population to continue using the device effectively
7 and safely.

8 DR. YASZEMSKI: Thank you.

9 Dr. Friedman?

10 DR. FRIEDMAN: I think the sponsor has
11 clearly shown the device is effective. In the
12 short time the study was conducted, it appears to
13 be safe, but I think we need post-market
14 surveillance to confirm that and watch it
15 carefully.

16 DR. YASZEMSKI: Thank you.

17 Dr. Kirkpatrick?

18 DR. KIRKPATRICK: I felt that the efficacy
19 was significant enough to well outweigh any safety
20 concerns, and I agree that post-market surveillance
21 is appropriate.

22 DR. YASZEMSKI: Thank you.

23 Dr. Finnegan?

24 DR. FINNEGAN: First, I would like to
25 compliment the sponsors on an elegant piece of work

1 and taking their time and doing extremely good due
2 diligence. It makes our lives much easier.

3 I do think this is revolutionary. It will
4 allow a whole lot of people who can't do certain
5 things to be able to do them--and I am waiting for
6 the first college student to "nuke" the software.

7 DR. YASZEMSKI: Thank you.

8 Dr. Naidu?

9 DR. NAIDU: Sponsors have done an
10 excellent, very commendable job and they have shown
11 the device to be safe and effective.

12 DR. YASZEMSKI: Thank you.

13 Dr. Abrams?

14 DR. ABRAMS: I concur. The sponsors have
15 shown this is a safety and effective device within
16 the context of the studies that they have done.

17 It relies a lot on good judgment from both
18 physicians and therapists who prescribe it, but so
19 does just about every piece of medical
20 instrumentation. I am encouraged also that we have
21 the post-marketing information that will help make
22 the device even better in the future.

23 DR. YASZEMSKI: Thank you.

24 Dr. Hannaford?

25 DR. HANNAFORD: It is too bad that the FDA

1 hasn't asked us to vote on whether this device is
2 "way cool" or not, so I will limit my discussion to
3 safety and effectiveness.

4 The trials showed safety and no adverse
5 events in Stair-Climbing mode. From purely an
6 engineering point of view, I have reservations, but
7 I am satisfied that the conditions address those
8 reservations.

9 DR. YASZEMSKI: Thank you.

10 Ms. Buzaid?

11 MS. BUZAID: I also understand and agree
12 with Dr. Hannaford that it is a "way cool" device.

13 I think that all the safeguards that were
14 put in place for the assessment and training are
15 commendable. I have actually never seen such
16 wonderful training materials, and that certainly
17 weighed in on my vote.

18 DR. YASZEMSKI: Thank you.

19 Dr. McQuade?

20 DR. McQUADE: I think the device
21 represents extraordinary innovation, and I am
22 surprised it wasn't here 5 years ago.

23 There are some minor things that we have
24 talked about which are not insurmountable, and to
25 my satisfaction have been adequately addressed.

1 DR. YASZEMSKI: Thank you.

2 Panel members, both voting and nonvoting,
3 FDA, sponsor, thank you all.

4 Mr. Demian?

5 MR. DEMIAN: This meeting is adjourned.

6 Thank you.

7 [Whereupon, at 5:08 p.m., the proceedings
8 were concluded.]

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