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UNITED STATES DEPARTMENT OF DEFENSE

DEFENSE HEALTH BOARD MEETING
DAY 1

Tacoma, Washington
Wednesday, April 23, 2008

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2

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P R O C E E D I N G S

(8:38 a.m.)

DR. POLAND: Welcome, everybody, to this meeting of the Defense Health Board. A number of important topics on our agenda you will see if you open up your briefing books, and we will go ahead and get started. We're privileged to have Major General Kelley. Dr. Kelley, would you call the meeting to order, please?

MAJ. GEN. KELLEY: We want to call the Federal Advisory Committee and the continuing Independent Scientific Advisory Board for the Secretary of Defense by the Assistant Secretary of Defense for Health Affairs and Surgeon Generals of the Military Department. I hereby call this

16 meeting to order of the Defense Health Board.
17 DR. POLAND: Thank you, Dr. Kelley.
18 Carrying on the tradition of our boards, I'm going
19 to ask in a minute that we stand for a minute of
20 silence to honor those who are here to serve, the
21 men and women who are sacrificing in serving our
22 country.

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7

1 Today is perhaps even more poignant than
2 most because one of our own board members, Dr.
3 Bill Fox, who many of you met, I think he's been
4 at, at least two of the meetings, was severely
5 wounded in Iraq while serving in his capacity as
6 the Chief Operating Officer for Project Hope,
7 which is an international organization that works
8 to improve the health of all peoples, especially
9 children.

10 As a former General Army Officer and
11 Regional Hospital Commander and a member of our
12 Board's Amputee Patient Care Panel, Bill has made
13 measurable and lasting contributions to medicine.
14 He did have a head injury as part of his convoy
15 being hit by an IED, and he's recovering at Walter
16 Reed Army Medical Center. So if you would, keep
17 him and his family in your thoughts and prayers.

18 (Standing moment of silence.)

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19 DR. POLAND: Thank you. Since this is
20 an open session, I'd also like to go around the
21 table and have the Board and distinguished guests
22 introduce themselves and, Dr. Kelley, if you don't

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1 mind, I'll start with you. We'll go around, and
2 then into the back.

3 MAJ GEN KELLEY: Dr. Joe Kelley. I am
4 the Deputy Assistant Secretary of Defense for
5 Clinical and Program Policy and the alternate
6 designated Federal Official for this meeting.

7 DR. LEDNAR: Wayne Lednar, Global Chief
8 Medical Officer and Director of Integrated Health
9 Services for the DuPont Company.

10 COL. HOGE: I'm Charles Hoge. I'm the
11 Chief of Psychiatry and Neuroscience at Walter
12 Reed Army Institute of Research.

13 COL. CERTAIN: I'm Robert Certain. I am
14 an Episcopal priest in Atlanta, Georgia, former
15 Prisoner of War and a few other things.

16 DR. CLEMENTS: John Clements. I'm the
17 Chairman of Microbiology and Immunology of Tulane
18 University School of Medicine in New Orleans.

19 DR. KAPLAN: Ed Kaplan, Professor of
20 Pediatrics, University of Minnesota Medical
21 School, Minneapolis.

22 DR. PARKINSON: Mike Parkinson. I'm
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9

1 currently serving as the President of the American
2 College of Preventive Medicine.

3 DR. OXMAN: Mike Oxman, Professor of
4 Medicine and Pathology at the University of
5 California, San Diego.

6 DR. McNEILL: I'm Mills McNeill. I'm
7 the Director of the Mississippi Public Health
8 Laboratory and a board member.

9 DR. SHAMOO: I'm Adil Shamoo. I'm
10 Professor at the University of Maryland School of
11 Maryland. Also, I'm a biofacis.

12 DR. MULLICK: Florabel Mullick. Director
13 of the Armed Forces Institute of Pathology.

14 COL. BADER: Christine Bader, Executive
15 Secretary for the Task Force on the Future of
16 Military Health Care.

17 CAPT. NAITO: Neil Naito, Director of
18 Public Health, the Navy Medicine.

19 LTC. HACHEY: Wayne Hachey, Director of
20 Preventive Medicine, OSD Health Affairs, Force
21 Health Protection and Readiness.

22 CAPT. JOHNSTON: Richard Johnston,

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1 British Liaison Officer.

2 CDR. SLAUNWHITE: Commander Cathy
3 Slaunwhite, the Canadian Forces Medical Officer in
4 Washington, D.C.

5 CDR. SCHWARTZ: I am Erica Schwartz, the
6 Preventive Medical Officer for the Coast Guard.

7 MS. JOVANOVIC: Olivera Jovanovic. I'm
8 with the Defense Health Board.

9 COL. JAFFEE: Mike Jaffee. I'm with the
10 Defense and Veterans Brain Injury Center in the
11 DoD Liaison to two of the subpanels on the TBI
12 Family Caregiver Program and the TBI External
13 Advisory Panel.

14 COL. LUGO: Good morning. Colonel Lugo,
15 Chief of Staff for the Defense Center of
16 Excellence for Psychological Health and Traumatic
17 Brain Injury.

18 MR. WILSON: Bill Wilson with VA
19 Compensation and Patient Service. I'm the Project
20 Manager for the Disability Evaluation System Pilot
21 Project.

22 CDR. FEEKS: Good morning. Commander Ed

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2 Marine Corps.

3 LTC. SILVER: Aaron Silver, Deputy Chief
4 Health Service, Support Division, J-4 Joint Staff.

5 COL. STANEK: Scott Stanek, Preventive
6 Medicine Staff Officer, Army, Office of the
7 Surgeon General.

8 DR. BROWN: I'm Mark Brown. I'm
9 representing the Department of Veterans Affairs.

10 DR. ZAKI: Sherif Zaki, Chief of the
11 Infectious Disease Pathology at the CDC.

12 DR. REDDICK: Bob Reddick, Chair of
13 Pathology at the University of Texas Health
14 Science in San Antonio.

15 DR. GARDNER: Pierce Gardner, Professor
16 of Medicine and Public Health at Stony Brook
17 University, School of Medicine.

18 DR. MILLER: Mark Miller, Director of
19 Research at Fogarty International Center in NIH.

20 DR. LUEPKER: I'm Russell Luepker, and
21 I'm Professor of Epidemiology and Medicine at the
22 University of Minnesota.

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1 DR. HALPERIN: Bill Halperin. I'm Chair
2 of the Department of Preventive Medicine at the
3 New Jersey Medical School and Chair of the
4 Department of Quantitative Methods of our School

5 of Public Health, and also Chair of the Committee
6 on Toxicology for the National Research Council.

7 DR. SILVA: I'm Joe Silva, Professor of
8 Internal Medicine, University of California Davis,
9 and board member.

10 RADM. GAUMER: I'm Ben Gaumer. I'm the
11 Assistant Deputy Surgeon General, Navy Medicine.

12 DR. LOCKEY: Jim Lockey, Professor of
13 Internal Medicine and Environmental Health,
14 University of Cincinnati.

15 DR. BLAZER: Dan Blazer, Professor of
16 Psychiatry at Deacon University Medical Center and
17 Professor of Epidemiology at the other basketball
18 school down there, the Road Hog with a lighter
19 blue color.

20 COL. GIBSON: I'm Roger Gibson and the
21 Executive Secretary for the Defense Health Board.

22 DR. POLAND: Greg Poland, Professor of

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13

1 Medicine and Infectious Diseases at the Mayo
2 Clinic in Rochester, Minnesota.

3 CDR. JATHAN: Jonathan Jathan, Deputy
4 Commander, U.S. Army Medical Research and Materiel
5 Command.

6 DR. BALLARD: Tim Ballard. I'm an
7 Occupational Medicine resident, University of
8 Cincinnati, Simple Flight Surgeon.

9 MR. PASTERIC: Steve Pasteric from
10 Canteen Corporation in Winnipeg, Manitoba.
11 DR. REYBOLD: Ridge Reybold, the Armed
12 Forces Institute of Pathology.
13 CPT. NEVILLE: James Neville, the Vice
14 Commander of the U.S. Air Force School of
15 Aerospace Medicine.
16 MS. TRIPLETT: Karen Triplett, CCSI
17 Prevent/Support.
18 MS. BUTLER: Nora Butler, Department of
19 Defense.
20 DR. POLAND: Okay, Colonel Gibson has
21 some administrative remarks before we begin our
22 morning session.

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14

1 COL. GIBSON: I want to thank the
2 Madigan Army Regional Medical Center, Fort Lewis,
3 for hosting this meeting of the Board. We'll get
4 an official welcome from those folks tomorrow as
5 the start of our tour. It should be a very
6 interesting tour.
7 Also, thank the staff here at the Hotel
8 Murano. I'd like to get your comments after the
9 meeting on what do you think of this hotel. I
10 think it's absolutely gorgeous.
11 And to all the speakers who worked hard

12 preparing the briefings for the Board. I also
13 want to thank my staff, Karen Triplett, Tina, and
14 all of their helping with the arrangements for the
15 Board, and Ms. Jarrett and Ms. Ward back home for
16 their invaluable assistance in putting this thing
17 together.

18 If you haven't done so, please sign the
19 attendance roster outside there on the table.
20 It's requirement for Federal Advisory Committee's
21 recount for all members in attendance.

22 For those who don't have briefing books,

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1 there are handouts on the table behind us of all
2 of the briefings that we're putting on today, I
3 believe. Restrooms are up the stairs, or
4 actually, they're down the hall. You don't have
5 to go up the stairs. There are restrooms right
6 before the stairs go up.

7 If you need faxes, telephones, et
8 cetera, help with that, see Karen, Olivera, or
9 Tina.

10 Because this is an open session it's
11 being transcribed, so make sure you state your
12 name before speaking and use the microphones so
13 our transcription person down there can pick it
14 up. However, since he's been with us now for
15 about, oh, I'd say eight or ten meetings, he

16 probably knows you all, so but still do it.

17 We have a limited number of See Me
18 Credits. I think two or three for this meeting,
19 but we have the forms so that in your briefing
20 books in back, so that we can complete those.

21 Refreshments will be available this
22 morning, and for the afternoon sessions we have a

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1 catered working lunch where we had breakfast this
2 morning for the board members, the stem speakers
3 and distinguished visitors.

4 There are a number of hotels nearby,
5 and, finally, two other things. The next meeting
6 will be September 4th and 5th in Washington, D.C.
7 where we will receive a series of updates from
8 subcommittee activities and draft recommendations.
9 Also, be aware that we have a number of
10 subcommittees that are going to be meeting over
11 the summer to address issues that will come to the
12 Board because of the organizational structure that
13 we have.

14 Finally, dinner tonight is at a
15 restaurant down by the water, and we need to know
16 how many folks are going to attend that dinner
17 tonight. Raise your hands. If your wives are
18 here, raise two, or you have a significant other

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19 here. What was the name of the hotel?

20 MS. JOVANOVIĆ: Woody's on the Water.

21 COL. GIBSON: Woody's on the Water It's
22 a nice place, has a beautiful view of the dock

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1 plus the mountains in back, so it's quite nice.
2 We'll meet at 6:45 in the lobby. There's lots of
3 parking down there, so we'll carpool down. It's a
4 little too far to walk.

5 DR. POLAND: Under Tab 2 you'll find the
6 copies of the slide for the first discussion on
7 the disability evaluation system. Our first
8 speakers this morning are Mr. Bill Wilson from
9 the Department of Veterans Affairs, Dr. Joe
10 Kelley, Deputy Secretary of Defense for Clinical
11 and Program Policy. They're going to provide a
12 status update on the DoD-VA effort to re-engineer
13 the disability evaluation system.

14 The members will recall we've had at
15 least a couple of briefings on this. We have
16 great interest in it, and we've asked to be kept
17 apprised of this effort and its progress, and the
18 DoD Demonstration Project in the National Capital
19 Region has been going on now for a few months.
20 So, we're eager to hear how it's going, and, Dr.
21 Kelley, I think you are our first speaker.

22 MAJ. GEN. KELLEY: All right. Mr.

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1 Wilson and I will be giving the presentation, and
2 what we'll do is I will start off giving some
3 introductory comments and overview. Mr. Wilson
4 will talk a little bit more about the specifics of
5 the program, and then I'll come back and do a
6 summary, and we'll be happy to take questions as
7 we go through.

8 Next slide, please. I think you're all
9 well aware and probably have had individual
10 briefings on all if not most of these different
11 commissions and task force that have been set up
12 over the last few years, some prior to the Walter
13 Reed incident, some after, but all have had
14 suggestions on how to prove the transition from
15 people who are injured or ill on active duty to
16 the VA system or to the VA system and back to
17 active duty, or to the civilian community. So
18 lot's of suggestions that have come up, some a
19 few, some large numbers of suggestions, and that
20 formed the basis of the next slide.

21 This has been taken very seriously by
22 the Department of Veterans Affairs and the

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1 Department of Defense, and we formed what we call
2 the Senior Oversight Committee which is chaired by
3 the Gordons, the Deputy Secretary of each
4 department, Gordon Mansfield and Gordon England.
5 So it's at the highest levels of the department
6 that the leadership is involving in resolving
7 these issues.

8 Now, they put those six and a few other
9 commissions together and came up with this
10 approach to dealing with it. There's an
11 overarching product, integrated product team, that
12 puts together the work of the functional area --
13 they call them LOAs -- Lines of Action. So the
14 disability system is the first line of action.
15 The others -- and we'll hear some -- you know,
16 it's almost time to go to sleep so we can all lay
17 on our left side.

18 The traumatic brain injury and
19 posttraumatic stress disorder; third is case
20 management; fourth is DoD-VA data sharing; fifth
21 is facilities; sixth, a clean sheet of paper which
22 is: How are we doing this transition process?

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1 How are we taking care of our people? What if we
Page 17

2 didn't have any anything that was in place right
3 now, and how would it look? And then seven is the
4 legislative and public affairs piece of this, and
5 then there's personnel pay and finance which is
6 the last of the action teams.

7 Now, there's names up there. Each of
8 these actions involves, or these line of action
9 groups is led by a senior executive service member
10 of the VA and DoD, so again, keeping it at a very
11 senior level. There's work groups that have the
12 right people working underneath that, but I want
13 to make sure that the senior leadership is
14 involved in working through these issues.

15 Next slide. So we're going to talk a
16 little bit more today on the LOA-1., which is the
17 disability evaluation system, and so there has
18 been a Council formed which we call the DAC. The
19 Disability Advisory Council, again senior
20 leadership chaired by the Under Secretary and
21 facing many of the issues that are dealing with
22 redesign. So we tested -- we've been involved with

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1 testing several different scenarios. There has
2 been several table-type exercises.

3 Before we did something, we have looked
4 at joint-duty rating boards. Much of the

5 problems as we were going through the disability
6 system that people were complaining about was the
7 length of time, the gap in service from the time
8 that someone was discharged from the military
9 until the time that the VA benefits started, and
10 then the whole ease of going through the whole
11 system. So those are the things that we were
12 looking at.

13 So we have a pilot project in place. We
14 would like to do this pilot, expand the pilot to
15 nationally, but we want to make sure we have the
16 right thing to expand before we start doing any of
17 the expansions. Too often we start programs that
18 may not be the best ones out there.

19 I think that it will be not a
20 okay-we'll-try-it in the National Capital Region
21 and then suddenly go everywhere, because the
22 National Capital Region has some unique

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1 characteristics in that there are medical centers
2 from both the VA and the Services in that area
3 that's different than Chicago where there's a
4 medical center from the VA but none from the
5 Services, or Rochester, Minnesota, where there
6 isn't a Service representative at all in that kind
7 of city.

8 Or it's small-town USA. So I think that
Page 19

9 it will expand as we're going along, but we're
10 pushing because the preliminary indications that
11 we're pleased with what's happening, not so much
12 that we're shortening the time frame completely,
13 but we are smoothing the process and eliminating
14 that gap between when you get paid by the military
15 and when VA benefits kick in.

16 Next slide. I'm going to turn it over
17 to Bill right now and let him talk a little bit
18 about the pilot.

19 MR. WILSON: Thank you, Dr. Kelley.
20 Just a little bit of background. I've been
21 involved with the DES pilots since the concept to
22 have a pilot came about, and I was the primary

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1 representative from VA during the tabletop
2 exercises where we looked at several of the
3 different factors of how do we build this to make
4 this work?

5 We were initially looking at things like
6 making it less complex, less adversarial. There
7 was some feelings by Service members that the
8 military examination at the military boards were
9 more adversarial towards them, and by bringing VA
10 into the mix, we had more of a neutral playing
11 field. We were looking at how to make the system

12 faster, more consistent, and to, as Dr. Kelley
13 said, get the Service member, now veteran, the
14 compensation that they're entitled to more
15 expeditiously.

16 Typically, what happens in the
17 traditional DES system, the MEDPED process, a
18 Service member is referred and goes through that
19 complete process which can take usually nine
20 months plus to go through, and then when they're
21 discharged from the Service, they file their VA
22 claim, and right now VA's averaging about 170-180

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24

1 days claims processing time. So we're looking at
2 about 450 days as an average from the time a
3 Service member was referred into the system until
4 they would receive their first VA payment.

5 So one of the main goals or
6 recommendations from all the commissions was to
7 shorten that time frame. You will see as we go
8 through some of the other slides here the way that
9 we looked at doing that was actually overlaying
10 the two processes, so that the VA doesn't wait
11 until that member is completely separated to begin
12 our process. At the same time we look at VA
13 working with DOD, kind of a hand-in-hand process
14 where we work together instead of waiting till one
15 does their business process completely, and then

16 we start into play.

17 The term "seamless transition" has ben
18 out there in the marketplace for quite a while,
19 and this added a new facet to seamless transition.
20 Seamless transition, you know, kind of had the
21 context of medical care of the severely injured
22 person as we do the hand-off to the polytrauma

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25

1 centers, back to maybe the military medical
2 center, then transition them to VA health care in
3 the community when they become a veteran. So
4 we're now adding into this mix of seamless
5 transition the award of VA benefits.

6 As part of that, and there's always a
7 continuing review process that VA does of what's
8 called the VASRD, the VA Schedule of Rating
9 Disabilities. This is a document under 38-CFR,
10 Code of Federal Regulations, that VA uses to
11 establish disability percentages for each
12 potential medical condition that might be
13 nonfitting, in the case for the Service member
14 being separated.

15 Next slide, please. When the pilot
16 started on November 26th of 2007, DOD and VA were
17 working together on this, but DOD had also engaged
18 the services of Booz-Allen-Hamilton, a private

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19 consulting firm, to provide project management,
20 project guidance assistance. Booz developed a
21 database, and what you're seeing on the slide here
22 and these numbers come out of the Booz database.

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26

1 There's two primary groups of people
2 from the military and from the VA that are the
3 outreach, the first person that that Service
4 member talks to. The first is the PEBLO, the
5 Physical Evaluation Board Liaison Officer, and
6 that's within DOD and each of the Services.
7 That's the person who walks that Service member
8 through the process of the Medical Evaluation
9 Board, the Physical Evaluation Board, and starts
10 them into the transition phase if they're going to
11 be separated.

12 That PEBLO has responsibility of making
13 sure that Service member gets to their different
14 appointments, different examinations, and compiles
15 a packet of administrative data that's required
16 by both the MEB and the PEB to make their
17 determinations.

18 The VA Military Services Coordinator is
19 kind of a counterpart to the PEBLO. They're VA
20 employees, they are assigned two of the military
21 treatment facilities around the country, and this
22 person has primarily had a role of being an

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27

1 outreach to make sure this, you know, initially
2 seriously wounded service member is aware of their
3 VA benefits, what we can do to assist them. If
4 there are certain benefits that that member can
5 obtain or use while they're still on active duty,
6 they assist that member in filing that claim for
7 the benefit.

8 When we added the DES pilot, we expanded
9 that job scope of the MSC where they're now
10 initially taking that claim for disability from
11 the service members. The way that the pilot's
12 constructed, when that service member is referred
13 into the DES, that starts the clock; that's Day
14 One and starts the referral phase, which is the
15 first set of blocks on the chart.

16 Let me explain the chart just a little
17 bit. The green was the target goal, yellow is the
18 mean, and blue the median. The green blocks were
19 the time frames that we established when we went
20 through the table-top exercises and designed how
21 this pilot was going to operate. This is what --
22 and this is a joint effort between VA and DOD --

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Page 24

1 how long we thought it would take for each one of
2 these different steps in the process to take
3 place.

4 And for the referral phase, we thought
5 we were looking at about five days. That referral
6 phase is the phase in which the member is referred
7 to the PEBLO. They start assembling the data that
8 they need, obtaining copies of the service medical
9 records, service treatment records that VA needs
10 for its business process, and makes the actual
11 referral to VA. What we're finding out is that it
12 is taking an average right now of about 10 to 13
13 days for this process to occur.

14 One of the reasons that we found this is
15 happening is when we designed at the tabletop,
16 when we designed the process, we were looking at
17 the target goals as being working days, but the
18 Booz-Allen database is only able to measure
19 calendar days. So we have a little bit of a
20 discrepancy: It was the way that the database was
21 built, so we're always going to be a little bit
22 off in some of these because we were anticipating

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1 worki ng days.

2 Now, if you refer a member on a Thursday
3 and you happen to have three or a four-day weekend
4 thrown in the mix, the referral phase is going to
5 exceed its time frame before that member can get
6 to the VA the following week.

7 The claim development phase is where the
8 Military Services Coordinator, the MSC, come into
9 play. They receive this referral from the service
10 member or from the Military Service. What that
11 referral does, we created a special playing form
12 for this process. For the top portion of the
13 claim form, it's filled out by DOD, and this
14 identifies the referring conditions, what makes
15 that service member unfit for service.

16 When we have our meeting with the
17 service member, we also give that service member
18 now the ability to claim additional disabilities
19 that they feel might be related to their military
20 service, but the Service might not consider
21 anything.

22 But VA, by law, is required to look at

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30

1 the whole person concept. We don't look at just
2 the unfitting conditions. And in our
3 claim-development phase, we also go through the
4 process of scheduling a medical examination, and

5 in the pilot one of the recommendations from all
6 of the commissions was to have a single source
7 examination or a packet of examinations that would
8 be used by both VA and DOD for the MEB process and
9 for disability compensation. That member doesn't
10 have to go through examinations while they're on
11 active duty and then separately go through a VA
12 compensation examination later. We're using the
13 same examination for both purposes.

14 The way that we work this out is, at
15 least in the National Capital Region, all of the
16 examinations are conducted at the VA Medical
17 Center in Washington. They are conducted in
18 accordance with the VA examination worksheets and
19 templates. When we went through the tabletop
20 exercise, we actually used real cases from the
21 year before, and we had the DOD physicians that
22 would sit on the MEBs and PEBs review our

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31

1 examinations to determine: Would that examination
2 tell them everything they need, to make that
3 determination at that point? And it was
4 universal s, yes, it would.

5 Once that claim development process is
6 completed, we move into the MEB evaluation phase
7 for the medical evaluation. That's the actual
8 examination itself. How long does it take from

9 the time we put that examination request in the
10 system until we get a completed examination report
11 back and deliver that to the PEBLOs. Our target
12 was 35 days; we're running about 41 to 44 days.

13 Some of the delay reasons we come to
14 that is time that it takes to get specialty
15 examinations. Just like within DOD, the
16 neuropsychiatric and the neurology examinations
17 are hard to come by, and those take time to get
18 scheduled and get that member in.

19 When you're looking at a resource-rich
20 area like the National Capital Region, and we're
21 exceeding our 35 days, one of the things that we
22 want to consider as we being to expand is what

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32

1 type of resources we're going to have available
2 for the specialty examination we're going to
3 require in these remote locations.

4 Once the medical evaluation is completed
5 it goes to the military treatment facility MEB
6 process, and they have a total of 35 days to run
7 through the MEB, and the total MEB process is 80
8 days, and again, we're still running slightly
9 outside that. But when we factor in the working
10 days versus calendar days, we feel like we're
11 still fairly well on target.

12 Since the pilot started -- DOD's data
13 was as of April 6th -- there had been 327 Service
14 Members referred into the pilot, about 17 a week.
15 There's 21, currently, that had progressed to the
16 PEB phase, and two currently in the transition
17 phase: They've been found unfit by the PEBLOs and
18 by the PEBs, they've signed their boards and
19 accepted that unfit finding, and they're in the
20 process of being separated from the Service. The
21 first member is actually separating the first week
22 of May.

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33

1 Now, from VA's perspective -- and this
2 is as of April 14th -- we've had 295 referrals
3 come through us, so you see a difference of 327
4 versus 295. The way I've kind of explained that
5 is like a big funnel: When the referral phase
6 starts and DOD starts putting people into the
7 system, that's when they're logged in a being
8 referred for the 327.

9 But it takes a few days for that PEBLO
10 to do their work and filter that process down
11 where they come through the bottom of the funnel
12 to VA. So that accounts for that difference right
13 here.

14 Another aspect of the pilot was that
15 there would be a single disability evaluation or

16 rating that would be done by VA that's binding on
17 both DOD and VA. One of the complaints that came
18 out from the service members and findings from the
19 Commission was some inconsistencies in how the
20 VA-scheduled rating disability was applied between
21 VA and DOD, and sometimes within the Services.
22 The Army might not apply it quite the same way as

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34

1 the Navy or the Air Force.

2 So to test this concept we have a single
3 rating, and to date we have completed 14 ratings
4 on people. The PEB has made it an initial finding
5 of Unfit and requested that rating and returned
6 that back to the PEBs. The MEBs have actually
7 found three service members fit and returned to
8 duty at that point, so they never progressed
9 through to the PEB phase.

10 The first member that's going to be
11 separating the first week of May will actually get
12 their first VA check July 1, 2008. One of the
13 agreements that we obtained from DOD in doing the
14 separation process was that the member would be
15 separated, typically, no later than the 28th day
16 of the month, which when then allow them to
17 receive their first VA payment in about six weeks
18 after that, which is the earlier date allowed by

19 law.

20 So instead of having to wait, eight to
21 nine months after separation, they're getting
22 their check the first day that they're allowed, by

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35

1 law, to get that payment check. The actual --
2 this first member was originally going to be
3 separated next week, however, due to excessive
4 leave they had to extend their separate a couple
5 of weeks to allow them to take up the excess leave
6 they couldn't sell back. Had that member
7 separated on the 28th of March as they were
8 intended, they would have received their first
9 payment check on June 1st. But by moving them out
10 to, I think May 6th is her separation date, she
11 will not get her first check until July 1st.

12 Next slide, please.

13 DR. POLAND: Can I just comment, because
14 there's a nuance there that I just caught from
15 General Kelley that might be important to the
16 Board if we go back one -- or at least I missed
17 it. Can we go back one slide?

18 So all during that time period they're
19 on Active Duty getting their pay, their benefits,
20 et cetera. So what's happened, then, if I
21 understand this, is we've gone from this
22 eight-month or so time from separation to first

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36

1 disability check, if you will, to six weeks. Just
2 to be sure everybody caught that, okay?

3 MR. WILSON: That is correct, sir, and
4 that is the intent of the pilot, to prove that we
5 candided [sic] it.

6 Yes, sir.

7 DR. LEDNAR: Wayne Lednar. While the
8 time to the first payment has been shortened
9 dramatically, during this time if they're on
10 active duty and this administrative process is
11 ongoing, is it fair to say that whatever is the
12 clinical service that the member needs, the
13 rehabilitation that they need, they're getting
14 this continuously throughout this entire time?

15 MAJ. GEN. KELLEY: Yes. Yes,
16 absolutely, and it could be done in either
17 facility. In other words, if DOD has that
18 clinical service that's needed, it could be done
19 in DOD, so right now I would say, for example,
20 with the empty patients, Walter Reed probably has
21 the leading program in the country for that. But
22 the VA has some of the best traumatic brain injury

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Page 32

1 programs, or blind treatment programs, in the
2 country, and so the patient would still be on
3 Active Duty but in a VA facility getting that
4 care.

5 Dr. Kaplan?

6 DR. KAPLAN: As I understand it, just to
7 be sure, this is from the pilot program that
8 you've described.

9 MR. WILSON: Yes, sir, this is only for
10 the pilot.

11 DR. KAPLAN: And this is the pilot
12 program that is just getting started under the
13 best of all possible circumstances, i.e., in the
14 Capitol Region with everybody attuned and so
15 forth? Maybe I'm jumping the gun, but are you
16 planning to talk to us about application of this
17 more widely? I'm concerned about things, for
18 example, 400 days that you mentioned earlier, if I
19 remember correctly.

20 I'm concerned about the fact that you
21 don't seem to have enough neurologists and
22 psychiatrists, so there's a hold-up at that

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1 situation, and that's under the best of all
Page 33

2 possible situations. I think the Board would be
3 interested in -- and, certainly, I would -- in
4 knowing how this is going to play out and what the
5 time limit is for that.

6 MR. WILSON: Okay, sir. The pilot was
7 initially conceived to last for one year. We are
8 -- and it kind of gets into my next slight right
9 now, so if there's no other questions on this
10 slide, we can go ahead and move forward.

11 DR. POLAND: Just go ahead through your
12 presentation and then we can come back to this.

13 MR. WILSON: Okay, so you'll see how
14 this kind of ties into the next couple of slides.
15 The pilot was initially conceived to run for one
16 year from November '07 through November '08. We
17 are currently in the process -- and I say "we"
18 meaning the leadership and the project management
19 teams from DOD, VA, and the Booz-Allen support
20 team -- of planning for expansion, the first
21 expansion of the pilot.

22 We had one series of meetings last

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39

1 month. Next week there will be another two-day
2 series and another at the end of May where,
3 hopefully, by the end of these three sessions the
4 leadership group will have a plan together that

5 will be presented to the SOC in June or July. The
6 SOC -- the Senior Oversight Committee -- will
7 actually make the determination of how and where
8 the pilot is expanded.

9 Now, one of the things I mentioned a
10 minute ago was that there was a perception of some
11 variance in how the rating schedule is applied.
12 What's actually going on this week back in Falls
13 Church is the VA training team that does the
14 training for rating specialists is conducting a
15 week-long session with physicians and PEB Board
16 presidents on how we apply the rating schedule.
17 And then it's kind of train the trainer concept,
18 and folks that come to our training here, we'll
19 expect them to go back to the five Service PEBs
20 and spread the wealth of information that they
21 have picked up.

22 Now, in NDAA 2008, there was a

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40

1 requirement in there where DOD now must comply
2 with the VA rating schedule.

3 So this, in cooperation between the two
4 agencies, which is why we came up with this
5 training plan.

6 The VA rating schedule has been the
7 standard for the Services prior to NDAA-08,
8 however the Services were allowed to create

9 certain variances of their own. NDAA-08 took that
10 out, so now they must apply full all the same way
11 that VA does, including binding court decisions
12 from the U.S. Court of Appeals for Veterans
13 Claims.

14 So we're in the process right now of
15 evaluating how we're doing, and like you said, so
16 we know we're in a very resource-rich environment
17 right now. Secretary Peake is very concerned
18 about too aggressive of an expansion of the pilot
19 because we don't know what we're going to have out
20 there. We don't want to just take and make a
21 process faster; we want to make the overall
22 process better and faster. We're not doing the

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41

1 Service member, soon to be Veteran of Service, if
2 we're only making it faster for them, but we're
3 not improving the whole concept.

4 So, as I say, we're currently working on
5 joint criteria. The initial scope of the pilot
6 was very aggressive. It was calling for the pilot
7 to expand every three months. After the first
8 three months, the National Capital, the initial
9 concept was that we would expand all military
10 treatment facilities across the country. The
11 second and third months we would expand to all

12 military treatment facilities worldwide, and the
13 fourth expansion would be to being reevaluation of
14 Service members separated under temporary
15 disability retirement lists for TDRL reviews.

16 And very early on, we realized that was
17 much too aggressive. We could not support that.
18 VA could not, DOD could not, so with the first
19 phase is actually at probably six to eight months
20 before we even being to expand.

21 The Services are looking at their
22 criteria, what they can support both from a

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42

1 logistical point of view, medical services point
2 of view, IT point of view, and personnel. And VA
3 is looking at this same process.

4 Some of the areas that we might want to
5 look at is what we call "medically underserved
6 areas." Someplace where it might take 100-150
7 miles to get to someone, get someone to an
8 examination where there is no DOD facility, there
9 is no VA facility that can support these specialty
10 examinations like you were talking about -- the
11 neurology, the psychiatry -- some military
12 treatment facilities are essentially now Super
13 Clinics, so they don't have a lot of these
14 resources and they outsource that to either the
15 Tri-Care Network or, in some cases, VA. And VA

16 has to outsource some of its treatment
17 requirements, depending on the location.

18 So we want to -- our goal for the
19 expansion would be to have a select number of
20 sites, maybe five or six sites, to expand that
21 would meet some of these medically underserved
22 criteria. We know what we can do in the big areas

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43

1 where we have a lot of resources like Washington,
2 D. C.

3 So let's get outside and see what's out
4 on the countryside. Next slide, please.

5 MAJ. GEN. KELLEY: If I could make some
6 comments here, and I'll catch them. I think this
7 kind of summarizes, but I think that you are
8 correct in your concern that this is just focused
9 on one area and has not expanded yet. But we want
10 to do it right.

11 We are doing some other things besides
12 this to take care of your concern about those
13 gaps, and so one of those things would be the Army
14 forming its DTUs, or warrior transit, WTUs,
15 Warrior Transition Units, and so these people have
16 a support system both for medical case management
17 and social case management, for lack of a better
18 term, to make sure that they're in for the right

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19 system so that they don't fall through the cracks,
20 get out as their husband through the whole
21 process, to make sure that they're taken care of
22 as they're going out.

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44

1 I would not say that we have the final
2 policy for case management, medical case
3 management or larger case management in place, but
4 all of the Services have expanded that case
5 management process on both fronts. So I don't
6 think we're seeing the issues of people falling
7 through. We are trying to pick some of those
8 things that are going on in the pilot and use them
9 as much as possible as we can.

10 DR. KAPLAN: In that regard -- Kaplan
11 -- in that regard, would you continue for a
12 second? Are we basically thinking about a backlog
13 of service people who are waiting to be processed
14 through this? And, if not, is the rate of
15 projected rate of the entry into the backlog or
16 into those that are going to need this kind of
17 service been taken into consideration?

18 MAJ. GEN. KELLEY: I don't have the
19 exact numbers, but backlog is an issue in terms of
20 how long it takes people to get into the system
21 and then come out the other side. As we see
22 today, and as you saw from the numbers that we

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45

1 presented, the numbers going in so far have been
2 much bigger than the numbers coming out.
3 Eventually, that should equalize so that you're
4 coming in -- because the numbers of accrual are
5 reasonably standard, you know, reasonably stable
6 now. About 17 a month are going into that.

7 So, eventually, that should be what's
8 coming out the other end of the process, but we're
9 not there, and we're trying to work that. That's
10 what these transition units are focused on. It
11 slips my mind what the name of -- the Marines have
12 a different one, which is the other big player in
13 that. Hmm?

14 SPEAKER: Wounded warrior regiments.

15 MAJ. GEN. KELLEY: Regiments. Wounded
16 warrior regiments, but same concept, you know, a
17 little bit different structure, but making sure
18 that the person gets taken care of through their
19 duty responsibilities, through their social,
20 through the, you know, job working, other things.

21 Now, we just had a very good report on
22 one of those places at Fort Drum where we sent

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Page 40

1 people, and Fort Drum and their community is
2 placing those people who are in those transition
3 units into the civilian community for internships.
4 So you want to be a car mechanic when you get out,
5 or let's put you into a garage and have you see
6 what that's like so you can start learning and at
7 least get a handle on it, and they've done that in
8 a number of different areas.

9 So we're trying to collect those lessons
10 learned and good ideas and share them across the
11 system. Some people do it better than others.

12 DR. POLAND: Roger has a comment, and
13 then Joe.

14 COL. GIBSON: I'm sure Dr. Kelley can
15 address this. When we start counting them,
16 there's some doctrinal differences between the
17 Services on how long they keep members in rehab
18 before they would start dealing with the Pueblo to
19 start through this process.

20 My question is, are we looking at those
21 differences, doctrinal differences at the OSD
22 level?

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1 MAJ. GEN. KELLEY: We are, and I think
Page 41

2 that that's why we don't have a finalized policy
3 yet, because there are some differences in how
4 people are handled and how long they want to keep
5 people.

6 I think some of the issues about the
7 housing for our veterans who are transitioning to
8 the civilian and the VA world had to do with the
9 fact that the senior leadership wanted to keep
10 these people on active duty until they were
11 processed by the VA so that they would get the
12 maximum amount of benefits and there wouldn't be
13 any gaps.

14 But when that happened, there wasn't a
15 housing plan to take care of this large number of
16 people, and so people made do and didn't make do
17 enough. So I think that led to part of the
18 problem of the senior leadership trying to keep
19 people on.

20 I think that it's amazing all the
21 Services are working to keep people on active duty
22 if they want to stay on active duty, and so, you

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48

1 know, to say that all blind veterans are going to
2 be retained on active duty would be an
3 exaggeration. But I know of one officer who's
4 blind who has been retained on active duty.

5 So, you know, a number of people who
6 have amputations, both upper and lower
7 extremities, have been retained on active duty,
8 and so that is part of the process of involving
9 the individual in the process, in the decision-
10 making process of how it's going to proceed
11 forward.

12 Could we go to the last slide, and let
13 me just kind of -- I think that we're trying to
14 get -- the lower part of the slide is kind of a
15 picture of where we're going.

16 I'm not going to spend a lot of time on
17 that, but that's how the pilot is going so that
18 you come out, the processing is done.

19 But kind of a summary is that DoD is not
20 going to be doing the ratings. The ratings will
21 be done by the VA. We, in DoD, in the old system
22 used to do the ratings, but only the ratings for a

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49

1 specific condition that was not fitting for duty.
2 And that has a considerably variability because
3 you can just think, if you are an infantry
4 soldier, you will have different physical demands
5 than if you are a senior officer who's doing much
6 of his work at a desk. And so when you come, are
7 you fit for duty, the fitness for duty
8 determination is based on the job that they're in

9 at that point in time.

10 Well, you can do a desk job, we will
11 retain you on active duty, you're in a desk job,
12 but you couldn't have the same standard for the
13 person who is an infantry soldier or marine taking
14 the hill because there's different demands. And
15 so it looked very different, and so not doing the
16 ratings, the DoD is doing the exams, but right now
17 we've contracted to the VA to do the exams. So
18 it's even more standardized.

19 But the rating comes from the VA, and
20 then if the person is found not fit for duty, that
21 becomes the rating that's used on the discharge.
22 And the claims would already be submitted so

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50

1 they're not doing that after they're discharged.
2 They are always submitted beforehand, and not a
3 second exam. And so trying to eliminate steps and
4 take care of, make sure we're not losing the
5 people, I think the biggest challenge has been and
6 still is for those transition units, is to monitor
7 the soldiers particularly in the Reserve and the
8 Guard who are back home for their
9 recovery/recuperation phase and how to make sure
10 that they don't get lost and that they're getting
11 the support that they need when they're not close

12 to any either VA or military facility.

13 DR. POLAND: Dr. Silva had a comment,
14 and then I'll -- we go down the line then.

15 DR. SILVA: Silva. Thank you for the
16 review. I think traction is occurring, it looks
17 like a lot of improvements; eliminating a
18 duplicate evaluation system would help.

19 On (off mike) that you talked about the
20 human factor when Colonel Gibson and I visit the
21 Intrepid Center, we have lunch with a couple of
22 amputees, and it was clear the military has a

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51

1 conscience there, and some of these people had no
2 otherwheres to go in their life. It takes a year
3 plus for some people, so you're always going to
4 balance that human factor, and somehow you work
5 through that.

6 One question is, what is the backlog, in
7 total? Is it a thousand? Five thousand?

8 MAJ. GEN. KELLEY: If I was testifying
9 before Congress, I would say: Let me take that
10 question for the record. I would have to get you
11 a breakdown. I don't -- off the top of my head.

12 DR. SILVA: Well, that is fair enough.
13 You don't want to go on record, it's an open
14 session, but that's a big hurdle, as you know.
15 Thank you.

16 MR. WILSON: Okay, if I could throw in
17 one little comment there, to give you an idea of
18 the scope of the pilot, when the pilot initiated
19 on November 26th in the National Capitol Region,
20 we took all new service members who were referred
21 for MEB at that point in time, not just the
22 severely wounded ill and injured but all service

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52

1 members. So we've actually seen that the
2 seriously wounded ill and injured component is
3 only about 15 to 20 percent of the total service
4 members referred through the DES process.

5 Historically, for the last two years,
6 the total number of service members who have gone
7 to PEB has been about 22 000. So you can kind of
8 do a little extrapolation if you wanted to come up
9 with some type of a backlog from that, but we
10 don't have an exact number of how many are out
11 there pending.

12 DR. POLAND: It gives you sort of a
13 magnitude of order, though.

14 DR. SILVA: Thank you.

15 COL. GIBSON: And again, I want to make
16 that comment about the differences. It depends on
17 where you start. There's a lot of folks that are
18 in rehab that haven't, because they're in rehab

19 who are still recovering, haven't started into the
20 system. We don't need to count those folks, and
21 some people are, and it makes a difference in the
22 total.

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53

1 MAJ. GEN. KELLEY: I would say in terms
2 of Roger's comment there that one of the things
3 that Group 6 of the Lollipop Chart, the Group 6 is
4 coming up with the definitions. And so we don't
5 have a standardized definition for all of these
6 conditions which is why it's hard to get some
7 data, and some of the data appears different
8 depending on the source.

9 DR. POLAND: Dr. Blazer, and then we'll
10 go around, okay?

11 DR. BLAZER: I know you're talking about
12 system here, but I'm also aware that the VA is
13 looking at its criteria for disability as well. I
14 think I've actually reviewed an ILM Report. I
15 don't know what the status of that is now, but I'm
16 wondering sort of if the criteria are
17 significantly changed for disability ratings, how
18 is that going to impact the system itself?

19 MR. WILSON: That would depend on how
20 that report comes out and whether the
21 recommendations from the report would be
22 incorporated or not. But, historically, from VA's

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54

1 perspective, if a service member has been granted
2 a disability compensation service connection for a
3 specific disability and a specific rate based upon
4 their condition at that time, and then there's a
5 change in the law that makes that criteria either
6 higher, more stringent to get a higher evaluation
7 or lower, that member, or veteran, who was
8 assigned that criteria prior to the change in the
9 law will not be penalized. We don't go backwards
10 and take that away from them.

11 So it would be on a point forward basis,
12 but it would depend on what comes out of those
13 commission -- or the Institute of Medicine
14 findings.

15 DR. BLAZER: I just wondered. So I
16 assume we're, at this point in time, there are no
17 immediate plans or no immediate things on the
18 horizon in terms of changing criteria. But my
19 sense was this could be quite major if it happens.

20 MAJ. GEN. KELLEY: Yes. I think there
21 is a process that is involved right now of
22 actively involving the TBI and PTSB to come up

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Page 48

1 with the criteria, because the criteria in the
2 VASRD are fairly old, and there's been much more
3 science since they were developed.

4 I would say that we just had burns
5 reviewed, and the DoD was much involved in that
6 process from early on in updating those. And so
7 -- and part of that had to do with looking at what
8 the injuries were and how they were inadequate to
9 try to fit burn injuries into what was in the
10 VASRD.

11 And so an approach, and so when either
12 DoD or VA identifies an area which seems to be
13 routinely having a difficulty or it's not current,
14 then there can be a rapid evaluation, rapid in
15 terms of government service rep that the
16 evaluation of that to make sure we get it right
17 and come out with new criteria.

18 But some of the criteria has not been
19 reviewed all the way back to World War II, and so
20 there is a process that's ongoing of: Let's review
21 all the criteria, which is going to take a much
22 longer period of time.

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1 DR. POLAND: If you follow onto that
Page 49

2 real quick, go ahead.

3 COL. GIBSON: Dr. Kelley, with respect
4 to the review, is it being approached from an
5 evidence-based standpoint. What I'm getting at is
6 a lot of the time with these ratings it doesn't
7 necessarily reflect the difference in income
8 associated with the disability compared with
9 somebody without but has some obligation or
10 quality of life issues as well in it. Can you
11 expand on how the review is being done?

12 MAJ. GEN. KELLEY: The review on the
13 VASRD is being done on clinical evidence-based
14 current science and practice, including both
15 diagnosis and treatment and expected outcomes.

16 The impact on lifestyle is probably not
17 specifically considered, but there are some
18 qualifiers that the VA can add on when there is a
19 major impact on the lifestyle.

20 MR. WILSON: Right, and that's referred
21 to a special monthly compensation. The other
22 thing that came out of the Dole-Shalala Report was

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57

1 for VA to pay a quality of life payment or loss of
2 quality of life payment. And this may refer back
3 to what you were asking about. VA has
4 commissioned IOM to do a study on the quality of

5 life payment, and we're supposed to get that
6 report back sometime August/September time frame.

7 COL. GIBSON: Thank you.

8 DR. POLAND: Dr. Kaplan?

9 DR. KAPLAN: One perhaps unfair
10 question, how long -- the longer these types of
11 things -- and you're to be commended for what's
12 been done -- but the longer they go on, the more
13 likely it seems to me they are at risk for them to
14 lose inertia, to lose momentum at that point.

15 And so if you had to gaze at the stars,
16 is this whole process -- "whole process" being an
17 unfair word -- is it going to take a couple of
18 years to finish, or is it -- where is the end?

19 MAJ. GEN. KELLEY: I think you're
20 absolutely correct in the concerns, and I think
21 that's the reason why between DoD and VA there is
22 such a high-level emphasis with an emphasis to

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58

1 have corrections in place for these findings
2 before the change in Administration, whoever that
3 may be.

4 As I look at things, I don't think, no
5 matter who wins in November and who the next
6 Administration is, I think that there will be
7 interest in these areas for at least the next
8 several years. And so the goal is to resolve as

9 much as possible before the change of
10 administrations, but I don't think there will be a
11 loss of interest, so I think that things that
12 cannot be resolved will have the emphasis to carry
13 on. But it's a very real concern approaching an
14 election.

15 MR. WILSON: And if I could add in one
16 comment on that as well, the Deputy Secretary of
17 VA has probably testified before Congress four to
18 five times since we've initiated a pilot on the
19 progress of the pilot, and we are constantly
20 receiving inquiries from General Accounting Office
21 on how the pilot was constructed, how it's
22 progressing. So there is quite a bit of political

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59

1 review coming down from the Hill as well as from
2 senior VA and DoD leadership. So this is very
3 high-profile project that, like Dr. Kelley said,
4 we don't see it dropping off the radar come next
5 year.

6 DR. POLAND: Who's next?
7 DR. PARKINSON: Parkinson. Again,
8 accommodations are for looking at the process and
9 the pilot trying to shorten it, but a couple of
10 questions and just either can respond to these.

11 First is, on the way out I know there's

12 many people are more aware of this major Class
13 Action Suit from two veterans' groups that are
14 around this issue that have just been filed and
15 are being heard. So any thoughts about how that
16 might play out in terms of either the visibility,
17 the pressure brought to bear on this pilot, any
18 which way that might inform the Board?

19 The second thing -- yes?

20 MAJ. GEN. KELLEY: You're talking just
21 about the mental health/suicide prevention thing?
22 Or --

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60

1 DR. PARKINSON: Again, the details I'm
2 not quite -- it was two major national veterans
3 groups that are suing the Department of Veterans
4 Affairs for backlog, essentially, and evaluations.
5 It's kind of is a backlog issue, I believe, and so
6 that's simmering along in the Judicial arm wall,
7 the Hill, and the Executive Branch works these
8 issues.

9 So any -- and it may not be politically
10 correct to say at this point -- but to think about
11 that, and it certainly is getting a lot of
12 prominence.

13 MR. WILSON: Actually, Mr. Tom Pamperin,
14 who is the Deputy Director of the VACNP Service,
15 who was supposed to be here briefing on this today

16 is in San Diego due to one of those logs in --

17 DR. PARKINSON: Okay.

18 MR. WILSON: -- you know, how that's
19 going to play out --

20 DR. PARKINSON: Who knows?

21 MR. WILSON: -- we really don't know.

22 But, the pilot we were instructed, both agencies

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61

1 by the President, to initiate the pilot in

2 November based upon existing law.

3 DR. PARKINSON: Right.

4 MR. WILSON: What could we do without
5 any legislative changes, and that's how the pilot
6 came to be in its current form right now. So
7 we're continuing to drive ahead. If other things
8 come out of this lawsuit or out of Congress, then
9 we'll have to adjust fire as necessary.

10 DR. PARKINSON: That was as much
11 information on it. I was not aware of it until I
12 read it in the paper yesterday enroute here.

13 The second thing is you made the comment
14 about resource intensity of this process. One
15 would think that if we're re-engineering a process
16 that has already got redundant pieces, as the
17 previous one had, that net, the resources should
18 be less. If you just stand back for a minute, and

19 that's what I'm curious about, your clean-sheet
20 exercise which is, I think, is an extraordinary
21 way to have it. In other words, you've got
22 somebody they've got a medical problem and need to

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62

1 be looked at, and right now under the revised
2 process it's taking three months, medium, which
3 means there's another 50 percent that are more
4 than three months out to whatever.

5 So the question I've got is, either in
6 the clean-sheet piece or in this piece, are we
7 looking at automation such that I can look up the
8 status of my case pretty much the way I look up a
9 UPS package, you know, on line as to see where
10 it's at? How does this interface or interdigitate
11 at all? I see foresee us with the bundles of
12 paper records that are moving across town from
13 Bethesda Naval over to the VA Medical Center at a
14 time and an era when everybody sang, you know, is
15 there an automation component to this with a
16 transparency and visibility component that the
17 veteran, no matter where they're living, can go on
18 line and see where my status is?

19 Is there at least somewhere in here an
20 Opt-In opportunity? If I'm an amputee, and it's
21 pretty obvious I'm an above the knee or below the
22 knee, can I just say, "I'll just take this and

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63

1 move on, thank you," without going through this
2 process, and not realize that may not be in the
3 statute now?

4 But I'm concerned, for all the reasons
5 we just said, is 90 days is a, let's say for the
6 argument, a best case scenario in for the majority
7 of people going through this process when you've
8 got three academic medical centers and the VA
9 headquarters that I'm not real optimistic, going
10 forward, unless we bring automation, new ways of
11 opting out or opting in, that we can reduce that
12 cycle time.

13 MAJ. GEN. KELLEY: Let me start with
14 some of those and Bill can help out. But the
15 issue first of opting out and opting in, that
16 option is given to the soldier earlier, when they
17 are beginning their recovery process. You don't
18 want to do it too early, you want them to have
19 some mental health stability before -- you know,
20 once they've dealt with their injury, do you want
21 to try -- you know, how, if your level is that you
22 don't want to go through the rehab, that's okay.

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Page 56

1 We try to make sure the people understand the
2 advantages of doing that, that's okay.

3 And they enter into the system sooner.
4 Whereas if the person says, "I'm injured and I
5 want to go back to active duty," they will go much
6 further through the rehab process before any kind
7 of decision is made to enter them into the
8 disability system, because that's their -- the law
9 is that anyone who goes in has to go through this
10 process.

11 So you can't opt out of the whole
12 process, but it's when you can enter the process.

13 The electronic records, it's an
14 interesting issue. We have done, I think, very
15 well in terms of making the clinical treatment
16 information available from DoD facilities to the
17 Veterans Administration. We have not done as good
18 a job as making sure all of the VA or the DoD
19 providers realize that we have bi-directional
20 information exchange, and they can get that
21 information.

22 So if you're working in the National

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1 Capital Region, you probably know that, because
Page 57

2 it's a big thing. If you're working out in the
3 hinterlands, you may not realize that you have
4 access to quite a bit of the clinical data -- not
5 all, but quite a bit of clinical data and how to
6 do it. So there's an education piece in there.

7 We have done less well but are now
8 working on the process for the disability
9 evaluation which is separate from the clinical
10 treatment. So clinical treatment which requires
11 rapid exchange of information, we're taking --
12 we're doing a good job. The disability system
13 which by law is a paper system, and the VA needs
14 to have the record of -- yeah, the medical -- the
15 record that's the official record to review, that
16 has led to some problems because we in the DoD do
17 not have a completely electronic record; we have a
18 mixed record as we're getting there.

19 And so making sure that all of the
20 inpatient care is printed out, that, you know, the
21 other thing -- and it all gets to the right
22 benefits advisor who's reviewing it -- could cover

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66

1 the whole career and the whole person leads to
2 some challenges which we are now addressing, and
3 we're behind the clinical piece on that.

4 And then your other question was on

5 resources, and if we're doing something faster,
6 shouldn't we free up resources? And the answer
7 is, yes, but you don't see that in this situation
8 because we, the resources that were applied to
9 this were based upon a pre-2001 level of
10 processing which was several hundred instead of
11 several thousand cases a year. So you had such a
12 big bowl that's going through you don't see any
13 apparent savings, even though you streamlined the
14 process because the volume has increased so much.

15 DR. POLAND: We have about 10 minutes
16 left for this discussion, so keep the questions
17 focused and we'll get around all the way.

18 DR. OXMAN: Oxman on the Board. Dr.
19 Kelley, two questions: First of all you made the
20 point that there's a lot of variability introduced
21 by the fact that if you're a commander on the
22 desk, you can return to duty, and if you're the

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67

1 same person with the same wounds in the field, you
2 can't.

3 Is there also, when you do that is a lot
4 of person-to-person variability on both sides the
5 patient -- is there a process going to, to codify
6 that as much as possible?

7 MAJ. GEN. KELLEY: The process to codify
8 that involves the commander's input. The

9 commander of the individual says, you know, I've
10 seen this person and they can or cannot do their
11 job. And so that should take into account the
12 individual variations because you have two people,
13 and one person is motivated and one isn't. And so
14 that goes under the commander input and analysis.

15 Is that perfect? I don't think so, but
16 we'll have something to -- yeah, that's kind of
17 the model right now.

18 DR. OXMAN: The other question is, I can
19 see that in the capital area if you need a
20 specialist to complete the process, they're
21 available. And yet in Small Town USA, they may be
22 totally unavailable, and the question is, is there

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68

1 some new innovative way that you're thinking about
2 providing that, even on itinerant justice?

3 MAJ. GEN. KELLEY: Yes. And I would say
4 that again both the VA and the DoD have altered
5 the funding for transporting people to get care.
6 So they've expanded the amounts, and if you have
7 to transport someone, whether it's yourself or
8 someone else, you know, you will be paid for that
9 to get to those consults that need to be done.

10 How we do it, you know, we'd like to
11 expand capability closer to where people are.

12 That isn't always as easy to do, especially with
13 looming national shortages in a number of
14 specialties.

15 DR. OXMAN: Thank you very much.

16 DR. SHAMOO: Adi I Shamoo.

17 MAJ. GEN. KELLEY: Yes.

18 DR. SHAMOO: One of the things I have
19 not heard yet, but maybe a little bit of it, what
20 can't we have a provisional evaluation by single
21 internists as to the disability? Half-hour
22 examination even. Common sense will tell you that

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69

1 in most of these cases what the disability is.

2 Let's assume they are off by 50 percent,
3 that's fine. This gives the system an incentive
4 to do a completed evaluation later on. This way
5 the veterans gets paycheck Day One like we heard
6 that in the campaign lately, Day One.

7 I mean why can't we do that? I don't
8 see -- is there a legislative prohibition of that?

9 MR. WILSON: It would take legislative
10 change to completely override the VA disability
11 rating.

12 DR. SHAMOO: But this is an evaluation
13 of the disability, just call it Step 1 and Step 2.
14 Or provisional and final within the existing
15 legislation. I bet you the Congress will not

16 object in this day and age under the atmosphere
17 towards our veterans.

18 MAJ. GEN. KELLEY: Let me make a comment
19 on that and go back, and I think I'll pick up some
20 earlier comments. In terms of if you would like
21 to be discharged, you'd have to go through the
22 military part, but you would not have to wait for

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70

1 the VA to do a determination before you could be
2 discharged, if that's what you wanted. So it's a
3 choice.

4 And so if you would choose to wait for
5 VA disability benefits, that's okay. You know: I
6 have been injured, I want to get out and get on
7 with my life. I don't want to stay around through
8 the process. You could do that.

9 The VA will back-pay all of those missed
10 payments between the time they make the
11 determination and the time when you were separated
12 when the determination should start. So that is
13 an option that is available to individuals.

14 The issue of if you're keeping the
15 people on active duty, they are getting a maximum
16 amount of benefits because the active-duty
17 benefits are larger than the VA benefits. And so
18 that's one of the reasons why you want to keep

19 people on the active --
20 DR. SHAMOO: But how about afterward,
21 the one who opted to become a veteran? Why can't
22 he have Day One, a provisional evaluation by an

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71

1 internist and then take six months for the
2 permanent evaluation?
3 MAJ. GEN. KELLEY: Well, again, as Mr.
4 Wilson said, the requirement for the VA to do
5 their determination involves the legal
6 requirement, is a whole person, whole life
7 evaluation.
8 DR. SHAMOO: I don't know what the
9 legislation -- does it say evaluation by a
10 sub-specialty neurologist or endocrinologist? I
11 mean does it go -- I have a hard time believing
12 legislations are that detailed.
13 MR. WILSON: It doesn't break it down as
14 to who has to do the evaluation. What happens,
15 the physician does not determine the level of
16 disability for VA compensation. That is done by a
17 VA rating specialist which is a nonphysician
18 reviewing the medical evidence of treatment in
19 service and the VA examination findings.
20 So, I mean there are two provisions
21 within the VA rating schedule for temporary
22 evaluations, and that's for the very seriously

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72

1 wounded that are being separated that -- they're
2 called prestabilization rating, which is -- that
3 person would not be able to be examined
4 immediately due to their physical condition;
5 however, they have to be examined within six
6 months or within a year after, and they're paid
7 this amount in the interim. But that's only for
8 the very severely wounded, which is a small
9 percentage of the personnel being separated from
10 the Service due to physical disability.

11 DR. POLAND: Okay, let's Russ, and then
12 -- we're making our way there, Bill.

13 DR. LUEPKER: Just a quick question.
14 First I want to say I'm very impressed. Six, nine
15 months ago when we first heard about this, it was
16 a devastating problem, I think, and, obviously,
17 you've been working to fix it.

18 The question that's a bit of confusion
19 to me, you talk about people who come in later to
20 be evaluated by the system. What percentage of
21 people are returning veterans from the -- not
22 veterans, active duty -- from the Middle East

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Page 64

1 conflicts as opposed to those who, you know, come
2 in later? What percentage are kind of fresh, in a
3 manner of speaking?

4 MR. WILSON: What per- -- that's kind of
5 a hard question to address here. Are you talking
6 about just from the injured coming back from the
7 theaters that are going to be separated, or from
8 the overall military population?

9 DR. LUEPKER: Yes, I'm talking about
10 what percentage are the people just coming back as
11 opposed to the overall population that needed
12 evaluation?

13 MAJ. GEN. KELLEY: I would say the
14 general figures without specifics, but looking at
15 the numbers, the numbers of people who have been
16 ill and injured baseline before 2001 haven't
17 changed significantly, and it's about doubled the
18 number. So it's about half of the people that
19 have gone through the system. And that's broad
20 generalization, but it's about half are new from
21 the current conflict on top of a similar baseline.

22 DR. HALPERIN: Yeah, this is an arcane

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1 system, if you will, so I'm going to launch right
Page 65

2 into the potential for major embarrassment, but
3 you'll bear with me. So we have a person who's
4 been in for 21 years and is 50 percent disabled,
5 all right? They would retire at about 50 percent
6 of their base pay. Bear through the examples and
7 then you'll critique it, okay?

8 So if they're in for 20 years, that's 20
9 years, that's 2-1/2 percent, that's 50 percent of
10 their base pay. If they're 50 percent disabled,
11 that means half of 50 percent, or 25 percent of
12 their base pay would then become disability pay,
13 meaning only that the Federal Government wouldn't
14 tax it. They don't get any additional money, they
15 just don't have to pay federal tax on it. It's
16 something.

17 Okay, the person sitting next to them
18 has been in for two years, all right? They get 50
19 percent disabled, two years times 2.5 percent per
20 year is five percent of their base pay. Five
21 percent of their base pay. If they get no
22 disability, they would get nothing, but because

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75

1 they're disabled they get 50 percent of five
2 percent of their base pay, and we call that
3 disability.

4 Now, of course, there's also medical

5 care from the VA, et cetera, thrown into the
6 package, but it seems to me that, you know, on the
7 one hand while there are major improvements in the
8 process have been made, it gets one faster to the
9 resolution, and the resolution is it shouldn't be
10 a mystery why somebody, let's say, who has 15
11 years in would rather stay on active duty rather
12 than collect disability, because it's a major pay
13 cut, and they're disabled. They can't go out in
14 the economy and get a job.

15 For the person who's been in for two
16 years, it's a disaster. I mean they get a trivial
17 amount of money, although they get medical care,
18 and they're disabled. They can't get a job. So
19 it seems to me we've improved the process to
20 getting an end point that isn't fair to the
21 veteran.

22 MR. JAFFRIN: The ones that get hurt the

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76

1 most -- John Jaffrin from MRNC. The ones that get
2 hurt the most are actually the ones in the
3 10-to-15-year period. They're, because of the
4 minimum payments and things like that. The ones
5 that are just in a short amount and then get
6 disabled, there's a minimum payment that they get.

7 It doesn't work out quite the way --
8 quite the way you described. It's not a

9 two-and-a-half times two years. But the ones that
10 do get hurt, it's actually a 10-to-15-year, those
11 veterans are the ones who are really unfairly
12 treated by the system.

13 MAJ. GEN. KELLEY: But going back, I
14 think that the issue, the veterans' pay for
15 disability is based on average salary. That's not
16 your average salary, that's average salary of
17 disabilities, okay.

18 The vast majority of those are based on
19 young people are lower enlisted ranks, and so they
20 have a very low salary. So a physician, if they
21 were injured and could not produce -- could not
22 work as a physician, would get the disability

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77

1 rating based on the average, which would be \$2,500
2 a month, which is probably significantly different
3 than they could make working as a physician -- a
4 pilot, you know, a skilled professional.

5 And so there is a different -- and that
6 is a completely different set of laws of how that
7 is established and how they determine the amounts
8 of compensation based on average disability. And
9 it has been different some in the past, but that's
10 the longest time period it's been the average of
11 the compensation.

12 So you're absolutely correct that it is
13 a major issue that people are not being
14 compensated, but the vast majority of people,
15 again -- and it's not based on future earnings.
16 Again, by law, it's not based on future earnings
17 potential; it's based on the earnings at the time
18 that they were injured.

19 MR. WILSON: And to carry that one step
20 farther, that's one thing that Line of Action 8,
21 the Pay and Benefits Working Group, is looking
22 into is different means of additional compensation

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78

1 for the wounded, ill, and injured service member
2 that's separated due to physical disability.

3 And there will be potentially new things
4 that come out of that legislative recommendations.
5 But it's strictly up to Congress what they decide
6 to create as law that, then, both agencies have to
7 live with.

8 DR. LUEPKER: Just so we have some range
9 finding here, could you tell us what a, you know,
10 a 22-year-old 50 percent disabled would get in the
11 mail every month?

12 MR. WILSON: From the VA perspective,
13 and VA disability compensation is totally
14 different and separate from what the Services
15 would pay, because the Services would pay either

16 severance pay or retirement pay based upon what
17 they were separated for. The service member might
18 have combat-related specialty compensation for
19 certain injuries, that's all separate from VA.
20 And I don't have the pay charts in front of me
21 but, basically, a 50 percent disability for a
22 single veteran with no dependents would run about

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79

1 \$1,000 a month. That's just ballpark, and that's
2 tax-free income.

3 DR. BROWN: Mark Brown from VA. I think
4 an important point that has to come out here is
5 that the VA disability compensation payments, as
6 bill pensioner, are different than the way DoD
7 does it. We don't prorate it based on that amount
8 of time that the person was in service.

9 If you have an other than dishonorable
10 discharge, and you have a 50 percent disability,
11 that's a fixed amount of money whether you were in
12 for two years or whether you were in for 20 years.
13 It's a fixed amount of money for that disability.

14 DR. POLAND: But layered on top of what
15 we just heard?

16 DR. BROWN: That I'm not sure. There's
17 this issue of getting co-payment from both DoD and
18 VA?

19 MR. WILSON: Yes, there are certain
20 times what's called concurrent receipt. If a
21 service member retires with 20 or more years of
22 active service, they receive whatever their

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80

1 retirement benefits will be. Then if they come to
2 VA and VA rates them at 50 percent or more
3 disabled, they are eligible to receive both their
4 military retirement and their VA disability. If
5 they're less than 50 percent, then they can apply
6 whatever the VA percentage is and get a certain
7 amount of their military retirement tax free.

8 But in order to receive the concurrent
9 receipt, they have to have 20 years or more, or
10 there was a change under NBAA-08 that if they are
11 military or medically retired due to a combat
12 injury and they don't have that 20 years, they can
13 still receive concurrent receipt as long as VA
14 rates them 50 percent or more. But that's only
15 for the combat injured for the current conflicts.

16 MR. JAFFRIN: And the confusion arises
17 -- John Jaffrin again -- the VA and DoD currently
18 use different interpretations of the schedule. So
19 you can get one percent when you're on your
20 military retirement and a separate percent from
21 the VA at the same time. So you can get 30
22 percent from a military disability evaluation and

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81

1 then 60 percent from the VA at the same time. It
2 is -- it's part of the issue that General Kelley
3 was looking into.

4 MAJ. GEN. KELLEY: If I could address
5 that, that is historically what has happened.
6 That will not happen under the new procedures
7 because the VA is doing the disability ratings,
8 and I was going to say something else.

9 MR. WILSON: Well, while you're
10 thinking, there still will be times under, for
11 instance, in the pilot where you will have two
12 disability evaluations, and VA is doing the
13 rating, because when we provide our rating to the
14 PEB, we have to first break out and give them one
15 rating on the medically unfitting conditions what
16 will be the determination for the character of
17 separation, be it severance pay, temporary
18 retirement or permanent retirement, and then we
19 give them an overall combined for all disabilities
20 because some of the disabilities that we look at
21 from a VA perspective may not necessarily be
22 medically unfitting. Or what might be medically

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Page 72

1 unfitting for one Service is not medically
2 unfitting to another Service.

3 DR. POLAND: Let's leave that aspect of
4 it, not because it isn't important, and Bill's
5 done a favor for the committee by point that out,
6 but we don't have that granular of information in
7 front of us, nor is that piece of it under our
8 sphere of influence. It's something that the
9 Board could comment on. It would seem that it
10 should be fixed to, you know, some level above the
11 poverty level, although to some degree the system
12 you're talking about, it's true in my own
13 institution. You get a severe disability as of
14 one or two-year employee, it's a different level
15 than a 20-year employee and very different pay.

16 So it's actually consistent with the
17 civilian sector with the difference being the
18 direct pay, not the benefit packages that surround
19 it. The direct pay might tend to be lower in DoD.

20 So let's leave that piece of it, if we
21 could, for now and then move on. Roger, you --

22 MAJ. GEN. KELLEY: Let me just finish my

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1 one comment.

2 DR. POLAND: Oh, yes. Do you remember
3 --

4 MAJ. GEN. KELLEY: Everyone who came out
5 with less than 30 percent disability and 30
6 percent disability had some keys in terms of the
7 VA disability system, but anyone that the Air
8 Force rated less than 30 percent, or Air Force,
9 Army, Navy, Coast Guard, will be -- is being
10 reviewed in the mental health arena because that's
11 where the posttraumatic stress, and there's a lot
12 of things. And so that is being reviewed to see
13 if those people should actually be rated at a
14 different rate based on a find in the VA
15 standards.

16 Difficult question because some of those
17 have fluctuating diseases. You have posttraumatic
18 stress, and the symptoms you're having, you may
19 have a lot of symptoms one time, and, you know, if
20 you came in for your rating and you didn't have
21 symptoms, there are some other issues there.

22 DR. POLAND: Roger?

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84

1 COL. GIBSON: My question goes -- and I
2 think the answer to both of these things is very
3 simple: Yes. But I just, for the record and to
4 look for the next step, as you're going through

5 the evaluation process of the pilot, it seems as
6 though there's a couple of things:

7 First of all, I believe that the, if a
8 -- correct me if I'm wrong -- that the Pueblos are
9 absolutely critical at the entry point that
10 they're properly trained, that we're putting the
11 effort towards curricula development, et cetera.

12 So the question is, are we doing that?
13 The second thing has to do with, we've already
14 identified that certain conditions requiring
15 certain specialty care are just going to take
16 longer, are you thinking about establishing
17 benchmarks so that we can measure that across the
18 system by category of injury for the future?

19 MR. WILSON: I'll give you a 50 percent
20 yes and a no. Yes, the Pueblo and the MFC boat
21 are very key critical contact points for the
22 service member and in the process.

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85

1 The contractor of the DoD is our
2 Booz-Allen, developed a training curriculum at the
3 start of the pilot for the Pueblos and the MFCs,
4 and that's being refined. You know, whether and
5 how that would be developed on a DoD level as far
6 as initial entry training for the different MOSs,
7 I really don't know about that.

8 Now, VA in March, we had a week long
Page 75

9 training seminar in St. Louis for the military
10 services coordinators. And the MFCs do a lot
11 besides dealing with the -- this is something new
12 coming into their arena -- and I spent all day on
13 Wednesday of that training seminar briefing them
14 and doing some training on this. And, in fact,
15 when I leave here today, I'm going over to the
16 Seattle regional office and spend the afternoon
17 with them, bringing them up to speed because
18 Seattle is going to be one of our disability
19 rating sites for DES.

20 So VA is aggressively tackling the
21 training aspect, and we have the training plans
22 that Booz-Allen is developing for both the MFCs,

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86

1 Pueblos, and actually for the Federal Recovery
2 Care Coordinators. But I can't speak for how
3 DoD's doing any internal training on their own.

4 As far as measuring any benchmarks for
5 particular diseases and the evaluation times and
6 such, the database that was developed for the
7 tracking and monitoring of this has, I think, 48
8 different metrics that it's measuring, but it does
9 not identify by specific disease process or
10 injury.

11 So that capability is not there right

12 now.

13 DR. POLAND: Okay, I want to --

14 MR. WILSON: I can tell you -- again, I
15 can tell you this, though, sir, that every time
16 one of the -- from my little chart I have -- every
17 time that one of our cases falls outside of that
18 estimated guidelines, both from BHA, from BBA's
19 project management and DoD staff, we get a call
20 from the Booz-Allen team because we have to
21 justify why we exceeded that projected goal, and
22 that has to be reported to the OIPT on a weekly

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87

1 basis.

2 So it's not officially tracked, but --

3 DR. POLAND: Let's move on. I want to
4 just summarize by saying that for the things that
5 were in your sphere of influence and under your
6 charge, I just want to echo Dr. Luepker's
7 comments. It's not often that the Board in a
8 six-month cycle sees this level of progress. And
9 I would characterize what you've done as efficient
10 responsive to a variety of expressed needs. And
11 what I particularly like in the wiring diagram
12 there is the accountability at a very senior level
13 for making sure that this continues to run well.

14 So I'm very pleased with that, and the
15 observation that you've moved from a serial to a

16 parallel process, which again I think brings a lot
17 of efficiencies into it. I think the Board can
18 comment on the financial outcome issue that will
19 go to a different group, and I wanted to
20 reiterate, I think, a major job now is going to be
21 this generalize- ability to, outside the national
22 capital area, and the challenges that will be, I'm

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88

1 sure, that will come up in terms of expansion,
2 particularly as, General Kelley pointed out, to
3 the Reserve and Guard components.
4 A couple of things that I want to leave
5 with. Any barriers or challenges or issues that
6 the Board can help with, we want to be supporters
7 of this initiative, and help to move this through.
8 This is not going to go away. We heard about it
9 in a couple of class action lawsuits. I don't
10 know if any of you saw it on ABC or 60 Minutes,
11 there was a kind of an expose type of thing of a
12 Marine Corps corporal who had gotten a head
13 injury, lost his spleen, et cetera, and he's got a
14 10 percent disability rating.
15 His mother's actually written me, and
16 I'll take it up with somebody later to see where
17 we could be helpful. But anything you can see
18 that the Board would be helpful in your mission

19 here.

20 MAJ. GEN. KELLEY: I think that the idea
21 that of encouraging the participation of more
22 people, I think that as we expand this, it's the

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89

1 medical specialties that we need to have access to
2 out in the communities where people are living.
3 And so -- I mean that's the kind of information,
4 you know, the more people that we could have
5 participate in our networks, in our programs, the
6 faster we can get those evaluations when they're
7 away from our own medical centers.

8 DR. POLAND: It makes sense.

9 MR. WILSON: Right. And, you know, the
10 other key issue -- and the gentleman over here
11 brought it up earlier -- was the IT, the interface
12 issues, line of action for anything that can be
13 done that can work within both current DoD
14 systems, VHA, and VBA systems, because even though
15 it's one VA, there's a lot of VHA systems that
16 don't interface with VBA, Veterans Benefits
17 Administration. Where we can eliminate the
18 duplicity, where we're having to make duplicates,
19 triplicates of everything to live in this paper
20 environment, you know, we are working with some
21 folks on Dr. Kelley's staff of some potential IT
22 shortcuts to expedite that process. But IT is a

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90

1 bit key component to this.

2 DR. POLAND: Well, again thank you, and
3 I think with the concurrence of the Board, it may
4 be something where it's worthwhile for us to send
5 a memo back just acknowledging the progress and
6 advocating for the two or three things now that
7 you've mentioned.

8 Finally, I think it might be appropriate
9 because of the time line that you indicated on
10 that pilot for us to hear back from you at our --
11 your pilot and implementation of some of these
12 things is in the August time frame. It might be
13 worthwhile for us to hear back at next year's
14 meeting, either the September or April meeting,
15 just so that we keep our fingers on the pulse
16 here.

17 So does the Board agree with sending a
18 memo, and -- okay. All right, thank you very
19 much. I appreciate the incredible progress that
20 was evident in this briefing.

21 (Applause)

22 DR. POLAND: We're going to move now --

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Page 80

1 what did I do with my sheet -- to the next item on
2 the agenda, which is the TBI Family Caregivers
3 Panel update. Lt. Colonel Michael Jaffee, who's
4 Director of the Defense Veterans Brain Injury
5 Center will give an update with regard to the TBI
6 Family Caregivers Panel. As the members recall,
7 this was a Congressionally- directed panel
8 operating as a DHB subcommittee, and so the DVBI C
9 is providing the day-to-day support for the panel.
10 In addition to providing the Board with periodic
11 updates, the panel will also present their
12 recommendations for a curriculum to the Board for
13 our deliberation when those are completed. So,
14 Colonel Jaffee? That's under Tab in your briefing
15 notebooks. Colonel Jaffee, you can go to the
16 podium, if you'd like. It's up to you.

17 COL. JAFFEE: In the interest of time, I
18 think I'll do it this way I do prefer to sitting,
19 but thank you for that introduction, and thank you
20 for having me here today. I'm going to kind of
21 give you a little bit of background on what I
22 think is kind of a slightly unusual panel in that

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1 it sort has a very much mission for deliverable
Page 81

2 and is somewhat time-focused as to when it will
3 stand down. So if we can move on.

4 All right, so, hopefully, if we can just
5 quickly review the creation of the TBI Family
6 Caregiver Panel again, kind of an unusual genesis
7 of this, review the purpose of how it's kind of how
8 they're defining themselves, describe the needs of
9 the TBI Family Caregivers, as well as summarizing
10 the highlights of the first panel meeting and kind
11 of review the ongoing process for curriculum
12 development.

13 So, actually, this panel came out of a
14 very specific verbiage from the 2007 National
15 Defense Authorizations Act, and it was actually
16 fairly prescriptive.

17 We heard some comments in the last
18 discussion about whether the legislation would be
19 significantly prescriptive, and this particular
20 one was down to the types of people that had to be
21 on this panel. So it was mandated to have 15
22 members with this current mission.

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93

1 Next slide. And the law was actually
2 pretty specific. It was specifying the wide
3 variety of people that had to participate on this
4 panel ranging from medical professionals,

5 including mental health professionals to actually
6 family caregivers and representatives of these
7 caregivers as well as the family advocacy
8 associations, DoD, and VA health and medical
9 personnel with the expertise in TBI in addition to
10 civilian personnel experts in development and
11 training curricula itselfs, or to educational
12 consultants and experts, as well as having actual
13 family members, the members of the Armed Forces
14 with TBI to be full participating members of this
15 panel.

16 So a pretty board-ranging prescription,
17 if you will, for putting a panel together like
18 that. So the, based on the prescriptions laid out
19 in the law of how these people had to be
20 appointed, they went through the typical DHB
21 appointment process with the whole flow eventually
22 going through the White House, and the final

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94

1 appointments were issued on 6 March 2008.

2 And so far, just for some support,
3 there's a project coordinator and project
4 assistant who are pretty much dedicated full time
5 to this initiative.

6 Next. And so some of the aspects where
7 DCO and DVVIC have a role is that the, initially
8 this mission went to USE/USE, and USE/USE kind of

9 had this mandate for the better part of a year,
10 and then they sort of decided that it might --
11 that they invited DVVIC to kind of relieve them of
12 that obligation, and that's when DVVIC took over
13 the support mechanism and then, subsequently,
14 we're going to hear about the Center of Excellence
15 with that ongoing coordination.

16 And so what we're trying to do is help
17 coordinate this panel to develop the curriculum
18 according to the Congressional mandate, help
19 facilitate the content accuracy going through an
20 evidence-based literature review, and also help
21 facilitate the implementation evaluation ongoing
22 efforts for family caregiver education.

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95

1 Next. So the tasks of the panel were to
2 review the literature and develop an evidence-based
3 for the actual curricula itself, develop
4 consistent curricula for TBI caregiver education,
5 recommend the mechanisms for the dissemination of
6 this curriculum through the DoD and the Department
7 of Veterans Affairs, and for that we do anticipate
8 working very closely with the Center of
9 Excellence, with the national outreach that that
10 helps provide.

11 Next, the panel selection. The panel

12 nominees were selected. Their contacts through
13 their long years in the field were kind of used to
14 use solicit recommendations as well as following
15 the guidelines that were provided by the law that
16 we sort of reviewed. A slate of panel nominees
17 was prepared. It was vetted through the
18 appropriate divisions of the Department of
19 Defense, including some ex-officio members,
20 expert consultants, and contingency members added
21 to the mandated slate.

22 Next. The panel nominee was finally

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96

1 forwarded for review at the end of October, and
2 again the following through all the process and
3 the vetting, the final approvals and appointments
4 came on 6 March. This kind of gives you a break
5 on it. It actually indicates that if you look at
6 the geographic distribution of the members on this
7 panel, the vast majority actually are from up and
8 down the East Coast.

9 We do actually have a member not too far
10 from here who's based at Madigan. Dr. Fred Flynn,
11 to add a little bit of geographic diversity, but
12 what this does is, on this map with the different
13 colors, it kind of shows the current system that
14 the DVBC and DCOE have with regard to regions for
15 educational coordinators right now where we have

16 about 15 people throughout the country.

17 So we do anticipate kind of tapping into
18 some of that regional distribution system as well
19 as expertise to try and add as much regional
20 breadth as we can.

21 Next. So the need is -- and why was
22 this law put in the first place? The need was

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97

1 perceived as being the stresses of care that can
2 be produced through proper education support.
3 Some of that has been demonstrated in the
4 literature, and based on that, Congress felt that
5 they wanted to try and do more with this for this
6 population.

7 Next. So the first organizational
8 meeting was actually two entire days held on the
9 9th and 10th of January in Silver Spring. All the
10 at the time, if you recall, since the final
11 appointments didn't come about until March, the
12 members of the panel are meeting really based on
13 consensus.

14 They weren't officially appointed at
15 this time, but they did receive a variety of
16 presentations on kind of what their mandates are,
17 their goals. They had a chance to discuss with
18 one another where they were at with that. Since

19 the appointments were pending, there was no actual
20 voting going on, but they were able to come to
21 consensus on some general areas of agreement.

22 They discussed the opportunities and

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98

1 challenges faced by the panel in developing the
2 TBI family caregiver curriculum.

3 Next. So some of the opportunities that
4 were identified was that it was felt that there
5 were some good examples out there from some other
6 disease processes. Model curriculum had been
7 developed for family caregivers of people with
8 dementia as well as spinal cord injury. They
9 wanted to create intel or curriculum to the needs
10 of the family caregiver of a person with traumatic
11 brain injury, and they wanted to identify the best
12 practices in family caregiving support and
13 education.

14 Next. Some identify challenges
15 including the lack of research on actual
16 caregiving related to TBI. There is some
17 research, but it's not a plethora of that. The
18 panels wish to inform family caregivers of the
19 range of treatment options even available,
20 although some are not traditionally covered by
21 insurance, and one of the biggest discussions that
22 was initiated on during that session was the role

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99

1 of cognitive rehabilitation which is still a
2 struggle for whether some insurance companies will
3 cover that or not, as well as the challenge of
4 incorporating an individualized component in the
5 curriculum.

6 To recognize that, it's hard to do
7 one-size-fits-all. We know that there's a
8 diversity of presentations in patients with brain
9 injuries, some of whom have different deficits or
10 different challenges to their quality of life, and
11 that the panel was hoping to recognize that, that
12 those differences could be tailored in any type of
13 curriculum which was presented.

14 Next. The panel members broke into four
15 small working groups. The first was an
16 expectations group that they were kind of working
17 on the goals of the curriculum content relating to
18 anticipating information resources to the family
19 caregivers to help them better understand TBI,
20 understand the DoD and the VA medical care
21 systems, and better understand some of the
22 prognoses and some of the things that could be

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Page 88

1 done to help maximize quality of life.

2 Next. A practical tools group. That
3 was really focusing on the actual curricula
4 content itself and to provide the information
5 skills and tools all meant to empower the TBI
6 family caregivers.

7 Next. The curriculum focus group, again
8 looking at the actual materials to educate, train,
9 and provide resources to this wide spectrum from a
10 variety of social and cultural backgrounds,
11 recognizing the educational needs to meet all
12 people from all backgrounds. Material were meant
13 to address the needs at each point on the
14 continuum of care from diagnosis to treatment and
15 rehabilitation, to reintegration to the service or
16 the community.

17 Next. The dissemination and format
18 group is meant to establish a variety of formats
19 of how is actually this curriculum going to be
20 rolled out and disseminated so that it could be
21 tailored to the actual unique individuals as well
22 as some of the populations and needs, and would be

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1 mindful of the different learning styles that
Page 89

2 certain people have that can respond better to one
3 style or another, especially the family members,
4 themselves. The patients who are on the panel
5 felt that mild was sort of being excluded in that,
6 so they wanted to have some way of sort of maybe
7 attending to some of the persistent mild patients
8 that have persistent problems. One of the
9 comments that some of the family members made was
10 there's nothing mild about this to the family. So
11 it sort of created for some great dialogue and
12 cross-talk amongst members of the panel.

13 Again, this was -- they were talking
14 about the percent of the people who persistent
15 symptoms because the medical literature tells us
16 that the majority of folks with mild will fully
17 resolve on their own. The materials were felt for
18 consensus had to address the changing roles of TBI
19 caregivers over a period of time. Different
20 challenges as different recoveries happen,
21 different settings are going to provide different
22 challenges as well.

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102

1 It was felt that they want to use
2 multiple modalities to accommodate the various
3 learning styles and a multimedia approach. A need
4 for a uniform definition of family caregiver that

5 reflects the broad definition of family,
6 apparently the point was made that families are
7 composed of many different components in our
8 modern era, and that the curriculum must contain
9 an interpersonal component to provide the
10 individualized guide through the TBI continuing
11 care.

12 Next. Initial positive steps were taken
13 toward developing a resource list of materials,
14 programs, and individuals to add a (off mike) of
15 the curricula, developing a list of distribution
16 channels for the completed curriculum.

17 Next. The second meeting is anticipated
18 in June. It will occur in the National Capital
19 Region. They are planning on having a town hall
20 component where local family caregivers of people
21 with TBI, as well as some of the representatives
22 of the some of the local advocacy groups, may be

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103

1 invited to provide suggestions on the content of
2 the curricula and the types of issues and things
3 that would be -- that from their perspective would
4 continue to be most helpful to them.

5 So we're broadening that net of not just
6 the family members who are on the panel, but
7 opening up that input to anyone that wants to
8 provide that to the panel. The modalities of

9 advertising this town hall component will include
10 announcements in the Federal Register, federal and
11 private list servers, the network of DVBI C and
12 DCOE, and local chapters of the Brain Injury
13 Association of America.

14 Next. It was felt that looking at some
15 of the characteristics of the caregivers that
16 represented diverse individualized and complex
17 component; they weren't easily categorized into
18 any simple demographic. They also recognized that
19 their needs do change over time, and that they
20 needed reassurance and hope throughout the entire
21 process.

22 Next. So the range of educational needs

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104

1 included basic information on TBI, help with
2 coping skills, assistance with problem solving,
3 and the ability to kind of know the resources to
4 seek and find support. Next. So, again, the
5 emphasis was on the multimedia approach, reaching
6 the broadest section of target audience possible,
7 incorporating end-users' feedback as the practice
8 developed.

9 A program needs to be developed to
10 pre-train program leaders who will be helping
11 implement this curriculum, recognizing that the

12 needs of caregiver education may differ due to
13 gender, race, ethnicity, and cultural factors, as
14 well as socio-economic factors and military rank.
15 Next. The panel plans to evaluate the efficacy of
16 the product before general release or as soon
17 thereafter with DHB assistance in that. They plan
18 to revise their curriculum based upon the
19 evaluation of the results in the first one to two
20 years of product use. And then an ongoing process
21 improvement approach, trying to improve the
22 product to get the best possible product possible.

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105

1 And then update the content as needed
2 where, I think, we're all aware that the science
3 of brain injury is continuing to proceed. We are
4 learning more and more every day, and that as new
5 things are discovered, that that might need to be
6 incorporated into the curriculum for the family.
7 The benefits of the curricula will help to provide
8 a uniform resource for the caregivers through a
9 consistent and concise message, tools for coping
10 and gaining assistance, giving hope while
11 navigating their post-TBI life. One of the things
12 we found was that different parts of the country
13 have different resources right now for providing
14 this family education.

15 So it's at least giving everyone a
Page 93

16 common parameter for a curriculum which will be
17 informative and accurate, providing the
18 self-management skills, as well as the effective
19 communication skills, to communicate not only with
20 individuals with TBI, but also with the caregivers
21 to communicate with the providers and healthcare
22 teams. That the process would be user-friendly

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106

1 and culturally appropriate and based on true
2 real-life experiences. And that sort of just
3 illustrates the need and I think that slide was
4 taken out of the revision. Okay? And that
5 concludes the presentation. I think we're open
6 for discussion.

7 DR. POLAND: Thank you. This is Greg
8 Poland. Let me start with a couple of questions.
9 A potential timeline, I don't think was mentioned.
10 Could you say something about when you expect to
11 have, let's just call it the pilot curriculum
12 ready to go?

13 COL. JAFFEE: To facilitate the process,
14 one of the things that is being done is a couple
15 of consultants are being done, and they actually
16 are in the process right now of developing sort of
17 a straw-man curriculum. And in that June meeting,
18 they'll actually -- the panel will have that

19 curriculum to build upon, to review, and further
20 elaborate on.

21 So their timeline was actually fairly
22 aggressive. They wanted to get the product out in

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107

1 approximately one -- within a year -- and do the
2 initial release and evaluation, which would take
3 another year or two years, so the entire process
4 we're talking two, three years tops. And then once
5 that product was released, evaluated, modified, we
6 got the distribution and dissemination down again,
7 then it would be time to consider whether it would
8 be -- whether the DHB would like that panel to
9 officially stand down.

10 DR. POLAND: Thank you. Just a few
11 other ideas or suggestions, which may already be a
12 part of it, but you can't say everything in a
13 short briefing. One would be to create a family
14 network system that might be web based. This has
15 been done in other avenues, for example, with
16 cancer, and patients and their families will
17 report back that it's a long distance support
18 system that they really like.

19 I would hope, too, that some of the
20 curriculum development experts that you have are
21 savvy about web-based applications of the
22 curriculum. I wondered about the possibility of

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108

1 including on the panel -- and maybe because of the
2 Authorization Act it would have to be ex officio or
3 something -- but actually recovered
4 high-functioning TBI victims themselves on the
5 panel rather than just family members. The reason
6 I'm attuned to that is you may remember the woman
7 called the Central Park jogger, Trisha Meili. She
8 just came to speak at the clinic. She had a severe
9 brain injury. And to hear her speak about what she
10 needed, not what she thought her family needed or
11 her employer, was enlightening to me. So, that may
12 be worthwhile.

13 And then I wonder about, in the longer
14 term, creating -- I don't know if you've heard
15 this term, I've been involved in a few of them --
16 Webinars? So they're web-based, real-time
17 seminars where you can have subject matter experts
18 give them, and across the world people tune in to
19 this as a way of disseminating best practices. It
20 can even be interactive with questions and
21 answers. And finally, some list -- not that it
22 would be the Good Housekeeping seal or something

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Page 96

1 -- but some sort of a list of civilian caregivers
2 or options and ideas that people, you know, in
3 various cities might take advantage of, but
4 wouldn't know about other than some sort of
5 coordinated word-of-mouth thing.

6 COL. GIBSON: That was a little dicey
7 for --

8 DR. POLAND: Yeah, I know. It's not
9 that you're approving them, you'd have to think
10 through that. Why don't we go around and we'll
11 try to catch each question. Dr. Lednar first.

12 DR. LEDNAR: Wayne Lednar. Thank you
13 for that briefing; a comment and then a question.
14 The comment about -- the panel, in their
15 discussions, were talking about mild and moderate
16 TBI and that there's nothing mild about this just
17 reaffirms that the Defense Health Board had as a
18 key interest mild and moderate. So that comment
19 by the panel, in fact, just reinforces what has
20 been a priority to this entity of the Defense
21 Health Board. So I'm glad that you're keeping
22 that invisibility.

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1 As I listen to the curricular thought
Page 97

2 process and content, clearly there was information
3 sort of in a health educational content sense
4 about TBI as a disease, about the spectrum, about
5 interacting in a transactional way with how we pay
6 for medical bills, whether it's DoD or VA. The
7 fact that those caregivers come in a variety of
8 types, cultural backgrounds, and other things,
9 what I didn't hear was that the content of this
10 caregiver education would be usable across the
11 entire group of caregivers.

12 Some caregivers will live in a location
13 where they do not have co-located family members.
14 Their family may be thousands of miles away. They
15 may not be geographically close to a good care
16 provider. They may have an employer who's not
17 committed to providing accommodations. They may
18 have another family issue, separate from TBI,
19 which is creating a very full plate of coping
20 issues and how do they factor all of this in. So
21 it's making sure our content on this issue is put
22 into a context that anticipates across the needs.

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111

1 And this comes back to what Dr. Poland
2 was saying about someone who's actually got the
3 condition, we should take advantage of what they
4 offer to us in the way of what they think would be

5 helpful for caregivers. So, I'd ask us to not
6 take too a medical mindset to this curriculum I
7 guess is the way shorthanded.

8 COL. CERTAIN: I'd underscore that
9 because one of the largest networks of caregiver
10 and family support in this country are faith
11 communities, and there's nobody from any faith
12 community as an official representative that shows
13 up on this Board. No military chaplains, no VA
14 chaplains, no faith group leaders, national
15 leaders; and if you don't tap into that network of
16 people, you're missing one of the biggest
17 opportunities to provide support for the families,
18 all kinds of support, including the psychological
19 and medical people who are members of those faith
20 communities and the payment of bills when bills
21 cannot be paid by any other source.

22 So I'd really urge you to go back and

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112

1 review the makeup of the Board and at least add
2 some consultants to the Board that can broaden your
3 horizons a good bit.

4 MAJ. GEN. KELLEY: Let me just make a
5 comment off of Colonel Certain's comment is that I
6 think that faith-based groups, they are often
7 trusted more than other people who are involved in
8 the process because there is that absolute

9 privilege between the priest and practitioner,
10 which gives another advantage of using faith-based
11 groups in dealing out with this.

12 COL. CERTAIN: That's been my
13 experience. Again, it's Robert Certain, I'm a
14 member of the Board, and obviously I assume that
15 one of the reasons I'm on this Board is to prick
16 your consciences on this particular issue, and to
17 advocate for inclusion, whatever the political
18 correctness is in the country. The reality is
19 that the military members are still highly
20 religious in a whole variety of faith communities
21 across the country.

22 DR. POLAND: Colonel Gibson, make your

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113

1 point and we'll work our way around.

2 COL. GIBSON: Let me address Reverend
3 Certain's comments here. By legislation, we were
4 pretty well hamstrung on who would be on this.
5 First of all, we talk about this town hall
6 meeting. The Board will be formally invited to
7 participate, including all of the subcommittees,
8 because there's interface between the Amputee
9 Board, there is a TBI external advisory
10 subcommittee that has just been stood up. The
11 reason I bring that up, it goes back to the

12 Legislation.

13 The way this legislation is written,
14 Congress expects this group to deliver their
15 product and then be disestablished. They don't
16 expect them to go on and on. Somebody's going to
17 have -- and I'm not going to use the word oversight
18 because there are technical issues about it -- but
19 somebody needs to provide care and feeding to this
20 curriculum after it's delivered as a product to the
21 Department of Defense. That's going to be this TBI
22 external advisory subcommittee. With respect to

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114

1 the additional members, we can do some things as
2 far as ex officio members and easily do subject
3 matter consultants who are able -- including
4 faith-based individuals -- who are formally invited
5 to participate in this whole thing. So I
6 recognized that as well early on in this, but thou
7 shalt do this.

8 DR. POLAND: And Colonel Jaffee (off
9 mike) the comments that you're hearing to the
10 panel from the Board -- okay. John? No? Ed?

11 DR. KAPLAN: Kaplan. Could you tell us
12 a little bit more about multicultural
13 considerations?

14 COL. JAFFEE: I think that was
15 recognized by the members of the panel that there

16 are differences and they wanted the curriculum to
17 attend to that. So one of the things that they
18 were hoping to do with their outside consultants
19 when reviewed was to make sure that whatever
20 information was presented or whatever
21 illustrations they were using, if they use
22 pictures or if they use any videos or the

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115

1 terminology used, that it was sensitive to all
2 cultural groups, and I think that they do plan on
3 using some consultants to assure that that is done
4 to make sure that we can appeal properly,
5 understand some of the backgrounds and beliefs,
6 make sure that we're not saying anything that
7 would turn off a particular cultural group, and if
8 there's a way to more directly appeal. So I think
9 the understanding is that there are differences
10 and that the hope -- and again, they were just
11 lining out the parameters, at this point they
12 haven't executed it -- was that we could
13 incorporate that diversity into the planning and
14 execution.

15 DR. KAPLAN: Thank you.

16 DR. PARKINSON: Excellent effort. I
17 just -- as someone who used to be in a federal
18 agency that commissioned curricula, I get almost

19 anaphylacti c when I hear the word. And I
20 understand the intent here, but I want to go back
21 to Dr. Poland because --

22 DR. POLAND: Because you get

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116

1 anaphylacti c --

2 DR. PARKINSON: -- I get anaphylacti c with
3 him, too. But in all seriousness, --

4 DR. POLAND: Even though I'm from
5 Minnesota.

6 DR. PARKINSON: That's right, that's
7 true, big black flies. Anyway, but I think the
8 emphasis here that I'd like to see us always come
9 back to is the word competencies and support.
10 What do I need to know, do, act upon as a family
11 member in a community of people with like
12 challenges, and the infrastructure on an ongoing
13 basis to help me, both ongoing and acutely.

14 So that is not necessarily a curriculum.
15 And so the more we can -- obviously you've got the
16 statutory language and the word curriculum, but I'm
17 very -- I just see yellow flags when I see the word
18 curriculum because I see books and background and
19 knowledge as opposed to skills, attitudes,
20 competencies, support, infrastructure. Those are
21 hard-hitting words, and in your effort I would
22 urge you to start with the competencies people need

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117

1 to have, the identification skills, the support
2 skills, those types of things. And put way back
3 here that word curriculum. It's just a caveat
4 because the last thing in the world that I'd like
5 to see as a member of the Board is something come
6 out like this and then what in the heck do we do
7 this in terms of mailing it out or putting it on
8 the Web. It's not -- it's the wrong approach and
9 then the semantics are important. It leads us down
10 that path a little bit. So even experts in
11 curricula development, it's like ooh, okay hold it,
12 let's back off a little bit. It's just a friendly
13 comment from someone who's been down this
14 curriculum road a lot.

15 DR. OXMAN: I would agree. I would
16 agree with Dr. Parkinson, and also emphasize the
17 importance of support and some kind of attempt to
18 both structure and monitor it. Now that may be
19 beyond the responsibilities of the committee, but
20 if it is, then the committee is doing something
21 that's inadequate.

22 COL. GIBSON: Structure and monitoring

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Page 104

1 will be -- that's the TBI subcommittee, that will
2 be part of their mission.

3 DR. SHAMOO: I would like to see we
4 formulate those points in a small comments and
5 letter to them rather than just ad-libbing it here
6 and it might not go anywhere.

7 DR. POLAND: It's a good point. It's
8 important and may be we should be a little more
9 formal in doing that. Mark?

10 DR. BROWN: Mark Brown. I like this
11 idea, basically, it sort of sounds to me like a
12 clinical practice guideline for family members who
13 are taking care of injured veterans who have
14 milder, perhaps more severe, traumatic brain
15 injuries. It seems like a good idea, although I
16 share some of the concerns that other people
17 raised about how these things can end up. But one
18 of the things that occurred to me is it seems like
19 there's a lot of literature now, information now
20 that shows there are more co-morbid conditions
21 with traumatic brain injury.

22 If you look at it as a clinical practice

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1 guideline, then it might be worth thinking about
Page 105

2 some of these other conditions that are associated
3 now with traumatic brain injury. I'm thinking
4 specifically of a PTSD. I think there's some
5 pretty good literature now showing that PTSD and
6 TBI overlap in at least symptoms, although not in
7 treatment. And I'm wondering -- I didn't hear your
8 group, in your discussion of how this is being laid
9 out, that you explicitly considered that
10 possibility, that family members who are taking
11 care of these veterans may be dealing with other
12 medical -- well, not may be, are likely to be
13 dealing with other medical issues than just the
14 TBI, that they need to take that into account.

15 COL. JAFFEE: That's an excellent point.
16 I think we're aware of the psychological
17 co-morbidities, as well as many of the medical and
18 physical co-morbidities, especially for the more
19 severely injured who sustained their injury in the
20 context of poly trauma in which there are some
21 additional needs as well. So I think that the
22 committee recognizes that and does plan to touch

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120

1 on some of that. With regard specifically to the
2 psychological aspects, there are initiatives going
3 on, not within a DHB panel, to develop a
4 curriculum for the family caregivers there. That

5 initiative is actually under the umbrella of the
6 Defense Center of Excellence, and we've already
7 started sort of making sure that we have an
8 ongoing collaboration to make sure that we're both
9 aware of each other's efforts, trying to develop
10 the best product for both.

11 DR. LUEPKER: Yeah. A couple of weeks
12 ago I had in my office Chaplain Marsh who is with
13 the Minnesota Guard and he'd done a tour in Iraq.
14 And he is trying to gather resources to help
15 veterans reintegrate, including TBI and PTSD, the
16 pancreas, and he was interested in us helping him
17 inform the public better about these people coming
18 back and how to help and deal with their issues,
19 everything from economic issues to family issues,
20 and so on. What struck me though listening to
21 this, and I think this is a great effort, is that
22 people out there in the Service are not waiting

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121

1 for the national plan because people have been
2 coming back from theater for years now. And
3 second, just, you know, before we develop a
4 hundred diverse programs locally to deal with
5 this, hopefully the committee would listen to
6 what's going on and work to integrate into the
7 overall fabric. So there is actually a national
8 plan and folks like this aren't going around

9 looking for volunteer effort, which we still need
10 undoubtedly, but to put together a program kind of
11 as an aside to his job with the Guard.

12 DR. POLAND: Thank you. Dr. Silva?

13 DR. SILVA: I presume that you're going
14 to translate this into other languages whether you
15 develop? It's not going to be only English based?

16 COL. JAFFEE: That would -- I think that
17 falls under the -- somewhat relates to the
18 discussion we're having with multicultural and if
19 there's a language barrier, then we would have a
20 need to make that available in other languages as
21 well. I think that the plan was to make sure that
22 the content was on target and on track, that we

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122

1 had some preliminary approval; and then once
2 that's done, we can move on to kind of the
3 dissemination phase which would include making
4 sure it's available in the appropriate and needed
5 languages.

6 DR. SILVA: Okay. Is the VA empowered
7 to provide family counseling, group sessions of
8 non-veterans?

9 DR. BROWN: Mark Brown as the VA
10 representative. I'll take that. That's a very
11 good point, and it's a real problem for us.

12 Legally, we only have the authority to treat
13 veterans. The healthcare and benefits we provide
14 is specifically for veterans. That's not 100
15 percent true; there are some very limited
16 opportunities to do things for family members, but
17 it usually is in the context of the health of the
18 veteran. That is, the health of the veteran is
19 affected by whether family is involved with --
20 then we can deal with that. But it's a serious
21 limitation, and it can -- we -- I'm not sure -- we
22 might have trouble doing something -- justifying

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123

1 doing something like this where the target
2 audience is help the family member. I mean, we
3 might be able to --
4 DR. POLAND: You could be disseminators?
5 DR. BROWN: We could be the
6 disseminators, absolutely, but we are, by
7 legislation, our target is the veteran himself or
8 herself.
9 DR. SILVA: Well, I know Mark, thank
10 you. The President knows of this Board, and
11 Colonel Gibson might visit some of our Centers in
12 Vision 21, and humanity being what it is, there's
13 a couple of hospitals who are bootlegging it.
14 They're doing the evening, Saturday morning, not
15 punching the clock, but because people

16 knowledgeable in this field recognize that a lot
17 of the curing is related through family members or
18 friends, everyone of defined family. But we've
19 been at this for five years now. We're slow to
20 identify the impact, and maybe someone should
21 start working with Congress to broaden the VA's
22 capability. That's the key to success. If you

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124

1 have a muddled brain, you can't walk yourself
2 through it.
3 DR. BROWN: I think Congress recognizes,
4 at least some members of Congress, and I've heard
5 of bills, legislative proposals to do something
6 like this, and we have had a little bit of
7 legislative impact that's helped us in this area.
8 For instance, we can do bereavement counseling in
9 the case of a deceased veteran, we can deal with
10 their families and provide them certain types of
11 support and counseling, psychological help. So I
12 think we're making some steps in the right
13 direction, but we're coming out from an
14 institution that has historically been very
15 focused on just the veteran, and I think it's
16 going to take some time to try -- I mean, I agree
17 with your point that considering the situation of
18 family members, particularly for medical issues

19 I like what we're talking about now, can be
20 absolutely critical.

21 DR. LUEPKER: Okay, thank you. Yes sir?

22 DR. ZAKI: I'm just wondering why this

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125

1 is called traumatic brain injury family caregiver
2 program if the family cannot have a role in
3 treating these individuals or really putting these
4 individuals through the programs?

5 DR. POLAND: I think the point is that
6 they can. It was in the case of the VA there were
7 limitations on what they could do. But the intent
8 of this is direct to the family members, correct?

9 COL. JAFFEE: Absolutely correct at any
10 military treatment facility or VA hospital if that
11 patient is under care. You know, there's
12 oftentimes interaction with the family between the
13 treatment team and the family, and what this
14 really is targeting more -- and they do that very
15 well in the VA, they're actually quite good at it
16 -- but what this really targets is what happens to
17 that patient, that family, when they're no longer
18 in that structure? When they're no longer an
19 inpatient at that hospital? When they have to --
20 they maximized their recovery and rehab, and
21 they're trying to get through their day-to-day
22 life, and how does the family help support the

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126

1 member? And I think that's really where the
2 families felt that they had the most needs, that
3 once they left that protective umbrella of the
4 hospital they were in, that they didn't have as
5 much support and that's where this program is
6 really meant to come in and help bolster that.

7 DR. POLAND: Okay. One comment from
8 Colonel Gibson and then we're going to take a
9 break.

10 COL. GIBSON: Thank you for all your
11 comments on this. Just as a reminder to the
12 Board, to the core Board. As core Board members,
13 you can play on any subcommittee you want at any
14 time. If you want to go to TBI meetings,
15 including closed meetings, and participate, all
16 you need to do is let me know and we will keep you
17 guys apprised of when they're having meetings.
18 This is an important issue. It's more complex
19 than original. We're a year behind on what --
20 from where Congress said we should be -- and all
21 the help we can get would be appreciated. Thank
22 you.

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Page 112

1 DR. POLAND: Okay, let's take a short,
2 15-minute break and we'll reconvene.

3 (Recess)

4 DR. POLAND: Okay, time for us to get
5 going here. We're going to hear now on mild TBI
6 injuries that U.S. Soldiers returning from Iraq
7 -- Colonel Hoge is going to do that. He's from
8 the Division of Psychiatry and Neuroscience at
9 Walter Reed Army Institute of Research. He's
10 going to both brief us on his recent New England
11 Journal article that I have not seen yet, but I
12 think is being passed out. It came out in
13 January. Many of you saw his 2004 article, which
14 I think was a lead article, and was just superb --
15 I just -- from a personal point of view -- the
16 attention that that brought to this issue among
17 healthcare providers is really an enduring
18 contribution to medicine.

19 He's got particularly special insights
20 regarding TBI, and it's not sort of a white tower,
21 ivy tower type view of it. He's been there, has
22 seen this firsthand, and I've asked him to give a

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1 little bit of background about that in terms of the
Page 113

2 mental health assessment teams that go out so that
3 the Board has that background.

4 COL. GIBSON: One comment: You Board
5 members did receive a copy of Dr. Hoge's
6 manuscript in the -- via email. I believe Lisa
7 sent it to you. So, it's there, along with all
8 the other thousand emails I can send you.

9 DR. POLAND: The floor is yours.

10 COL. HOGE: Thank you very much. Can
11 you all hear me? Okay. This is kind of awkward.
12 I usually -- I'm not used to holding a mike. I'm
13 used to having my hands free. Thanks so much for
14 -- it's a great honor to be here and talk with
15 you. I think you'd asked me to talk just briefly
16 about mental health advisory teams, and just as a
17 little bit of background, I run a research program
18 at Walter Reed Institute of Research that has
19 teams co-located in Europe -- we have a detachment
20 in Europe and a group in Washington, D.C. that's
21 engaged in a variety of mental health survey
22 research, intervention research, development of

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129

1 training materials, looking at screening
2 instruments, improving and validating screening
3 instruments. And a lot of the work that we do has
4 pretty significant policy implications.

5 One of the key efforts that we've had
6 ongoing is to deploy teams into Iraq on an annual
7 basis to conduct mental health surveys, both of
8 soldiers deployed throughout the operational
9 environment and of healthcare professionals --
10 mental health professionals, primary care
11 professionals, and chaplains, and others who are
12 working in the mental health area. And from those,
13 there's been a lot of lessons learned as to how
14 many resources are needed, the distribution of
15 resources, how well they're working in theater
16 barriers, and stigma.

17 And then more recently, we've broadened
18 our interest into mild TBI because of a suggestion
19 by Deb Warden a couple of years ago to include
20 traumatic brain injury questions on our surveys.
21 Because we do systematic data collections in
22 brigade combat teams, she thought this was an

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130

1 ideal opportunity to look at the interface between
2 combat experiences, injury, TBI, and other, you
3 know, and health concerns. So we asked a
4 fundamental question -- with our survey
5 methodology -- our survey methodology is very
6 different than clinical methodology, clinical
7 evaluations, because it's a standardized
8 assessment, conducted in a standardized way, using

9 validated instruments at one point in time, so
10 it's cross-sectional.

11 There are limitations, but there are
12 also strengths to that. And one of the key
13 strengths is the ability to maintain, to utilize
14 very standardized validated tools and maintain
15 independence of variables, independence of injury
16 variables, the outcome variables. And we asked a
17 fundamental question: What's the relationship of
18 mild traumatic brain injury during deployment to a
19 variety of health outcomes post deployment?

20 So I'm going to talk -- this talk is
21 going to discuss the results of that study in
22 brief, I'll summarize that, which was published in

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131

1 the New England Journal of Medicine this past
2 January. But I'm also going to lay the groundwork
3 for a much broader discussion, looking at the
4 literature, how this article fits in with the
5 literature, and what the implications are, I
6 think, in terms of current policies. And so it
7 may be a bit of a different talk from -- because
8 it's -- we're really talking about a medical
9 phenomenon, sociological phenomenon, political
10 phenomenon, interfacing in a very unique way right
11 now with this particular war and there's a lot of

12 issues therein. I had a lot of problems putting
13 this talk together.

14 Normally, I don't have -- I give
15 hundreds of presentations -- but I knew I didn't
16 have a lot of time and I wanted to make it
17 succinct, and I just couldn't do it. It was
18 impossible. So I apologize upfront.

19 I'm sure you're all aware of what TBI
20 is, but just to reiterate, mild traumatic brain
21 injury is a blow or jolt to the head that results
22 in temporary physiological alteration in

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132

1 consciousness or loss of consciousness. There may
2 be a gap in memory, amnesia. And the definition,
3 if the loss of consciousness extends for more than
4 30 minutes, by definition it's not mild, that's
5 moderate TBI. But the vast majority of folks who
6 are experiencing mild TBI in Iraq are actually not
7 even having loss of consciousness, most are having
8 just simple alteration of consciousness that's
9 very temporary in nature.

10 Mild TBI is synonymous with concussion,
11 but for some reason, the term mild TBI has become
12 dominant right now. And I think that's very
13 unfortunate because I think terminology and how we
14 apply terminology in labeling actually has an
15 impact in terms of expression of symptoms, and

16 I'll talk about that quite a bit later on.

17 I'm going to talk only about mild TBI,
18 I'm not talking about moderate and severe TBI, and
19 I want to make that distinction upfront. So we're
20 talking about mild TBI or concussions. That's
21 what the subject is.

22 With concussion, when a concussive event

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133

1 happens, it's normal to have some sorts of
2 symptom, headaches, you know, sleep disturbance,
3 maybe some balance problems or dizziness, maybe
4 nausea initially. These things go away very
5 rapidly and football concussions, for instance,
6 we're talking about generally hours to at the most
7 a few days. If it's repeated concussive events,
8 maybe up to two weeks, but in general, these are
9 very short-lived symptoms that resolve very
10 quickly.

11 A certain percentage of people go on to
12 develop persistent post-concussive symptoms. And
13 there's a lot of issues with -- there's a lot of
14 definitional issues and problems with case
15 definition of what post-concussive symptom or
16 symptoms are or syndrome. There's really no
17 validated case definition as yet for
18 post-concussion syndrome. And so, by and large,

19 people are just talking about post-concussion
20 symptoms, and that's problematic because how do
21 you study a disease if there's no case definition.
22 But that's, in fact, what's happening

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134

1 now is that individuals are having concussions in
2 theater, they're expressing symptoms when they
3 come home, and those symptoms are automatically
4 attributed to the TBI because we don't have a
5 validated case definition for the illness that
6 we're purporting to study. And so that also makes
7 it impossible to study the epidemiology of the
8 disorder. What are post-concussive symptoms?

9 They're generally talked about three
10 categories of symptoms, but I think that's very
11 artificial. Physical, behavioral, and cognitive
12 symptoms overlap. We're talking about health
13 symptoms in general. I'd like to just use the
14 term physical health symptoms, but from now on
15 when I use the term physical health symptoms, I'm
16 talking about cognitive, behavioral, and physical
17 health symptoms. And these are things like
18 headaches, sleep disturbance, fatigue,
19 irritability, dizziness, concentration problems,
20 memory problems, balance problems, ringing in the
21 ear, blurred vision, reduced ability to tolerate
22 stress. Okay? That's a criteria in, I think, the

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135

1 ICD-10 or the DSM-IV criteria utilizes that
2 terminology. Reduced ability to tolerate
3 emotional states or alcohol. Those are, again,
4 criteria within either a code of 5 that's part of
5 DSM-IV or ICD-10. You can see these are fairly
6 non-specific symptoms -- they are totally
7 non-specific symptoms in some respects.

8 There's a lot of momentum behind mild
9 traumatic brain injury. There was a CDC report to
10 Congress in 2003 that identified this as a serious
11 public health, a grave public health concern. The
12 incidence was reported in multiple different
13 reports from different posts and in the news media
14 and special commissions that have been set up as
15 around 20 percent of troops deployed to Iraq and
16 Afghanistan have sustained at least one mild
17 traumatic brain injury event, which is a
18 concussion, often blast related.

19 There's been a lot of concerns about
20 repeated exposures, and, thus, it's been labeled
21 the signature injury of this war. And there's
22 been various commissions that have looked at this

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Page 120

1 matter, including the AFEB in a memo to Health
2 Affairs in August '06. Nine hundred million in
3 FY07 Congressional appropriation went to -- split
4 50/50 for PTSD and mild TBI, and key
5 recommendations -- and this is just, you know,
6 very broad brushstrokes, but key recommendations
7 of all of these commissions have been to conduct
8 population-wide screening post-deployment to make
9 sure we don't miss anybody with mild traumatic
10 brain injury and assure that Service members get
11 care. That sounds like a very noble, worthy, and
12 worthwhile goal, but is it achievable is another
13 question.

14 The other recommendation that's been
15 made by a number of commissions have been to
16 conduct -- and actually it's been mandated by
17 Congress to conduct -- baseline neurocognitive
18 assessments on the entire population so that we
19 can measure changes over time. There's some
20 issues with that because we have no validated
21 cognitive assessment tool to do that with, okay?

22 Some people may disagree with me on

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1 that, but that is a fact, according to me. What
Page 121

2 DoD has done so far has been to establish a common
3 definition with VA for TBI, and it's a reasonable
4 definition. It's what I showed you for mild TBI,
5 and then there's a definition for moderate and
6 severe. It's a very reasonable, acceptable
7 definition. The problem isn't in the definition;
8 the problem is how you operationalize that
9 definition on a survey, questionnaire, health
10 assessment by a clinician.

11 How you discuss that definition with
12 your patient, and what you do with the information
13 that you collect as a result in the medical
14 record. That's where the problem lies, not in the
15 definition itself. Published clinical guidance
16 for both in theater and for garrison setting --
17 and when I say garrison setting, I'm really
18 talking about post-deployment. What do you do
19 with all these Service members who come back and
20 are identified in the screening processes as
21 having had a mild TBI, and now they may be having
22 symptoms that have been persistent, that they

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138

1 attribute to that, or that the health
2 professionals think may be attributable to that.
3 So, there's been some guidance put out as to
4 specifically how to treat symptoms and to manage

5 individuals who have concussions in the garrison
6 setting or are identified as such.

7 Population-wide screening is now being
8 rolled out. It's being sort of phased in, there's
9 been pilot projects that have been ongoing and now
10 it's going to pretty much be population-wide, it's
11 been incorporated into the new post-deployment
12 health assessment and principle health
13 reassessment processes. And baseline mandatory
14 neurocognitive assessment testing has been
15 mandated as of January '08 by Health Affairs. And
16 the ANAM has really -- has been selected as the
17 instrument to utilize for that.

18 Do I need to define terms or is
19 everybody aware of what -- ANAM? It's an
20 automated neurocognitive assessment matrix, I
21 think, is what it stands for. It's been in
22 development through Army funding, DoD funding, for

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139

1 30 years, and there's very very little good
2 validation data that's in the published
3 peer-reviewed medical literature.

4 TBI specialty clinics are popping up all
5 over the place. And there are numerous education
6 efforts, some of which are guided by good risk
7 communication strategies, many are not. In fact,
8 I'd say most are not. Assumptions that are

9 driving the DoD policies and these are, in fact,
10 assumptions, although they are propagated as the
11 truth over and over again. Mild TBI's on the same
12 continuum as moderate and severe TBI. That's very
13 problematic and there's a lot of evidence that
14 suggests that it's not on the same continuum.

15 I think it's probably fair to say that
16 if a soldier's knocked unconscious for 20 minutes,
17 that's probably on the same continuum as being
18 knocked unconscious for 30 or 40 minutes or an
19 hour. But if they're knocked unconscious for a
20 few seconds, that's probably not on the same
21 continuum. And the evidence epidemiologically,
22 pathophysiologically, and clinically, suggests

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140

1 that they're not on the same continuum. And what
2 is problematic about this assumption is that many
3 of the educational programs and clinical programs
4 are geared toward TBI in general, without really
5 being designed around a need for separate types of
6 programs, clinical programs, and evaluation
7 processes for mild verses moderate and severe.

8 There's an assumption that blast may
9 cause unique health effects. The physics -- a
10 blast physics and the casualty data that are
11 coming out now suggest that primary blast

12 overpressure injuries are very rare, and that it's
13 very unlikely that there's large numbers of
14 soldiers walking around who've had, you know,
15 minor injuries or mild concussive events that are,
16 in fact, had primary blast overpressure. The fact
17 of the matter is in open-space blasts where most
18 of these occur, primary blast dissipates very
19 rapidly.

20 But the shrapnel throw, the fragment
21 throw, and the fire extends out way beyond the
22 area that the primary blast overpressure

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141

1 encompasses; therefore, if you're exposed to
2 primary blast overpressure, by and large you've
3 been decimated by the fragments.

4 The case definitions for mild TBI and
5 post-concussive symptoms or syndrome, whatever
6 you want to call it, are sufficiently valid.
7 There has been no validation using control groups
8 and blinded clinicians. Am I correct on that, has
9 that changed? I don't think that's changed yet.
10 Symptoms usually resolve in one to three months,
11 but persistent post-concussive symptoms are not
12 uncommon, reported frequently in the literature at
13 15 percent. This is also clinical lore.

14 The truth is that most of the concussion
15 literature suggests that symptoms resolve within 7

16 days, and in repeated concussions on the football
17 field, for instance, it can be a little longer
18 than that. And persistent post-concussive
19 symptoms, Malcolm McCrae is one of the top experts
20 in TBI and has published a book on mild TBI and
21 persistent post-concussion syndrome, and he
22 relooked at the very studies that have been cited

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142

1 time and time again that led to this 15 percent
2 figure. And he reanalyzed -- he relooked at those
3 data and concluded that the real figure is 3 to 5
4 percent, but the 15 percent continues to get
5 propagated. Mild TBI overlaps with and may be
6 confused with PTSD. No, actually not. TBI, I
7 mean mild TBI is simply the concussive event in
8 theater. PTSD occurs later.

9 What overlaps with PTSD or
10 post-concussion symptoms, which are general and
11 diffused, are general medical symptoms that
12 overlap with hundreds of other conditions. And
13 yet the focus, for some reason, has been on PTSD
14 and TBI. In fact, training has been rolled out
15 that actually lumps the two together, almost as if
16 they're one entity. Careful clinical history
17 perhaps with the help of cognitive testing can
18 distinguish symptoms due to mild TBI. I don't

19 think there's any evidence that that's the case.

20 A silent epidemic requires a high index
21 of suspicion. That's been sort of propagated
22 initially, you know, well, I won't go there, but

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143

1 it's the -- this is sort of part of clinical lore.
2 The reason why we do screening is because we may
3 miss -- you know, individuals may be having
4 serious health concerns that they're walking
5 around with that have been untreated, and, in
6 fact, there's been reports in the literature and
7 in the news that many of the social woes, you
8 know, chronic alcoholism, incarceration rates, and
9 that kind of thing are due to head injuries in
10 childhood. But the epidemiological evidence for
11 that is very very weak. It doesn't matter what
12 label we use since mild TBI means the same thing
13 as concussion. That's -- I think I'll prove that
14 wrong as the talk goes on.

15 Screening for mild TBI is imperative for
16 appropriate care. And that is predicated on
17 having specific treatment for mild TBI so many
18 months after the injury. Okay? So this is
19 adapted from work by McCrae and Iversen and
20 others, looking at mild TBI, the distinction
21 between mild TBI and moderate and severe TBI.
22 Clinically, in terms of case definition, in terms

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144

1 of natural history, in terms of the
2 epidemiological evidence for causation, the
3 classic Sir Bradford Hill criteria, all of which
4 is quite distinct between mild TBI and moderate
5 and severe TBI. And you can digest this may be --
6 I'll just move on because of time.

7 This is the new post-deployment health
8 screening questions that have been put on the PDHA
9 and PDHRA. So what it says, question number 9a:
10 During this deployment, did you experience any of
11 the following events? Blast or explosion. That
12 doesn't say were you injured, were you, you know
13 -- did you have a blow to your head, did you have
14 a jolt to your head due to a blast? No, it just
15 says were you -- did you experience any of the
16 following. Everybody's who deployed will say yes
17 to that question, absolutely everybody. Did any
18 of the following happen to you or were you told
19 happened to you immediately after any of the
20 events you just noted in question 9a? Loss of
21 consciousness or knocked out? Dazed, confused or
22 saw stars? How many people who deployed have been

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Page 128

1 dazed when they're exposed, even remotely, to
2 blast? Confused? Confusion's pretty much the
3 norm in that kind of environment. Didn't remember
4 the event, had a concussion, had a head injury. A
5 lot of soldiers don't know what the term
6 concussion is.

7 They know bell-rung, being knocked out,
8 those kinds of terms. Okay, so then the next
9 question is did any of the following problems
10 begin or get worse after the event you noted in
11 9a? Memory problems, balance, and then they have
12 seven symptoms, okay, which by virtue of their
13 location on the survey and the way the questions
14 are being asked, are automatically attributed to
15 the injury. So there's your attribution link,
16 okay? There is no way studies that are going to
17 be coming out that are going to show huge odds
18 ratios, you know, for physical symptoms correlated
19 with mild TBI.

20 But these are not independent questions,
21 they're not independent from the injury question,
22 they're not independent variables, okay, as part

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1 of one questionnaire. And they've only selected
Page 129

2 seven symptoms. In our study in the New England
3 Journal of Medicine we found that the TBI, yeah,
4 in deed, had higher rates of these symptoms, but
5 they also had higher rates of gastrointestinal
6 symptoms, heart palpitations, racing heart, and
7 sexual dysfunction, okay?

8 Foundation of population screening is to
9 understand the risk factors. So what are the risk
10 factors -- what do we know about persistent --
11 about the risks of developing persistent
12 post-concussive symptoms after a concussion?
13 Well, it turns out that it really has almost
14 nothing to do with the injury severity, okay?
15 Those measures really have not been correlated,
16 with the exception to some degree of repetitive
17 concussions, and may be duration if you get out to
18 the 20, 30 minute range of loss of consciousness.
19 But by and large there's been conflicting data
20 about repetitive concussions.

21 The NCAA study showed that, in deed,
22 there was a higher rate of -- longer duration of

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147

1 recovery with repetitive concussions, but the NFL
2 study did not show that, so there was
3 inconsistency in the data. But the key risk
4 factors that have been time and time again proven

5 in multiple studies have been depression, anxiety,
6 and PTSD. Co-morbidity leads to persistence --
7 correlated associated with persistence of
8 symptoms. If there's any medical disability or
9 legal processes, then that -- you're going to get
10 persistence of symptoms. And that's been shown.
11 The WHO Task Force on traumatic brain injury --
12 that was sort of their sole conclusion for what
13 the world's literature showed pertaining to the
14 principle risk factor for persistence of symptoms.

15 The other thing that's interesting is
16 the expectation. There's been a number of studies
17 that have shown that the expectations and beliefs
18 that patients have about the seriousness of their
19 condition is actually strongly correlated with
20 symptoms. And that has led to cognitive education
21 approaches that have actually been shown to be
22 effective. So if you educate a person after a

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148

1 concussion, that you're going to get better
2 quickly and provide reassurance and provide
3 education that this is the natural course and will
4 resolve very quickly and have full expectation
5 recovery. They'll get better faster than if you
6 don't do that.

7 If you tell them, on the other hand,
8 you've been exposed to blast and we don't know

9 that much about blast exposure, and there may be
10 long-term effects that we haven't been able to
11 measure yet, and this is mild traumatic brain
12 injury, that's going to have a very different risk
13 communication message than if you say this is
14 concussion that you encountered, this IED
15 explosion, you just had a concussion.

16 Clinically, it's very much the same as
17 any other concussion; clinically, it's very much
18 the same. And, yeah, there may be some blast
19 things that we don't fully understand, but the
20 brain has this remarkable capacity to heal. It
21 has plasticity. And there's every expectation
22 that you're going to get over this very very

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149

1 quickly. So that's two different types of
2 messages.

3 The other foundation for population
4 screening is having effective intervention. So
5 what evidence-based treatments are available for
6 mild TBI, identified through post-deployment
7 screening assessments? And the answer's none.
8 There's no evidence-based treatment except
9 cognitive education provided not in the
10 post-deployment period because there's no studies
11 done, but acutely. So we know that cognitive

12 education works. There's good evidence for that.
13 We're left, really, with treating symptoms.

14 Regardless of the ideology, if there's
15 headaches, if there's sleep problems, etc., then
16 that's what we have to treat. We don't often --
17 cannot tell what the ideology of those symptoms
18 are, the question comes down to what is the best
19 and most scientifically sound evidence-based
20 approach to the management of symptoms. There was
21 a good report by Ronin and Jam in 2005 that
22 outlined criteria for population-level screening

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150

1 for mental health conditions, but it's very
2 applicable to mild TBI because mild TBI, i.e.,
3 post-concussive symptoms, are symptom-based
4 conditions that involve behavioral and mental
5 health symptoms as well as other types of
6 symptoms. And a screening test needs to be
7 simple, precise, and validated. There needs to be
8 adequate staffing.

9 Most importantly, potential benefits
10 from the screening program need to outweigh the
11 risks. And in this case, we really haven't been
12 able to demonstrate any of these -- none of these
13 criteria have been effectively met. Even the
14 important health problem question is debated.

15 There is very real risk of iatrogenic

16 harm from what is currently being done with our
17 current programs. So when there's a
18 combat-traumatic event that results, say, in a few
19 seconds loss of consciousness or being dazed or
20 confused temporarily, may be there's some acute
21 symptoms, sleep disturbance, nightmares,
22 irritability, concentration problems, headaches.

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151

1 And then they go into the post- deployment period
2 where we start screening repetitively for this
3 disorder called mild traumatic brain injury. And
4 that is an evaluation process that involves the
5 interface with a clinician who is operating under
6 the same assumptions that the program itself is
7 operating under as a general rule. And so with
8 any intervention in clinical medicine, there are
9 risks. There's guarantee that there will be
10 iatrogenic consequences.

11 It has to happen because it's a clinical
12 intervention that's occurring actually on a
13 population level that's impacting the care, the
14 health care, of all Service members who have a
15 history of a mild TBI in theater. So labeling can
16 lead to symptoms. Inconclusive cognitive and
17 neuro-imaging studies can lead to confusion in the
18 patient. Do I have something that's serious or

19 not, are these symptoms that I'm having really
20 related to this problem or not.

21 Medication side effects, failure to
22 provide effective treatment for the real problem,

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152

1 like PTSD for instance. Use of rehab services
2 designed for moderate and severe TBI now being
3 used for mild TBI with really very little evidence
4 to support that. Poor risk communication,
5 disability seeking cost, etc. There's several
6 studies that have looked at the correlation
7 between the belief that one has about their
8 illness -- it's not just true for mild TBI, but
9 it's also true -- if you tell people when they
10 walk into the clinic and they have no history of
11 hypertension and you give them a report that they
12 have hypertension, they immediately become
13 symptomatic. Statistically, they have higher
14 rates of symptoms just from the information that
15 was communicated to them.

16 DR. SHAMOO: You keep saying that, but
17 what percent of them keep having those symptoms
18 just once when you diagnose them, because you are
19 giving the impression it's 100 percent of them get
20 those symptoms when you tell them? What percent
21 of them have those symptoms if you tell them they
22 have something?

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153

1 COL. HOGE: Like mild TBI?
2 DR. SHAMOO: Yeah.
3 COL. HOGE: I don't know the answer to
4 that. I can tell you that in the post-deployment
5 screening, about 20 percent of soldiers are
6 indicating that they had a concussion event and
7 about half of those -- correct me if I'm wrong --
8 about half of those are indicating that they still
9 have, and this is months, may be months, after the
10 injury, but it's -- they're still having those,
11 one of those seven symptoms, one or more of those
12 seven symptoms. So, it's about 10 percent of all
13 the soldiers coming out of theater are
14 symptomatic, have symptomatic mild TBI by the
15 definitions that are currently being used. Now
16 that doesn't correlate at all with the literature
17 where it's three to five percent rather than 50
18 percent. Does that make -- am I answering your
19 question?
20 DR. SHAMOO: No, I'm really not clear.
21 I want to know if you tell somebody he has a
22 problem, what percent of those somebody they're

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Page 136

1 going to say yeah, I have a problem.
2 COL. HOGE: I don't know. I'll have to
3 --
4 DR. SHAM00: I mean -- because you keep
5 saying it as if it's 100 percent, and I'm saying
6 that that's a false impression.
7 COL. HOGE: No, it's absolutely not 100
8 percent, but there are numerous studies that have
9 shown significant differences in the expression of
10 symptomatology, based on the way in which the
11 information is communicated. And I can't tell you
12 what -- I don't --
13 DR. SHAM00: That I have no doubt.
14 COL. HOGE: -- but I have the data -- I
15 can -- the hypertension study, for instance, was
16 in the '70s. It was a New England Journal of
17 Medicine article in the '70s, a classic study,
18 which I've got on my computer and I'll -- now you
19 make me want to look it up because I want to know
20 what the effect size was. Okay.
21 The study that we did has been
22 criticized because it's a simple, based on survey

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1 data of soldiers, surveys obtained three months
Page 137

2 after they came home from deployment to Iraq.
3 These were brigade combat team soldiers, so these
4 were infantry soldiers, mostly male, young. And
5 this was not a clinical evaluation. They were
6 administered a survey, it was an anonymous survey,
7 they didn't have to put their name or social
8 security number on the survey, and it was not
9 linked to clinical care. It's the way we've done
10 a lot of our other studies, the assessments in
11 Iraq, the 2004 New England Journal of Medicine
12 article, and it's been -- it's a tried and true
13 method that's been validated time again.

14 The prevalence rates that we reported in
15 2004 have now been replicated by the VA, they were
16 replicated last week, an Iran study that was
17 released, using a very different methodology --
18 they've now been replicated in a number of
19 different ways on a population level, using post-
20 deployment health assessments with clinicians --
21 we've looked at that and compared -- so these are
22 pretty good methods. We used standardized

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156

1 validated scales for PTSD, depression, physical
2 health symptoms, and we added post-concussive
3 symptoms that were -- those symptoms out of the
4 seven that were not on the physical symptom

5 checklist -- that we used on the survey.

6 And we also asked about injury and we
7 used the DVBIIC questions for TBI. We used as --
8 we asked soldiers, did you have an injury during
9 deployment from a blast or bullet fragment, fall,
10 etc.? Was that injury -- did you -- did that
11 injury cause you to lose consciousness? Be dazed
12 or confused? Have memory problems? Those are the
13 kinds of questions that we asked. And then we
14 compared all of those soldiers who said they had a
15 mild TBI with soldiers who had other injuries, and
16 we had another comparison group which was those
17 who had no injury at all. Scales were separate on
18 the survey. There was no linkage of the -- you
19 know -- they were independent.

20 And the analysis control for
21 demographics, combat intensity, injury mechanism,
22 multiple blast exposures, and other variables, and

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157

1 we had a reasonably good participation rate. We
2 had a great participation rate and a reasonable
3 availability. Yes sir?

4 DR. KAPLAN: Kaplan. Could you just
5 briefly tell us, what is the effect of somebody
6 filling out a questionnaire like that if they
7 think that that might influence whether or not
8 they get disability when they get out of the

9 Service?
10 COL. HOGE: Yeah. We've done those
11 kinds of comparisons and you get lower rates if
12 there's any identification. If they put their
13 name on it or their social security number, they
14 won't endorse -- they feel a little bit freer to
15 endorse -- I think they endorse a little more
16 honestly when there's no link in any way, either
17 to healthcare or to some other outcome. And in
18 this case, this was a research study with informed
19 consent. It was totally anonymous.
20 They were, you know, they could opt out.
21 They didn't have to answer the questions if they
22 didn't want to. The questions were in no way going

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158

1 to be -- you know, they weren't going to come back
2 and track them down. In fact, we didn't have
3 identifiers on the questions, and so it would not
4 be linked to disability in any way. And that's an
5 important -- that's a very very important question
6 you asked because of what the literature shows on
7 disability, because that's not the case necessarily
8 for other evaluations going on.
9 COL. GIBSON: Charles, you use the word
10 independent up there. Are you talking about on
11 the survey the independent seven, or are you

12 talking about the statistical term of
13 independence?

14 COL. HOGE: No. No, on the survey. So,
15 they were asked -- there was an injury section,
16 there was a -- asked about loss of conscious, etc.
17 There was a physical symptom checklist that
18 included the post-concussive symptoms on a
19 different section of the form. There was PTSD and
20 depression measures on a different section for in-
21 combat frequency, etc. They were all -- they
22 weren't linked to one another.

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159

1 We found that out of the 2500 soldiers,
2 5 percent reported an injury event with loss of
3 consciousness, which is very consistent with
4 what's been seen at other posts. Another 10
5 percent reported an injury event in which they
6 said they were dazed, confused, or saw stars.
7 Again, I don't think we know -- we have no
8 understanding at all how many of those had
9 physiological disruption in their brain function.
10 So, I can't tell you that the prevalence figures
11 that DoD has reported are accurate. We don't
12 know. But this is highly consistent with what has
13 been reported. And then another 17 percent of
14 soldiers had other injuries. Blast mechanism was
15 associated with mild TBI. Mild TBI --

16 Percent of the soldiers with mild TBI
17 reported blast mechanism. And it was only 25
18 percent, I think, for those with other injuries,
19 so falls being the most common mechanism of other
20 injuries. So, these were notable combat events
21 with close proximity to blast. There were often
22 other circumstances that happened in battle, you

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160

1 know, buddies getting injured or killed at the
2 same time during these explosions. These were
3 pretty significant combat events.
4 And just very briefly, this shows simple
5 percentages -- the paper that we passed out has
6 all the odds ratios and adjusted odds and that
7 kind of thing. But these are just simple
8 percentages for those with what we're called mild
9 TBI with loss of consciousness. We looked at
10 dazed or confused separately to try to see if that
11 had equivalent specificity as the loss of
12 consciousness and other injury. And you see that
13 those who said they endorsed loss of consciousness
14 were much more likely to have PTSD or depression.
15 Forty-five percent reported -- met the screening
16 criteria for PTSD, and let me go back here. And
17 then they also had a much higher rate of poor
18 general health, high rates of physical symptoms,

19 high rates of post-concussive symptoms, high rates
20 of other non-specific symptoms, missing work,
21 sick-call visits, and it was very highly
22 statistically significant compared with other

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161

1 injury and also particularly with the non-injury
2 category. Now, if we'd stopped right there, which
3 is what we did with our first submission of this
4 paper. We said this is a really important
5 problem. This TBI, mild TBI, is associated with a
6 host of physical health effects. This is a very
7 very significant public health problem.

8 And we submitted that and it got
9 rejected because the reviewers didn't feel that
10 there was sufficient controlled analysis and
11 understanding of what was really going on. So we
12 went back to the drawing board and we reanalyzed
13 the data to look at what really was going on. And
14 what we found was that -- so I'm just looking at
15 this line right here, which is the nice linear
16 trend showing very -- this is a very high physical
17 symptoms score on the checklist, 25 percent of
18 those with a loss of consciousness verses 16
19 percent verses 11 percent. And this is the
20 P-value for that relationship, unadjusted.

21 Now look at what happens when you
22 stratify it by PTSD, non-PTSD. Virtually all of

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162

1 those individuals who had high physical symptom
2 scores were in the group that also met criteria
3 for PTSD, okay? And you no longer see -- this
4 relationship is no longer so clear cut. In fact,
5 it's not significant anymore. This is just
6 another example of the same thing -- is there a
7 pointer here? That's all right. Okay, great.
8 So, up here is that, you know, unadjusted -- so
9 this is the whole sample, the 5 percent that lost
10 consciousness, altered mental status, other
11 injury, and you see a nice linear trend here. And
12 then down here you lose that trend when you break
13 it into PTSD. Look at what happened with some of
14 the post- concussive symptoms?

15 Sleep disturbance, you see a nice linear
16 trend, altered mental status, also was
17 significantly different than other injury. But
18 down here, you lose that relationship. And you
19 see that PTSD really is the driver for a lot of
20 these symptoms. Okay, same, concentration
21 problems; looks like there's a very strong
22 correlation with TBI, not so fast. Look at what

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Page 144

1 happens when you break it into PTSD, non-PTSD --
2 irritability, okay, same thing, memory problems,
3 okay? Now that's just the raw, sort of raw,
4 unadjusted, you know, this is just a simple
5 stratified analysis. I always just try to do this
6 first before doing logistic regression because I
7 want to know what's going on with the data.

8 And we saw this type of relation with
9 virtually every outcome we looked at. Every --
10 one of the symptoms -- the head -- you know, use
11 of medical services, sick-call visits, high
12 physical symptoms, post-concussive symptoms, you
13 name it. The only thing that remained significant
14 was headaches, and only in the 5 percent of
15 soldiers who had loss of consciousness. So there
16 was an important relationship there, but for a
17 relatively small percentage of the sample. And
18 even there, PTSD still was the driver for
19 headaches. Look at the difference in percentages
20 between those with PTSD and non-PTSD.

21 DR. SHAMOO: Because I want to follow
22 everything the same and that has -- could you go

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1 back -- are you telling us that PTSD does not
Page 145

2 overlap with mild TBI?
3 COL. HOGE: It overlaps with
4 post-concussive symptoms.
5 DR. SHAMOO: It does?
6 COL. HOGE: Yeah.
7 DR. SHAMOO: So you don't know if it is
8 the MTBI causative to PTSD or PTSD causative of
9 MTBI?
10 COL. HOGE: Well, we put them in the
11 regression model and there's no -- the direct
12 relationship between a history of concussion and
13 the physical symptoms went away completely when we
14 put PTSD in the model. It removed the
15 relationship -- it's what we call in epidemiology
16 confounding or mediation in the psychology world.
17 DR. SHAMOO: But they do have PTSD?
18 COL. HOGE: Well, a proportion of the
19 sample. So here's the whole sample -- the entire
20 sample is here, okay? So here's the end sizes.
21 So this group that had loss of consciousness --
22 about a little less than half of them, 40 percent,

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165

1 had PTSD, and out of that 124, the other 60
2 percent had, you know, no PTSD, okay? Now in this
3 260, divided out, a smaller percentage had PTSD
4 and then the rest were no PTSD. This 435 broke

5 out into 70 and 363, okay? So now we have two
6 groups: Those who met criteria for PTSD and those
7 who did not meet criteria for PTSD. And now we
8 looked at the simple relationship, again, of
9 injury type.

10 Was there an association any longer with
11 loss of consciousness or altered mental status,
12 i.e., mild TBI, and these health outcomes. And the
13 answer is no. We don't see it for those with PTSD
14 and we don't see it for those without PTSD. So the
15 relationship is -- this is all a spurious
16 relationship. This is not a -- this relationship
17 is only by virtue of the fact that the prevalence
18 rate of PTSD has this -- you know, tracks in this
19 manner. Does that make sense?

20 SPEAKER: You're saying it's spurious
21 because the PTSD correlates to the reporting of
22 brain, of brain injury?

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166

1 COL. HOGE: No. PTSD -- well, PTSD
2 correlates to the presence of brain injury. But
3 PTSD also correlates to the health outcomes, so
4 it's this kind of relationship. Let me show the
5 next slide, it's this kind of relationship. So,
6 you know, the combat event, TBI, leads to high
7 physical symptoms, post-concussive symptoms, and
8 there's a nice high odds ratio. And then PTSD

9 also has a direct relationship to physical
10 symptoms and to the combat event, so there's a
11 high odds ratio for combat event leading to PTSD.
12 And there's a nice significant correlation of PTSD
13 leading to physical symptoms. You put them in the
14 model together though, and this adjusted odds
15 ratio plummets, the unadjusted plummets with the
16 adjusted to non-significant.

17 DR. POLAND: I think we'll need to keep
18 moving on. It's sort of classic epidemiology and
19 we can spend some time afterwards on the sideline
20 talking about it. Let me remind everybody to use
21 their microphone. We're giving PTSD to the
22 transcriptionist, so --

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167

1 COL. HOGE: So, this is -- here's what I
2 think is going on. Let me tell you my hypothesis
3 of what the mechanism is. I think a combat event,
4 a soldier who's in the middle of a fire fight, or
5 the soldier who's in the middle of a patrol, or a
6 soldier who's convoying, experiences a blast or is
7 in a fire fight and gets momentarily knocked
8 unconscious or dazed or confused, can't do their
9 job, even for a brief period of time -- that was a
10 very close call on that soldier's life. It was a
11 very life-threatening event. He was not able to

12 do his job, which also jeopardized his team
13 members. Often there are other events that
14 happen. A lot of times when you talk to these
15 soldiers who've had concussions, you know, they're
16 saying yeah, well I was the lucky one. Okay?

17 A lot of times their buddies weren't so
18 lucky during that same event. Or maybe during the
19 blast event that they encountered the week earlier
20 or the week later, okay? These are cumulative
21 effects that happen. So the combat event, with the
22 loss of consciousness, is a profoundly traumatic

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168

1 event and it leads to memory encoding and the fear
2 -- physiological fear response and autonomic
3 reactivity and neuroendocrine dysregulation and the
4 whole bit, the whole cascade that leads to PTSD.
5 And PTSD, like depression and other anxiety
6 disorders, there's a tremendous literature on the
7 association of PTSD, depression, and anxiety
8 disorders on physical health symptomatology.

9 Folks who have PTSD are much more likely
10 than individuals who don't have PTSD to have a
11 host of medical symptoms because they have
12 dysregulated neuroendocrine systems, autonomic
13 reactivity, immune system dysregulation. So there
14 are profound physiological neurochemical
15 biological effects as a result of PTSD. So I

16 think combat events leading to PTSD, and then the
17 PTSDs leading to physical symptoms, and that
18 explains why we see high physical symptoms that we
19 think is associated with TBI. Okay, now that
20 doesn't mean that for some individuals there isn't
21 an association, okay? But, statistically, on a
22 population level out of 2500 soldiers, okay, the

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169

1 vast majority of these symptoms could not be
2 attributed directly to the TBI. Okay? I hope
3 I've convinced you of that. Clinical implication
4 of this is very direct. Screening for mild TBI
5 months after injury will likely result in large
6 numbers of Service members being unnecessarily
7 referred for evaluation and treatment of
8 non-specific symptoms attributed to brain
9 injuries.

10 When the real cause of their symptoms
11 may be stress responses, you know, physiological
12 responses to stress, trauma, PTSD, depression, the
13 brain injury label, I think, is problematic.
14 Unintended iatrogenic consequences, I think, will
15 occur. And let me show you one example, good
16 example, of that right now. Not a case report,
17 but just simply looking at the DoD website for the
18 guidance that was put out on what to do with

19 soldiers you identify as having traumatic brain
20 injury when they're here in the garrison
21 environment. And two of the things stood out to
22 me. If they have sleep disturbance that you think

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170

1 is related to TBI, give them a trial of Trazodone
2 and Ambien. That's very reasonable; those are
3 first-line agents for sleep.

4 But look at this, if co-morbid symptoms
5 or other PTSD symptoms, give them a trial of
6 quetiapine. That's an atypical antipsychotic that
7 has profound metabolic effects and a variety of
8 other side effects. Weight gain, you know,
9 dysregulation of blood glucose, etc. Now there's
10 no evidence whatsoever -- this is not an
11 evidence-based recommendation, but that's out
12 there. That's been pushed to the Services, it's
13 been widely propagated, and people are doing this
14 clinically. For irritability, give a six-week
15 trial of an SSRI or an SNRI like venlafaxine. One
16 of the principle side effects of venlafaxine is
17 hypertension, okay?

18 So, there will be side effects. It has
19 to happen; it can't not happen. But this isn't
20 really being discussed, I think, sufficiently.
21 Now I think there are some simple answers to this
22 problem, and that's why I'm kind of impassioned

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171

1 today because I feel like you have the capability
2 as the Defense Health Board to influence policy in
3 a very profound way. And I think the solutions
4 are simple. I think we need to revamp our
5 approach to post-deployment screening to minimize
6 risks. And there's some simple ways that we can
7 do that, which I'll talk about in just a second.
8 I think the second thing is that we need to build
9 the structure of care for mild TBI symptoms,
10 remove the attribution component, put this firmly
11 within primary care, and not with specialty TBI
12 clinics or de facto TBI clinics that are sprouting
13 up all over the place.

14 Because those are specialty -- specialty
15 care is very different than primary care
16 interventions. And then we need to disseminate
17 effective risk communication. And this is very
18 much evidence based, so -- well, the screening is
19 kind of -- I think it's common sense, and then the
20 primary care intervention is evidence based. The
21 screening -- some of the things that can be done
22 is screen for all injuries of the PDHA time point

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Page 152

1 only, decouple the symptom questions from the
2 injury questions, and have the provider ask about
3 symptoms, and then focus on treatment of symptoms
4 without necessarily attributing them to TBI. And
5 then don't rescreen. You know, get the history
6 once, get a good history of all the injury events
7 that happened in theater, do a thorough
8 examination of the individual when they come home.
9 What kind of injuries did you have? What
10 happened? Tell me about them.

11 Are you having any health problems that
12 you think are deployment related? Let's take care
13 of those problems. Here's what we can do about
14 them. And then don't keep rescreening for this
15 entity called mild traumatic brain injury for
16 which we don't have any definition at that late
17 stage. Screen for depression and anxiety and
18 PTSD. Okay, that's for the screening.

19 For primary care, I think the foundation
20 for care needs to be based in primary care. And
21 there's -- we already learned this lesson with
22 Gulf War I. And it led to a clinical practice

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1 guideline that's very much evidence based, that is
Page 153

2 based on the step-care approach, the management of
3 unexplained physical symptoms within the primary
4 care context. And that is a process which takes
5 care of the symptoms, takes care of the patient,
6 and also minimizes the iatrogenic risks associated
7 with multiple referrals and evaluations,
8 unnecessary evaluations. And there's
9 collaborative care models in primary care that
10 address mental health problems, and the
11 interrelationship between mental health problems
12 and physical health problems, which is exactly
13 what we're seeing in this.

14 And then the effective risk
15 communication, there's already -- this is the
16 evidence base for mild TBI. This is -- we've got
17 a good track record. Tell people they're going to
18 get better, use proven cognitive behavioral
19 techniques, throw out the mild TBI label, use
20 concussion instead. It has less stigma for
21 families and soldiers. They understand it better,
22 a lot better. Mild TBI is an oxymoron; less

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174

1 likely to be confused with moderate and severe
2 TBI. Reserve the brain injury label for moderate
3 and severe TBI. Draw on sports concussion
4 analogies. Minimize speculation about possible

5 blast effects, which can be detrimental. And
6 that's it. Thank you very much.

7 DR. POLAND: Thank you. Obviously, an
8 area of intense interest and concern, including to
9 this Board, so we'll open it up for questions
10 here. Dr. Silva?

11 DR. SILVA: Yes, thank you for that nice
12 review. Quite frankly, I'm with you, Adil. I
13 read that paper in the New England Journal several
14 times and I really didn't know what it was saying.
15 Maybe it's just me as I get older; had too much
16 traumatic stress syndrome, but that's a very
17 important study and you made a courageous
18 statement to just wipe out the term, which is so
19 embedded now of mild TBI. I look at it as sort of
20 tsunami that's on a roll, it's rolling over all
21 kinds of sectors of our societies, so I think
22 you're courageous.

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175

1 I have just a technical point here. And
2 that is we've been very scrupulous on following
3 FDA recommendations and approvals, and you're
4 using here these SSRI's and NSRI's, do they have
5 approval for the symptom complex that you've
6 indicated and we formally put it up on one of our
7 sites?

8 COL. HOGE: Yes, that's a grave concern
Page 155

9 to me. Yes, it's hung on the website, it's been
10 put out by the TBI, you know -- the individuals
11 who have been responsible for disseminating policy
12 for TBI within DoD. And there is no appropriate
13 approval and evidence base to support that
14 recommendation.

15 DR. POLAND: Dr. Lednar?

16 DR. LEDNAR: Wayne Lednar. Thank you
17 for taking us through the various issues of this.
18 As I was thinking about it, it seems that we need
19 to start with the end in mind. If the end in mind
20 is restoration of individual mission capability,
21 that's a different end than finding pathology. So
22 if we need to decouple mild TBI from the rest of

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176

1 the continuum, moderate to severe, we need sort of
2 a good way to sort of know when there's enough
3 clinical evidence to suggest that we've got a
4 medical issue that really needs to be diagnosed
5 and appropriately managed. One of the points that
6 struck me as you were talking is that the combat
7 theater experience that results in a mild TBI is,
8 in fact, a life threatening one, a traumatic one,
9 a serious one.

10 And nothing that we should do should
11 convey any kind of a message of trivializing it.

12 It's not necessarily a medical long-lasting
13 consequence, but it is a significant event. So
14 coming back to the initial starting point, if it's
15 restoration of mission capability, then what is the
16 right thing to do at the initial time of event?
17 What's the message to deliver? And may be that
18 gets back to your recommendations about the sports
19 medicine experience. But to know that we're
20 conveying that with the real sense that we care
21 about the warrior, we want to be doing the right
22 thing. We don't want to be sort of creating

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177

1 connections which produce iatrogenic injury,
2 medical system-caused morbidity, but we -- there's
3 an art form to this. And a lot of this is not very
4 medical. So we need to be thinking about this, not
5 as a subspecialty, not as a group of medication
6 technology developers, but as a group who's trying
7 to manage the, you know, the whole story for the
8 good of the individual soldier around mission
9 accomplishments. This is a very complex set of
10 system issues that, I think, we all have to keep in
11 mind.

12 COL. HOGGE: I agree and I've sort of
13 been accused of kind of minimizing, trying to
14 minimize the problem. And I hope that's not --
15 I'm not conveying that. I think there's a very

16 real problem. These soldiers who've had
17 concussive events are ill. They have much higher
18 rates of mental and physical health symptoms and
19 use of medical services, and they're struggling
20 and suffering. What the ideology of those
21 symptoms are is only important in as much as it
22 drives clinical care and appropriate communication

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178

1 to mitigate those symptoms, and that's sort of the
2 key thing. And one of the most important messages
3 for soldiers to hear is when you have a -- here's
4 what a concussion is, and yes, it's the same thing
5 as what people are calling mild TBI, but here's
6 why we're going to call it concussion.

7 And if you have a concussion on the
8 battlefield, go see the medic, and this is why you
9 need to see the medic, and make sure you're seen,
10 and don't let your buddy blow off their concussion
11 and just ignore it. Make sure they go in and get
12 seen. That's the time -- that's the education
13 message that needs to go out to the soldiers and
14 leaders. And that's the only message that needs to
15 go out to them. They don't need to be burdened
16 with a whole bunch of information about moderate
17 and severe and, you know, the debate that we're
18 having about PTSD. And it certainly does not need

19 to be coupled with PTSD training, which is what's
20 happening right now. It needs to be just a very
21 simple message to soldiers and leaders about
22 getting help on the spot, you know, at the point of

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179

1 injury. Because once they come home, all bets are
2 off; there's absolutely -- we're going to get it
3 wrong. We're getting it wrong.

4 DR. POLAND: I hate to be the timekeeper
5 here, but we're about 40 minutes over and lunch is
6 up there. So we've also got two more briefings on
7 it, but that doesn't mean we can't take a couple
8 of very focused questions specific to Dr. Hoge's
9 content expertise. The more general, important
10 questions, too, that you have, I think we could
11 hold for after the other two briefings. So if
12 there are very focused questions --

13 DR. PARKINSON: Focused comment. This
14 is Persian Gulf Syndrome all over again. Either
15 we intervene now aggressively, evidence based and
16 effectively across multiple venues, including the
17 education effort we just heard about. Colonel
18 Certain and I had a long, extensive conversation a
19 few minutes ago. Getting the right story is key
20 to not unnecessarily medicalizing, stigmatizing
21 people at an early stage. So I commend the
22 recommendations. I personally support 95 percent

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180

1 of what I saw in Colonel Hoge's presentation, and
2 I would urge us to go offline and talk about what
3 this body needs to do about it.
4 DR. POLAND: Dr. Shamoo?
5 DR. SHAMOO: I finally understand it,
6 and thank you. That is very courageous of you to
7 make that recommendation. But it's been something
8 I have had concern for several years on this
9 Board, even the predecessor. We hear only one
10 sided presentation, and you did an excellent job.
11 I need to see someone who works exactly in the
12 same field who holds different view, because I am
13 a non-expert. I cannot challenge the intimate
14 details of what he is saying. As you all know,
15 analysis can be redone differently and get to a
16 different conclusion. Now there may not be. This
17 may be the case everybody agrees that this is the
18 only way to interpret it; then the conclusions of
19 Dr. Parkinson would be correct.
20 COL. GIBSON: I need to follow up on
21 that. You have two more lectures, or two more
22 presentations, today that will expand on this.

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Page 160

1 I'm not saying they're going to conflict, but they
2 will expand. Charles, you are courageous. I do
3 want to make one comment about the AFEB's
4 recommendations, remarkably paralleling what
5 Charles is talking about. Do this in theater, do
6 post-deployment questioning until you get the
7 ability to educate, clinically evaluate, and get
8 soldiers to present when they have a concussion,
9 and oh by the way, do not over interpret
10 post-deployment screening questions. You guys
11 were very clear about that in this process. I
12 also agree with Dr. Parkinson, we need to jump on
13 this now. We have additional comments, plus a
14 subcommittee, on TBI that will go into much much
15 more depth on this.

16 DR. POLAND: And that's where some of
17 the subject matter experts that's on the committee
18 that can give us a lay of the land in where this
19 fits in the spectrum of how experts think in the
20 field about this.

21 COL. HOGE: This is a field, as Allen
22 Roper said, this is a field dominated by expert

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1 opinion and very little evidence, and the way -- I
Page 161

2 mean that's true, yeah.

3 DR. POLAND: Other comments that
4 again --

5 CAPT. JOHNSTON: Richard Johnson. Just
6 one question really. You're suggesting that the
7 loss of consciousness is a marker for the severity
8 and the life-threatening nature of the injury --
9 life-threatening nature of the event. That
10 explains the increased risk of PTSD. I'm happy
11 that's a reasonable mechanism. But are you happy
12 that you've excluded the possibility of some
13 physiological link between the --

14 COL. HOGE: No, no. There could be a
15 physiological link, but PTSD doesn't happen after
16 being knocked unconscious on the football field,
17 okay? So pathophysiologically, there's not a
18 direct link there, okay? It does happen after
19 motor vehicle accidents because motor vehicle
20 accidents are life threatening. It happens in
21 spades in combat, I think, for the same reason.
22 That doesn't mean that there might be, you know --

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183

1 with an already stressed brain that is stressed
2 physiologically from 24/7 combat, 4 hours' sleep a
3 night. I mean the average duration of sleep a
4 night for soldiers in the operational environment

5 that we just measured was 5 1/2 hours a day,
6 24-hour period, often off-cycle, out of their
7 circadian rhythm pattern. The cumulative
8 cognitive deficit associated with that is
9 enormous. And you add -- so there are already
10 profound effects that are going on, you know --
11 and it may be that when you get a blow to your
12 head on top of that, that it adds insult to
13 injury. There may be something like that going
14 on. But I think that the data speak for
15 themselves. And we shouldn't jump to that
16 conclusion and then build a whole program based on
17 those premises, which scare soldiers, elevate
18 their anxiety, make family members think that
19 their loved one has a brain injury when all
20 they've had is a concussion. You wouldn't do that
21 with football players. I mean you wouldn't -- you
22 wouldn't say you're going to be out of the game,

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184

1 this could be -- this could go on for -- you could
2 have symptoms for a long period of time, and that
3 must explain why you can't find your keys every
4 morning, and why you get in arguments with your
5 wife.

6 DR. POLAND: I'm sorry to interrupt, but
7 we really do need to keep moving along here,
8 especially when you get to the argument with your

9 wi fe. Russ?
10 DR. LUEPKER: Yeah, it's very helpful
11 because I was knocked out on the football field
12 and I've worried about that. I do understand
13 confounding, and I just want to make certain I
14 hear what you're saying or whether I'm extending
15 you further because this was very helpful. So, is
16 it -- are you saying that TBI is not the result of
17 -- the symptoms that relate to TBI are really
18 manifestations of PTSD and not a concussion?
19 COL. HOGGE: Yeah, or they're the
20 manifestations of the physiological downstream
21 effects associated with PTSD, okay? In some
22 respects, we're -- what the outcome is is health

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185

1 symptoms. And then we're trying to explain those
2 health symptoms somehow mechanistically and I'm
3 using -- here I'm using the construct of PTSD,
4 which is a -- it's a defined symptom-based
5 condition to explain -- it better fits the data.
6 It fits the data a heck of a lot better than the
7 mild TBI construct, that's for sure. But it's not
8 a perfect construct either. You know, PTSD has
9 well-codified, well-validated definitions,
10 there's a good neurobiology that we know about it.
11 You know, there's a lot of -- and there's specific

12 treatment for PTSD that's -- so it's different
13 than mild TBI, but it doesn't explain the --

14 DR. LUEPKER: Do you think that TBI is a
15 more socially acceptable diagnosis to the patient
16 to -- as compared to PTSD?

17 COL. HOGE: That's another bit of
18 clinical lore. I don't know. I don't know if it
19 is or not. I hear that a lot. I hear it, but I
20 think on the whole in the conversations I've had
21 with soldiers, I would say it's not so clear cut.
22 I think the mild TBI label is substantially more

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186

1 stigmatizing than concussion. Whether or not
2 soldiers would prefer to be labeled as mild TBI
3 instead of PTSD is such an artificial debate, but
4 people are actually having that debate. It's
5 insane. We're not talking about mild TBI here.
6 We're simply talking about a collection of
7 symptoms and if they meet PTSD criteria, okay.
8 That's yes or no. And then if they have symptoms
9 --

10 DR. HALPERIN: If you view this
11 collection of symptoms as the case, it's related
12 to PTSD. You've shown that. Is the length of
13 time one is knocked out, unconscious, etc., an
14 effect modifier for PTSD, or is it unrelated?

15 COL. HOGE: In our sample it was

16 unrelated, but that's because the vast majority of
17 the folks who -- the 5 percent of Service members
18 who got knocked out, almost all of them fit into
19 the few seconds to two-to-three minute category.
20 There were a few that went longer than that, but
21 not numbers that were substantial enough to really
22 look at that.

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187

1 DR. HALPERIN: So, the effect, the
2 outcome, which is this broad global collection of
3 symptoms, it's related to PTSD, and whether or not
4 one is knocked out is -- that is not an effect
5 modifier, either yes or no you were knocked out?

6 COL. HOGGE: It's an association with
7 PTSD.

8 DR. HALPERIN: It's an effect modifier.
9 You have more PTSD if you're knocked out than not
10 knocked out?

11 COL. HOGGE: Is it an effect modifier or
12 a confounder? I think it's --

13 DR. HALPERIN: Well, effect modifier is
14 something that you're looking for; confounder is
15 something you want to get rid of. So, if you want
16 to see whether getting knocked out --

17 COL. HOGGE: Maybe effect modifier is
18 the better term. I'll have to think about that.

19 I chose the term -- in the paper I struggled with
20 this and I chose the term mediator because in
21 psychological, you know, in the psychological literature
22 when one variable erases the direct effect between

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188

1 -- you know, variable A and the outcome variable,
2 if variable B erases that effect and explains the
3 outcome, then that's viewed as a mediator. But
4 the problem with the mediation model is that it's
5 assumed to be longitudinal and with our
6 cross-sectional data, we couldn't be sure.

7 DR. POLAND: Let me grab the Admiral and
8 then we'll break.

9 COL. HOGE: It's a good question.

10 ADM. GAUMER: Colonel, I just have one
11 comment to make and that really has to do with a
12 concussive event during combat. Any concussive
13 event during combat is going to be related to
14 post-traumatic stress. How we deal, how we
15 communicate that event to the member may well
16 determine whether or not they have a
17 post-traumatic stress disorder. Is that correct?
18 I mean --

19 COL. HOGE: I think how we --

20 ADM. GAUMER: Whether they have, whether
21 they develop, go on to develop post-traumatic
22 stress disorder is different than having it

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189

1 immediately after the event. Is that correct?
2 COL. HOGE: I think that what we can
3 modify is their chances of going on and developing
4 persistent health symptoms of a general category.
5 I don't know if we can modify the prevalence rate
6 of PTSD. I think a lot of factors that drive PTSD
7 are things like biological and genetic factors
8 that predispose certain individuals to PTSD, which
9 is non-modifiable. So there's a limited amount
10 that we can do, but I think education about
11 concussion, appropriate education about
12 concussion, can mitigate the health effects, the
13 physical health effects.
14 ADM. GAUMER: But somebody who has a
15 concussive event, telling them that they got their
16 bell rung is different than telling them they have
17 TBI.
18 COL. HOGE: Absolutely. Absolutely, and
19 that -- and we need to be telling them that they
20 got their bell rung. Yeah.
21 DR. POLAND: All right, thank you.
22 We're going to break for about an hour for lunch.

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Page 168

1 (Whereupon, at 12:26 p.m., a
2 luncheon recess was taken.)
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2 (1:30 p.m.)

3 DR. POLAND: All right, if people will
4 take their seats, we're going to go ahead and get
5 started.

6 There has been a request for something
7 sweet, so wanting to please all, at 2:30 there
8 will be -- I think they're brownies -- outside the
9 door. You'll have to apply to receive one! All
10 right.

11 Our next speaker's going to be Colonel
12 Lugo, I hope I say it right, Lugo? Is that right?
13 Chief of Staff to the Director at the Traumatic
14 Brain Injury Psychological Health Center of
15 Excellence, and he'll brief us on this new Center.
16 We're handing out copies of the slides and they'll
17 be in Tab 5, under your Tab 5.

18 COL. LUGO: Okay, well thank you. I
19 hope that's not too loud. My name's Colonel (off
20 mike). Can you guys hear me? While he's setting
21 up, I'll just give a couple of introductory
22 remarks.

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192

1 First of all, I'm here on behalf of
2 Colonel Loree Sutton, the Director of our Defense
3 Center of Excellence for Psychological Health and
4 Traumatic Brain Injury, and I say it that way

5 because we go by DCoE, although our name may be
6 changing in the future and that's one of the
7 issues that we're working with in the Department
8 of Defense. And then our name as is written up
9 here -- and I'm going to talk about the
10 organization of the DCoE and the -- where we're at
11 on the NICoE, which is the National Intrepid
12 Center of Excellence for PH and TBI. Again, that
13 organization does not exist yet, but it will be
14 our clinical arm, and I'll talk about that a
15 little bit.

16 By way of background, I have just
17 finished -- I've been working this job for about
18 three months. I had it while remaining as
19 Director of the DoD Executive Agencies for the
20 Army in the Army Surgeon General's Office, but as
21 of last week, I only have one job now. I'll
22 sorely miss the Executive Agencies, including AFIP

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193

1 and a few others, some of which you may hear from
2 today and tomorrow. I launched into this world of
3 PH and TBI, and trust me, I am not a clinician.
4 I'm a healthcare administrator, came up in the
5 healthcare operations side of the house, spent
6 most of my 25 years in Service in operational and
7 tactical units in the Army, with my last job being
8 a commander of a combat support hospital, 212

9 Combat Support Hospital in Germany and had the
10 opportunity to deploy that organization to
11 Pakistan for the earthquake relief support down
12 there. So, a lot of my background has to do with
13 soldiering and leading soldiers and doing that
14 sort of thing. So I have a few stories to tell
15 Dr. Hoge about concussions and getting bounced
16 around. We good now?

17 Colonel Sutton sends her regrets. Her
18 schedule and her life is not her own anymore.
19 She'll get promoted on 9 May and it'll change even
20 more. So I'm charged with synchronizing,
21 integrating, orchestrating, the staff of the
22 Defense Center of Excellence and working with our

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194

1 wonderful Centers of Excellence in their
2 respective areas, and I'll talk to those. Slide
3 please, or am I doing it? You got it? Okay.

4 So I'm going to give the quick overview
5 of our missions, organizations, and milestones for
6 the DCoE and then the NICoE, and then give a
7 summary and then entertain questions. Any
8 questions you have about our organization I will
9 answer. If you start asking me about prevalence
10 rates or issues with TBI and PH, I'm going to
11 defer to the experts in the room. Dr. Jaffee on

12 my left and Dr. Hoge, if he's back in the room,
13 although I'm starting to get dangerous. Slide
14 please.

15 By way of overview, just to put things
16 in perspective, you see on the left some of the
17 rows of the Health Affairs and then the Military
18 Community and Family Policy. Right off the bat,
19 the Defense Center of Excellence is not a
20 policy-making organization. We inform policy. We
21 assess the effects of policy as we're growing.
22 We'll probably wind up later on ghostwriting

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195

1 policy, as you all know how the world of DoD
2 works. And then this National Intrepid Center of
3 Excellence, which I'll talk to a little bit more,
4 will be our clinical arm, but it will be more than
5 just assessing and providing advanced diagnostics
6 and developing treatment plans for our patients.
7 There might be some research that will go on in
8 that facility, and I'll describe that a little
9 more. We work very closely with the Deputy
10 Assistant Secretaries of Defense in Health
11 Affairs, Dr. Joe Kelley and his side of the house
12 for clinical policy and programs, Ms. Embrey on
13 the Force Health Protection and Readiness, and
14 many others. Slide please.

15 By way of history, I mean we've heard
Page 173

16 today already about the effects and the direction
17 from -- that NDAs and the various external
18 commissions and the amount of dollars that were
19 given to the Department of Defense to identify and
20 initiate many actions and programs across the
21 department. In a nut shell, if I may -- and I'll
22 get to our mission in a second -- we see ourselves

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196

1 as being charged as the Department of Defense's
2 front door for all things PH and TBI.
3 Notwithstanding my comment about policy, so if it
4 comes in and it is a policy issue, we get it, we
5 get it to the right place, or we collaborate with
6 those policymakers, policy writers. And we work
7 across the Department of Defense, across the
8 federal government, across the nation, and already
9 we have queries and have some initial
10 collaboration, dialogue, with other nations, and
11 intend to do more of that in the future. So the
12 notion of a global Center of Excellence is not so
13 farfetched. Our director is asking for that to be
14 considered and has formally presented that to the
15 senior leadership, medical leadership in the
16 department, and may take that up to the SOC, the
17 Senior Oversight Committee that was mentioned
18 earlier. We'll see where that goes.

19 We're one of those organizations that,
20 right now, funding is not an issue for us, though
21 it may be, and we have to plan for it. So we're
22 going to be involved with the Program Objective

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197

1 Memorandum (POM) procedures. That is, determining
2 what our requirements are for funding in the out
3 years. We're going to be dependent on
4 supplemental funding certainly this year and next
5 year. Staffing -- we're young, we're standing up,
6 we're -- sometimes I describe our organization as
7 -- and it may be cliché to some of you, but we're
8 an aircraft that barely has a frame on it. We're
9 flying. We have a bare minimum crew on it, very
10 little maintenance staff on, and we don't control
11 our rate of speed or (off mike) on most days.
12 Certainly Colonel Sutton does not. And many
13 people jump on and off of our aircraft as we go,
14 and produce now sort of thing. But it's flying,
15 although you would think that would be impossible.
16 And that is, we are accomplishing our initial
17 objectives as a Center. Slide please.

18 This is our vision. We had a summit
19 back in February where we did that mission
20 analysis and determination of objectives and
21 goals. So keeping the faith with our warriors'
22 families and leaders and communities is where we

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198

1 want to be, and you can take that word faith and
2 draw your own conclusions. So, therefore, our
3 mission is to maximize those opportunities. And
4 warriors is a broad term. It's not just those
5 that deploy and fight. We're talking about all
6 our Service members and those associated with
7 them. And we want to build this collaborative
8 network. And so we're thankful for this
9 opportunity here where we can talk about our
10 Center, meet folks, inform you of what we're
11 doing, and hopefully you'll reach out back to us
12 and share with us best practices, identify
13 additional networks that we can tap into. And the
14 focus is on resilience, recovery, and
15 reintegration when all is said and done, for both
16 PH and TBI. Slide please.

17 This slide Colonel Sutton spends a lot
18 of time on, and really we could brief off of this
19 slide and not talk the rest. So the rest of the
20 slides will go a little fast. Everybody has one
21 of these charts in their organizational structure
22 of the world revolves around me. Colonel Sutton

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Page 176

1 quotes Mr. Fisher of the Fisher Foundation as
2 saying "this is the tree of life." So I wanted to
3 identify that we were a center of centers. And
4 you've already heard from the National Director
5 for DVVIC and what they do, and the grand history
6 that they've had in working in the world of TBI
7 over the last 16, 17 plus years. We also -- and
8 so these Centers, in these colors right here, are
9 at different levels of integration with our Center
10 of Excellence. The integration extent of DVVIC is
11 a little more so than, let's say, the Center for
12 Deployment Psychology, which is based out of
13 USUHS, and even more so than the Deployment Health
14 Clinical Center led by Colonel Chuck Engle out of
15 Walter Reed, based out of Walter Reed. I failed
16 to mention the CDP Chair, led by Dr. David Riggs
17 out of USUHS. And then most recently, we have
18 begun working with, collaborating with, the Center
19 for the Study of Traumatic Stress led by Colonel
20 Bob Ursano, again also out of USUHS. DVVIC, of
21 course, is our largest Center, and then these two
22 Centers are the smaller ones, but their mission

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1 and their accomplishments are tremendous. The
Page 177

2 NICOE, National Intrepid Center of Excellence, is
3 a facility that's going to be built with the
4 generous gift led by Mr. Fisher and the Fallen
5 Heroes Fund, the same organization and individuals
6 generally involved with standing up the Amputee
7 Center in San Antonio, Texas. Mr. Fisher and the
8 Fallen Heroes Fund have already proffered and the
9 Department of Defense have accepted a gift of this
10 Center, which will be built by them and equipped
11 by them, a \$50 to \$70 million facility that is
12 going to be built on the grounds in Bethesda,
13 across the street from their Command Wing, there
14 by the helipad. Looks like they will break ground
15 this summer and he wants to -- Mr. Fisher has set
16 a challenge for all to build that thing faster
17 than the one in San Antonio and at 14 months or
18 less from breaking ground to seeing patients.
19 I'll talk more about that a little later. So,
20 we're very proud to be associated with, to be
21 working with, and integrating DVBC, CDP, DHUC,
22 CSTS, and sort of have our own organization stand

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201

1 up with us in the coming years. You see the
2 different associations that DVBC has with the
3 outlying site. It's the same thing with DHCC, and
4 I'm sure you can ask Colonel Jaffee about his

5 organization a little bit more. But we can't do
6 what we do in the DCoE and in the Department of
7 Defense without collaborating with, partnering
8 with, the organizations that you see listed here.
9 And I'll talk to some more of those initiatives.
10 Slide please.

11 This is a little more -- a better
12 description and highlights of some of the things
13 that our Centers do right now or intend to do, by
14 no means not all encompassing at all. Very, very
15 important partnerships, collaborations, and
16 integration with the Centers. Slide please.

17 This chart indicates our current
18 organizational structure. We do not have all
19 these directors on board, but we have their name
20 and their inbound. So, this organization chart to
21 some of you may look like a military organization,
22 to some of you it may look like an academic- type

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202

1 organization, or to some a more scientific medical
2 organization. So our intentions are to have the
3 Director, right now a flag officer, Colonel Sutton
4 just recently announced with collaboration with
5 the VA. Secretary Peake has named Dr. Sonja
6 Batten, who has been working with the DoD's Red
7 Cell over the past year and works over there.
8 She's going to come in sometime in June and be our

9 Deputy Director for the entire Center. We've got
10 inbound senior executives for both Director for PH
11 and TBI. Both military officers, Captain (Select)
12 Zimmer is coming in for the PH side, and pretty
13 soon we're going to announce an officer coming in
14 for the TBI side. Right now, standing right here,
15 that might be the longer in-state organization
16 where I have all the administrative operations
17 staff. Today, however, I'm right here since I am
18 serving as a supervisor and rater for these
19 directors. Perhaps it might change when we get a
20 new -- the deputy director in.

21 We've organized ourselves with a
22 strategic plans directorate, resilience prevention

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203

1 operations, and then clinical standards --
2 standards of care for both PH and TBI. Training
3 and education, research, and then this directorate
4 still evolving as to what they will do. Their
5 main focus is on research and surveillance
6 efforts, and we wanted to coordinate with the
7 Armed Forces Health Surveillance Center who you'll
8 hear from a little later on and others. And also
9 we want to look at the quality assurance and
10 program evaluation, both internal and external. A
11 broader clearing house advocacy and outreach. A

12 lot of capability or objectives that we have
13 there, including a 24/7 call center that we want
14 to establish in the near future, and finally, a
15 directorate that will take a look at all things
16 tele-health and technology. Again, our mission
17 charter is across the Department of Defense and
18 partnering with other federal organizations,
19 national and global. We have phases; we are in
20 our initial operating capability, Phase 1. We are
21 occupying space and (off mike). We will be moving
22 a good chunk of our organization to Silver Spring,

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204

1 Maryland, where we will bring in some of the
2 Centers and some of the staff from the Centers,
3 beginning in July through the fall. And then when
4 -- about the time that the NICoE is built and we
5 start seeing patients is when we expect to have
6 full operating capability. I took off the budget
7 numbers. I just didn't want to get those budget
8 numbers out there in the public yet, although a
9 lot of the numbers are out there already. But out
10 of those \$900 million that the Department of
11 Defense received, the Department -- the Center of
12 Excellence received quite a good chunk of that
13 money, well over \$100 million, both in operating
14 dollars and research and development dollars.
15 Slide please.

16 Like any organization, we have a concept
17 of operations, and we have milestones to get
18 there. I'm not going to belabor these things,
19 but, you know, we're already here. We've already
20 developed a concept of operations for the NICoE
21 and a charter for that NICoE because we needed to
22 get that done to influence the design and

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205

1 construction of that facility, and we're doing the
2 same thing for DCoE. Big task for us; and where I
3 think we will rely on a lot of external
4 organizations and advisory boards is this gap
5 analysis in all things PH and all things TBI.
6 Slide please.

7 We have lots of highlights. Colonel
8 Sutton chose to just put a few here, but our
9 highlights are numerous just in a matter of a
10 couple of weeks. The recent Rand study that was
11 released took some of our time in terms of
12 analysis in providing feedback to our key leaders,
13 and also discussing with the media. We've been
14 involved already, even though we only have a few
15 people on our staff, with working with the Army
16 and other folks in terms of reviewing research
17 programs and making recommendations on programs
18 that should be funded. And then we have RDT&E

19 dollars, research dollars that we control and can
20 determine which proposals should be funded or not,
21 and all scientifically reviewed, peer reviewed,
22 and programmatically reviewed. Our Centers really

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206

1 do the work, the bulk of the work out there, and I
2 could talk all day, all night, about those guys.
3 Tremendous work being done by DVBI C, CDP, DHUC,
4 CSTS. Slide please.

5 NI CoE, a similar overview. Some of us
6 use the term, this will be our crown jewel, but
7 really all our Centers are crown jewels in one
8 respect or another. Similar history, staffing,
9 we're developing that. I'll show that in a
10 second. We got to get on with it in terms of
11 hiring -- identifying staff to hire and then doing
12 the hiring actions. Slide please.

13 This is the vision for the NI CoE, and
14 some of you are welcome to ask questions about
15 this or comment on it. Essentially, this facility
16 is going to be focused on an intensive outpatient
17 evaluation, diagnostics, initial treatment plans,
18 and long-term follow of patients. Ideally, these
19 patients will be referred to us. Many of them
20 likely will be the more challenging, difficult
21 cases, likely will be co-morbid type patients, and
22 they'll walk out of there with a well-developed

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207

1 treatment plan. While they're at our facility --
2 housed, by the way, likely in additional Fisher
3 homes that Mr. Fisher's going to build on Bethesda
4 on top of the ones that are already there. I
5 believe there are at least two more that he's
6 going to make happen -- but while there, we will
7 certainly use the cutting-edge, evidence-based
8 practice and use the best technology possible.
9 Frankly, the Fallen Heroes Fund and our staff are
10 looking at what are we going to put in this
11 facility? What is state of the art? What is
12 emerging? What is the best out there? And in
13 doing so, we're also going to employ some research
14 tools, and out of that I believe will be some
15 research that will get done whether -- and this is
16 where Mike can help me out, but whether we get
17 into clinical investigations or not, we shall see.
18 There's a lot behind all of that. We want to
19 facilitate this maximum recovery, and eventually
20 we want to return these warriors back to their
21 communities with a robust treatment plan. Slide
22 please.

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Page 184

2 capabilities are going to be. We expect all that
3 environmental stuff and all those design approval
4 steps to happen in the next month and a half, and
5 in June break ground, and by October '09 to have
6 -- open the doors and see patients. And you do
7 the math on that, and if you're familiar with
8 military construction or any kind of construction
9 -- and equipment, with state-of-the-art equipment,
10 hiring the best staff available, and not just in
11 the military, but we want to go across the nation.
12 By the way, we would certainly welcome advice and
13 references, referrals, of the best of the best out
14 there to come work in our facility. Slide please.

15 We have not done this alone. We could
16 not have. We've had a large work group with
17 representatives from all of these organizations.
18 We're thankful to have the VA and the NIH, and the
19 folks from USUHS and the folks from the National
20 Naval Medical Center, and then the design group
21 that Mr. Fisher brought on, working together to
22 achieve all of these great results, and anybody

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210

1 knows Mr. Fisher and what he can accomplish, and
2 if you know anything about our young,
3 still-standing, growing organization, we're going
4 to make this happen. We're committed. We have

5 the leadership support to do it. Slide please.

6 In doing all of this, you've got to have
7 products out there. You've got to document what
8 you're doing, not just for historical purposes,
9 but to guide and refer. And we have all of that.
10 We have a concept of operations. We have a
11 charter. We've developed manning documents.
12 We've developed capabilities documents. We can
13 make many of these available to folks that are
14 interested in working with us. Slide please.

15 This is the current design. I don't
16 think it's going to change much externally. If
17 enough -- if you're familiar with Bethesda, this
18 side back here is where the command side of the
19 facility is there and the President's helipad is
20 over here. You guys know more about this than I
21 do, but Colonel Sutton likes to describe the
22 L-shape aspect of this building and then the sort

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211

1 of curved right side of this facility. And I
2 don't think the designers did that by accident, by
3 the way. It's going to be a tremendous facility.
4 You see that. We started out with approximately
5 60,000 square feet; we're now in the 80,000 square
6 feet. I think we're going to hold there because
7 there's only so much room on this little hilltop.
8 And it's going to be two stories, and you see the

9 rest of the description there. Slide please.
10 This is a NICoE FACI -- I realize there
11 are some acronyms in here; I can help you with
12 them a little later on, if we need to -- but this
13 is what I was trying to describe in terms of
14 having the best of the best in terms of
15 capabilities and staff. We're working every day.
16 Mr. Fisher has identified donors to provide,
17 procure, or just donate the dollars to get this
18 type of equipment.
19 We have milestones. We have a project
20 plan. So just wanted -- the purpose of this slide
21 is to show you that we're into details, in the
22 weeds of planning, and then we're able to step

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212

1 back and have those major milestones. So, come
2 June, July, we shall see what comes out. We don't
3 expect to have a big groundbreaking, shovel-type
4 stuff ceremony for this unless that's what the DoD
5 wants with regards to other facilities on
6 Bethesda. Slide please.
7 So, it went rather quickly. This is a
8 summary of what we've talked about. We're very
9 excited. We appreciate everybody's interest in
10 what we're doing, everybody's support. I tell you
11 Colonel Sutton can pick up the phone or send an

12 email and call and ask anybody for assistance, and
13 everybody comes running to help, everybody's
14 offering to help. Certainly this Board and us are
15 -- we're going to be collaborating quite a bit in
16 the future with the Family Caregiver Panel, the
17 subcommittees both for TBI and PH, and working
18 with many members here in your capacities back in
19 your organizations. Slide please.

20 I'll leave you with this and then take
21 any of your questions. This particular poster is
22 representative, or an initial depiction, of a

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213

1 broad national campaign that we want to start
2 addressing stigma issues. We're calling it a
3 pro-resiliency campaign, a take-off from the NIH
4 campaign of Real Men, Real Depression. Looking at
5 it -- Real Warriors, Real Battles, Real Strength,
6 and yes, playing on those words a little bit and
7 focusing on resiliency, recovery, and
8 reintegration. You'll hear more about this
9 national pro-resilience campaign. By the way, if
10 I may take 30 seconds there, if there's an area
11 for the Board to may be consider in the future:
12 Just like you're hearing or receiving information
13 on TBI, and I'm sure in the future you'll be
14 hearing on PH, the whole issue of resilience and
15 resiliency may be something you want to take a

16 look at, because we sure will seek advice from
17 folks on where should we head on that. And we
18 want to get buy-in from our line officers and our
19 line leaders in terms of resilience.

20 Why don't we leave it there, and I'll
21 gladly take some of your questions, comments.

22 DR. POLAND: Thank you. We'll start

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214

1 with Dr. Silva.

2 DR. SILVA: Silva. Thank you for a nice
3 review of what's coming up. You're obviously on a
4 fast track. Can we eventually get the research
5 programs that are funded? You mentioned in the
6 area of 75 programs recommended. When that
7 decision's made, I think it would be interesting
8 to look at it, what the list -- and what the areas
9 of focus are going to be. And this represents a
10 lot of monies, I think, isn't it? What does this
11 represent? \$100 million?

12 SPEAKER: Three.

13 DR. SILVA: How much?

14 SPEAKER: \$300 million.

15 DR. SILVA: Pardon me.

16 COL. LUGO: Yes, the total allocation
17 was \$300 million for research programs. Working
18 with the Medical Research and Materiel Command and

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19 the CDMRP office, those decisions have been made.
20 They're still procurement-sensitive and so the
21 announcements will come shortly. And then we've
22 made our own internal DCoE assessments for

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215

1 additional programs to be funded.
2 COL. GIBSON: Just a follow up with
3 that. We've got these two subcommittees that will
4 be interfacing directly with respect to the
5 research. What we could do for the core Board as
6 the subcommittees come back and brief us is start
7 talking about the scope of it. If I understand
8 Angel's approach -- or the approach that he
9 defined -- it's very similar to the
10 Congressionally directed medical research program
11 -- when you start talking protocols, a peer
12 review, quality of research, and then a
13 programmatic review. In addition to that, an
14 opportunity for groups like this and these two
15 subcommittees to start talking about
16 prioritization of subject matter with respect to
17 those things. So, with respect to the categories
18 of research, we won't -- hopefully -- we won't get
19 into the peer-review process. That's really not
20 our game.

21 DR. POLAND: Dr. Lednar?

22 DR. LEDNAR: Wayne Lednar. Thank you
Page 191

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216

1 for that presentation. I guess a question about
2 whether this thought is in scope for the Centers
3 of Excellence. Clearly you're going to raise the
4 bar about how to diagnose, treat, and manage
5 psychological health and other issues, so from a
6 medical care point of view, care will get better.
7 I like the focus on what is mission relevant. I
8 mean, the reason we're doing this is not just to
9 be good doctors, but to have a mission-supporting
10 impact. We don't do enough of that in medicine.
11 So my question about scope is whether or not, as
12 you develop these standards about psychological
13 health, will you be carrying those across to what
14 you might call the med-surg side of the house?
15 So, if we really are a cardiologist and we want to
16 provide good patient outcomes, we take care of the
17 patient and not just their coronary vasculature.
18 And there are increasing data showing that if you
19 provide for the psychological health aspects of
20 patients in their medical-surgical care, you'll
21 get better medical-surgical outcomes. So, will
22 you cross over this schism that exists between the

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Page 192

1 mental health world and the med-surg world to
2 improve the clinical outcomes on the med-surg
3 side?

4 COL. LUGO: The simple answer is yes.
5 The deeper answer I will defer to my colleagues on
6 responding to that, but we -- part of our charter
7 is to identify and collect best practices in the
8 world of PH and TBI, and then get that back out
9 there. Whether it's from out to the point of
10 injury, through working and collaborating with the
11 policymakers and the combatant command side of the
12 house, or whether it's working with the VA and the
13 follow-on care that our warriors get when they
14 become veterans. So the answer can only be yes to
15 your statement. Did you want to add any more
16 comments to that?

17 COL. JAFFEE: One of the visions of the
18 Center of Excellence is to establish the means and
19 mechanisms to disseminate and distribute that
20 information, as well as collate it and review it.
21 And that's where that clearinghouse function came
22 in that Colonel Lugo had on his diagram as the

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1 extrication and training sections, kind of taking
Page 193

2 some of those best practices and being able to
3 make those available. And so it's certainly -- I
4 think within the purview, I think the main
5 questions are how best to execute and how to make
6 that the most effective.

7 DR. LOCKEY: Jim Lockey. Thank you for
8 the comprehensive review. When I looked at the
9 slide where you reviewed the capacity of NICoE,
10 you had -- it was very comprehensive -- but one
11 aspect that was missing was visual impairment.
12 That may be related to TBI. Is that going to fall
13 someplace else under the Center of Excellence or
14 is that outside the Center of Excellence?

15 COL. LUGO: We are aware and will be
16 collaborating with the DoD's efforts for the
17 Ocular or Eye Center of Excellence, which is still
18 in development in terms of concept. But we're
19 certainly going to be working with patients that
20 may have those injuries, and Mike wanted to
21 address that a little further.

22 COL. JAFFEE: It's certainly an

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219

1 important area of the -- the NDAA did sort of
2 mandate that the DoD establish an Eye Injury
3 Center of Excellence, which was to focus -- one of
4 the foci that was identified was to address the

5 issues of visual impairment in the setting of
6 traumatic brain injury. There's a DoD champion
7 that's been named to lead that effort, and as well
8 as sort of a DoD ophthalmologist, there's some VA
9 leaders as well. General Kelley may want to speak
10 to this. There's an organizational meeting, and I
11 think that effort is in development and well under
12 way. The issue came up as to whether that Center
13 should be a part of the Center of Excellence, but
14 for a variety of reasons, it looks like they'll be
15 their own Center. They have a network concept, I
16 think, in mind, but there will be a close
17 affiliation and working relationship between the
18 DCoE and the Eye Injury Center of Excellence. I
19 don't know that there's another place in the DHB
20 that would be a good place to provide that
21 oversight like we talked about this morning, and I
22 think that we talked about adding that to the TBI

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220

1 External Advisory Subcommittee to make sure that
2 that gets done. But that's certainly an important
3 issue.

4 MAJ. GEN. KELLEY: I think that's a good
5 summary. It looks like the Army is going to be
6 the executive agent for the Center of Excellence
7 for eye care. And we actually did -- in the
8 process might want to make that the Center of

9 Excellence for Eye Care, focused on ocular
10 injuries, and because we already had the Traumatic
11 Brain Injury Center, we wanted to keep that
12 focused on the TBI issues broadly to include
13 visual issues. And so, from the conception, the
14 idea is that they would work together, realizing
15 that -- with the thought process that if either
16 one was part of the other one, you would lose
17 something. You would lose the emphasis on that.
18 And so the TBI injury and their visual impact
19 would be by Dr. Jeffries' organization and the
20 DCoE. And then the physical traumatic eye
21 injuries, or traumatic injuries to the ocular
22 nerve rather than -- there may be some TBI

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221

1 traumatic injuries, but there are some additional
2 ones that you may not be able to see. So, there
3 was a thought process that you don't want to have
4 a Center of Excellence that just keeps getting
5 bigger and bigger and bigger and has everything,
6 and then everything loses its emphasis.

7 COL. LUGO: Can I -- point of
8 clarification if I may. In the NDAA, you may see
9 language that said the DoD will establish a Center
10 of Excellence for PH, a Center of Excellence for
11 TBI, and then this Center of Excellence for Ocular

12 or Eye Injuries. Our organization was formed to
13 combine the Centers of PH and TBI, so we're one
14 Center addressing those two requirements. But
15 certainly there'll be collaboration with this
16 emerging Center. I mean, recently Colonel Sutton
17 got asked to go testify on the VA side of the
18 house with the Army and talk about our initiatives
19 and intent on establishing the Eye Center, so, no
20 doubt that we will be collaborating.

21 DR. POLAND: Colonel Lugo, could you
22 comment, because it wasn't clear with sort of the

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222

1 diagram you showed there. For both DCoE and
2 NlCoE, what are the reporting relationships? And
3 who do they report to?

4 COL. LUGO: Yeah. I should have
5 outlined that first. The DCoE is accountable to
6 and reporting to Dr. Casscells, the Assistant
7 Secretary of Defense for Health Affairs. Colonel
8 Sutton is a Special Assistant to him for PH and
9 TBI, and the Center reports to the Director of
10 TRICARE Management Activity (TMA), which is Dr.
11 Casscells. So, that's who we were accountable to,
12 but we are supported by and we work with TMA and
13 the rest of the (off mike). And, of course, Dr.
14 Casscells is accountable to Dr. Chu and the rest
15 of the world.

16 DR. LOCKEY: Jim Lockey. One other
17 question. When there's funding available for
18 research, is that funding going to flow through
19 the Center of Excellence? And is it going to --
20 is there going to be an extramural part and
21 intramural part? Or where does the funding --
22 what's the budget for the Center of Excellence,

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223

1 particularly in relationship to research endeavors
2 to fill gaps?

3 COL. LUGO: Certainly. I could speak to
4 this year and to the intent of the future. Out of
5 that \$300 million, we got a chunk of that that was
6 under our control to determine what research
7 initiatives to fund. Using the same process that
8 the rest of the Department of Defense did through
9 the Medical Research Materiel Command and the
10 Congressionally mandated Research Development
11 Program. And we collaborated on both sides. We
12 were part of those programmatic reviews that CDMRP
13 did for those programs, and then our \$45 million
14 that we had this year -- and I can talk to that,
15 that's public knowledge -- we used that and used
16 the same peer-reviewed initiatives. In other
17 words, they made the cut, but did not make the
18 funding cut. And we took a look at those and

19 decided on which ones to fund from our specific
20 perspective, though we were involved in the
21 overall prioritization of the initiatives that
22 were funded. So in the out years, we will

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224

1 continue to be involved in such a matter. I can
2 speak to next year; in the program years, there
3 will be some policy decisions that need to be made
4 because the funding flowed through HA, TMA, into
5 the Line of Action number 2 lead, which happens to
6 be Ms. Embrey, in terms of determining how the
7 funds were allocated. We envisioned in the future
8 that that responsibility will fall primarily on
9 our Center, though still having the approval
10 authorities reside with the ASDHA, Dr. Casscells'
11 level.

12 DR. POLAND: Okay. Dr. Shamoo and then
13 we're going to cut off the discussion and move on
14 to the next one.

15 DR. SHAMOO: Research with the brain
16 brings with it, just in general, a host of
17 cutting-edge ethical issues and challenges, and
18 especially if there is a component research with
19 this population, this highly sensitive population.
20 And since you have already funded 90 research
21 projects, I was wondering if you have already
22 incorporated some ethical (off mike) sort of

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225

1 concern on these topics. If not, you should.
2 COL. LUGO: Again, my depth of knowledge
3 in that particular is not that deep, but I assure
4 you that we have incorporated that review, or that
5 aspect of deciding what to fund. And we welcome
6 feedback from you and others on how to better
7 approach that. And I'll certainly take that back,
8 because I do want to know the exact answer on how
9 we did it. But CDMRP and MRMC, they do this year
10 in and year out. And it all eventually leads to
11 time back to an answer of the research we do is
12 tied to supporting our warriors and the readiness
13 of our warriors and their families, so there's a
14 link.
15 DR. POLAND: Thank you. All right,
16 thank you very much. Our next speaker then will
17 be Lt. Colonel Jaffee. He'll give an update on
18 the Traumatic Brain Injury External Advisory
19 Committee. We also, of course, have Dr. Kelley,
20 the Chair of this newly formed DHB Subcommittee
21 with us today.
22 COL. GIBSON: He's not here. That's the

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Page 200

1 other Dr. Kelley and he's not here.

2 DR. POLAND: Aah, so you're not going to
3 take that one, too? Talk about dodging a
4 bullet. Okay.

5 COL. GIBSON: Dr. Kelley is not with us
6 today. He had a conflict at the last minute and
7 was not able to attend. So, Dr. Jaffee, you have
8 the con.

9 COL. JAFFEE: So thank you. So, let me
10 go on to the next slide. My goal for this
11 briefing is to just kind of put things in context.
12 We put a lot of different terms thrown around,
13 just to kind of do a quick review, a kind of all
14 the organizational things that have happened,
15 really, over the past year or so, putting some of
16 the TBI issue in perspective. And then our goal,
17 really, in my role as liaison to the panel, was to
18 really outline what some of the challenges are and
19 facilitate discussion. And I'm going to kind of
20 tell you about -- summarize some of that -- some
21 of the information that they got, and in an
22 abbreviated form and talk about kind of the

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1 priorities that they have identified at this point
Page 201

2 in time.

3 So, I'm going to start off by
4 illustrating for you some of the scientific
5 debates set in form this issue, and how that also
6 directly relates to some of the policy challenges
7 as we talk about the components and makeup of the
8 TBI External Advisory Subcommittee and their
9 preliminary plans. Next.

10 So, to put into perspective the scope of
11 the problem, depending on which data set that you
12 use. In this particular case, I'm using DoD and
13 JTTS primarily. You have a total number of
14 wounded, there being over 31,000 as of April 22nd.
15 According to JTTS, two-thirds of the wounds from
16 OIF/OEF are related to blast, again that's talking
17 about all wounds, not just traumatic brain injury.
18 Of soldiers exposed to a blast, according to JTTS,
19 41 percent had evidence of a TBI. If we take a
20 look at some of the DVBIC data, looking at Walter
21 Reed, just about a third of the battle injuries
22 who required in-patient treatment at Walter Reed,

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228

1 meaning they likely came home through the aerovac
2 system, were found to have a co-morbid traumatic
3 brain injury. Another way of tracking this that
4 those of us in the Air Force sometimes use is

5 looking at the aerovac system. We know that 21
6 percent of aerovac patients have had at least one
7 head and neck trauma code, but oftentimes that
8 system doesn't account for all of the diagnoses
9 that people may have. If we kind of take a look
10 at the current breakdown, if we're looking at
11 these combat injuries, the vast majority are, in
12 deed, mild at 85 percent, with moderate accounting
13 for 7 percent, the severe is 4 percent, the
14 penetrating 3 percent, and unknown 1 percent. And
15 just kind of want to make one comment, on that
16 penetrating of 3 percent, that most of the
17 injuries we're dealing are, in deed, considered
18 closed, which is a marked difference, if you will,
19 say from some of what we considered head injuries
20 from the Vietnam era, if you look at the Vietnam
21 head injury data base. The most challenging or
22 the most heterogeneous, I should say, of this

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229

1 population is mild. Because when we say that,
2 we're counting some of the folks who were being
3 identified in some of the post-deployment
4 screening, and a lot of what we talked about
5 earlier with Colonel Hoge, as well as those who
6 are identified as part of co-morbidity. So when
7 (off mike) told us they're screening, they're
8 screening people who are seriously injured enough

9 that they required evacuation from the theater.
10 And they found on 20 percent of those people
11 screened positive to have had a co-morbid head
12 injury as part of their injury pattern. Next.

13 When we talk about the issue of
14 traumatic brain injury, it's very important to
15 realize that we're talking about a broad spectrum
16 and variety of severity of injuries, from mild to
17 moderate to severe to penetrating, as well as a
18 broad variety of set clinical settings where this
19 occurs. Everything from the level 1s, 2s, and 3s
20 of the casualties in theater to the NTF care, be
21 it a standard out-patient clinic or soldier
22 reprocessing center, to one of our more

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230

1 significant med cens, all the way down to the
2 transition to the VA care, those programs that
3 provide community reentry care, as well as return
4 to duty. It's important to realize that the
5 resources and challenges at each of these settings
6 are different. And so we really heard a lot of
7 very stimulating discussion, dealing with a subset
8 of the milds, really primarily at the SRP Center,
9 but that really represents one part or one
10 dimension of this entire broad spectrum. And the
11 reason I'm mentioning this is because the purview

12 or charge of the TBI External Advisory
13 Subcommittee is to cover this entire spectrum.
14 I've been to some meetings in Washington where
15 people want to sit down and solve the TBI problem
16 in an hour, but then I'm always wondering which
17 part they want to take on because it is such a
18 broad and overarching type of challenge. Next.

19 So the DoD, the military, is aware of
20 the importance of this for operational concerns,
21 and this is one example of studies which show the
22 increase in reaction time following a concussion.

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231

1 This is the baseline reaction time; one hour later
2 it's twice as long and more significantly in this
3 particular study, it was actually just as elevated
4 four days later. Without going through all the
5 details, it took about -- between five and seven
6 days for the two populations to normalize, the
7 controls verses those who had a concussion. And
8 what makes this even more interesting when I show
9 this is that this data is actually from the sports
10 concussion literature. This is actually taken
11 from cadets at West Point from football or boxing
12 who had a concussion. So we talk about some of
13 the other challenges, like we mentioned a bout of
14 concussions in combat, there's some additional
15 things to consider. The reason I put this in here

16 is I've done a lot of briefings, for line
17 commanders in particular. They talk about the
18 medical aspects that sometimes doesn't grab their
19 attention, but when you show them this, they
20 translate this in their mind and to direct
21 operational impacts with regards to the safety of
22 themselves -- I'm sorry, safety of the soldier, as

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232

1 well as the possible effects of the mission or
2 patrol that they're on, if they aren't able to
3 react as quickly. Next.

4 At the same time, I think we're aware of
5 a sequence of events with the Washington Post
6 articles, which actually just recently won the
7 Pulitzer Prize, causing a lot of attention which
8 led to a whole variety of these commissions and
9 reports. Anyone of us who was working in a
10 military treatment facility over the past year,
11 you would be hard pressed to not have encountered
12 at least one of these agencies as they came
13 through during their investigations and
14 commissions, which has really served to further
15 highlight the importance of this issue and the
16 reason why it's being addressed at the highest
17 levels of the DoD and the VA. Next.

18 At the same time, increased public

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19 awareness was coming about. Certainly Bob
20 Woodruff did more for public education than any of
21 our initiatives in the DoD, which certainly
22 continue to drive this increase in attention and

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233

1 desire to make sure we're addressing this issue in
2 a proper manner. Next.

3 And so, General Kelley showed a very
4 similar diagram like this earlier to kind of show
5 how some of the lines of action were established
6 to deal with the situation. And we're talking
7 about the TBI and psychological health for groups
8 together at the Line of Action number 2. As he
9 mentioned, Ms. Embrey was the, continues to be,
10 the LOA 2 lead. And on this diagram we have right
11 here the Red Cell, and that was one of the initial
12 groups that was formed to start dealing with this
13 issue. Next slide.

14 So it was put together and consisted of
15 representatives from each of the Armed Services,
16 as well as the VA. They were dealing -- they had
17 -- the TBI panel and a psychological health panel
18 -- they were looking at a variety of these reports
19 that came in and they held a number of summits for
20 TBI. There was first a DoD and VA summit, and
21 then another one a month later was open to the
22 civilian and academic community as well. All of

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234

1 which was looking at what's going on currently
2 with addressing current policies, and how can we
3 centralize and disseminate aspects. And by
4 design, the Red Cell has since stood down, but one
5 of their capstone achievements -- the next slide
6 -- was the recommendation and initial concept of
7 operations for the development of the Defense
8 Center of Excellence, which we just heard a lot
9 more information on. And again, this sort of goes
10 in to some of the component organizations, the
11 Defense and Veterans Brain Injury Center has been
12 named as the kind of TBI operational component of
13 the Center of Excellence. Of the current Centers,
14 we're the only ones that are solely dedicated to
15 TBI, and one of the only ones who cover the entire
16 spectrum, both combat-incurred as well as the
17 civilian-incurred. So let's kind of talk a little
18 bit more about what that is looking like if we're
19 to be the operational center. Next slide.

20 I'm going to just keep on clicking
21 through. So this is -- as Colonel Lugo indicated,
22 this has been in operation for over 16 years,

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Page 208

1 formed by a Congressional action back in 1992.
2 It's a unique collaboration between the DoD, the
3 VA, and originally the Brain Injury Association.
4 Three main charges from this Congressionally
5 directed program: To be the subject matter
6 experts for the DoD in clinical care and
7 standards, to develop clinical research programs,
8 as well as education. We've had some additional
9 missions that have been assigned to us from OSD
10 Health Affairs, one being the Office of
11 Responsibility, now for the DoD's surveillance to
12 assist in force management determinations, and
13 more recently we been asked to operationalize the
14 pre-deployment cognitive testing policy that was
15 developed by Health Affairs. Next.

16 Again, this goes back to the original
17 legislation that stood up the Defense and Veterans
18 Brain Injury Center with a mission of determining
19 and supporting best care practices for individuals
20 with traumatic brain injury through clinical
21 research and educational initiatives while
22 providing a disease-management system in the DoD

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1 and the VA. Next.

2 This just kind of shows you a little bit
3 of kind of where we're spread out with some of the
4 geographic diversity. It doesn't include all of
5 our Centers, but it does show that we are trying
6 to incorporate a broad spectrum throughout CONUS.
7 And over the past couple of years, we actually now
8 have more of a worldwide reach when (off mike)
9 joined our network. Next. This kind of shows you
10 where many of our sites are. We actually have two
11 additional clinical sites that aren't on this
12 particular slide, located at Camp Lejeune and Fort
13 Hood. But we have military lead sites, being at
14 Walter Reed and San Antonio, those are Wilford
15 Hall and Brook Army Medical Center. On the West
16 Coast: San Diego Naval. Associated sites include
17 Fort Carson, (off mike), Fort Bragg, and
18 Pendleton. The VA sites may seem familiar, as Dr.
19 Cussman of the VA has helped educate me. DVVIC
20 sort of set up these locations, and then the
21 structures from DVVIC were built upon to develop
22 the poly trauma system, so these are the same

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237

1 sites where the poly trauma system that was built
2 upon the original infrastructure. And we have a
3 couple of civilian partners; one in
4 Charlottesville, Virginia, and the other in

5 Johnstown, Pennsylvania. And the reason why those
6 were incorporated into the network was at the
7 time, they were offering programs designed for DoD
8 members in transitional reentry rehabilitation for
9 those people that were still having problems with
10 executive functions, who had maximized traditional
11 rehab. Neither the DoD nor the VA had such
12 programs at the time. I think these have been
13 considered successful models, such that the VA has
14 subsequently incorporated those programs into
15 their poly trauma centers. And by having this --
16 this allows us to really provide the entire
17 spectrum of care through a variety of clinical
18 settings as I went through before, and that some
19 of our initiatives from in theater to coming back
20 home to the NTFs through the VA to transitional
21 reentry and perhaps back. So this allows us to
22 look at the full spectrum of care, both in-patient

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238

1 and out-patient. As Colonel Lugo indicated, the
2 NICOE concept right now is really focusing only on
3 out-patient or ambulatory patients. Next slide.

4 In our capacity, we've been asked to
5 provide sort of the impartial subject matter
6 expertise to the DoD on a variety of panels,
7 including Defense Science Board. The CDC, NIH
8 have been involved with consultations on a variety

9 of other initiatives, and we try and do so in a
10 multi-disciplinary manner so we evaluate the new
11 findings and research from all clinical
12 disciplines and try and integrate these things
13 into a coherent synthesis that we can use for our
14 scientific consultations. Next.

15 So let's just kind of take a look at
16 what we know. We do know that the Army of the
17 Services is bearing really the brunt of traumatic
18 brain injuries. When we look at this, it really
19 has to do with kind of what your missions are, and
20 that the Army has most of these missions, what we
21 call outside the wire, outside the protective base
22 in theater. So when we add that up between the

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239

1 Reserves and soldiers, it's almost two-thirds of
2 the injuries are actually incurred by the Army.
3 The next Service which is affected is the Marines
4 with an accounting of just about a quarter of
5 them. The Air Force and the Navy, based on their
6 missions which primarily include being more with
7 inside a base, aren't as exposed to those kinds of
8 risks. Next.

9 When you look at the mechanisms of
10 injury, we know that blast is involved in more
11 than half of the injuries in theater that are

12 currently going on right now. Next.

13 Which brings up the issue of how do we
14 get at some granularity of what the true incidence
15 of concussion or mild TBI is in redeployers,
16 meaning people who are well enough that they
17 didn't have to be evacuated from theater and
18 rotated home with their unit. And approximately
19 10 to 20 percent of these people have screened
20 positive on supplemental post-deployment surveys
21 that have been done in a variety of locations.
22 And as Colonel Hoge mentioned, of those,

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240

1 approximately half had resolved with no current
2 symptoms. What oftentimes gets lost in the
3 discussion is that a screen does not equal a
4 diagnosis. It's merely a screen, and it
5 identifies those people who need further
6 evaluation. And because people had symptoms, and
7 they had had a concussion in theater, it doesn't
8 necessarily mean that the symptoms were from the
9 concussion. There could be a variety of other
10 things, but all it means is that these people are
11 screened and deserve further evaluation. To put
12 that in perspective, the VA has done a much better
13 job at sort of tracking that question. They have
14 a screening process; 20 percent of the folks who
15 enter their system from OIF/OEF have screened

16 positive. A positive screen under the VA means
17 that they answered affirmatively on all four of
18 those questions, not one of the questions, but all
19 four of those questions. A chart review done on
20 150 charts in the VA showed post-concussive
21 diagnosis was made in only three to six percent,
22 meaning that after they did a thorough evaluation,

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241

1 they were able to determine that some of the
2 symptoms in this case that had been persistent,
3 weren't necessarily attributable to the concussion
4 that that individual had. So this is a
5 perspective that sometimes gets lost in the
6 discussion. I don't think it's well understood by
7 the media about what these screens are, that
8 they're not actually a diagnosis. Okay. Next
9 please.

10 We're trying to understand the incidence
11 of concussion in theater. The MHAT-5 recently
12 added TBI questions. They found that 11.2 percent
13 of Service members endorsed having a concussion or
14 mild TBI with symptoms. This appears to be
15 consistent with prior post-deployment surveys if
16 you take the stance that half of the symptomatic
17 people, the 10 to 20 percent, would sort of be
18 within that. It also is consistent with the

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19 results of the Rand Survey that was released last
20 week had, although again its methodology of
21 assessments was different. So it does appear that
22 we are sort of getting some consistency when we

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242

1 look at this issue with the percent that's
2 screened. As Colonel Hoge mentioned, the
3 concussion and screening has been added to the
4 PDHA for all Services as of 1 April 2008. Next.

5 So talking about some of the current
6 debates that are going on, this is a quick
7 illustration of a blast wave with the overpressure
8 and underpressure aspect. Next slide.

9 But there's a number of theories of
10 blasts. And I don't think it's fully accepted by
11 the scientists that we know exactly what's going
12 on with blast and the injuries. Certainly, the
13 most discussed has been the
14 overpressure/underpressure wave. It should be,
15 theoretically, associated with Bero trauma. An
16 ongoing debate in the scientific world is how does
17 the wave transmit to the brain. There's a
18 vascular hypothesis that's really supported by Dr.
19 Cernak and colleagues at Johns Hopkins. They
20 believe that that wave gets transmitted through
21 the great vessels in the thorax up to the brain.
22 This is opposed to what I call a direct hypothesis

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243

1 where the wave itself enters through the skull,
2 eyes, or ears. There's been some theories of air
3 embolism, although I don't think -- that's not
4 been one of the more favorite theories, certainly
5 development of cavitations has received discussion
6 that correlates more with the underpressure aspect
7 of the wave as opposed to the overpressure aspect
8 of the wave. And more recently there's been some
9 concern about electromagnetic fields that may be
10 released as part of an explosion if you're in the
11 vicinity of a blast and what effects that may or
12 may not have as well. Next.

13 Colonel Hoge mentioned this frame of
14 reference that in theory with this frame of
15 reference as you go farther out, the aspects of
16 the wave should dissipate with the cube and the
17 denominator. But the physicist will debate that
18 this is true, but it depends. But not many people
19 are in this perfect frame of reference of being in
20 an open-space explosion. And that's when some of
21 the wave physicists get concerned about it; if
22 there's any other vehicles or buildings or

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Page 216

1 anything in the vicinity, that the waves may
2 bounce or amplify off of that. And they believe
3 that there's a theoretical possibility that even
4 someone who's farther away from the epicenter may
5 be more affected than someone who's closer based
6 on those types of physics. That's another area
7 where even the basic scientists or scientists are
8 debating amongst themselves. Next.

9 Trying to understand the effects of
10 blast. There's a variety of animal data from
11 shock tubes or from detonation, deflagration
12 experiments, that's a very slowly controlled
13 detonation. Neuropathological correlations have
14 shown axonopathies, edema, and astrogliosis,
15 meaning that there's some direct damage being done
16 from the blast wave, at least that would be the
17 suggestion of these animal studies, as well as
18 some of the alterations and gene expression of
19 some of the enzymes as well. Next.

20 It's harder to translate this to human
21 data, and one of the reasons is that most of the
22 blast-associated combat injuries that we see are

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1 multiple modalities. I tend to call it -- my
Page 217

2 slang term for that is I call it blast plus,
3 meaning that in addition to the blast wave itself,
4 that blast may have caused a humvee to roll over.
5 And now you have the motor vehicle accident
6 component of the injury, which is another
7 mechanism of injury. Or there may be shrapnel
8 flying around which caused a penetrating aspect to
9 the injury. To date, if you look at the
10 literature, there's only one soldier with para
11 clinical evidence of primary blast without any
12 other modality. So our chances to study primary
13 blast have been pretty limited in a human setting.
14 Next.

15 And this is some imaging from that one
16 case that we know about where you can kind of see
17 in the collapsed cerebellum this kind of lesion
18 that's there and there's been some functional
19 imaging correlates showing that. And as time went
20 on, there was some improvement that was seen in
21 that functional imaging as well. Next.

22 Which leaves us with some of these,

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246

1 again, ongoing questions. A lot of the scientists
2 are saying well, is the path -- what is the path
3 of physiology of blast? And so the question is is
4 that path of physiology actually different? Since

5 most of these injuries are blast plus, are we
6 really comparing two or more injuries to a single
7 injury? We talk about multiple mechanisms verses
8 a single mechanism. Is the natural history of
9 recovery different if you have a blast component
10 verses a non-blast component, and is there a
11 different pattern of co-morbidity. And that was
12 a very interesting discussion that we had earlier
13 about some of those psychological co-morbidities.
14 Next.

15 One of the ongoing aspects which I think
16 is still of operational concern to the military
17 where we need more science is the cumulative
18 effects of repeat cerebral concussion. We're
19 still not able to answer with great scientific
20 conviction how many is too many? Or how do we
21 assess that? And what are the cumulative effects?
22 Instead that is something that we're hoping to

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247

1 identify as an area that's in need of further
2 research and evaluation. Next.

3 So what I would think as some of the
4 biggest current policy controversies that we're
5 faced with right now is in these kind of four main
6 categories: Looking at the definition of
7 nomenclature, the DoD definition is currently
8 based on that utilized by the American Congress of

9 Rehabilitation Medicine, which tends to be the
10 standard in the medical literature. And again,
11 that definition does incorporate using either loss
12 of consciousness or alteration of consciousness.
13 So the debate is should we go with LOC only?
14 Well, we know that sensitivity, and specificity
15 especially, is much higher than if we use
16 alteration of consciousness, but are we getting
17 away from using what are considered some of the
18 standard medical definitions and how can we best
19 incorporate this? The ICD coding sort of plays in
20 to how you define it. But with all these
21 definitions and nomenclature, there was a panel
22 between the DoD and the VA with equal

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248

1 representation of the psychological health
2 community as well as some of the variety of the
3 TBI community. There's a joint proposal which is
4 being put forth to revise the ICD-9 codes that
5 will help us get better granularity in tracking
6 and better understanding of what's going on. And
7 that proposal is making its way up. I believe
8 it's at the national level. The CDC was asked to
9 comment on it before it makes its way to the World
10 Health Organization that has final say over ICD-9
11 codes.

12 Post-deployment screening, a big area of
13 controversy. I think that Colonel Hoge did a good
14 job sort of covering that as an issue that needs
15 review and consideration. Should it be on the
16 PDHA or PDHRA? And if so, how should it best be
17 done? Certainly, the risks of screening, causing
18 iatrogenic harm, certainly have been a theoretical
19 issue. I think enough cases and data from the
20 past several years. Is there a way to evaluate
21 our current data base to kind of look and see if
22 we can -- are we doing this correctly and what has

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249

1 been the evidence to date in practical terms as
2 opposed to theoretical terms. Certainly a big
3 issue that we were talking about earlier was the
4 psychiatric symptoms, the issue of co-morbidity
5 verses a differential diagnosis, and certainly how
6 best to kind of deal with this controversy. And
7 another controversy that has been generating
8 discussion within the DoD is that of
9 neurocognitive testing. The utility of base
10 lining, the utility of testing post-injury in
11 theater; if that's done, how would you implement
12 that in a rational way in theater, as well as for
13 a role in post-deployment? Next slide.

14 So we're just kind of touching on these
15 definition challenges really because we're trying

16 to link the clinical phenomenon, meaning a change
17 in consciousness, to a physiological event. And
18 that physiological event that really is the
19 physiological definition of concussion is that
20 there's a metabolic cascade and storm of
21 neurotransmitters, but we really can't see that.
22 And so we are left with kind of these clinical

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250

1 observations of alteration or loss of
2 consciousness. Next.

3 And this just kind of illustrates what
4 we're trying to get granularity on as we talk
5 about some of the things at the neuronal level
6 with these metabolic changes, especially with the
7 influxes of calcium, causing a whole host of other
8 changes within the neuron. Next.

9 So, getting into the psychiatric
10 co-morbidity aspect -- next slide -- we spent a
11 lot of time earlier talking about this very unique
12 challenge, especially in the context of mild TBIs.
13 And again, it's those mild TBIs, not necessarily
14 in the context of other injuries, and certainly
15 it's been intimated there's a number of symptoms
16 that can be found in both what have been described
17 as the post-concussive symptoms following a head
18 injury, as well as in PTSD. One of the things

19 that I found as this discussion's gone on that I
20 haven't found as particularly, I think, helpful --
21 and I'm coming at this from the perspective as
22 both a neurologist and a psychiatrist, so I tend

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251

1 to think of these things in parallel -- that a lot
2 of the discussion has been informed by an
3 either/or paradigm. We have to box it. It has to
4 be one of these or the other. And in my
5 experience, that may not be the best model,
6 especially when we have so many of these
7 interdependent variables that we have going on.
8 And certainly when we take a look at some of the
9 things, anyone -- when we talk about these
10 clusters of symptoms, when we have the psychiatric
11 symptoms, we have the cognitive symptoms, the
12 physical symptoms; they don't occur in a vacuum
13 and each one affects the other. So we know, for
14 example, that if you're not sleeping, a physical
15 symptom that may affect your cognition, that if
16 you have depression or other psychiatric factors,
17 that can amplify certainly headaches or other
18 physical symptoms. As a neurologist, I think
19 we're very -- gained years of experience of that
20 in headache clinics with people dealing with their
21 psychological stresses. As a psychiatrist, we
22 would call that psychological factors affecting

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252

1 physical condition. The other part of this
2 dynamic that makes it even more challenging is
3 that we know from the data that we have -- and
4 Colonel Hoge's article actually did a good job
5 illustrating this -- that if you take a look at
6 the injury patterns and you take someone who has a
7 TBI as part of their injury pattern compared to
8 those that have an injury pattern without TBI,
9 those that had the co-morbid TBI have a much
10 greater percentage or risk of developing PTSD than
11 those who were injured without that co-morbid TBI.
12 So, it sort of makes you think if there was -- how
13 does that dynamic play out? Is there something
14 going on? That same relationship has been shown
15 in the Oklahoma City blast data, as well as data
16 that were also not from blast. And so with --
17 it's a very complicated set of intermingling
18 factors that really just sort of poses challenges
19 for us. What we've been trying to do is to
20 identify, through a holistic approach, identify
21 the needs of the patient in being able to kind of
22 map that out to the treatments themselves. What

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Page 224

1 we're still trying to figure out is, are the
2 treatments different? If someone has PTSD in the
3 context of traumatic brain injury, is that
4 different than the management of PTSD. That's
5 another unanswered question. The Institute of
6 Medicine in one of their reports suggested that it
7 may be different, but the reality is that we don't
8 the data really to make that determination one way
9 or another. Next slide.

10 This just kind of is more of a classical
11 slide, illustrating some of the brain behavioral
12 relationships that sometimes are a challenge. One
13 of the concerns that we've had from the media and
14 from other people is that for people that may have
15 had a head injury, that then developed some
16 behavioral issues which lead to disciplinary
17 problems. Whether they've had a thorough
18 evaluation -- just want to make sure that we
19 aren't missing a medical situation which may be
20 causing some of the issues. There's been a number
21 of high-profile cases, which have been brought to
22 the forefront, kind of a look to assure that the

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1 process is going on, certainly a wealth of
Page 225

2 literature which does correlate some behavioral
3 changes to certain regions of the brain which can
4 be injured. Next slide.

5 So the issue of neurocognitive testing,
6 this other hot area of debate, just want to remind
7 people -- I think Colonel Gibson reminded us
8 before -- there actually is a set of guidance from
9 the Armed Forces Epidemiology Board from August
10 '06 which addressed screening as well as
11 neurocognitive testing. And it actually -- we're
12 going to assure that the members of the TBI
13 Advisory Panel get full copies of that report that
14 was done by the Armed Forces Epidemiology Board so
15 they kind of see where the standing
16 recommendations are at. But that was one of the
17 impetuses that led the DoD to kind of start their
18 policy. One other thing that gets lost in this is
19 the only policy that the DoD has right now is that
20 they do pre-deployment testing. There is no
21 mandate to do post-deployment testing in a DoD
22 policy, nor for that matter is there a mandate to

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255

1 do in-theater testing although there's plans to
2 implement such a program. Other aspects where the
3 guidance has been coming from is the TBI Task
4 Force report. Next slide.

5 The DoD Independent Review Group also
6 addressed this topic. The Red Cell put together a
7 group of outside experts, neuropsychologists and
8 other experts, to look at this issue and they did
9 support the use of neurocognitive testing, feeling
10 that there was enough evidence that it should be
11 useful and helpful. One of the, I think,
12 challenges that we're going to be faced with is
13 the most recent NDAA, which again mandated the use
14 of pre-deployment testing, but they also mandated
15 the use of post-deployment screening. And it's
16 not clear whether they mean population-based or
17 just those who have been identified with an
18 injury. And there is, I think, a number of
19 scientific concerns that if such a program were
20 implemented on a population-based post-deployment,
21 then that's something else that I think we'll need
22 to proceed with with caution, and I hope with good

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256

1 advice from the Defense Health Board. That will
2 allow us to stay out of trouble with Congress, but
3 also follow sound and good medical sense to make
4 sure we're not causing more problems by
5 implementing such a population-based program in
6 that particular setting. Okay, next.

7 So what's going on now with this? The
8 current policy has actually named to use the ANAM

9 in a spiral approach. There's a number of other
10 instruments available. Certainly there's a number
11 -- each has their own strong advocates to make
12 sure that that instrument is the one that is used
13 to kind of deal with that. A head-to-head study
14 is being conducted with the five leading
15 instruments. The National Academy of
16 Neuropsychiatry was asked to name an impartial
17 panel to make sure that the study design analysis
18 was done against the most scientific valid
19 information possible. Because a lot of these
20 issues are computer based and will need to be
21 integrated into the DoD systems, OSD Health
22 Affairs has also launched analysis of

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257

1 alternatives, focusing on these systems' IT
2 issues, which might also help drive some of the
3 decisions that -- in the future for that as well.
4 The reason why ANAM was currently selected as it
5 is free to DoD because the DoD developed it, and
6 that a variety of military norms are available
7 that are being used to kind of help in determining
8 what the abnormalities are for those who have been
9 injured. Next slide.
10 So the purposes of the DHB TBI External
11 Advisory Subcommittee are to assist the DHB in TBI

12 policy recommendations to the DoD, and also to
13 serve as an advisory panel to DVVIC as well as the
14 Defense Center of Excellence. They kind of have
15 this dual mission if you will. Next.

16 And this is a list of the community
17 members. This is also in your notebooks as well,
18 which outlines their contact information. Next.

19 The first organizational meeting was
20 held last week. It was a one-day organizational
21 meeting, so they couldn't get as much done as they
22 might have done in a two-day meeting. They were

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258

1 able to complete all their paperwork, their
2 requisite ethics brief, getting their briefing to
3 the Defense Health Board. They received briefings
4 on the DCoE and DVVIC, as well as briefings on the
5 TBI issues and controversies. And in the
6 Department of Defense, they had time to do some
7 initial planning and brainstorming. A chairman
8 was selected, which is Dr. James Kelley. Dr.
9 Kelley by training is a neurologist. He also has
10 advanced training, I think five years, with the
11 psychological training, and actually holds
12 academic appointments in the Departments of
13 Neurosurgery and Physical Medicine Rehabilitation.
14 Next.

15 So some of the initial issues, which
Page 229

16 were identified by the Subcommittee that they
17 wanted to address, were the assessment and
18 management issues related to return to duty. This
19 includes the whole issue of neurocognitive
20 assessments. But kind of looking at the whole
21 issue of the operational focus of return to duty,
22 as well as a variety of assessment and management

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259

1 -- means to do assessments, not just
2 neurocognitive assessments, but if there's any
3 other types of technologies or resources available
4 for that. The whole issue of screening, again
5 looking at the benefits verses potential (off
6 mike) risks with an evaluation of the available
7 data. For both of these aspects or issues, it was
8 identified that there would, in deed, be a large
9 overlap with some of the psychological health
10 concerns, and it was anticipated that they would
11 be coordinating and perhaps collaborating with the
12 PH Advisory Subcommittee which is to be stood up
13 by the Defense Health Board. Okay. Next slide.

14 Other issues that were identified
15 included looking at prevention measures, both at
16 detector and dosimeter technology with some of the
17 initial efforts that are going on there. Looking
18 at helmet design; there's been a lot of ongoing

19 recent activity going on with that and the Board
20 wanted to be involved with that. Getting back to
21 the question that was raised earlier about
22 reviewing the aspects from the research program

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260

1 that was also identified by the Subcommittee that
2 they wanted to review the scientific priorities
3 and do a gap identification. And they requested a
4 review of the Congressionally directed medical
5 research program processes and results. And I
6 think that would also include the results of the
7 secondary DCoE review as well.

8 They also identified delivery systems as
9 an area they wanted to get into. Looking at the
10 available resources, sort of speaking to the issue
11 of what is the best way to deliver care, and do we
12 have the proper resources to do this? As we
13 discussed earlier, it was felt that the issue of
14 eye injuries did not come up there. I think I
15 agree with Dr. Lockey, this is a very important
16 issue and we're going to add this, with the DHB's
17 concurrence, to the initial issues identified that
18 will be added to their portfolio to do some
19 initial work on. Next.

20 So future meetings -- their goal is to
21 have six meetings a year. It was felt this would
22 be a combination of telephone and in-person

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261

1 meetings, and the next meeting is targeted for
2 June of 2008. In the interim, a variety of policy
3 documents is being collected. One observation
4 that was from the meeting is that the members of
5 the panel had varying levels of knowledge and
6 familiarity with some of the DoD policies, and
7 some were very much involved having the DoD
8 consultants in the past. DVBC, for example, has
9 utilized a lot of outside consultants when
10 developing some of the clinical standards, and
11 some of those members are on the panel. Others
12 had not as much experience with the Department of
13 Defense, so we're trying to get a common set of
14 resources and references to get everyone up to
15 speed so they can really start addressing some of
16 these issues. I think that's the last slide. I
17 thank you for your attention.

18 DR. POLAND: Very good, and good to see
19 and hear that progress. Given the speed and
20 alacrity with which you're moving through these, I
21 think it would be a good idea that we'll sort of
22 count on a briefing from you at each of our

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Page 232

1 meetings related to how important I think this is.

2 COL. GIBSON: I would recommend not only
3 that Colonel Jaffee be there, but we would have
4 had Dr. Kelley here today except he got tied up.
5 So I -- we would expect that this Subcommittee
6 would continually provide updates on their
7 activities to the Board.

8 DR. POLAND: Okay. Dr. Kaplan and then
9 Dr. Parkinson.

10 DR. KAPLAN: Would you go back, Colonel
11 Jaffee, to the slide where you showed the
12 organizational setup of the various centers? It's
13 -- this one -- what is it? Slide 15 or so. It's
14 the slide with boxes -- that's it. Could you
15 clarify for me, please, you have VA sites,
16 military sites, and then sites that are Army,
17 Navy, and then several different kinds of sites.
18 Could you tell us, or perhaps I missed it, what
19 the uniformity is in those sites? Is there -- are
20 there uniform protocols? If so, is there a data
21 collection system from all of those sites, or are
22 they fairly independent?

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1 COL. JAFFEE: So, with this -- what
Page 233

2 we're really looking at is a network of sites. So
3 one of the things that DVBIC is challenged with is
4 taking this network, which is I think been
5 considered fairly successful, and giving this its
6 expanded responsibility with some more of these
7 DoD-wide functions with regard to surveillance and
8 with regard to being an operational component.
9 It's so important that we have that relationship
10 with the Center of Excellence, which allows us to
11 have that DoD-wide reach for implementation and
12 promulgation of some of these efforts.

13 So that's a transitional thing that
14 we're going through. Now when we look at the
15 sites themselves, there are certain commonalities.
16 Each of the sites has to be a lead site if you
17 will. So the four VA sites, as well as the lead
18 on military sites, does have a function. It plays
19 as someone who's in charge of research, someone
20 who's in charge of the clinical aspects, (off
21 mike) manager, regional care coordinator that
22 provides some of the -- makes sure -- as well as

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264

1 an educational director. So there's certain key
2 positions or core positions which are common to
3 each of the sites which then needs to be in place
4 that allows for a network of research to occur, I

5 think is what you asked about. So there are
6 certain protocols which happen at all the sites.
7 There are certain protocols which happen at only
8 some of the sites. For example, we just launched
9 a protocol looking at the use of methylphenidate
10 with regard to recovery, and that's only occurring
11 at the VA sites. As well as each of the sites
12 sometimes has their own individual pilot projects
13 as well. So there's a variety to this network
14 that allows for a variety of combinations.

15 The surveillance function is a
16 commonality, which has been done at these sites.
17 But that is actually a big challenge the DoD has
18 is to translate the current surveillance into a
19 more automated system that everyone can use with
20 the same types of parameters and similar types of
21 aspects. There's a lot of activity right now
22 going on just to achieve that goal.

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265

1 DR. KAPLAN: So is there a way --
2 clarify for me -- for exchange of those things
3 that are common and discussion of those aspects
4 that are not uniform?

5 COL. JAFFEE: Certainly some of the
6 sites, or not all the sites, have the same
7 protocols, but sometimes their own individual
8 pilots. We take a look at some of the associated

9 sites and the clinical sites -- and when we call
10 clinical sites, it means we have people who all
11 they're doing is helping provide clinical care --

12 DR. KAPLAN: Well, what happens to the
13 data that comes from those places?

14 COL. JAFFEE: Oh, okay.

15 DR. KAPLAN: Is it looked at by some
16 central -- the national headquarters?

17 COL. JAFFEE: Is it evaluated? Is it --

18 DR. KAPLAN: Yes, the data is collected
19 by headquarters, it is forwarded onto FH, P and R,
20 and Health Affairs, and I believe that Colonel Cox
21 and his shop in Epidemiology, they do more of the
22 analysis, and that information is more used for

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266

1 the policymakers, so, our job is more to implement
2 and operationalize the system for its collection
3 --

4 COL. JAFFEE: Does it get back to the
5 clinical centers or the research centers? The
6 data?

7 DR. KAPLAN: Yes. I mean, the
8 individual centers have access to their own data.
9 That's correct.

10 COL. JAFFEE: But what about other data
11 from other places? In other words, I guess I'm

12 asking to clarify for me what the coordination is
13 among all those boxes up there.

14 DR. KAPLAN: Well, there's a
15 headquarters function which provides the
16 coordination, so, the headquarters' function is
17 actually located in the national capital region,
18 and, so, that --

19 COL. JAFFEE: And is there feedback?

20 DR. KAPLAN: Yes, there is ongoing
21 dialogue and feedback between the sites.

22 COL. JAFFEE: Thank you.

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267

1 DR. POLAND: Mike?

2 DR. PARKINSON: Yes, Parkinson. Thank
3 you, Colonel Jaffee for this, and, also, Colonel
4 Lugo before.

5 You know, sometimes you better be
6 careful what you wish for because you might get
7 it, and I think we're collectively, broadly here
8 in the situation where to my crude arithmetic
9 we're one point billion plus in new appropriations
10 for a wide variety of programmatic activities and
11 we're trying as fast as we can to figure out how
12 to put together with much good thought and much
13 good infrastructure.

14 My concern, and, again, we bring this up
15 in the constructive sense in what I think the DHP

16 is for as an outside appointed body is that, in
17 our desire to spend the money, that we not create
18 a nickel of excessive infrastructure to support
19 what is basically getting our active-duty members,
20 our guard and reserve members and their families
21 back to full functionality.

22 And, while it's great to build a

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268

1 research enterprise that gets into the nuisances
2 of \$300 million dollars of research spend, I would
3 hope that the various bodies would welcome our
4 comment, perhaps, on where that goes because there
5 is no amount -- every nickel could be spent by the
6 academic-industrial enterprise to relatively
7 little affect unless we're careful, just as a
8 caveat.

9 Number two is of the 6,000 people that
10 are currently enrolled in the program, how does
11 one get in? What is the criteria for getting in?

12 And, again, this may be taken offline
13 because there's a series of questions here, and
14 what mix of those come in under the psychological
15 health versus the TBI concussive route?

16 On crude numbers, it looks as if we got
17 6,000 people in the current program that the 4 to
18 1 ratio of active-duty to reserve and guard in the

19 army and 12 to 1 ration of active-duty to reserve
20 and guard in the marines. It doesn't necessarily
21 reflect, to my knowledge, the array of
22 distribution of troops that we got over there

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269

1 since the beginning of the war over five years,
2 which was more like 40 to 50 percent guard of
3 reserve.

4 Maybe I'm wrong, but those numbers -- it
5 looks like an access issue here, which gets to my
6 next question, is: How are we measuring service
7 access across the country to people who have
8 these?

9 The goal here is to improve services,
10 and the rhetorical question is: A citizen who
11 sees \$1.2 billion being spent, how much more can
12 we do if we just increase the reimbursement rates
13 under TRICARE and create the types of
14 infrastructure we talked about earlier with peer
15 to peer support groups, online counseling
16 sessions, types of things that Colonel Certain
17 talked about? I mean, real-time skill building
18 among about 6,000 people who, frankly, probably
19 may or may not have any more access to services
20 based on the influx of \$1.3 billion.

21 So, these are questions going forward.
22 I just lay out the panoply of service, how we're

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270

1 measuring program effectiveness at the individual
2 level, the person who has these in terms of how
3 they're satisfied with their services, is their
4 family more functional?

5 Because, at the end of the day, that's
6 really what is was all about going into this,
7 which is what got us all the money in the first
8 place, but we got to be careful because we've had
9 experience with other targeted earmark research
10 programs and breast cancer and in whatever. Now
11 that we're becoming a mini NIH in DoD for a lot of
12 reasons, we just need to keep our eye on the ball,
13 and if we could help in that regard, please let us
14 do it.

15 That's my overall impression of what
16 this is, is that the service aspects, the access
17 aspects, and the outcome aspects in terms of
18 functionality about keeping a job and having a
19 good relationship with my spouse, I've got to be
20 in here, and it's relatively a short trip so far,
21 you know, in terms of those issues, at least in
22 terms of this presentation.

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Page 240

1 DR. POLAND: Dr. Hoge?

2 DR. HOGGE: Yes, just to follow on with
3 that, on your current policy, controversy (off
4 mike), I was struck by the fact that there was --
5 that structure of care was not on there, and it
6 seems to me that that's an enormous area of
7 controversy in policy. Either structure of care
8 is the foundation upon which the screening program
9 is based, and the structure of care, primary care
10 versus TBI specialty care is an enormous
11 consideration for mild TBI in any case.

12 And I had one other comment, but after
13 you if you want to respond to that first.

14 COL. JAFFEE: I think you and I agree on
15 that, and we discussed that before.

16 DR. HOGGE: Right.

17 COL. JAFFEE: I had the same challenge
18 you did with brevity here, so, that was actually
19 discussed, and that was actually one the main
20 bullet points that the external advisory committee
21 decided to take on with getting into the resources
22 and so forth. That speaks directly to the

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1 structure here.

2 DR. HOGE: Wonderful to hear. And then
3 just a thing on page 3 where you showed the simple
4 reaction time and commented that this is something
5 that resonates with commanders, that there's an
6 alteration and simple -- a lengthening of simple
7 reaction time after concussion, this was from a
8 1991 data collection. It was replicated
9 subsequently and published in 2004.

10 This particular study that you quoted
11 had no control group. The replication study had a
12 control group and showed exactly the same
13 relationship for both the concussed cadets as well
14 as the control cadets. Exactly the same
15 relationship. Actually, it went out to 14 days,
16 not 4 days, but there was absolutely no difference
17 between the concussed and the controls, and the
18 authors concluded that it was probably due to the
19 stresses of the academic environment. Okay?

20 So, this is one -- this is a key example
21 of what is seen all over the place in a propagation
22 of data, you know, believed that this data means

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273

1 such and such and it's really misinformation.

2 COL. JAFFEE: I think that speaks to the
3 challenge, and there's been a number of subsequent
4 studies and replications, some of which show that,

5 others which didn't.
6 The one you're focusing on, which makes
7 our job all the more challenging, to be able to
8 make sure that all the literature is actually
9 evaluated when making these decisions and not just
10 picking and choosing some which might support a
11 particular point of view.

12 DR. POLAND: Dr. Halperin?

13 DR. HALPERIN: Yes, I heard several
14 times about eye injury, and I just want to express
15 enthusiasm for the role of surveillance and really
16 detailed surveillance when it comes to eye injury.

17 And Newark, in a way, I'm sure it shares
18 a lot of the issues with the military, and by
19 doing detailed surveillance in Newark on
20 penetrating eye injury, we've been able to
21 identify occupational injuries, intentional
22 violence, falls, and motor vehicle injuries as a

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274

1 cause for a global penetration. It's really not
2 terribly amenable to therapeutic surgery, but
3 especially from the points of view of nail gun
4 injuries and such is amenable to prevention. And,
5 given the size of the military and the diversity
6 of things that go in it and the lack of
7 surveillance for eye injury in the civilian
8 population, I think it's a small issue. It was

9 talked about very briefly, but it really has a lot
10 of potential for minimizing disability.

11 DR. POLAND: Yes, sir?

12 MAJ. GEN. KELLEY: Let me just answer
13 that a little bit. I think that's right, and I
14 think that, actually, the joint trauma or theater
15 trauma system helped to identify early on a spike
16 in eye injuries, and now it is very uncommon to
17 see anyone out there without protective glasses
18 on.

19 Now, the best ones that weren't used as
20 much as the ones that look like cool sunglasses,
21 but they're still glass-protective, and, so, we
22 have actually cut down on some of the direct eye

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275

1 injuries through the use of that program.

2 Fielding something that was acceptable
3 to the troops in looking at that, and, so, we are
4 trying to act on our data as we go through.

5 DR. POLAND: That's a good point. Just
6 don't make them DCGs.

7 MAJ. GEN. KELLEY: Yes.

8 DR. POLAND: All right.

9 CDR. SLAUNWHITE: Commander, can I
10 respond? Thanks, CDR Cathy Slaunwhite.

11 One of the considerations I've had as

12 we've heard these presentations, seeing that about
13 80 percent or so of those with traumatic brain
14 injuries are in that mild concussion or
15 concussion-like category, of those coming back
16 from deployment and with consideration of
17 neurocognitive screening pre-deployment, I guess
18 I'm thinking of all of these people in uniform who
19 will have a motor vehicle accident, you know,
20 Continental USA or a sports injury, and, I mean,
21 is it theoretically possible that there be a
22 movement to screen everyone given that there are

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276

1 mild traumatic brain injuries or concussions that
2 we expect here in addition to deployment, and I
3 guess I'm just thinking how far could it reach to
4 do this kind of screening activity, and, again,
5 what our value would be after the fact?

6 So, just an observation.

7 DR. POLAND: Yes, a bit imponderable,
8 but of interest would be that, at a minimum, one
9 does that in a control group, so, just as we've
10 seen so you can understand the data within the
11 concussed group.

12 COL. JAFFEE: There's been some
13 discussions to that very point ongoing at Health
14 Affairs, looking at the long-term plan of what do
15 you do with this program, and those discussions

16 have evolved to the theoretical hospitality of
17 incorporating that into part of the periodic
18 health assessment, the CHA. So, that data would
19 be there whether or not you're deploying, that's
20 the same periodic assessment that every
21 active-duty member has to go through.

22 There's no plans yet to implement that,

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277

1 although that's been discussed as a longer-term
2 vision, but the priority was felt as sort of
3 target the higher-risk community with deployment
4 first and see how that program works. But, so,
5 that thought has been there, I know it's been
6 discussed, although it's not currently being
7 operationalized.

8 DR. POLAND: One other comment. Yes.

9 DR. ZAKI: It's very interesting that
10 you bring up the fact that there are things that
11 help the soldier and there are things that we look
12 at from a research point of view, the take forever
13 and we may or may not get to a point whereby it's
14 going to be useful or not.

15 Of this \$300 million that's being given
16 for research studies or research endeavors, is
17 there a breakdown between the practical
18 application in terms of just making glasses like

19 you're talking about, or is this basic research
20 that's fundamentally not going to help the
21 individual who's currently in the theater?

22 MAJ. GEN. KELLEY: Again, I think

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278

1 there's a sculpt from basic research to clinical
2 research, so, there are some drugs that may be
3 neuroprotective that have retrospectively looked
4 -- we've identified some progesterone
5 beta-blockers or some -- so, without -- because
6 the exact titles, because of the sensitivity,
7 can't be released, but I would say there are
8 probably more shifted on this first time to
9 understanding the physiology of the disease, of
10 the injury, so more of a shift toward basic
11 research, but covering the whole spectrum.

12 DR. POLAND: I think we're probably
13 going to need to cut the conversation now.

14 And, Colonel Gibson, you had more?

15 COL. GIBSON: Just one final comment.

16 This TBI external advisory subcommittee of the
17 Board has got some tremendous challenges in front
18 of them. They didn't get the easy questions; they
19 got the hard ones, and they're going to be working
20 their tails off. As board members, if you can
21 support that process, if you're willing to attend
22 meetings and provide additional insights to them,

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279

1 that would be incredibly helpful. Understand this
2 is hard stuff that they're doing.

3 DR. POLAND: I know there are a few
4 other comments, but maybe you could ask them
5 offline.

6 We're getting to be about an hour and a
7 half behind schedule here. In an effort to keep
8 everybody's glucose spikes up, there are sweets
9 outside there. I highly recommend you don't eat
10 them, but, if you so desire, could we make it not
11 so much a social break, because we'll that tonight
12 for dinner, but go out, go to the bathroom, grab
13 your sweets and come back in and we'll restart.

14 Thank you.

15 (Recess)

16 DR. POLAND: I just learned that dinner
17 is actually at 6:15, so, we stay on task or we
18 don't make dinner. They are mutually exclusive
19 outcomes, so, we're going to keep moving and try
20 to keep questions focused and ongoing here.

21 So, you have a --

22 COL. GIBSON: I have a AT&T Nokia phone

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Page 248

1 that seems to have just appeared, and -- oh, it's
2 yours? Okay. Done. Thank you.

3 DR. POLAND: But we were a little
4 surprised about the outgoing calls. I'm kidding
5 you.

6 All right. Our next speaker this
7 afternoon is LTC Wayne Hachey from the Office of
8 the Deputy Secretary of Defense for Force Health
9 Protection and Readiness. He's going to provide
10 an update on the Department of Defense pandemic
11 influenza preparedness.

12 I need to publicly thank Wayne. Last
13 week, I gave a briefing on pandemic influenza at
14 the air force academy, and, at the 11th hour,
15 realized there were some crucial pieces of the
16 evolving defense plan that I didn't have, and
17 Wayne sent slides within minutes. So, I publicly
18 thank you for that, Wayne.

19 LTC. HACHEY: Now I get to tell you
20 which slides were actually correct.

21 (Pause)

22 LTC. HACHEY: So, like death and taxes,

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1 I'm back to provide a pandemic influenza
Page 249

2 preparation update, and the agenda for the update
3 would be describing the current status of H5N1 and
4 then what are we doing as far as vaccines,
5 antivirals, and risk communications?

6 So, since we briefed the Board last
7 December, what's been happening as far as human
8 cases, and the hotspots are, again, Indonesia with
9 the lion's share of the cases, then Egypt, and
10 it's now up to seven cases and three deaths,
11 followed by Vietnam and China.

12 So, overall, the total number of cases
13 for 2008 is cases with 23 deaths, so, we're
14 tracking along pretty much the same thing as last
15 year. So, if the current trend continues, with a
16 little seasonal variation, we should be seeing
17 totals that mimic 2007 and 2006.

18 While Indonesia continues to be a
19 problem, sample sharing continues to be an issue.
20 They still have the highest number of cases with
21 case fatality rate exceeding 80 percent. They
22 also have a high level of viral circulation in

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282

1 their avian population, as evidenced by a 20
2 percent of their 1.4 billion chickens that are
3 scattered in 30 million backyards. Thirty-one or
4 thirty-three provinces are infected, and a number

5 of provinces have endemic disease in some areas.

6 Along with a highly-decentralized
7 administration, under resource of national
8 veterinary services, a lack of engagement with
9 commercial poultry producers, and the inability to
10 implement a comprehensive communication strategy,
11 the problems that we're seeing in Indonesia are
12 likely not to go away in the short-term.

13 Just to be a bringer of more good will
14 and cheer, there's also a question if their
15 poultry vaccine continues to be effective, and
16 there's been at least one confirmed co-infection
17 in Indonesia with H5N1 and seasonal influenza.

18 Now, on the bright side, the
19 international community is engaged. Currently,
20 there's 1,350 local government offices that have
21 been trained and are working with village
22 communities. Surveillance and response teams are

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283

1 working in 193 of 448 districts, and by June,
2 they'll be 2,000 teams in over 300 districts, so,
3 they're moving in the right direction.

4 The FBO is providing technical and
5 policy advice, and, this year, major donors have
6 invested the sum of \$25 million towards their
7 mitigation efforts.

8 Well, we're still seeing some human to
Page 251

9 human transmission. Two cases or two clusters
10 since I spoke to you last. One in Pakistan and
11 one in China, but the good news is that it's still
12 a fairly difficult disease to catch.

13 So, the Government of Indonesia recently
14 reported at the International Conference of
15 Emerging Infectious Diseases this year a study
16 that they performed looking at the exposure of
17 close contacts, and there was a total of 257
18 contacts, 130 healthcare workers, 90 family
19 members, and neighborhood contacts with known
20 positive cases. In fact, only 4 percent of the
21 healthcare workers followed appropriate infection
22 control measures. And, despite this, there's no

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284

1 evidence of H5 infection in any group. In all of
2 the cases of human to human transmission thus far,
3 oddly, have occurred in blood relatives.

4 Now, the virus continues to be a moving
5 target with new clades and subclades added, which
6 seems to be almost a daily basis, and one example
7 is what's happened in Vietnam.

8 Looking at 2005 to 2007, there have been
9 multiple sublineages to include clade 1, clade
10 2.3.4, and 2.3.2. Now, you'll probably notice
11 that we added another number to the subclades,

12 which leads us to the new clade designations.

13 The goal for the new clade designations
14 was to have a uniform designation of emerging
15 lineages of high-path, H5N1, and the system was
16 developed by a collaborative working group made up
17 of WH, OIE, and FAO.

18 Now, the good news is that they did
19 maintain some of the old clade numbers. The bad
20 news is that there are now 10 clades with
21 subclades and sub-subclades.

22 So, the designation criteria, again,

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285

1 they tried to maintain previously-designated clade
2 numbers, so, 2 remains 2 and 1 remains 1, and,
3 after that, everything has changed. The new
4 designations are based on the phylogenetic tree
5 with the H5N1 progenitor closest to the Guangdong
6 196 strain designated as clade 0, which used to be
7 the old clade 3.

8 Some clade numbers start with 3, and the
9 clades are designated by the presence of a
10 distinct common node shared by at least four
11 isolates.

12 DR. OXMAN: Oxman. I'm sorry to
13 interrupt you, but what segment is used for the
14 basis of that?

15 LTC. HACHEY: The hemoglutin. So, if

16 you look at what's happened since 2008 as far as
17 the new clade nomenclature, in China and Vietnam,
18 it's primarily clade 2.3.4. Egypt remains clade
19 2.2, and Indonesia might be 2.1.3, but we don't
20 know because they're not sharing any samples. But
21 they used to be 2.1.3, and we're assuming that
22 that's remained unchanged.

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286

1 So, in summary clade 1, there's only
2 been a few recent samples isolated, but antigenic
3 variance have been detected as early as just last
4 year, but it appears to be replaced by clade 2.3.4
5 in Southeast Asia.

6 Clade 2.1 remains restricted to
7 Indonesia, and, again, represents the largest
8 number of cases, but 2.2 has an increasingly
9 geographical range with increasing incidents of
10 human cases. So, 2.2 may be the leading player as
11 time goes on. And 2.3.4 has expanded in Southeast
12 Asia, and it's now the predominant strand in that
13 region.

14 So, with that threat, there's been a
15 number of vaccine candidates that have been
16 developed, and this one laundry list is the ones
17 that have completed regulatory approval. And that
18 includes vaccines with a clade 1 strain, 2.1, 2.2,

19 and 2. 3. 4. But, in addition to that, there's a
20 number of other vaccine candidates that are either
21 pending regulatory approval or are candidate
22 vaccine preparations, and this is an incomplete

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287

1 list, but just gives you a flavor that there are a
2 number of potential of vaccines or vaccine
3 candidates out there as the virus continues to
4 mutate.

5 So, along with that, this is no longer
6 the proposed DoD vaccine strategy. It was signed
7 last Friday, so, this is now the DoD vaccine
8 strategy, and it recognizes that there's a
9 multitude of vaccine candidates, and DoD doesn't
10 have the resources, nor is there an adequate
11 industrial base to have adequate amounts of
12 vaccine to address each threat in order to protect
13 the entire DoD population.

14 The other problem is that, even if we
15 did have unlimited resources and the manufacturers
16 could supply vaccines in adequate amounts, even
17 with match strains, the immunogenicity is not
18 terribly reassuring. And we'll see some slides
19 that reflect that.

20 So, our current strategy is to delay
21 pre-pandemic vaccine acquisition until there's an
22 effective vaccine with adequate cross protection

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288

1 that becomes available. And that looks like it's
2 probably about two years down the road.

3 Now, we reported vaccine stability at
4 the last DHP meeting, and we have good news and we
5 have bad news. The bad news is that stability has
6 become an issue, particularly for the A Vietnam
7 2004 and 2005 strains that are in bulk storage.
8 Respectively, there's been a loss in potency with
9 the 2004 and 2005 strains of 18 and 45 percent.

10 Now, the good news is that the same
11 vaccine that's been filled and finished appears to
12 be stable with no loss in potency. So, for DoD,
13 that was somewhat reassuring, that most of our
14 Vietnam strain-based vaccine, the clade 1 vaccine
15 that we currently have has already been filled and
16 finished. So, sometimes, it's better to be lucky
17 than good.

18 DR. OXMAN: Will you excuse me again for
19 keep interrupting you, but -- it's Oxman. Do you
20 think the stability or the lack of stability of
21 the bulk preparations maybe an aggregation
22 phenomenon and really, in that respect, not real

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Page 256

1 in that it's done by -- I presume it's done by
2 hemagglutination.

3 LTC. HACHEY: Actually, in a briefing
4 that we had just last week, that was not the
5 opinion of HHS, the folks who are actually doing
6 the stability testing, and they're somewhat unsure
7 why the Vietnam strain that's in bulk storage, has
8 lost its potency and the Indonesian strain has
9 not, also in bulk storage.

10 So, they were at a loss to explain why.
11 I suppose that may be a possibility for someone
12 much brighter than I to figure out.

13 So, the next thing I'd like to do is
14 talk about vaccines that are on horizon, and, with
15 that, discuss cross-protection issues, where
16 we're at as far as a universal vaccine, adjuvanted
17 vaccines, and live attenuated vaccines.

18 So, first of all, going to the GSK split
19 viron vaccine, one study that was reported last
20 year looked at the effects following two doses at
21 3.8, 7.5, 15, and 30 micrograms with and without
22 adjuvant. And, across the board, the adjuvanted

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1 formulations were much more immunogenetic.
Page 257

2 The cross reactivity with the adjuvanted
3 vaccine with the dose as loss at 3.8 micrograms
4 for a clade 2.1 threat was 77 percent. So, at
5 least in this particular study, fairly reassuring
6 that when this particular vaccine or a
7 modification of this vaccine is available, this
8 may be our short-term, magic bullet.

9 A study that's being done by the CDC
10 right now is looking at an open label of Phase I
11 and II study enacted a H5N1 vaccine. And, after
12 two 90 microgram doses of the clade 1 base vaccine
13 and nothing new, about 40 percent had a greater
14 than a fourfold rise by microneutralizations.

15 So, again, less than half of the folks
16 who received the 2 90 microgram doses have
17 evidence of protection.

18 Now, they took the converters and they
19 tested for reactivity to a clade 2 challenge, and
20 for a clade 2.1 challenge, they had a 83 percent
21 that responded. For clade 2.2, 67 percent, and
22 for clade 2.3.4, only 28 percent.

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291

1 So, depending on which cross challenge
2 you have, you had variable levels of
3 cross-protection, but that's only in that 40
4 percent of the converters.

5 Another study looking at immunization
6 of, again, two doses of non-GSK, adjuvanted, or
7 non-adjuvanted vaccine, those, again, who were
8 zero positive were tested for cross-reactive
9 titers, and for an alternative clade 1 challenge,
10 she was 98 percent, for 2.1, 64 percent, and for
11 2.2, 80 percent, and, with this particular
12 adjuvant, there's no consistent result associated
13 with the adjuvant as far as the level of
14 cross-protection. So, a very different story than
15 what we saw with the GSK adjuvanted vaccine.

16 Moving on to universal vaccine,
17 ACAM-FLU-A has been examined both with and without
18 adjuvant, and the best response with 90 percent
19 conversion rates, at least with their proprietary
20 QS21 adjuvant, animal studies demonstrated 70
21 percent survival following a clade 1 H5N1
22 challenge, and the Phase I trials are now

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292

1 completed and they're looking at further trials.

2 So, this is on the horizon, but nothing
3 that is going to be available in the next few
4 years.

5 Another universally-based vaccine
6 proponent is using the M2 cytoplasmic tail. This
7 one group of investigators noticed that deletions
8 of the M2 cytoplasmic tail resulted in growth

9 defects of seasonal flu, H1N1 viruses in vitro.
10 So, they use the same talin mutant as a live
11 attenuated vaccine against H5N1. And MISA
12 received a lethal challenge with both homologous
13 Vietnam-derived clade 1 virus and a clade 2
14 Indonesian 705 challenge. Had protection against
15 each. But, again, this is mouse data.

16 Moving onto live attenuated vaccines,
17 the current activities, not surprisingly, this is
18 led by Metamune, and, in this case, in conjunction
19 with Johns Hopkins University and NIH, and they're
20 doing a number of things. One is creating a
21 library of vaccines representing each subtype with
22 pandemic potential, so, H2 and H4 through 16.

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293

1 Also in their activities is a Phase I
2 proof of principle trial looking at safety,
3 infectivity, one versus two doses as regimens,
4 immunogenicity, and shedding a virus and healthy
5 subjects. They're also banking the sera from
6 vaccinated volunteers, and they plan on using this
7 bank sera to test newly-emerging viruses for the
8 degree of drift and also being able to predict the
9 ability of the library virus to cross-protect
10 against the actual pandemic strain.

11 Now, all of the live attenuated vaccines

12 are based on the Flumist A/Ann Arbor attenuated
13 genetic backbone, and attached to that backbone
14 are 2H5 vaccines and H9 and an H7.

15 Well, the good news is that all the
16 vaccines are well tolerated by healthy adults.
17 Unfortunately, the vaccines were much more
18 restricted in replication and less immunogenic
19 than what's seen with a seasonal flu vaccine.

20 As far as replication, they got adequate
21 replication with H7 and 81 percent, 31 percent
22 with H9, and 10 to 47 percent with H5. And the

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294

1 majority of the subjects only showed virus on the
2 first day.

3 Immunogenicity is a little bit
4 different. Ninety-two percent with H9, sixty-two
5 percent with H7, and only zero to eleven percent
6 with H5.

7 So, it's not that the Avian hemoglutin
8 in neuraminidase genes might be further
9 attenuating the vaccine for humans, and further
10 studies are warranted to investigate the role of
11 receptor specificity, how the virus enters, and
12 the interaction between the Avian hemoglutin and
13 neuraminidases with the internal protein genes of
14 that genetic backbone.

15 Now, on the other hand, both mouse and
Page 261

16 ferret data demonstrated also low replication in
17 the airway but good match and unmatched
18 cross-protection. So, there's more to follow.

19 DR. POLAND: Wayne, was that after one
20 or two doses?

21 LTC. HACHEY: The human data?

22 DR. POLAND: Yes.

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295

1 LTC. HACHEY: Two.

2 DR. POLAND: Two. Moving on to the
3 adjuvanted vaccine, the GSK adjuvanted vaccine
4 that's currently in trials in Europe, Prepandix
5 received positive opinion from Europe's Committee
6 on Medicinal Products for Human Use. So, clinical
7 testing is ongoing there. This is based on a
8 clade 1 antigen.

9 The one that they proposed for the U.S.
10 is based on a clade 2 antigen. But they found
11 that they have acceptable safety and
12 reactogenicity profiles and a fourfold increase in
13 serum neutralizing antibodies with
14 cross-challenges. Seventy-seven percent with the
15 Indonesia clade 2.1, seventy-five percent with
16 clade 2.3.4, and eighty percent with Turkey, clade
17 2.2.

18 So, again, at least this particular

AA DHB-04_23_08.txt
19 version of an adjuvanted vaccine, with this
20 adjuvant, is reassuring and this may be available
21 within about two years.

22 Also, animal studies demonstrate 100

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296

1 percent survival following 2 doses with, again,
2 doses as low as 3.8 micrograms, even with
3 heterologous challenges. But always remember mice
4 lie and ferrets exaggerate.

5 So, even though a lot of this data is
6 reassuring for our rodent friends, we still need
7 to wait and see with a little more robust human
8 data.

9 Well, everybody wants antivirals, which
10 leads us to the DoD antiviral strategy.

11 In our new addendum that was just signed
12 last month, establishes local supplies equal 30
13 percent of the population at risk both at fixed
14 OCONUS and deployed settings. It remains at 10
15 percent in CONUS mainly because of storage issues.

16 Our new strategy or our refined strategy
17 focuses on early treatment and the use of
18 post-exposure prophylaxis for close contacts.
19 Outbreak prophylaxis is limited to high-risk
20 individuals, particularly healthcare workers and
21 first responders, and a select few with really
22 special roles that absolutely have to be

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297

1 protected, and, also, a select few who do not have
2 any access to medical support.

3 The overall strategy for this to work
4 really requires the early and consistent
5 implementation of non-pharmacologic
6 interventions, driving the attack rate down to at
7 least 20 percent. Also, rapid diagnostics will
8 enable a more effective use of antivirals.
9 Unfortunately, as far as rapid diagnostics,
10 nothing is commercially available yet.

11 There are two that were recently
12 presented at, again, the International Conference
13 on Emerging Infectious Disease, which the DoD is
14 at least participating or partners in. One is a
15 rapid antigen test strip testing underway at NHRC
16 in (off mike), reassuring no false positives with
17 100 clinical specimens. And, of the 29 H5 samples
18 submitted, they have positive results in 26.

19 Another rapid diagnostic test under
20 evaluation is a multiplex antibody panel for the
21 detection of Influenza A and B, and it couples on
22 antibodies sandwich assay with electroluminescent

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Page 264

1 detection apparatus. They have also tested 100
2 samples, 20 flu A, 20 flu Bs, and 20 had nos, and,
3 currently, they have 88 percent sensitivity and 96
4 percent specificity. And, in ongoing trials,
5 they'll be evaluating for specific H1, H3, and H5
6 antibodies.

7 DR. KAPLAN: Excuse me. Are those in
8 the in vivo or in vitro?

9 LTC. HACHEY: Actually, I'd have to get
10 back to you on that.

11 DR. KAPLAN: Is that laboratory samples
12 or from patients?

13 LTC. HACHEY: Oh, this is lab samples,
14 yes.

15 DR. KAPLAN: In other words, that was
16 done in the laboratory and not in patients?

17 LTC. HACHEY: Right. I couldn't leave
18 without at least one ferret study, and this one is
19 reassuring in that, over a year ago in our
20 antiviral policy, we developed the concept, post-
21 exposure prophylaxis using more of a treatment
22 regimen rather than a prophylactic regimen for

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1 post-exposure prophylaxis. And it's reassuring to
 Page 265

2 see that, at least in this one study dealing with
3 ferrets, that it looks like we are probably on the
4 right track.

5 So, this one study looked at ferrets
6 given Osetamivir for 10 days in either 5 or 10
7 milligrams q.d. or 2.5 or 5 milligrams BID.
8 Treatment started four hours after the infection
9 and prophylaxis was started one day after
10 infection or after inoculation. And then the raw
11 challenge with a lethal dose of a clade 1 H5N1s.

12 Well, the 5 milligrams per kilo per day,
13 just given q.d., prevented death but did not
14 prevent severe illness. The 10 milligrams given
15 once a day reduce symptoms, but you still had
16 pathology observed in the internal organs. But at
17 2.5 or 5 milligrams per kilo BID, 100 percent
18 survival, no symptoms, no systemic viral spread,
19 and no organ pathology. And with 5 milligrams
20 BID, they also had no viral replication in the
21 upper airway after three days. And, extrapolating
22 that, 5 milligrams per kilo in a ferret is about

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300

1 the same as 75 milligrams in a human.

2 Furthermore, Osetamivir did not prevent
3 infection, but did prevent the release of virus
4 from infected cells, and they still antibody

5 production following inoculation. So, Osetamivir
6 did not interfere with the serum antibody
7 production at any dose.

8 So, if people wind up acting like
9 ferrets, it will be fairly important to know who
10 we actually treated because they would potentially
11 be immune.

12 Another example where, again, we might
13 actually be on the right track is this one paper
14 recently produced looking at model and targeted at
15 layered containment influenza pandemic in the
16 United States. And there's three separate models
17 of targeted layered containment that included
18 post-exposure prophylaxis. They assume 67 percent
19 of the infections were symptomatic, 60 to 80
20 percent, ascertainment of symptomatic cases. All
21 of the cases were treated, which is consistent
22 with our guidelines, and then all (off mike)

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301

1 contacts also received antivirals.

2 This chart, a thing to look at is
3 intervention, one, you don't do nothing. So, you
4 make no attempt at stopping the pandemic, at least
5 as far as social distancing or the use of
6 antivirals.

7 Scenario two, it's an effort, but you
8 have a fairly high threshold. Compliance is only

9 30 percent for closing schools and for quarantine,
10 whereas 3 and 5, kind of like Sears and good,
11 better, best, this is kind of better and 4 and 6
12 is best with a fairly low threshold as far as when
13 you would implement therapy.

14 So, three different models, one by the
15 Imperial College, another by the University of
16 Washington, and the third by the Virginia
17 Bioinformatics Institute. And all three showed
18 pretty much the same thing: That if you do
19 nothing, you will hate life, with attack rates
20 ranging from 40 to upwards to 60 percent. Whereas
21 even if you have only percent compliance with
22 scenario two, you can see that, regardless of the

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302

1 model you pick, your attack rates drop down
2 substantially. And then if you use scenario four
3 or six, which is, again, the more Draconian
4 approach, you know, early implementation, fairly
5 high compliance, the pandemic all but goes away.

6 Now, keep in mind this is a model,
7 models often lie, but it does give us some
8 evidence that the path that we're taking may be
9 appropriate.

10 This is also from the same paper, a
11 sensitivity analysis for just workplace and

12 community social distancing, and you can see with
13 different or not, as you go across the spectrum
14 that the severity of the disease gets worse, and
15 as you also move across your compliance with
16 social distancing, it ranges from 0 up to 50
17 percent, and, as you increase your compliance only
18 up to 50 percent, you can see that slope of that
19 curve is fairly sharp.

20 And then the last thing as far as this
21 one particular paper, again, no interventions, a
22 fairly pronounced attack rate, but with scenario

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303

1 two, again, I wouldn't quite call it a token
2 effort, but a 30 percent compliance, fairly light
3 entry as far as establishing these measures, your
4 attack rate drops fairly precipitously with just
5 NPIs alone, and then further with case treatments,
6 and then further with targeted antiviral
7 prophylaxis. And then, as you -- more robust as
8 far as your response.

9 Scenario three is kind of the better in
10 the good, better, best comparisons. The effects
11 of the pandemic are blunted fairly impressively,
12 and that's independently with the three different
13 models.

14 Moving onto Tami flu -- I'm sorry,
15 finishing with Tami flu and moving onto risk

16 communi cations.

17 One new ini ti a tive we' re ju st start ing
18 wi thi n DoD is the devel opment of a risk
19 communi cations ki t, and the pri ma ry pur pose of the
20 ki t is a risk communi ca ti on tool, and thi s also
21 in tro duces peo ple to some of the hard ware that
22 they' re go ing to need to mi ti gate the pan demic

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304

1 wi thi n their house hold. So, the gui del ines that
2 are in cluded in the ki t are in for ma ti on about
3 so ci al di stan ci ng, in fec ti on con trol, high li gh ti ng
4 hand-wa shi ng, it di scus ses mask use, when and how
5 to use a mask, and also where to get more
6 in for ma ti on.

7 So, the rea son for the ki t is to get the
8 in struc ti ons in to peo ple' s hands and to ac tu ally
9 have them read them. The car rot be hind the ki t
10 in cludes 2N95 masks, four sur gi cal makes,
11 in struc ti ons of where you can get more on your
12 own, and a rea son a ble-sized con tai ner of (off
13 mi ke) hand-wa shi ng sup plies so that those
14 be ha vi o ral pat terns can at least be well
15 in tro duced, and, a gain, di rec ti ons of where fol ks
16 can get more sup plies.

17 Now, there is some ques ti on of shoul d we
18 have ju st all N95s, such as sur gi cal masks, and

19 there is some evidence, at least as far as
20 infection control within a household that either
21 one will probably do. This one study looked at is
22 there a difference between mask type for community

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305

1 mitigation, and they compared N95 masks with
2 surgical masks.

3 Now, the numbers are fairly small. They
4 recruited people with suspected flu-like symptoms,
5 they yielded 9 with either flu A or B, they tested
6 them on the second day of illness when they were
7 spewing virus everywhere, and participants coughed
8 into petri dishes 10 centimeters away, either
9 wearing no mask, an N95, or just a surgical mask.
10 And, regardless of what kind of mask they used,
11 either an N95 or the surgical mask, there was no
12 growth on the plates, whereas those without a mask
13 had a rather robust growth.

14 Any questions?

15 DR. POLAND: Dr. Clements?

16 DR. CLEMENTS: Thank you. I just had a
17 couple of questions, and, actually, one I'm
18 seeking -- both I'm seeking information.

19 One is risk, this risk communication
20 kit. Is this actually in the plans, and is there
21 a proposal to distribute these, or when would they
22 be distributed? Is this like more duct tape and

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306

1 Saran Wrap here or is there a reason to put this
2 out without some real indication that a threshold
3 has been crossed?

4 LTC. HACHEY: The current plan is to
5 package the kits within this specific year, and
6 then to send them out to our TRICARE prime
7 addresses as, again, a risk communications tool.
8 So, our plan isn't to wait until the balloon is
9 about to go up and then mail them out, but to get
10 the message out there preemptively, and if we have
11 to repeat this every year or two, then that'll be
12 a process that we would be considering.

13 DR. CLEMENTS: How widely distributed
14 would you see that being?

15 LTC. HACHEY: How wide?

16 DR. CLEMENTS: How widely distributed?

17 LTC. HACHEY: To all of our TRICARE
18 prime addresses.

19 DR. CLEMENTS: For distribution to all
20 the -- I mean, what's the broader area network
21 that that would be distributed to in terms of
22 number of persons, number of households?

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Page 272

1 LTC. HACHEY: Oh, it turns out to be
2 about 1.5 million addresses.

3 DR. CLEMENTS: And, actually, my real
4 question was about you've listed several vaccines
5 that you've said optimistically would be available
6 within a couple of years, most of use adjuvants
7 that are not approved for use in the U.S.

8 So, is there something about those
9 adjuvants? I mean, the only one that we have
10 approved for use in the U.S. Is alum, and even
11 though there's an Influenza A vaccine with MF59
12 used in Europe, it's not approved for use in the
13 U.S.

14 So, what's the basis for the optimism?

15 LTC. HACHEY: Well, the only vaccine
16 that is likely to see at least submission for FDA
17 approval is the GSK adjuvanted vaccine. The
18 others are a number of years behind GSK. And
19 their right now starting Phase II clinical trials
20 here in the U.S. There are plans for Phase III
21 trials with DoD participation as far as a
22 component of those Phase III trials.

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1 So, the company's target is submission
Page 273

2 to the FDA with potential approval within the next
3 two years. But, again, everybody else is years
4 behind that.

5 DR. CLEMENTS: Wayne, a couple of
6 questions --

7 LTC. HACHEY: Oh, and just one other
8 thing, as far as that particular adjuvant, if you
9 think of everything that you could possibly think
10 about that you would not want to have in an
11 adjuvant as far as PR is concerned, not scientific
12 merit, which is the public relations. This one
13 has a little alum in it, it has thiomersal, and it
14 has even just a touch of squalene, which is
15 probably why it works and works much better than
16 any of the other adjuvants. But it does have
17 somewhat of a PR hurdle to get over.

18 DR. POLAND: I was glad to see DoD's
19 participation in some of the areas that you
20 mentioned, but has there been any movement in DoD
21 participation in clinical trials of the vaccine
22 candidates?

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309

1 LTC. HACHEY: There is. There's, again,
2 at least for the GSK adjuvanted vaccine, we're
3 part of the Phase III clinical trials.

4 DR. POLAND: I know about that one, and

5 that's if it gets funding.
6 LTC. HACHEY: Yes, and that's, at this
7 point, because of competing demands on personnel
8 time within DoD, that's been our kind of starting
9 point.
10 DR. POLAND: And my second question,
11 could you just say something about the select
12 subcommittee's recommendation about using the
13 clade 1 vaccine that DoD has in offering it to
14 high-risk individuals? Can you say something
15 about the uptake of that?
16 LTC. HACHEY: We have offered it to
17 essentially our lab workers who are currently
18 working with H5 strains, and, thus far, it's been
19 offered, but they've elected not to take it to
20 date.
21 DR. POLAND: Okay. Who had it? Mike?
22 DR. OXMAN: Can you tell us what clade

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310

1 is involved in the recent extensive chicken
2 outbreak in Korea?
3 LTC. HACHEY: I can't, but I can find
4 that out for you.
5 DR. OXMAN: And the other, just a
6 comment, and that is if we're talking about --
7 LTC. HACHEY: Although, if I were to
8 venture an educated guess, it would probably have
Page 275

9 to be 2.3.
10 DR. OXMAN: 2.3.
11 LTC. HACHEY: Because 2.1 is only in
12 Indonesia, 2.2 is in Europe, Egypt, and there in
13 Southeast Asia is primarily 2.3, so, probably 2.3.
14 DR. OXMAN: And I just wanted to make a
15 comment on the issue of adjuvant, and it was
16 focused a little bit more with talking with one of
17 my good old friends at the FDA.
18 If we're talking about pandemic vaccine,
19 one shot save the world, that's one thing, but I
20 know that the companies are interested in
21 extending this to seasonal vaccine. There are
22 really grave concerns about safety, including

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311

1 oncogenicity unrelated to virus, of any adjuvant
2 that functions as a non-specific adjuvant, and,
3 so, I think we really ought to make a distinction
4 between worldwide emergency pandemic influenza
5 vaccine and where the companies are going, and
6 that is to spare anagen and, therefore, make more
7 money and vaccinate more people with adjuvanted,
8 annual vaccination, which I think there's no
9 safety data whatsoever, and, to the best of my
10 knowledge, none is being collected.

11 DR. POLAND: Pierce?

12 DR. GARDNER: Sir, just to follow-up on
13 that concern, of course, the meeting we had at
14 Naval Medical Center a half and a half ago, it
15 seemed to me we heard presentations from many
16 manufacturers, and many of those came away most
17 impressed with what Flumist was doing at that
18 time, and, of course, you get around all the
19 adjuvant issues once you start using a live virus
20 vaccine.

21 And my other recollection was that
22 almost everybody said we're on the brink of a

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312

1 tissue culture, or they were going to make it by
2 the carload and I guess can you fill us in on --
3 we haven't heard much about Flumist lately, and,
4 secondly, what is happening in the industry with
5 regard to achieving tissue culture, which was
6 offering the promise of being a more agile in
7 responding to bad choices and making seasonal
8 vaccine or making the library for the Avian Hs and
9 Ns that we could use to respond quickly.

10 LTC. HACHEY: Well, the series of slides
11 that I had about live attenuated vaccine is
12 essentially the Flumist version of a pre-pandemic
13 vaccine, and the problem is that it's fairly easy
14 to make, it requires just a small amount of
15 anagen, but there had been some problems as far as

16 getting it to grow in human upper respiratory
17 track. And, if we're lucky, the next pandemic
18 will be a H9, which tends to grow much easier in
19 human upper respiratory track, but the big problem
20 we've been having thus far with the early trials
21 that are actually heard down at Hopkins is that it
22 just doesn't grow well in people.

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313

1 DR. POLAND: I think we're going to move
2 on unless there's something really pressing.
3 We've got a couple more presentations and then an
4 administrative session. So, Wayne, thank you.

5 We'll next hear from Mike Oxman. He
6 represented the Board at the FDA vaccines and
7 related biologics advisory committee meeting in
8 February. This meeting was the first time, I
9 think, in modern history where all three viruses
10 in the trivalent influenza vaccine changed in one
11 year, and Mike has got just a few slides to sort
12 of brief us on the results of that meeting.

13 DR. OXMAN: Only 78 slides.

14 DR. POLAND: He does that to get --

15 DR. OXMAN: Only 78 slides in 5 minutes.

16 No, first of all, this is a very different
17 picture, and this is the seasonal influenza
18 vaccine, and there the attempt is to cope with the

19 anti genic dri ft.

20 And what we're doing really is, each
21 year, at about -- in February, because as long as
22 the vaccine is made in eggs, you've got to have a

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314

1 tremendously lead time, which means that you're
2 guessing what's going to match next years'
3 vaccine, and it's always a guess, and the best bet
4 is dependent on what's circulating this year.

5 And this is what I mean by the antigenic
6 drift. If you'll see that if you have somebody
7 who has no previous experience -- and this is some
8 actual clinical data with A/Victoria/75, H3N2 --
9 the attack rate for symptomatic infection was 27
10 percent with no prior experience. If you had a
11 related vaccine, which, of course, it drifted
12 some, it was only two years drift and you had only
13 a 4 percent attack rate. If it had 4 years to
14 drift, and that's this row, then an 8 percent
15 attack rate, and if it had 5 or 6 years to drift,
16 and that's this row, you had about an 18 percent
17 attack rate. So, that's what you're facing.

18 And this is the result of the meeting.
19 Now, WHO had already made their decision a week
20 before the meeting, and, unless there's good
21 reason -- I think there's a sensible reluctance
22 not to contradict the WHO conclusions. And this

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315

1 decision was made with respect to the H3N2, which
2 was the predominant -- at the end of this year's
3 flu, that the CDC had received a bunch of
4 specimens, but they hadn't yet characterized them.
5 So, we didn't know whether the most recent
6 experience in the United States was well matched
7 with the A/Brisbane/10/2007, but they made the
8 decision to go along with that, confirming the WHO
9 recommendati ons.

10 And, in this case -- and I'll show you
11 the next slide -- all three components were new
12 components for the coming year, so, they had all
13 changed from these past years, 2007, 2008 vaccine.

14 Now, I heard a couple of days ago that
15 they now have characterized a number of the H3N2
16 isolates from the late part of this year's
17 epidemic, and they do match, fortunately. The
18 choice of Abra as being October 2007-like virus,
19 so, we're lucky at that level of the guess. Of
20 course, if next year's virus is kind and is
21 similar to this year's, we'll be in good shape.

22 And this is just the last three years of

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Page 280

1 vaccine, and what you can see is that, going from
2 the 2005, 2006, not shown, you have in the
3 2006-2007 vaccine, you have 2 new viruses, only
4 one was changed, the H1N1 in the 2728 vaccine that
5 we just are finishing with, and next year's
6 vaccine is shown here in red as all three as new
7 viral strains. And, again, we're going to be
8 under this tremendous pressure of time until we
9 move from egg-based to tissue culture-based
10 vaccine or something even beyond that. And that's
11 all I have to say.

12 DR. POLAND: Thanks, Mike. Just one
13 small correction because we keep talking about it.
14 I don't think it's "tissue." I don't think it's
15 tissue culture, it's suspended mammalian cell
16 culture.

17 DR. OXMAN: Yes. Mammalian. It's cell
18 culture.

19 DR. POLAND: Yes.

20 DR. OXMAN: I should have said cell
21 culture rather than tissue culture.

22 DR. POLAND: Okay. Questions at all

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1 about that?

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(No response)

DR. POLAND: Okay, thank you. I'll give a brief update to the Board next on the biowarfare counter measures. This was a meeting of the Infectious Disease Control Subcommittee two weeks ago. With the Board's new organization structure, remember, the bulk of the work is now going to happen at the subcommittee, panel, et cetera level, and to comply with our charter and with FACA statutes, we have to be sure that we discuss and deliberate any subcommittee activity vote requirements.

We spent a day together, and we had an overview of the DoD Biodefense Program from Colonel Jarrett in the OSD Force Health Protection and Readiness Office, another briefing on research and development initiatives from Dr. Galloway of the Defense Threat Reduction Agency. The next briefing was advanced development of biodefense countermeasures from the Joint Requirements Office, and then a transformational, medical

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318

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technologies initiative that was discussed through DTRA.
I can probably summarize it by saying there were three things that we learned. One is

5 we won't yet make our recommendations because the
6 changing chairman's threat list still has not been
7 released, and this has been -- I'm not sure what
8 influence we have on this, but this has been an
9 ongoing issue that we're just not getting that,
10 and, hence, cannot fulfill, codified by our -- by
11 statute, I think it is, that says we're supposed
12 to deliver these on a yearly basis.

13 So, we're reluctant to make
14 recommendations absent what we're told is a very
15 different threat list than we have seen in past
16 years.

17 The second was that, as we listened to
18 DTRA and the joint requirements and the
19 transformational medical technologies initiative,
20 it was apparent that, if it worked, it required
21 more boxes on a wiring diagram to work together
22 seamlessly than is probably possible.

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319

1 It doesn't mean that the work doesn't
2 occur, but it appeared to me -- and as we
3 questioned them, and those of you that were there,
4 please add to it -- it was slow, it depended on
5 one person in one agency having a personal
6 relationship and knowing the other person so that
7 communication could occur. There was uneven
8 formal lines of communication, and, so, it results

9 in sort of what we've seen, a slow, kind of
10 cogwheels that don't match process.

11 The third thing -- perhaps I'm biased --
12 but I viewed with alarm is that the dollars going
13 into vaccine countermeasure research are small and
14 shrinking compared to other areas of inquiry, and
15 I do view this with some alarm, and we talked
16 about it not to the point of resolution, but it is
17 of concern, and, perhaps, something that, once we
18 see the threat list and make our formal
19 recommendations, we, perhaps, would incorporate a
20 few of these observations into it.

21 So, let me open it up first to other
22 subcommittee members that were there for any

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320

1 additional observations or clarifications, and
2 then we'll take any Board questions.

3 Mike?

4 DR. OXMAN: Just to push you a little
5 further as to why you're alarmed about the
6 relative paucity of investment in vaccines, I
7 suspect that's because, as we have more and more
8 terrorist groups, biowarfare technology is
9 something you can do in your garage and is a much
10 greater risk than nuclear technology.

11 DR. POLAND: Right.

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12 DR. OXMAN: Is that why --
13 DR. POLAND: Correct, yes.
14 DR. OXMAN: -- you're so concerned?
15 DR. POLAND: The Rand Institute did a
16 study looking at the cost of producing civilian
17 casualties per kilometer of geographic area.
18 Nuclear weapons were, I think, about \$900,
19 conventional weapons were in the \$400 or \$500, and
20 biological weapons were \$1.
21 Other comments? John?
22 DR. CLEMENTS: So, coincidentally, I was

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321

1 not at that meeting, because, on that very day, I
2 was reviewing grants for the JST0 and for DTRA and
3 for the transformational technology program, so, I
4 have additional insight into this.
5 DR. POLAND: Perfect, yes.
6 DR. CLEMENTS: There's actually some
7 really serious problems within the program that I
8 think we should talk about before we write a
9 recommendation.
10 Just one that I'll just point out
11 because I feel very strongly about this is that,
12 because the military personnel now have to compete
13 for grants, they're actually competing within the
14 same organization with one another for the same
15 projects, so, what winds up happening is that,

16 rather having the command work together to solve a
17 problem, you have a command with three or four
18 competing interests working against one another
19 trying to solve the problem, often using the same
20 technologies and the same resources. It's
21 extremely inefficient.

22 And the other is that they're determined

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322

1 to spend their \$400 million, so, as you get down
2 the list of things that would never pass the cut
3 in a standard NIH review for the quality of the
4 science, those things are going to get funded, and
5 they're going to get funded because they're not
6 going to turn the money back, and they're not
7 going to save the money for the fiscal year;
8 they're going to fund those programs, even though
9 some of them are probably not where we would
10 really like to see them be.

11 So, I think we have some opportunities
12 here to have some input into this process.

13 DR. POLAND: Thank you, and we need to
14 be sure to get your insights, John, when we write
15 that memo.

16 Mike?

17 DR. OXMAN: Following-up on that, is it
18 possible to either have or develop a mechanism

19 where if you turn back \$200 million, you have at
20 least \$100 million of it added to the following
21 year's budget? Is there any way to carry funds
22 over and beyond fiscal year?

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323

1 COL. GIBSON: Only in our spirit of
2 influence.

3 DR. CLEMENTS: Yes. First of all, it's
4 not our spirit of influence, and, second of all,
5 we could have OMB come and talk to us because
6 that's what you're talking about; you're talking
7 about very clear guidance within the FAR on how we
8 execute money. Unless you have an MBA, I don't
9 think you completely understand all of those
10 issues, so, I really wouldn't want to go there.

11 DR. POLAND: Mark?

12 DR. BROWN: Yes. If I can just get a
13 point of clarification on the types of grants
14 these are. Are these a one-year type of grants or
15 are they more like NIH, that it's understood that
16 it's one-year funding and out --

17 SPEAKER: (off mike) information before
18 this goes on?

19 DR. SHAMOO: Adil Shamoo. With all due
20 respect, what you have is privileged information,
21 and you're talking about privileged information,
22 and there's going to be more questions about your

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324

1 privileged information and you may be violating
2 confidence of the review process.

3 DR. POLAND: Well, I think I would
4 interpret the broad comments that were made, that
5 they wouldn't violate standard --

6 DR. SHAMOO: They have to stay very
7 broad.

8 DR. POLAND: But I don't think we can
9 talk about individuals or projects.

10 DR. SHAMOO: Okay.

11 DR. BROWN: This is a very general
12 question about the type of funding that DoD has
13 for research.

14 Are these type of grants one-year grants
15 or are they more like NIH grants, which are
16 understood to be out-year funding, as well, for
17 more or less, five-year periods?

18 DR. POLAND: They actually fall under
19 multiple categories, so, there are some one-year,
20 two-year, and three-year program grants, depending
21 upon the type of project and where it is in the
22 pipeline.

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Page 288

1 DR. BROWN: Thank you.

2 DR. POLAND: Joe? Joe is there, too,
3 so.

4 DR. SILVA: Yes, and I agree with a lot
5 of your comments, but I would like to add an
6 optimistic note, is that (off mike) and DTRA has
7 developed some platforms that are very bold, I
8 believe, for new drug developments, such as
9 anti-budding drug for viruses, which would be
10 incredible to get, and another broad area is
11 therapy to increase the immune system in a broad
12 base way, because, as you already implied, people
13 are going to create new bugs or nature is doing it
14 under its own steam.

15 So, if you had some broad-based platform
16 -- that's the philosophy -- you could tackle many
17 future entities that may fall in the dangerous
18 pathogen list. I found that very promising.

19 DR. POLAND: Good point.

20 DR. SILVA: Thank you.

21 DR. POLAND: We're done with that brief.
22 I do want to take a moment before we go into

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2 Colonel Stanek, who, I understand this will be
3 your last meeting, and then what?

4 COL. STANEK: This is Colonel Stanek.
5 I'll be moving about 20 feet to take my boss's job
6 at the Proponency Office for Preventive Medicine.

7 DR. POLAND: A bloodless coup or what?

8 COL. STANEK: Very bloodless.

9 DR. POLAND: So, if we can, I'd like to
10 -- with Colonel Gibson, we'll go up to the podium.

11 So, we have a little plaque here
12 presented to Colonel Scott Stanek with deepest
13 appreciation for his outstanding contributions as
14 the Defense Health Board Preventive Medicine
15 Liaison office, and we engraved on here "Thank you
16 for your selfless and dedicated support." He's
17 been with us from September of 2004 until today.

18 Scott, a few words.

19 COL. STANEK: Well, it's actually been a
20 great pleasure for me to be with the Board. My
21 first involvement with the ABP was in, I think,
22 January or February of 1995, when I did a

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327

1 presentation as a PM resident on Varicella
2 vaccine, and I've been associated -- attended
3 quite a few boards since then, but my greatest
4 enjoyment from the Board has been working with all

5 its fine members and just being in sidebar with
6 all the conversations you've been having.

7 And I personally would like to thank all
8 of you for taking your time to be a part of the
9 Board and donate your expertise to take care of
10 soldiers and servicemen, and thank you, and you
11 may see me again if my replacement, Colonel Robert
12 Mott, can't make one of the meetings and I may
13 have to come back and take his place.

14 Thank you.

15 DR. POLAND: A couple of reminders. So,
16 we will meet -- I think it's at 6:15.

17 SPEAKER: 6:45.

18 DR. POLAND: 6:15.

19 SPEAKER: 6:45, I thought.

20 DR. POLAND: No, no, it's been changed.
21 I can't remember if we're meeting in the lobby at
22 6:15 or we're supposed to be there at 6:15. We'll

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328

1 find out.

2 COL. GIBSON: Lobby. Lobby.

3 DR. POLAND: Okay. There are directions
4 available. I gather parking is an issue, but
5 there's a glass museum next door where you can
6 park and get a validated ticket.

7 What time should we meet in the lobby?

8 SPEAKER: 6:15 in the lobby, 6:30

9 reservations.
10 DR. POLAND: Okay.
11 COL. GIBSON: We'll carpool down. There
12 is a nice parking lot there. It will get
13 validated for afterwards.
14 Last night, we had problems with
15 parking, but tonight shouldn't be problematic, so,
16 we'll carpool.
17 DR. POLAND: I'm going to ask the board
18 members to be on their best behavior since there's
19 a lot of glass around. No throwing things at the
20 Chair.
21 All right. We're going to go into
22 administrative session. We'll end the formal

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329

1 board, and I'll ask the core Board subcommittee
2 ex-officio members, the DHB staff, and the service
3 liaisons to remain, and we'll ask everybody else
4 to leave the room, and we'll see you at dinner.
5 And, if not, then we start tomorrow at 8:30.
6 Will we have the same sort of breakfast
7 setup, Roger, tomorrow at 8:30?
8 COL. GIBSON: Yes.
9 DR. POLAND: Okay. All right.
10 SPEAKER: 8:00.
11 COL. GIBSON: Yes, 8:00 for breakfast,

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8:30 for registration.
13 DR. POLAND: All right, correction. All
14 right, thank you, all. We're adjourned.
15 (Whereupon, at 4:23 p.m., the
16 PROCEEDINGS were adjourned.)
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