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UNITED STATES DEPARTMENT OF DEFENSE

DEFENSE HEALTH BOARD MEETING

DAY 2

Tacoma, Washington

Thursday, April 24, 2008

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1 PARTICIPANTS:

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3 Jersey Medical School Acting Associate Dean New
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4 Medicine and Dentistry of New Jersey
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14 Diseases Section Department of Veterans Affairs
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- 15 MICHAEL D. PARKINSON, MD, MPH
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16 Officer Lumenos
- 17 GREGORY A. POLAND, MD
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18 Diplomate, ABIM
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19 Translational Immunovirology and Biodefense
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21 Professor, Former Chairman Department of
Biochemistry and Molecular Biology University of
22 Maryland School of Medicine

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- 1 PARTICIPANTS (CONT'D):
- 2 JOSEPH SILVA, JR., MD
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- COL ROGER GIBSON, DVM, MPH, PhD, USAF, BSC
4 DHB Executive Secretary Ex-Officio Members

5 MARK A. BROWN, PhD
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16 Surveillance Assistant Secretary of Defense for
17 Health Affairs
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20 British Liaison Officer British Embassy
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2 CDR CATHERINE SLAUNWHITE
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12 US Coast Guard Headquarters
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- 9 Associate Dean of Academic Affairs
Stony Brook University School of Medicine
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21 Armed Forces Institute of Pathology
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- 2 OLIVERA JOVANOVIĆ
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- 3 DAN G. BLAZER, II, MD, MPH, PhD
4 Professor, Duke University Medical Center
- 5 COL MICHAEL S. JAFFEE
- 6 COL ANGEL LUGO
- 7 COL ROBERT DEFRAITES
- 8 CPT JAMES NEVILLE
- 9 COL RANDALL ANDERSON
- 10 COL CHARLES HOGE
- 11

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P R O C E E D I N G S

(8:42 a.m.)

DR. POLAND: I think we'll get started here. We're a few minutes early, but remarkably I think we have everybody here, so we will do that. A couple of announcements. One is that you'll notice outside against the wall three of their scientific posters, so take a look at them. One's quality improvement and the other two are vaccine related. They're all vaccine related, but different topics. It's part of this idea of bringing more academics into the meeting, and I would invite other agencies or other individuals who have posters that are related to the work of the Board to please feel free to bring them to the

16 meetings. I think it would be grand if our walls
17 were covered with those sorts of things and that
18 some of our break time might be used for those
19 discussions. It may have a number of fallout
20 beneficial effects such as building scientific
21 collaboration between members of the Board and
22 some of the agencies here, and who knows where

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7

1 that could take us either as a group or as
2 individuals. So please feel free to do that.

3 I'm cognizant of the fact that several
4 of you have travel plans. In the nature of the
5 West Coast like this, you either leave by noon or
6 you leave by 1:00 a.m. or something, so I will try
7 with your help to move things along and if
8 necessary we may have to flip-flop one or two
9 things.

10 So let's go ahead and get started.
11 We've got a lot to do. Dr. Kelly, would you call
12 the meeting to order, please?

13 SECRETARY KELLY: Thank, sure will. As
14 the Alternate Designated Federal Official for the
15 Defense Health Board Federal Advisory Committee
16 and Continuing Independent Scientific Advisory
17 Board to the Secretary of Defense via the
18 Assistant Secretary of Defense for Health Affairs

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19 and the Surgeons General of the Military
20 Departments, I hereby call this meeting of the
21 Defense Health Board to order.

22 DR. POLAND: Thank you, Dr. Kelly.

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1 Continuing the tradition of our Board, I'm going
2 to ask in just a second that we stand for a minute
3 of silence. I think this is important. I don't
4 want it to become rote or routine, but hope that
5 people will take the time to reflect on why we're
6 here. To me personally the privilege of serving
7 on this Board is an opportunity to serve and in
8 this war few of us are asked to sacrifice much of
9 anything. So please if you would consider that.
10 I neglected to bring it this time, but at the next
11 Board meeting I'm going to bring a video that gets
12 a little bit at the nature of the sacrifice that
13 our countrymen and -women are being asked to make.
14 So if we could, could we stand to honor those who
15 have served?

16 (Moment of Silence.)

17 DR. POLAND: Thank you all very much.
18 Again it's an open session today so we'll go
19 around and we'll go to the left today to introduce
20 ourselves and then for guests and others who are
21 in the room.

22 COL GIBSON: I'm the Executive Secretary
Page 7

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1 for the Defense Health Board.

2 DR. BLAZER: I'm Dan Blazer, Board
3 member.

4 DR. LOCKEY: Jim Lockey, professor of
5 pulmonary medicine and environmental health,
6 University of Cincinnati.

7 RADM. GAUMER: Ben Gaumer, Assistant
8 Deputy Surgeon General, Navy Medicine.

9 DR. SILVA: Joe Silva, professor of
10 internal medicine, University of California,
11 Davis, and Board member.

12 DR. HALPERIN: Bill Halperin, Department
13 of Preventive Medicine, New Jersey Medical School.

14 DR. LEUPKER: Russell Leupker. I'm
15 professor of epidemiology and medicine at the
16 University of Minnesota.

17 DR. MILLER: Mark Miller, Director of
18 Research, Fogarty International Center, NIH.

19 DR. GARDNER: Pierce Gardner, professor
20 of medicine and public health at Stony Brook
21 University.

22 DR. REDDICK: Robert Reddick, Chair of

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1 Pathology at the University of Texas at San
2 Antonio.
3 DR. ZAKI: Sharif Saki, Chief of
4 Infectious Disease Pathology at the CDC.
5 DR. BROWN: I'm Mark Brown. I'm
6 representing the Department of Veterans Affairs.
7 COL. STANEK: Scott Stanek, Preventive
8 Medicine Staff Officer, Army OTSG.
9 LTC. SILVER: Aaron Silver, Deputy
10 Chief, Health Services Support Division J-4 on the
11 Joint Staff.
12 COL. ANDERSON: Randall Anderson, the
13 Director of the Military Vaccine Agency.
14 COL. DEFRAITES: Bob DeFraites,
15 Director, Armed Health Surveillance Center.
16 COL. NEVILLE: James Neville, Vice
17 Commander of the School of Aerospace Medicine.
18 CDR. SCHWARTZ: Erica Schwartz,
19 Preventive Medicine Officer for the Coast Guard.
20 CDR. SLAUNWHITE: Commander Cathy
21 Slaunwhite, Canadian Forces Medical Officer at
22 Canadian Defense Liaison Staff, Washington, D.C.

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2 British Liaison Officer.
3 LTC. HACHEY: Wayne Hachey, Director of
4 Preventive Medicine, Health Affairs, Force Health
5 Protection and Readiness.
6 CAPT. NAITO: Neil Naito, Director of
7 Public Health, Navy Medicine.
8 COL. BADER: Christine Bader, Executive
9 Secretary, Task Force on the Future of Military
10 Health Care.
11 DR. MULLICK: Florabel Mullick,
12 Director, Armed Forces Institute of Pathology.
13 DR. SHAMOO: Adil Shamoo, professor,
14 University of Maryland School of Medicine and a
15 Board member.
16 DR. MCNEILL: Mills McNeill, Director,
17 Mississippi Public Health Laboratory.
18 DR. OXMAN: Mike Oxman, Board member,
19 professor of medicine and pathology, University of
20 California, San Diego.
21 DR. PARKINSON: Mike Parkinson,
22 President of the American College of Preventive

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12

1 Medicine.
2 DR. KAPLAN: Ed Kaplan, professor of
3 pediatrics, University of Minnesota, and a Board
4 member.

- 5 DR. CLEMENTS: John Clements, Chair of
6 Microbiology and Immunology at Tulane University
7 School of Medicine in New Orleans.
- 8 COL. CERTAIN: Robert Certain, former
9 prisoner of war, retired Air Force Chaplain and
10 member of the Board.
- 11 DR. LEDNAR: Wayne Lednar, Chief Medical
12 Officer, DuPont.
- 13 SECRETARY KELLY: Joe Kelly, Deputy
14 Assistant Secretary of Defense for Health Affairs,
15 Clinical Programs and Policy, and alternate
16 federal official today.
- 17 DR. POLAND: Greg Poland, professor of
18 medicine and infectious disease, Mayo Clinic,
19 Rochester.
- 20 MR. DREBOLD: Ray Drebold, Armed Forces
21 Institute of Pathology.
- 22 MS. HIGH: Dedrina High, support staff

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- 1 for the Defense Health Board.
- 2 MR. PASCHAK: Steve Paschak, Cangene
3 Corporation.
- 4 MR. KANE: Joseph Kane, Advanced Bio
5 Services.
- 6 COL. JAFFIN: Jonathan Jaffin, Deputy
7 Commander, Army Medical Research and Materiel
8 Command.

9 COL. BALLARD: Chris, occupational
10 medicine resident, University of Cincinnati and
11 soon to be Commander of Aerospace Medicine at
12 Elmendorf Air Force Base.

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

17 MR. ENGLISH: Good morning. I'm Dave
18 English and I'm from the Western Regional Medical
19 Command from MILVAX.

20 MS. ELLIS: Bridget Ellis. I'm manager
21 of regulatory policy at Plasma Protein
22 Therapeutics Association.

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1 DR. POLAND: Colonel Gibson will have
2 some administrative remarks and then we'll get
3 started.

4 COL GIBSON: I want to thank Magidan
5 Army Medical Center, Fort Lewis, for being our
6 host for this meeting. We will be doing the tour
7 this afternoon and get an opportunity to go out
8 there. I also want to thank the Board members for
9 being available for this tour. What we do is we
10 try to go to the various military installations in
11 the United States to give the Board members two

12 things. To give the Board members an opportunity
13 to understand what it's like to be a service
14 member, what their daily routine is like, what
15 their risks, what their concerns and health
16 concerns are. Sometimes I know Board members have
17 to leave and get back because they have conflicts,
18 but if we're not going to do that, if we're going
19 to leave early, all of us, then there's no reason
20 to go out to these things. The other thing that
21 you're doing is showing the flag and it's an
22 important, important job. So I commend you all

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1 for staying and not jumping on a plane as soon as
2 the business part is done. Thank you very much
3 for that.

4 Thank you to Tina Olivera and Karen for
5 what they're doing here today, and thanks to Lisa
6 and Jean back home. Sign the attendance roster if
7 you have it. That's a requirement. That's about
8 it. The CME stuff, if you need to fill that out,
9 please see Karen and she'll take care of it.

10 Thank you.

11 DR. POLAND: Randy, before we start we
12 do have one bit of unanticipated bit of business
13 and that is that we've learned that this is
14 Captain Johnson's last meeting with us. Is that
15 correct? So we'd like if we could to prevent the

16 DHB coin to you. Very few of you will understand
17 this, but I trust Richard will, stone the crows --
18 his uncle, that he's been with us all this time.
19 Those are common English sayings. I have no real
20 understanding. My pastor who's British told me --
21 do they mean something? Maybe tell us what they
22 mean.

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1 SPEAKER: I think the meanings got lost
2 a long time ago.

3 DR. POLAND: One of a series of gaffs
4 that I make. Richard, it's been a delight to have
5 you here and we'll be interested to hear a little
6 bit of what your next duty station is and what
7 you'll be doing -- information about the liaison
8 who will be taking your place, but I can say it's
9 a pleasure to have worked with you and very much
10 appreciate the input that you've had the Board.

11 SPEAKER: Thank you very much.

12 (Applause.)

13 SPEAKER: It's been a real pleasure
14 working with you. A more interesting and
15 entertaining group of people would be hard to
16 imagine. But I have also been really impressed
17 with the work that you do. I think you make a
18 genuine and important contribution to the health

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19 of service members particularly here, but that
20 affects those across the Atlantic as well and I
21 hope I've been able to contribute a little bit to
22 that process. My next job is a staff job in

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1 London looking at quality management in health
2 care, a joint job trying to get the three services
3 to work together, so I'm sure it's going to be a
4 challenge. My relief will be here hopefully for
5 the next meeting in September. He joins in
6 August. He's a medical services officer called
7 Alan Cowan. He's a very active and dynamic guy,
8 and although he's not a physician, I'm sure he'll
9 catch up and use his brain to good effect. That's
10 all I want to say, really. Thank you very much
11 for looking after me and being polite to the
12 Englishman amongst you, but it's been a real
13 pleasure. Thank you.

14 (Applause)

15 DR. POLAND: Our first presentation this
16 morning will be by Colonel Randy Anderson who
17 Director of the Military Vaccine Agency and he'll
18 give us an update on MILVAX and the vaccine health
19 care centers.

20 COL. ANDERSON: Thank you, ladies and
21 gentlemen. I appreciate this opportunity to come
22 and give your annual report of the military

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1 vaccination programs. This is the agenda that I'm
2 going to follow this morning, looking at these
3 items. Just kind of as a recap for many people
4 who haven't been familiar with our program, we now
5 are a DOD Executive Agent for Immunization
6 Programs. We started off back in 1998 as the
7 Anthrax Vaccine Immunization Program. It expanded
8 with the Smallpox Program in 2002 and has slowly
9 grown to cover all the different vaccinations
10 since that time. We are now celebrating our
11 tenth-year anniversary and putting together a
12 little historical report to cover our lessons
13 learned from that time.

14 The bottom bullet there is a new one
15 that we've added since the last time I briefed
16 this Board. The Force Health Protection Council
17 made the decision that the Vaccine Health Care
18 Centers would fall under the Military Vaccine
19 Agency and for that reason we've expanded our
20 mission and scope to include that clinical
21 function they also provide. Many of the other
22 features such as education and scientific

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1 understanding of vaccines were things they also
2 cover and so it blended in nicely, and I'll
3 discuss that a little bit further on.

4 One of the ways that we provide our
5 services is in addition to an Operations Division
6 and a Communications Division back at the Office
7 of the Surgeon General in Falls Church, Virginia,
8 we also have a network of analysts. Mr. Dave
9 English who introduced himself this morning is one
10 of our regional analysts here in Washington. I'd
11 say the reason I put this slide up here is this
12 provides one of the best outreaches in abilities
13 to touch the operational forces to find out what's
14 happening out there in the field. You can see we
15 also have someone in Hawaii, over in Germany,
16 Okinawa and Korea. We find out almost immediately
17 whenever there's an adverse reaction case, when
18 there's a shortage of vaccine, when there's maybe
19 a policy misinterpretation, and it provides us the
20 liaison almost immediately and then we can work
21 with the service to resolve this. This has just
22 been an invaluable tool for the execution of our

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1 mission.

2 Let me jump into the Vaccine Health Care
3 Centers. We still have the four different Vaccine
4 Health Care Centers, the one up at Walter Reed,
5 one down at Fort Bragg, Portsmouth, and down in
6 San Antonio. While they have a regional basis,
7 they also are tailored toward the different
8 services, with Portsmouth for the Navy, San
9 Antonio for the Air Force, and the other two for
10 the Army. The different services that they
11 provide are listed around that diagram of them
12 there. One thing that I do want to highlight is
13 that they're advocacy. There was some concern
14 when there was the decision to put the Vaccine
15 Health Care Center under the Military Vaccine
16 Agency because you do not want to lose that
17 ability to be the advocate for the patient to have
18 that external viewpoint when you're putting them
19 with the people who are developing mandatory
20 policies. I think we've done a very good job of
21 preserving this. They will still have the
22 advocacy point and there is not the intervention,

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1 but that's something to be careful of when you try
2 to mix these two types of organizations together.
3 They still provide different education
4 and outreach. Those two features have been

5 combined with our organization which was doing the
6 same thing using many of the same tools, but now
7 it's combined and we're speaking with a single
8 mission, a single vision. We do maintain a
9 24-hour DOD Clinical Call Center that is used
10 sporadically, but it's a nice feature to have. We
11 track the different number of calls, where they
12 come in from, and then there's a clinical review
13 policy through our organization, the Vaccine
14 Health Care Center, that reviews how they answered
15 the calls. It is an external and not a DOD
16 services that provides that.

17 Some of the challenges that they
18 continue to face, the large numbers of people and
19 to have four small organizations that do that. I
20 think many people believe that the understanding
21 of immunizations and the complexity of the adverse
22 event case management is well understood by most

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1 physicians, but that is not the truth. So the
2 quicker we can get those cases into this little
3 clinical center of excellence, the faster and
4 better results we have found with that.

5 I was going to provide a little
6 statistic on the number of caseloads. They have
7 tracked 1,899 adverse cases since they began in
8 2001. That doesn't mean that there's that many

9 adverse cases or that those numbers match exactly
10 what's happening, but those are people who might
11 have been concerned about a vaccine and had a
12 reaction and wanted to try to find out if
13 causality was through a vaccination they received.

14 The other thing that's still a challenge
15 for us and for this organization is the complexity
16 of military immunizations especially when you
17 throw in mandatory, and then you have the multiple
18 anthrax and smallpox and all these other
19 vaccinations that are not commonly given in the
20 civilian population. You're always dealing with
21 the risk communication, the perceptions, plus are
22 there any true adverse events that are associated

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1 with multiple or -- vaccinations. That's
2 something that we continue to research and look
3 into.

4 Jumping ahead to your anthrax policy,
5 like I said, that began back in 1998. Many people
6 in this room have been around for that. It has
7 expanded, it's retracted with shortages of
8 vaccine. Federal judges have put a halt to the
9 program. We executed the first emergency use
10 authorization in the United States. We went into
11 a voluntary period for a year and a half. Then in

12 October 2006 the Deputy Secretary of Defense
13 announced the policy that we execute today, that
14 is, that it's mandatory for those at highest risk,
15 mainly those over in the CENTCOM and Korea areas
16 of operation, and a few special mission units.
17 That policy is I would say in line with
18 recommendations of this Board who said target
19 those at highest risk and not everybody. We also
20 allow voluntary vaccinations of anybody who
21 started the series and wants to continue the
22 series of get their annual boosters. Then there's

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1 a third population, those who are not going to a
2 high-risk area and haven't started it can't have
3 it at all. With those three different groups,
4 it's hard to implement that worldwide with
5 100-percent accuracy, but I feel our forces and
6 the people in the field are doing a great job with
7 that.

8 As of September 2007, we've expanded
9 that predeployment window of when they can start
10 their vaccinations from 60 days to 120 days.
11 That's a real positive thing. That allows the
12 commanders a longer time to get their people
13 vaccinated for anthrax to get over three doses in,
14 for smallpox to get them vaccinated when they can
15 be away from their family members but not pushing

16 those vaccinations into the theater of operations.
17 Since the beginning in 1998 we've given
18 7.4 million doses to 1.9 million individuals. You
19 can also see that the production is steady. The
20 manufacturer is making plenty of that. The one
21 big change that's happened in this last year is
22 that there's been the decision that instead of the

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1 Department of Defense purchasing this vaccine
2 right from the manufacturer such as we've done, we
3 will purchase it from the strategic national
4 stockpile. So as vaccine expires from Health and
5 Human Services' national stockpile, we will
6 purchase that at a reduced rate and prevent some
7 of that loss that they've been experiencing, and
8 that was a recommendation of the GAO.

9 We continue to have multiple studies
10 looking into this. We continue to sponsor
11 different endeavors by Dr. Pittman up at USAMRIID
12 looking at this with a firm belief that as long as
13 we're using this vaccine we should continue to try
14 to know everything about the vaccine.

15 The final bullet there is we're still
16 waiting on the route change and dose reduction.
17 As I understand currently, the manufacturer had
18 submitted that to the FDA. The FDA has returned

19 it to the manufacturer with some clarification.
20 We really are looking forward to that. Yes, sir?
21 SPEAKER: I'm sorry to interrupt, but
22 I'm a little confused. You seemed to say we were

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26

1 purchasing HHS's expired vaccine.
2 COL. ANDERSON: Expiring. Right, we
3 will not use expired vaccine. The goal was to get
4 it with about a year of shelf life left on it, but
5 6 to 9 months, that will be coming out of the S&S
6 to the field. The field really should not notice
7 a difference other than it's coming from a
8 different address.

9 Here's a little media interest of the
10 vaccine and you can see the peaks and valleys.
11 This has driven a lot of our workload over the
12 years. In addition to each of those peaks with
13 the media, there are also peaks with congressional
14 and other products that we've had to develop. As
15 you look at the bottom here, the final 3 or 4
16 years really have reduced in the number of high
17 peaks that we experienced back in 2001 and 1998.

18 Moving on to the Smallpox Program, this
19 program since it began in 2002, we have now
20 screened 1.6 million people and vaccinated 1.5
21 million. I like to highlight to the field when I
22 go out there and speak that that difference is

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27

1 very important. There are over I think about
2 110,000 people who were screened and not vaccinated,
3 and for this vaccine that is very important and we
4 continue to emphasize the importance of the
5 screening process. The policy for those being
6 vaccinated with smallpox is very close to that
7 with anthrax, those at highest risk, once again
8 CENTOM, Korea, and special unit missions.

9 We have had three cases of eczema
10 vaccinatum reported, 61 cases of contact transfer,
11 once again, mainly the bandage falling off,
12 rubbing up against your spouse or Marines playing
13 basketball. There have been no other significant
14 changes with the adverse event profile of this
15 vaccine, and of course, over the last 2 months
16 we've transitioned from Dryvax over to the new
17 ACAM 2000 product, and I will speak to that a
18 little bit at the very end of the presentation.
19 Media interest about this has been very low. You
20 can see there have been a few little spikes, the
21 eczema vaccinatum case of the child in Chicago, but
22 other than there, there has been very little to no

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Page 24

1 interest in it from the media and Congress.

2 Looking at the seasonal influenza
3 program, we continue to protect the force. This
4 was a very good year. We had over 90 percent of
5 the personnel vaccinated. Putting that onto a
6 commander's report card, that's what we have done
7 with the readiness reporting, is a very positive
8 thing. We turn that on and they watch that, and
9 so it's not just the medical personnel who are
10 pushing it, but also the line commanders. This
11 year we had 3.5 million doses of the vaccine. We
12 continue to use mass vaccination for the flu drive
13 at certain locations to practice training if there
14 ever were a pandemic.

15 One of the interesting side effects of
16 changing the intranasal vaccine from frozen to
17 refrigerated is that we pushed more of that into
18 the CENTCOM area of operation, but they now are
19 finding that the bulk of it was overwhelming for
20 them. So this year there has been a request not
21 to use the intranasal vaccine over in CENTCOM.
22 The positive side of changing it from frozen to

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1 refrigerated is that you no longer have to have
Page 25

2 freezers and it was much easier to get through
3 customs.

4 Additionally, Dr. Cassells has signed a
5 new civilian health care personnel policy. I know
6 that's been a recommendation of this Board and
7 something we're very happy about. Of course, the
8 military is already covered under a mandatory
9 program, civilian health care workers are covered,
10 but this now goes into the non-DOD personnel
11 contractors. It can be written into the
12 contracts, worked out, and that can be a condition
13 for employment. So we're very happy with that
14 change. There will be about a year or 2-year
15 transition and commanders of the different medical
16 treatment facilities will start reporting that
17 out.

18 Dr. Hashi covered the pandemic influenza
19 vaccine yesterday. We have that -- we bottled it
20 and we brought some ready for us. We came up with
21 a nice policy. Our organization built some
22 beautiful glossy tri-folds. We put implementation

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30

1 instructions out there and we didn't get many
2 takers. The people that it was targeted for, the
3 people that this Board recommended, the lab
4 workers, I would say there's probably a perception

5 of risk and the feeling of the efficacy of the
6 vaccine. There were plenty of other people who
7 were knocking on the door trying to get the
8 vaccine, but currently the way the vaccine is
9 licensed and with the recommendations of DOD and
10 this Board it was not really aligned for them.

11 This is the magic slide that covers
12 everything else and I have highlighted a few
13 things on there. Coming down on the left side we
14 have the Japanese encephalitis vaccine. We're
15 looking at a replacement vaccine and we're hoping
16 for FDA approval either at the end of this year or
17 the beginning of next year. My organization is in
18 touch with and dealing closely with the
19 manufacturer on working any phase four
20 post-marketing surveillance requirements of that
21 and we'll be a part of implementing that vaccine.

22 The next one that I've highlighted down

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31

1 there is HPV. That is something that I think we
2 continue to wrestle with in the services and the
3 Department of Defense on should this be a
4 mandatory vaccination for all female accessions or
5 should we stick with what our policy is now that
6 at your first well woman that's the time on one-
7 on-one interact with these people and try to
8 transition that way. There still is a lot of

9 discussion within our ranks about what the DOD
10 policy should be.

11 We continue to do the tetanus,
12 diphtheria, and pertussis, with the pertussis
13 added in there we're trying to get the next time
14 they came in for their tetanus shot to make sure
15 they get pertussis and implementing that. Then on
16 the right side, the edno virus type 47. Just this
17 week a lot of results came out of the final phase
18 three clinical study and was very, very positive.
19 I don't know if the Board has been briefed on the
20 great results of that, but now as we look ahead
21 we're looking at a BLA submission in August of
22 this year, hopefully licensure at the mid to end

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32

1 of 2009, and in that interim period we'll be
2 working with the DOD policy and making sure that
3 the dollars are aligned there. They have put a
4 wedge of money in there to make sure that it
5 carries us out at least through FY 13, but we
6 still do not know the cost of the individual doses
7 of vaccine.

8 The other thing that I would like to
9 highlight and Dr. Poland mentioned is that we've
10 put a couple of our posters out there. The Army's
11 program, the accession screening program, I

12 briefed you that last year we had started
13 implementing that and now after a year and a half
14 of screening our basic trainees for measles,
15 rubella, HEP- A, HEP-B, and bercela, we have found
16 that we have averted 197,000 doses of vaccine.
17 Those are doses that did not have to be given
18 because someone was tested sero- positive and so
19 in a year and a half with \$5 million saved. Of
20 course, the Air Force has been doing this and
21 we're working closely with the Navy to implement
22 that for them and the Marines, and also we've made

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33

1 with the Coast Guard. But that is just a great I
2 think implementation of a recommendation that came
3 out of the AFEB.

4 One of the things that our organization
5 continues to work on is education. That has just
6 been a huge endless hole. When you start to try
7 to figure out exactly how many clinics are out
8 there and how many people are providing
9 vaccinations, you have to realize that the way
10 some of the services work is a medic could fall
11 into an immunization clinic and then work in there
12 for a few years and then go on and do something
13 else. It is not like we have people who are
14 trained specific for immunology and that's all
15 they ever do. So coming up with all those

16 different types of little locations, the National
17 Guard and Reserves, different places that give
18 vaccinations, we've come up with about 1,500
19 different locations worldwide that actually
20 provide and they scope from giving thousands a day
21 at such as a deployment site to maybe one or two a
22 month if it's a Reserves site. So getting in

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34

1 there, working with those people and making sure
2 they have a standard understanding of
3 vaccinations, adverse reporting, case management
4 if there's a problem, is something that is a
5 driving force for us trying to reach out to them.

6 One of the tools that we've developed
7 and have been using is the Clinic Quality
8 Improvement Program tool. It's pretty much an
9 Excel spreadsheet, a self-evaluation for the
10 clinic saying here's what you should be doing,
11 here's what tells you need to do, here's how you
12 can find it, and then working through a plan to
13 implement it. That is one of the posters that we
14 have put outside there just to show you how that
15 has worked so far.

16 One of our main pillars of our
17 communication products is our website. We
18 continue to get about 1,200 unique visitors every

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19 day to this. Through this website you can find
20 out all of our policies for each of the services,
21 for the areas, for DOD news. We have been
22 transitioning to an interactive product. We have

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35

1 got celebrity endorsements up here through public
2 service announcements, videos, iPod downloads.
3 Adobe Connect is a product that we can do live
4 training where someone sits in a studio and
5 reaches out. We did that with the ACAM 2000
6 product. We advertised that and worldwide said if
7 you have questions about this, sit down with our
8 expert. We gave them a presentation and answered
9 their questions and we a great response when we
10 ran that five or six times, and I think that
11 environment will be our platform; prerecorded
12 training sessions where we can record who's
13 completed the training. It keeps transcripts. We
14 can get them continuing education credits. And
15 then also that we can run live things to deal with
16 their questions one on one in a -- learning
17 scenario. Our website also continues to have
18 these 31 diseases, and behind each of those 31
19 diseases is a tab that's got information pages,
20 the vaccine information statement, the package
21 inserts, all of that information about each of
22 those different diseases and the vaccine

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36

1 associated. As you can see, each of the tabs has
2 AFEB recommendations or the Defense Health Board
3 recommendations and we post those directly
4 associated with each disease so they're out there.
5 Finally, the top five initiatives that I
6 think our organization needs to focus on. With
7 the anthrax and the small programs, the interest
8 and the amount of effort that we have to put into
9 that is diminishing. We've been able to focus
10 more on quality of improvement, trying to get out
11 there and train people under a standard, and also
12 the post-marketing surveillance is going to take
13 up a lot of our time. I mentioned the transition
14 of the ACAM 2000. The actual operational
15 transition went very, very well. We were given a
16 short window of shifting that vaccine from once
17 again the national stockpile. We went down to the
18 CDC's S&S and worked with them directly to make
19 sure that the bottles and the packaging and
20 everything looked good; the requirements from FDA
21 to have a medical guide shipped to the field. The
22 requirement finally came up that all we had to

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Page 32

1 send to the field was a CD. We were concerned
2 that that was not going to translate into an
3 actual single product getting into the hands of
4 every person vaccinated so we went ahead and
5 printed those and shipped those out in equal
6 quantities to the number of doses. Then we had 1
7 month to destroy all of the Dryvax vaccine before
8 that manufacturer pulled its license and that was
9 very successful and we got all that documented.

10 The part that's ahead of us now is the
11 post-marketing surveillance and there are five
12 different major areas to that, long-term,
13 shorter-term, a registry, tracking how well we do
14 the screening. While the requirements for that
15 post-marketing surveillance is really on the
16 manufacturer, we are the people who have to help
17 them implement it, make sure it's done correctly
18 working with the Vaccine Health Care Center on a
19 registry. There's a lot of benefits from that.
20 Yes, sir.

21 SPEAKER: Randy, sorry to interrupt you.

22 COL. ANDERSON: No problem.

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1 SPEAKER: I just want to be sure that
Page 33

2 that's an old picture and that there are no jet
3 injections.

4 COL. ANDERSON: I was going to get to
5 that later, but that's exactly right. That is an
6 old picture. We continue to see pictures of
7 anthrax vaccine being distributed to the wrong
8 location, people using pictures of the TB tine
9 test as a vaccination picture. That's what we're
10 trying to get away from, that mentality of just
11 line up and shoot them. The ACAM 2000 transition
12 is going good but there are many years of hard
13 work ahead and from time to time we'll be working
14 with the new the Safety, Efficacy, and
15 Surveillance Working Group to bring those issues
16 to them.

17 I mentioned the anthrax vaccine. We're
18 looking at that new route change going from
19 subcutaneous to IM. That's going to be a very
20 positive thing when it gets here and we're just
21 waiting and waiting with great anticipation
22 because that pretty much reduces, 60 percent of

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39

1 females and 30 percent of males, that experience a
2 local reaction to almost near zero. So the
3 perception take from the field will be better.
4 The dose reduction, just taking out one dose, will

5 be great. The implementation is a little bit hard
6 if you think about our electronic tracking
7 systems, if I had four already and I take out that
8 one, where is my next dose and we're working
9 through all those issues with all the different
10 service tracking systems. Then distribution just
11 to make sure that that executes properly coming
12 out of the S&S in that there are always issues
13 when you change an established procedure.

14 I mentioned immunization tracking
15 systems. We are making ground on this. The
16 Electronic Health Record Tool which you're pretty
17 much all familiar with. The immunization module
18 that was added to that was an old product of the
19 Air Force's tracking system. It was hardwired on
20 there. Many of the features did not work. In
21 certain examples it has cross-populated
22 immunization data where it shouldn't. So

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40

1 everybody now agrees that that is broken. We've
2 gotten congressional interest and an amount of
3 dollars that was given to us this year to help fix
4 that and so we are well on our way and that is a
5 great stepping stone to coming up with a universal
6 immunization tracking tool. I think there will
7 still be services having their own systems in the
8 field and there's a need for that since ALTA

9 won't be everywhere right away.
10 I mentioned earlier that outreach to 100
11 percent of the people. That is a very hard thing
12 to do but we're trying to establish at least how
13 many people in each type of clinic, what type of
14 people, and how often they should have
15 reeducation, education on the policies, and trying
16 to at least establish a standard for them and make
17 sure that every one of them knows about the
18 services available. Finally, those DOD basic
19 standards for immunization training. Each of our
20 services train people who give vaccinations a
21 little bit differently. There is some great
22 interest among the services here to say let's

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41

1 establish that core, what should people do, either
2 through online training or through hands-on
3 training in OJT and then what kind of an
4 evaluation before they start giving vaccinations.
5 We're well on our way with that and think that
6 that will be a great step in providing a standard
7 of care across the whole Department of Defense.
8 That said, I would be happy to entertain any of
9 your questions.
10 DR. POLAND: Thank you. Let me just ask
11 a few quick questions, Randy.

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COL. ANDERSON: Yes, sir.

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DR. POLAND: First of all, I want to say for the record how pleased I am that the Department has issued the civilian health care workers that are contracted with DOD's influenza and immunization policy. I think that's a real leadership stance and the Department will be widely recognized I think for that. The second is that the myopericarditis issue that you referenced is something that the Infectious Disease Subcommittee has had interest in and we

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42

1 will circle back to that. I just wanted to
2 mention it. We won't deal with it today, but we
3 had interest in the ongoing resolution of those
4 that were identified with myopericarditis.

5 You had one slide on the Immunization
6 University and I'm sorry I missed that one. Is
7 that available to non-DOD personnel, the teaching
8 module?

9 COL. ANDERSON: Yes, sir. All the
10 different features we have done two different
11 ways. One where you come in and register and so
12 that way we can maintain almost a transcript of
13 what you've completed, what you're participating
14 in, what we recommend to you. And also we do it
15 as a guest so guests can just come anonymously and

16 parti ci pate.

17 DR. POLAND: Then fi nally, harken ing
18 back to 1998 or 1999 when we di d a DOD-wi de review
19 of immuni zati on poli cy, we had i denti fi ed a number
20 of servi ce di screpanci es and what the
21 recommendati ons were, how they were impl emented,
22 et cetera. Is that also a focus of MILVAX and are

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43

1 there still outstanding issues in that regard?

2 COL. ANDERSON: I would say it's still a
3 focus. I think it's gotten a lot better since
4 that time. There are still very minor -- some of
5 them are based on missions. I can't think of any
6 single one that pops out.

7 DR. POLAND: No big issues?

8 COL. ANDERSON: The di scussi on of HPV
9 has probably been the one that brings it to the
10 forefront and how di fferent servi ces feel at
11 di fferent times. But otherwi se we pretty much
12 have got a standardized recommendati on.

13 DR. POLAND: Mark and then Pierce.

14 SPEAKER: My questi on was related to the
15 comment that Greg just made. Vaccines are very much
16 based on risk assessment of both endemi c and epi demi c
17 di sease and it's quite a change of geospati al
18 di stri buti on over time. You talked a bit about the

19 programmatic surveillance of adverse events but I
20 didn't hear very much about disease surveillance and
21 how the two might go together, whether or not there
22 is a process and a coordination that you do with

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44

1 overall DOD surveillance for some of these diseases.
2 And is there also a process for change in the policy?
3 You have quite a complicated list of vaccines
4 including measles, mumps, rubella, and I assume you're
5 talking about the family members as opposed to perhaps
6 the service members. I'm not sure who that means.

7 COL. ANDERSON: That is for service
8 members that I mentioned.

9 SPEAKER: So is there a centralized
10 process that you go through periodic reviews of
11 these recommendations as needs change over time?

12 COL. ANDERSON: I would say it's not
13 set, every single year or every 2 years we look at
14 every single policy and see if it's still
15 established there. It takes on a natural
16 progression and it's an ongoing process and there
17 are so many different people at play all the way
18 from the people in the field who are happy to
19 reduce the number of vaccinations because that's
20 cost for them, back up to policy people such as
21 the people in the room here. We do take that to
22 our different committees but there is not a set

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45

1 process that looks at those, but it's always
2 ongoing when we start looking at what is the
3 benefit of taking a certain vaccine off of the
4 recommendation we do so, but for most part we
5 watch the ACIP recommendations. We don't deviate
6 unless it's a bio threat and for those we do have
7 a very set process and very formal and bringing
8 all the different people to the table.

9 DR. POLAND: Pierce?

10 DR. GARDNER: A quick question. The
11 myopericarditis issues with 168 cases, about 1 per
12 10,000 or a little more. In the transition to the
13 ACAM 2000, how many doses of the new vaccine have
14 been used and has the rate for the new vaccine
15 been similar to that for the dry vaccine?

16 COL. ANDERSON: We give about 16,000
17 doses per month of smallpox vaccine and we're only
18 into our second month of giving that, so I think
19 it's a little bit too early to tell, but we're
20 also at a level of heightened surveillance I would
21 say. We have seen no change. It was anticipated
22 that there would be no difference.

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Page 40

1 DR. POLAND: And I can say that's what
2 the non- DOD clinical trial showed was the
3 suggestion there was no difference.

4 DR. GARDNER: How big were the clinical
5 trials?

6 DR. POLAND: Not large enough to be able
7 to get at the tens of thousands you really need.

8 DR. GARDNER: The other question I had,
9 you purchased 3.5 doses of influenza vaccine last
10 year and Wayne educated me last night that the
11 live or attenuated vaccine is used quite widely in
12 the military. What's the breakout in those 3.5
13 doses between the killed and the live vaccine?

14 COL. ANDERSON: I'll answer your
15 question. I've got it before me but I didn't
16 bring it up there. While I look, I also wanted to
17 mention that every year based on distribution
18 there is excess, some that's not used and they do
19 a good job of spreading it around. But this also
20 as a good news story the people over in Hawaii
21 PACOM you might have seen in the press did a
22 collection. They brought it in from all the

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1 services and other locations and was able to share
Page 41

2 it legally with some of the Micronesia countries
3 and it was very positive based on how you can do
4 the sharing. The shipment of it was done by
5 civilian organizations as a donation as well.

6 DR. GARDNER: Wayne mentioned some
7 logistical issues and that the shipments of the
8 live vaccine were cumbersome and less popular for
9 far-reaching sites.

10 COL. ANDERSON: We used this year 1.8
11 million doses of FluMist.

12 DR. GARDNER: So roughly fifty-fifty?

13 COL. ANDERSON: Right. It was a little
14 bit over 50 percent which is pretty significant
15 for us.

16 COL GIBSON: Just a very quick comment.
17 The Board has established a Work Group for Vaccine
18 Safety and Efficacy and they will be meeting on
19 June 2nd. We will go into excruciating detail
20 about a bunch of issues with respect to efficacy.
21 The Department wanted that, the infectious disease
22 members of the Board were much in favor of it, so

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48

1 we went ahead and that was established for the
2 record.

3 DR. POLAND: Wayne?

4 DR. LEDNAR: A question I have is, is

5 the global animal health experience informing the
6 military vaccine agencies? As we're talking about
7 assessing risk and developing policy in regard to
8 changing risks globally, are we seeing any
9 connection between animal health and in our
10 thought process on human vaccine use?

11 COL. ANDERSON: I can't think of any
12 examples where that pertains. I'd be happy to
13 hear any recommendations of how we can incorporate
14 that into the review process, but I don't know if
15 any.

16 DR. POLAND: Ed?

17 DR. KAPLAN: I compliment you on the
18 report. It's very comprehensive. I have a couple
19 of questions. One relates to the issue that Wayne
20 just brought up and that is we've recently
21 received from GEIS I believe the information about
22 what's going on in Korea with avian influenza and

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49

1 I notice that your four centers are all in the
2 United States. I'd like you to address the issue
3 of how you get feedback from overseas since it
4 appears at least from the slide that you showed
5 that there are no overseas bases. Maybe that's
6 just a misunderstanding on my part.

7 As far as the other question is
8 concerned, recently as you are aware there has

9 been an outbreak of measles in this country and
10 among the places that have been at least talked
11 about are San Antonio and San Diego and I wonder
12 how this gets into the system or does it get into
13 the system.

14 The third question, I wonder if it's
15 possible perhaps at this meeting that Roger
16 referred to on June 2nd for us to see what this
17 immunization toolkit looks like. It's probably
18 not worth sending us each one of those kits, that
19 might be a waste, but at least to let us look at
20 it firsthand.

21 Finally, to follow-up on Russell
22 Leupker's question before, I wonder if the issue

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50

1 of purchasing nearly expired vaccine is not a
2 disaster waiting to happen in terms of public
3 relations and I wonder if you'd like to comment
4 about that.

5 COL. ANDERSON: Let me take them in
6 line. I would say the overseas presence, and I
7 think when you mentioned the four locations you're
8 talking about the Vaccine Health Care Centers. We
9 went through a thorough process within the
10 Department of Defense a review taking up the Force
11 Health Protection Council and it was clearly

12 established that we would not expand at this time,
13 that those four centers based upon their workload
14 could handle it. I think with email and
15 teleconsulting and all the other tools that were
16 used, I think they can provide their services to
17 internationally as long as you've got the people
18 in the field who know that their services are
19 available and that's where the bigger challenge
20 is. I threw up the slide of our regional
21 analysts. One of the things we hit upon is every
22 time you go out and talk to a clinic, make sure

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51

1 they that there's a Vaccine Health Care Center.
2 If they don't know, then it's that delay before
3 all of a sudden those people are called and we've
4 run into a couple cases of that because we are an
5 extra layer. There are still infectious disease
6 specialists, there are immunologists around the
7 services, so this is just an added buffer layer
8 and it's not the only service available to them,
9 but making that they're tied back to the experts
10 is what's so important especially with adverse
11 reactions. And we do have an analyst who sits
12 over in Korea and when all of a sudden he hears
13 about a case, it's tied right back within hours to
14 the VHC.

15 The second issue you brought up was
Page 45

16 measles. We have different committees that deal
17 with that. When we hear of an outbreak we go back
18 and we look at kind of protection, what is our
19 current policy, how well is it being implemented
20 and make adaptations from that. Even with
21 influenza outbreaks, before we had distributed all
22 of our vaccine we were having outbreaks down in

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52

1 Fort Benning, Georgia, which wasn't probably one
2 of our top priorities and we switched our
3 distribution policies to meet the needs and that
4 continues to different outbreaks such as that.

5 The immunization toolkit that you
6 mentioned, we would be very happy to send that to
7 every single member of the Board. It's
8 periodically updated, it's online, but it's a
9 great tool. People really like it and it covers
10 each of the vaccines. So we'll make that happen.
11 Was there a fourth one?

12 DR. GARDNER: Expired vaccine.

13 COL. ANDERSON: Expired vaccine, yes.

14 The challenge there is of course first of all
15 we're up against a GAO report that says DHSS, you
16 are just wasting millions of dollars. So as long
17 as it's still licensed and we're able to get it in
18 the clinics and use it, I see the efficiency

19 between interagency cooperation important there.
20 From an operational standpoint, the point I've
21 been arguing with the people coordinating this is
22 we need as long a shelf life as possible. A lot

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53

1 of times people will forget that we put vaccine on
2 a ship and it goes to sea and we don't have
3 resupply and when you have something like a six-
4 dose regimen, you've got to have enough vaccine
5 there and you don't want to stop because your
6 vaccine expired and you don't want to put people
7 in the field in the position where I forgot that
8 that expired. So it's a very deep concern and
9 something we're in the transition of educating on.

10 DR. POLAND: Let me ask Roger to just
11 make one comment to clarify something.

12 COL GIBSON: You had mentioned about
13 feedback and what's happening overseas. We're
14 going to have from the Armed Forces Health
15 Surveillance Center. Keep in mind that MILVAX is
16 the execution arm of vaccine policy for the
17 Department of Defense and as we get information it
18 drives policy change which then he puts into play.
19 We don't want to go around that, i.e., Bob, we'll
20 talk about how we get data and how we're doing
21 surveillance and how that's feeding policy change
22 because the four sites are really more dealing

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54

1 with problems with the vaccinations, adverse
2 reactions and those types of things, and that's
3 their focus, the clinical focus on the people who
4 have had vaccinations or there is a question of
5 whether or not this individual should get a
6 vaccination because of their medical history. So
7 that's what those four places are focused on. If
8 you go to the slide before that, he had the slide
9 that showed that there were places overseas that
10 were doing the monitoring.

11 DR. CLEMENTS: My point is that it would
12 be important, and I think you've answered the
13 question, to know what's happening so that it gets
14 feedback into their system.

15 MAJ. GEN. KELLEY: It was the earlier
16 side and it's the bigger network that does the
17 monitoring.

18 DR. OXMAN: Two questions. First of
19 all, I noted that you talked about the issue of
20 making HPV vaccine mandatory and that raised the
21 question of what's the basis for deciding to make
22 a vaccine mandatory which isn't related to force

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Page 48

1 readiness and protection, so I just wondered if
2 that's within the domain of MILVAX or is that a
3 policy decision outside of MILVAX.

4 COL. ANDERSON: It's also like to
5 clarify something that Dr. Gibson said. As the
6 operational arm to execute policy, we really don't
7 write the policy for the services. We're
8 hopefully the coordinator and the synchronizer per
9 se. There are different ways a policy can come
10 down, the Department of Defense one standard
11 policy services executive or each of the services
12 go ahead and execute. If there isn't a concern to
13 make a vaccine mandatory because of operational
14 concerns such as anthrax or smallpox, there can
15 also be regions within the services that have done
16 the analysis and if we vaccinate our sessions and
17 our people against HPV, we will save future
18 dollars in health care or treating cancer or those
19 kinds of issues. So it can be service specific
20 based on other reasons besides force health
21 protection on the battlefield.

22 DR. OXMAN: Does MILVAX have a seat at

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1 the table in the formulation of such policies or
 Page 49

2 is that done completely separate from you?

3 COL. ANDERSON: Typically we do.
4 Definitely for DOD, we're one of the final shops
5 for coordination. For service policy they can
6 execute on their own, but most of the time there
7 is an inter-department discussion in working out
8 those policies so they're not totally out there by
9 themselves.

10 DR. OXMAN: My second question was the
11 issue of future planning with respect to
12 adenovirus vaccine. Is that something that's on
13 the table now looking at the possibility that you
14 might down the line want to have a vaccine for
15 adeno-14 or adeno-21 or adeno unknown at this
16 point?

17 COL. ANDERSON: Once again as the
18 operational arm I execute what's FDA approved and
19 can be used, but that is definitely something
20 within the Department of interest and of concern
21 that the vaccine we have coming doesn't cover 14
22 which has been highlighted over the last year, but

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57

1 that typically is driven by other entities and
2 different organizations.

3 COL. GIBSON: One quick comment. I'm
4 going to put him on the spot. You were asking

5 about vaccine policy. Captain Naito, can you give
6 us 3 minutes on the JPMPG?

7 CAPT. NAITO: For those of you who don't
8 know, JPMPG is the Joint Preventive Medicine
9 Policy Group where all the services' preventative
10 medicine heads get together currently about once a
11 month and go over any and all issues related to --
12 and what's hot and what's kind of constantly
13 brewing. Certainly immunizations is one of those
14 things that is constantly brewing and certainly
15 adenovirus issues at our recruit camps is a
16 concern. Currently with regard to things such as
17 adenovirus at least the Navy perspective, again
18 the nonvaccine approach is what we really stress
19 with regard to the hand washing, for lack of a
20 better term, social distancing and things like
21 that.

22 I have a personal interest along with

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58

1 Commander Luke looking at the adenovirus
2 perspective from a different point of view with
3 regard to the convalescent plasma serum therapy
4 which we'll get into later. But with regard to
5 the immunization since we're on that topic, the
6 Navy is working with our recruit camps and we'll
7 speak to this later I believe with regard to using
8 the titers and aiming our vaccinations that way.

9 I had a good talk with Colonel Anderson about
10 getting some funding to get that pushed through
11 further, so again that transition going from
12 mandatory vaccinations to titers is a tough one
13 for us, but I think with some funding we can
14 bridge that gap hopefully this year.

15 Other things with regard to
16 immunizations, we did do the flu vaccine, so again
17 the whole Thiomersal issue, I think kudos to the
18 Air Force in that regard. So it looks like we'll
19 have enough Thiomersal-free vaccines available
20 with regard to flu that I think we're going to
21 pretty much make it available to everybody who
22 wants to order it. So again that issue is seven

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59

1 states that have a mandate for Thiomersal-free
2 vaccines being available, but we're going to make
3 it available to anybody else who wants it as well
4 so that was I think a good success for this year.

5 COL. STANEK: The point is, the JPMPG
6 meets once a month. MILVAX is at the table.
7 JPMPG is a policy recommendation group. They go
8 back to their services, they go to Health Affairs.
9 So that feedback loop that you were talking about
10 and having MILVAX at the table, the answer is a
11 very, very clear yes.

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COL GIBSON: If I can add one

12
13 clarification, JPMPG do not policy. It's a forum
14 for essentially those of us on the end of the
15 table, and Roger, to get together and see what's
16 going on within our services and reach a
17 consensus. But then it goes back to the
18 individual services where it gets signed off.
19 JPMPG itself doesn't write the policy.

20 DR. POLAND: Is there anybody else with
21 a comment?

22 DR. PARKINSON: I want to start with a

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60

1 little different facet. It seems like over the
2 10-year history of MILVAX you have moved into more
3 generic immunization support for the entire 6
4 million beneficiary population of the MHS. Can
5 you articulate a little clearly how you evidence
6 that? For example, are you involved in tracking
7 along with the services HEDIS measures for
8 immunization rates in the pediatric population?
9 Are you involved in proactive communication
10 campaigns through the TRICARE website and/or
11 consumer facing materials around this threat to
12 pediatric immunizations right now in the wake of
13 the recent decision to compensate a pediatric
14 patient? There's a furor out there I'll tell you
15 in the professional medical societies going on

16 right now, the American Academy of Pediatrics, the
17 American College of Preventive Medicine, what can
18 we do to stem this misperception. And if you are
19 the hub of the immunization effort now in the MHS
20 and not just operational vaccines, how are you
21 evidencing that in terms of the things that you're
22 doing?

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61

1 Finally, do you track for example on
2 your website where those 1,600 hits are coming
3 from? Do you have consumer hits as well as health
4 care provider or technician hits? Do you see your
5 website as a consumer facing site or predominantly
6 a provider support site? These are all embedded
7 in this emerging role and I just want to make sure
8 that the Board has it right. Are you the hub for
9 immunization 6 million person support and if so
10 what does that mean for your business model?

11 COL. ANDERSON: Starting with the
12 retirees and children, we are not. Starting with
13 anthrax and that was what started us, in this
14 first round that was signed a year and a half ago,
15 the DOD directive and the joint regulation, was
16 really focused more on the military population. I
17 think there's a lot of people covering the other
18 parts of it, the retirees and the pediatrics, not

19 that it's all coordinated, but there have been
20 efforts there primarily coming through TRI CARE or
21 through the local clinics. One a year in the
22 month of August we expand. We outreach and make

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62

1 it military immunization month and that's the
2 month that we focus on. We go out to retiree
3 clinics, the PX's and really focus on trying to
4 touch those two groups that we normally don't just
5 to make sure of shot schedules and answering their
6 questions about the different pneumococcal and
7 those kinds of vaccines, but it is not part of our
8 core mission. It very likely could be, it's just
9 that I don't feel right at this time that we are
10 ready to expand into that. My deeper concern
11 right now because other people are doing what have
12 been discussing is the quality of improvement of
13 the education and the execution at every one of
14 those clinics and every one of those people. I
15 think that is in much dire need of my services and
16 my staff to focus on that right now. Once that's
17 properly in place and standardized, then we can
18 move onto the next hot button issue, but we are
19 not ready to go there.

20 DR. PARKINSON: It may be for the Board
21 members that as we take on the expanded scope of
22 the DHB that we make sure that populations don't

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63

1 fall through the cracks. So have we seen a
2 decrease in pediatric immunizations post these
3 events, for example, is very important.

4 MAJ. GEN. KELLEY: And I would say,
5 Mike, we do follow that. Our recommendations are
6 pretty much based on the national recommendations
7 and so we are not doing a tremendous amount of
8 research into developing new things for those
9 populations that aren't our active-duty
10 population. However, we do follow benchmarks, the
11 HEDIS-like measures, and immunizations, and
12 actually that was one that almost got dropped off
13 but we insisted because it's a pediatric one
14 that's widely accepted, you compare your norms to
15 the civilian community which is readily available,
16 and so that will stay on there.

17 Speaking of that, based on our data
18 collection, we have not seen a drop-off in
19 immunizations, and I say speaking on our data
20 collection because we have only been several years
21 of collecting the data particularly on our
22 pediatric age group and they have a lot more shots

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Page 56

1 to get. So the data has been getting better and
2 the numbers have been going up. I suppose there
3 could have been a drop, but our numbers don't show
4 that there's a drop as we get better data and so I
5 think we're going forward with better data and we
6 are following it and haven't really seen a
7 drop-off. I think that we'll have more emphasis
8 because one of the projects that we're going
9 through right now is to actually give facilities
10 more money if they are in the higher levels of
11 HEDIS ranges so that would be a factor that if you
12 had all of your pediatrics above 75 percent, have
13 all of their immunizations, that facility would be
14 rewarded.

15 COL. ANDERSON: Just to also answer your
16 last question about the website, we do track
17 exactly where people come from. There is no way
18 of determining if this person is an individual
19 concern or a provider but we do track where they
20 come from, dot.mil or Air Force or Navy locations.
21 What's really important to me is where they go,
22 how much time they spend there. If I'm putting up

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1 stuff that nobody visits or it's not of interest,
Page 57

2 then I stay away from it. If I see something that
3 draws a lot of interest, then maybe we need more
4 information in that area and so that is tracked
5 all the time.

6 DR. POLAND: A couple more questions
7 that relate directly to MILVAX and then we'll move
8 on. Russ first, then Mike, and then Mark.

9 DR. LEUPKER: Since you've assured us
10 that the vaccine you're getting from HHS is not
11 close to expiration, I would encourage you as
12 suggested here to expunge the word expiration when
13 you're describing this because it's like waving a
14 red flag in front of folks. Just a public
15 relations idea.

16 COL. ANDERSON: The contract says 6 to 9
17 months that it will have, but I know exactly the
18 risk communication point you're making.

19 DR. OXMAN: This may not be the ideal
20 time to ask the question and it may reflect my
21 personal ignorance, but in an area of the issue of
22 policies and where does the recommendation begin.

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66

1 One example would be adenovirus because that's not
2 going to come from the FDA, it's not going to come
3 from outside the military. It's a relatively
4 unique problem for the military. So the question

5 I have is where is the beginning of the
6 recommendation for shall we and if so when and if
7 so how with a live attenuated vaccine or with a
8 killed vaccine with plasma, all of these should be
9 part of one decision process? Where is that
10 happening now and who's taking the lead in that?
11 I have the sense that there are many different
12 independent foci within the individual services
13 and that kind of initiation of planning and
14 initiation of policy can happen in many different
15 places, but I'm not aware of where it is.

16 DR. POLAND: Who can best answer that
17 question?

18 COL. ANDERSON: I think I can. First of
19 all, set every single vaccination goes through
20 this process. Each one seems to take on a little
21 bit different life of its own. But pretty much
22 the people who carry it all the way from the

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67

1 concepts, coordinating it with their different
2 services, up to execution are sitting in the first
3 half of this room. It's with the JPMPG, with Ms.
4 Embrey's office, with our office. All of those
5 organizations take on the issue, try to come to a
6 consensus if it's going to be a DOD individual
7 policy. Also if we are having confusion or if we
8 can't come to a consensus, sometimes bring it to

9 the Defense Health Board for your position on it.
10 And other times when the Board brings us an issue,
11 then work it at our level and work it up through
12 the policy. Anybody else? That's my take on it.

13 COL GIBSON: You've basically covered
14 it. It comes from a lot of places including this
15 Board who would make a recommendation to start it.
16 Keep in mind though that it needs to be a
17 deliberative process. I would say that
18 particularly with 14 what we need to do is
19 understand the natural history and the prevalence
20 of that problem over time before we invest \$30
21 million to approach that issue.

22 DR. OXMAN: It would seem to me that if

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68

1 this were analogous to a very large corporation
2 with factories all around the world that there
3 ought to be one committee, one spot in the whole
4 organization where you bring the question,
5 shouldn't we think about an adeno-21 vaccine or an
6 adeno-14 vaccine? I don't have any sense that
7 there's one spot within the DOD.

8 DR. POLAND: So what you're hearing is
9 there isn't such a thing currently.

10 DR. OXMAN: Yes, and I think there
11 should be.

12 DR. POLAND: I will point out in our
13 review from 1999 that that was one of the eight or
14 so recommendations that that be established. So
15 we should maybe revisit that in the Infectious
16 Diseases Subcommittee. Mark?

17 DR. BROWN: Thanks. A quick question I
18 think. You showed a slide of media interest in
19 the anthrax vaccine from I think 2000. It was
20 very interesting and it showed a lot of spikes
21 early on and then a kind of diminution over time.
22 Is that reflecting an increased acceptance of this

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69

1 vaccine among active-duty service members or is
2 there less concern among the recipients,
3 particularly the active-duty members who are
4 receiving this vaccine and those who are affected
5 by the mandated vaccination? Is there greater
6 acceptance of this as a good idea?

7 COL. ANDERSON: I would say it's a mix
8 of things. I would say there is still a
9 perception that the risk isn't there for some
10 people. There is still a larger population that
11 says I'm told to do it and no problems, go ahead
12 and get it. And there are other people who say
13 it's the more educated service member that we have
14 these days who say I have to get this, let me go
15 to the internet and find out what's there and

16 there's still the misperception and a lot of bad
17 science readily available.

18 I'd say the acceptance though is better.
19 I think what that chart more accurately reflects
20 is all the effectiveness of its advocacy groups
21 for those who don't want to be vaccinated and who
22 don't feel that it should be mandatory. As a

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70

1 follow-up, there have been the two federal cases.
2 We had the anthrax one which put the stop to
3 program. Finally when the Food and Drug
4 Administration came back with their final rule and
5 final order, that resolved that case. The second
6 case which was in the courts over the last 2 to
7 2-1/2 years, the main thing going against the Food
8 and Drug Administration was saying they still had
9 not properly licensed the vaccine and the one case
10 against DOD saying that we had not followed the
11 dosing regimen by when we stop someone we start
12 where we left off. That case was just dismissed
13 by the judge within the last 4 months. So those
14 two cases have not resolved, and when there's not
15 a big case, when there's not a lot of hot things
16 going on in the media, have kind of lost interest
17 in it.

18 DR. POLAND: We need to move on. Thank

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19 you very much, Randy, for that briefing. I'm
20 doing our best to keep on schedule here because
21 I'm cognizant of the need for some of you to leave
22 so what I'm going to do is make the break after

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71

1 the Health Risk Assessment. Let's go on to the
2 next presentation which is a question to the Board
3 on a Joint Pathology Center. Dr. Gibson is going
4 to lead off with the question and then Dr. Kelley
5 will discuss the ongoing work of the DOD's Joint
6 Pathology Work Group.

7 To introduce this question about the
8 Joint Pathology Center we need to go back and
9 provide some background information. We go back
10 to 2005 when the Defense Base Closure and
11 Realignment Commission provided their
12 recommendations relative to the Armed Forces
13 Institute of Pathology. They recommended that the
14 AFIP be disestablished except for the National
15 Medical Museum and the Tissue Repository. The
16 Armed Forces Medical Examiner's Office, the DNA
17 Repository, and the Accident Investigation Group
18 would move to Dover Air Force Base. You can read
19 that. This is what BRAC recommended,
20 disestablishing, taking AFIP apart under the
21 assumption that the workload or the needs of the
22 Department for pathology capabilities would be

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72

1 absorbed into other DOD and other federal
2 agencies. The President accepted that and because
3 of the way the law was written, Congress then
4 allowed it to be passed into law in November 2005,
5 and the BRAC Commission has been moving to execute
6 on that.

7 In 2008, the National Defense
8 Authorization Act directed that the President
9 establish a Joint Pathology Center. This is not
10 just armed forces, this is joint which would
11 include all the other federal agencies to meet
12 their needs for pathology education as you can
13 read there. At the minimum, this Joint Pathology
14 Center was to include those issues that are
15 bulleted in front of you and the President was to
16 determine which agency should take it although
17 Congress indicated that it should go to DOD unless
18 the President thinks it should go some place else.

19 This resulted in the establish of a work
20 group that Dr. Kelley leads to make determinations
21 and to come up with a plan for how to establish
22 the Joint Pathology Center without interfering

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Page 64

1 with the established law relative to BRAC.
2 They're working on that. The question that ASDHA
3 is asking you is to review their strategic plan
4 for the establishment of the center and provide
5 your opinion on the appropriateness and
6 feasibility of the plan, and keep in mind the BRAC
7 Commission as you do that. The short straw here
8 is that the President needs to determine by 2008
9 where it's going to go. So with that I'll turn it
10 over to Dr. Kelley to talk about the work group.

11 MAJ. GEN. KELLEY: Health Affairs
12 chartered a work group which has senior
13 representatives from all of the involved DOD
14 agencies and inviting Health and Human Services
15 and the Department of Veterans Affairs to
16 participate in this as they go through.

17 The key, and this is getting the camel
18 through the eye of the needle, of getting a
19 program that establishes a Joint Pathology Center
20 that does those four things which if you look at
21 the BRAC law says you can't do them. So there is
22 some wiggle room in there, but it's kind of a fine

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1 line that as we go through this process I don't
Page 65

2 think everyone will be happy with whatever comes
3 out. These are the four services that the Joint
4 Pathology Center just have, consultation,
5 education, research, and maintaining and
6 modernization of the Tissue Repository. The
7 options that we looked at trying to find things
8 within this within the law that we could do. Do
9 we have to redo the business plan? Do we use
10 another agency? Looking for other options. Can
11 we keep what the current business plan is?
12 Actually, we can't really keep the current
13 business plan because it doesn't mention anything
14 about a Joint Pathology Center so we have to do
15 something other than the current plan.

16 At the last meeting we discussed these
17 different options. We had option 7, the slides
18 were sent in originally before the last meeting,
19 so 7 actually became a couple of options with one
20 reporting directly to TMA and another work an
21 executive agency. Since these are the things that
22 we discussed and are continuing discuss, since we

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75

1 had a multi-voting and narrowed that list down,
2 but that isn't released yet and there's a lot of
3 sensitivity to that so I'd be happy to share that
4 with you in closed session but not the open

5 session if anybody would like to discuss the
6 options that were selected as potentially the best
7 coming out of there.

8 Funding. That's a very good question.
9 There is no funding in the law that says you will
10 establish the center and the issue has to go with
11 the BRAC law because those things are
12 disestablished and the money of that
13 disestablishment piece is already pulled out of
14 the budget and the future plans. So part of this
15 will be figuring out a cost-effective way to do
16 this and then seeing if the funding will come or
17 Congress can always say fund within the money
18 we've given you even though it's a new
19 requirement. So we are looking at a way that we
20 can have a Joint Pathology Center that can meet
21 the requirements of disestablishing AFIP and then
22 establishing a Joint Pathology Center that

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76

1 includes but doesn't violate because the law also
2 says you will follow the BRAC law. The second law
3 that says establish a Joint Pathology Center says
4 you will follow the BRAC law. So we're working on
5 that and that's pretty much where we are right
6 now, looking forward. We will come back with some
7 options to the Board to review our deliberations
8 relatively quickly, and so this is moving fast.

9 We're trying to put some more finalization on some
10 of the models that we have and some funding
11 associated so we see what those costs are in the
12 various options.

13 DR. POLAND: I don't want to get into
14 the details of that yet so the plan is that this
15 established working group will bring their product
16 to the Board for comment so we will know the
17 details and we'll comment on that, or to the
18 Subcommittee. So let's not get operational or
19 details yet.

20 DR. LEDNAR: I think I have a
21 big-question question. While the future needs to
22 comply with BRAC and the four missions that need

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77

1 to be accounted for, the question I would have is
2 for the current state of AFIP, a we had a
3 portfolio of what they do for the Department of
4 Defense. Will at some point we get to see how
5 those missions beyond the four are going to have a
6 future?

7 MAJ. GEN. KELLEY: If you would like
8 that, we could. I think there's probably a short
9 briefing of course we were familiar with, but a
10 10-minute briefing that goes through what are the
11 functions and putting those laws together. There

12 are some options on the functions that weren't
13 specifically disestablished and are specifically
14 told to be present in the Joint Pathology Center
15 and there has been a review group, not the same
16 one, but a group before the first business plan
17 was written on how to deal with those various
18 issues. So actually that probably is a reasonable
19 thing for you to review in terms of did DOD get it
20 right in what they determined needed to be
21 maintained and not.

22 DR. OXMAN: Not to pin you down on

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78

1 details, but it's such a major difference if it's
2 yes or no, is this contemplated to include more
3 than just tissue so that it would be for example a
4 collection of materials from a research project or
5 a serum bank, et cetera? Are those on the table
6 as well?

7 MAJ. GEN. KELLEY: The tissue repository
8 is maintained by law. The other repositories, the
9 DNA repository and some of those other things are
10 maintained because the Armed Forces Medical
11 Examiner's Office is maintained; it's moved, but
12 it's maintained. So some of those are covered in
13 that, but the intention would be to maintain those
14 things. That's one of those things that's in the
15 area of retain these things.

16 DR. POLAND: Just one other question.
17 Is the idea of the Joint Pathology Center that it
18 will include animal pathology? The reason I ask
19 is, in fact I just recently got a request from the
20 Navy-Marine Mammal Program and they've got a real
21 issue with their dolphins. Will this include
22 those possibilities?

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79

1 MAJ. GEN. KELLEY: The veterinary
2 pathology residency is one of the items that DOD
3 said we need to retain and so there's active
4 planning going on on where's the best place to
5 locate that. Some of that planning is put on hold
6 because it may be best to leave it in a Joint
7 Pathology Center but there is some other planning
8 from before going on to move it to I think it was
9 San Antonio. No, to keep it here in the D.C.
10 area.

11 DR. MULLICK: Yes, it was going to go to
12 RIAD but only for the residency program. No
13 budget.

14 DR. POLAND: We're going to move on now
15 to the next briefing. This will be Dr. Bill
16 Halperin. The Board was asked to address an issue
17 involving an environmental risk assessment
18 conducted by DOD at Balad Air Base in Iraq. Dr.

19 Halperin as you know leads the Occupational and
20 Environmental Health Subcommittee in these efforts
21 and he'll provide some background on the issue and
22 discuss the Subcommittee's approach. You have a

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80

1 copy of the question in your notebooks. Bill?
2 DR. HALPERIN: Thank you. Before I
3 start the presentation, off the record I wanted to
4 present a few slides that will set a background.
5 First of all, how many of you have read the -- so
6 summarize a pivotal work of the 21st century,
7 errors are not the result of individuals. Errors
8 are the result of failing systems. So let's keep
9 that in mind. The next is in thinking about some
10 precepts to think about this report, I had the
11 choice of either going to The New Yorker or to the
12 New England Journal of Medicine so I chose The New
13 Yorker.

14 A problem that clinicians and others
15 were confronted by all the time, you don't get
16 what you need, you get a lot of what you don't
17 need, you got to sort it through and in the
18 process you got to not make an error. We're
19 talking \$1,500 to find the dots and another \$1,500
20 to connect them. Sometimes the answers are in
21 front of us and we can't put not just 2 and 2, but
22 1 and 1 and 1 together to figure it out. So the

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81

1 information by itself is only part of the deal.
2 The third, if you will, is we have lots of
3 information technology, we just don't have any
4 information. So a lot of thinking about how
5 errors occur is a matter of thinking about the
6 systems but also what's coming through the systems
7 and are they really serving the purpose.

8 To start the official presentation, all
9 of that of course is off the right because I don't
10 have copyright for any of it, this is a
11 Subcommittee to assess health risk assessments
12 having to do with burn pit exposures at Balad Air
13 Base in Iraq. It's a committee and I'll introduce
14 them in a minute. The outline is to go over the
15 charge to the DHB, to introduce the Subcommittee
16 members, tell you a little bit about Balad, to
17 give you a little bit of background about health
18 risk assessment in general, and then about the
19 health risk assessment that was done by the
20 military for this air base, then provide an
21 overview of the status of the review, and then
22 we'll talk about the path forward.

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Page 72

1 This comes from a memorandum from Ms.
2 Embrey to Dr. Poland on 2/29/08 and it's a very
3 good summary, and this is what it says. That burn
4 pits were used in Balad for stuff. It started off
5 with a few tons of stuff and at the peak before
6 they went to use of real industrial incinerators
7 it was about 500,000 pounds a day of stuff and the
8 stuff consisted of food-related byproducts from
9 Taco Bell and McDonald's, et cetera, it consisted
10 of military munitions, it consisted of just a
11 whole bunch of stuff, and the way it was burned
12 was by putting jet fuel on it. If you can
13 imagine, this is a very big pit and it created a
14 lot of smoke, it created a very smoke environment,
15 and this went on for a couple of years. So that's
16 what's really generating the issue, a smoky
17 environment and what are the health effects.

18 The military I'll use broadly did
19 extensive air sampling at the base and in spring
20 2007 based on that air sampling came up with some
21 erroneously high levels of dioxin in the results
22 clearly exceeding military exposure guidelines,

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1 and we'll come back to that issue. These
Page 73

2 erroneous results led to some pre- and
3 post-deployment survey of some highly exposed
4 individuals at the base, about 25 individuals, to
5 see whether in fact there was more serum dioxin
6 post-exposure than pre-exposure and that's part of
7 the health risk appraisal. The erroneously high
8 levels of dioxin led in the risk assessment to
9 erroneously high levels of estimate of excess
10 cancers that would be expected, so you can see how
11 this thing starts to roll along. When the error
12 was determined, that led to a revised health risk
13 assessment and that's essentially what we're
14 reviewing now, the revised health risk assessment.
15 In Ms. Embrey's comments I don't usually count up
16 these words in other charges, but I did in this
17 one, she mentioned quickly, she mentioned earliest
18 convenience, all of those words are there and it
19 will become clear why there's a real urgency to
20 get this done and why it's really almost done by
21 now.

22 This is the Subcommittee. You know all

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84

1 of the people now. Gary Carlson you don't know.
2 Gary Carlson is the Director of Toxicology at
3 Purdue and he's going to be a consultant to the
4 committee and he's already offered his comments.

5 And the unknown person is a doctoral-level
6 certified industrial hygienist who we're trying to
7 get on board the train and the train may actually
8 complete its job before we get him on, so that
9 person may not be there, and everybody else you
10 know.

11 This is Iraq. All of these numbers are
12 air bases. This is Baghdad. Number 15 over here
13 is Balad. Balad is now a city of 25,000 people
14 that occupies probably 25 square miles with a big
15 uninhabited area around it and that's where this
16 incineration was going on, but Balad is only if
17 you will a sentinel. This kind of incineration is
18 probably going on at lots of other air bases and
19 lots of other military bases and there's a lot of
20 potential for environment pollution and personal
21 exposure of people at the base. And I'm not even
22 sure whether these are air bases before or after

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1 the initiation of the war.

2 The risk assessment and the federal
3 government, this is just background. I think a
4 lot of us know this. It was codified by the
5 National Academy of Science in 1983 in what is
6 called The Red Book. Risk assessment consists of
7 hazard identification, are the agents there
8 potentially hazardous, and the answer in this

9 situation is yes. Is there a dose response
10 relationship between the agents and the effect?
11 What's the magnitude, duration, route, description
12 of exposure by person, place, and time? And this
13 should be part of the health risk assessment and
14 we're going to be asking the question of whether
15 this is adequate in the health risk assessment.
16 Risk characterization which ultimately is how you
17 take all of those dots and put them together and
18 say what's the effect going to be on either
19 disease in general or cancer specifically, so this
20 is the actual quantitative risk assessment.

21 To continue, the risk assessment is
22 separate from the risk management. That is, let's

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86

1 put in an industrial level incinerator, or the
2 risk communication, what do we tell people about
3 the risks, so these are three separate components.

4 The health risk assessment can certainly
5 consist of uncertainties. You're only collecting
6 a moderate amount of information. There are
7 uncertainties. There is variability in that
8 information. It leads to point estimates with
9 confidence intervals, et cetera. So there's
10 variability, there's uncertainty in what kind of
11 estimate of risk one can make. That assumes that

12 there are no errors. This is variability. This
13 is through error in the data. That is, is there
14 data quality? Was data essentially miscoded,
15 mis-entered, et cetera? So risk assessments can
16 be wrong because of uncertainties, because of
17 errors, and also if one goes essentially beyond
18 the data that you can have. You can extrapolate
19 either too high or too low and come up with
20 something that's beyond what you really should be
21 predicting.

22 At Balad there were area samples for

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87

1 products of combustion. There was an assessment
2 of respiratory disease surveillance data comparing
3 respiratory disease in Balad versus other military
4 areas in Iraq. There was the pre- and
5 post-deployment sero survey for TCDD. And there
6 was a quantitative risk assessment.

7 What's the status? This goes back and
8 gives you a little bit different history. In the
9 fall of 2007 before there was a request from Ms.
10 Embrey there was a request for SMEs which I now
11 understand to be subject matter experts with the
12 members of our Subcommittee to talk with the folks
13 in the military who had done the risk assessment
14 and that included myself, Wayne, Jim Lockey, and
15 John Erbel. So the four of us read the

16 preliminary report, not this revised report, but
17 the preliminary report. We read it and we
18 listened to the authors, and it's like the
19 fundamental competency of a physical saying is
20 this patient sick? Regardless of everything else,
21 is this patient sick? The subject matter experts
22 said there's something wrong in your report. We

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88

1 couldn't put our finger on it. We advise strongly
2 that the authors try to dig to the bottom of it,
3 but they were expressing the dioxin exposures at
4 the air base were probably 1,000 times higher than
5 what they should be leading to all sorts of
6 estimates of risk, 1,000 times higher than you
7 would like them to be, and the group of us said
8 there's something wrong with this report. We
9 don't know where it is. It may be in the data.
10 We just don't know where it is. You got to find
11 it.

12 After that review, there was an internal
13 release of the report unrevised to field
14 commanders and the Office of the Secretary of
15 Defense, so the word not on the street but within
16 the military was the risk assessment is this 1,000
17 times high level than probably it was in reality.
18 The report did not reflect the ad hoc comments

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19 from the SME. At some point, and we'll find out
20 as time goes by how this happened, they did find
21 the error and the error appears to be one of those
22 simple dosage errors, you ask for things in

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89

1 micrograms and they're given in picograms or vice
2 versa and suddenly the patient's got too much or
3 too little. The same thing can happen in risk
4 assessment. You put the wrong units in and you've
5 got a real problem, and that's the basic issue
6 here.

7 That led to a revised risk assessment
8 and that's what we're reviewing, and then Ms.
9 Embrey's request for the DHB to review the revised
10 risk assessment. We've already now received
11 comments on the revised risk assessment from
12 members of the committee where it's being
13 consolidated now. We've had meetings while we're
14 here. We have I think reached consensus. We have
15 to pull it together, revise, get some review, and
16 we hope that we'll have this report done literally
17 hopefully in a matter of I wanted to say days but
18 weeks from now and get this done. I got my first
19 email from "I'm a sergeant at Balad" telling me
20 what all of this means to him and it's based on
21 erroneous information that's got to be corrected
22 before it becomes engrained and really alarming,

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90

1 so we really need to get this done. Questions
2 from the DHB or anybody else?

3 DR. POLAND: Bill, thank you, and
4 particularly thank you for moving with alacrity on
5 this because for the reasons that you mentioned,
6 it's important that the error be corrected as
7 quickly as possible in the psyche of everybody
8 who's touched this. Questions at all for Bill?

9 COL GIBSON: One comment first. The
10 report that we've writing is part one. The
11 Subcommittee through the Board is answering the
12 issues with respect to the review of this revised
13 risk assessment. Phase two is to look at how DOD
14 does risk assessments particularly in a combat
15 environment, a contingency operation, hostile
16 area, and to provide general comments on that
17 whole process to include how to do QC to make sure
18 that the process has the right checks and balances
19 in it so we don't have these types of problems
20 again.

21 DR. HALPERIN: It comes back the issue
22 of how the system has to be tweaked. It's not why

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Page 80

1 this error occurred, but how the system has to be
2 tweaked to avoid this happening.

3 DR. POLAND: Bill, can I ask that you
4 communicate with Roger the time in which you think
5 that will be done so that Roger can communicate
6 with Ms. Embrey saying you'll have this and you'll
7 have this on your desk by such and such a date
8 because I know she's concerned and that's a great
9 service from the Board if we can quickly give
10 advice?

11 DR. LEDNAR: As a Subcommittee member,
12 personally I'd like to thank Bill for the
13 leadership he's brought to this very complex
14 issue. One of the points, the picture of Iraq and
15 the numbers of all the air bases in Iraq brought
16 out to me that this question arose at one of those
17 air bases. The practice or question of the burn
18 pit goes on at more than just Balad. So I think
19 as we understand this site and this question, we
20 need to be sure that if there's something about
21 the practice of disposing of refuse that should be
22 different for some reason on the basis of the

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1 understanding of the correct data using the model
Page 81

2 we have to be sure that those learnings get
3 leveraged and that's more than just in the Middle
4 East, it's more than just CENTCOM. So to the
5 extent that this practice goes on in theater
6 anywhere in the world, we need to make sure again
7 that there's a system way to leverage these
8 learnings and institutionalize them.

9 DR. POLAND: Mark?

10 DR. BROWN: That was a very interesting
11 presentation. I would echo Wayne's comment that
12 it seems like there may be something systematic
13 going on here in terms of waste disposal
14 techniques going on in theater. You couldn't get
15 away with this kind of waste disposal here in the
16 United States. I know back in the 1960s the way
17 the military would get rid of excess chemical
18 weapons for instance was the same way, throw them
19 in a pit and burn them. We don't do that any
20 more, so that's one issue.

21 The other point I would make is I
22 thought your presentation was really timely and I

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93

1 would just add the comment that from VA's
2 perspective we have heard about this from veterans
3 and concerns about this so this incident or this
4 issue and this kind of situation and the potential

5 consequences I think can be a problem and I agree
6 with your points that this is something that needs
7 to be looked into I think.

8 DR. POLAND: Aaron, you have sort of a
9 unique background in this regard. Would you like
10 to make any comments?

11 LTC. SILVER: I would. Thank you, sir.
12 This is really good, and it is needed. I think
13 that one of the things for me is that there needs
14 to be more of a peer review on things before they
15 get out. About the way that we're doing waste
16 management in the field, we have to understand
17 that this started out as a fire base and expanded
18 greatly and waste management is done by engineers
19 which are completely separate from medical. The
20 bottom line is the Balad burn pit could be really
21 any place over there. It's not right in the area,
22 it's about 4 kilometers from the actual base

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94

1 itself, and wind direction and so forth.

2 We have something called the Overseas
3 Environmental Baseline Guidance Document at the
4 OEBGD that we use as our guidelines outside of the
5 Continental United States for doing things like
6 waste management. While it didn't have anything
7 in it that said if you're going to be at a
8 location for 12 months you need to move to a

9 different type of waste management, they're
10 rewriting that and I think that that will be very
11 helpful in the future knowing when we need to
12 transition in planning for that in the entire
13 planning process.

14 Back to the environmental health piece,
15 we need a better way I think to conduct
16 environmental assessments, environmental versus
17 industrial hygiene because I think it's much
18 harder when you're talking about open-air
19 contaminants outside of things like the criteria
20 pollutants. It's very hard.

21 DR. POLAND: Thank you.

22 DR. SHAMOO: I think Dr. Silver may have

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95

1 answered some of my concerns, that your implied
2 conclusion that the risks are minimal to the
3 soldiers, but I wonder if you've taken into
4 consideration the length of time. This has been
5 going on for 5 years, we are in the sixth year,
6 and if it continues up to 10 years what is the
7 effect on our soldiers. But another concern would
8 be your main concern for the population. What is
9 the air pollution going to do to infants in the
10 nearby areas? Have you done any thinking on that
11 or you should or should not?

12 DR. HALPERIN: They do have a station
13 set-up at Balad that does the criteria pollutants
14 and really the only pollutant that is potentially
15 above the limit is particulate matter and that's
16 through the entire region. In some cases there's
17 a little issue with ozone but no worse than most
18 metropolitan cities in the United States. We do
19 that in Iraq and Kuwait. We have stations in both
20 locations.

21 DR. SHAMOO: But in the United States we
22 don't want to live all of us in L.A. Right?

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96

1 Population in L.A. Especially 15 to 20 years ago
2 was horrendous and controls became stiffer and the
3 pollution went down.

4 DR. OXMAN: Just a generic question, I
5 think you touched on it inadvertently, and that is
6 there a procedure for the vetting of any report
7 like this before it's distributed?

8 DR. HALPERIN: Absolutely, sir. I know
9 that the organization that wrote the report has
10 one but this got by it.

11 COL GIBSON: I wouldn't say got by it.
12 What I would say is that the issue was they
13 followed what they thought was the correct path to
14 inform through their surgeon general on up. The
15 issue is the error wasn't caught until way

16 upstream, way upstream. In addition, because of
17 the grapevine we have a lot of concern of service
18 members who are getting false information, rumor
19 and innuendo, thus the need to get this done fast
20 and have an external group that is well respected,
21 objective, review the process, make their
22 comments, thus it isn't just the Department of

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97

1 Defense saying oops, it's oops, you guys did this,
2 this was a mistake, you fixed it and it's okay
3 now.

4 DR. MILLER: With reference to that,
5 Roger, I think the first issue is a public
6 relations issue about the premature release of
7 information and confidence restoration in the
8 process and that not only in this particular event
9 but future and current events. My question also
10 relates also then to the specificity of the
11 findings and this is just one base of many and
12 there are probably changes of time and practices
13 and stuff that are disposed of in the various
14 difference bases so I would wonder in order to
15 restore confidence whether or not that you having
16 one sentinel site may well want to restore some
17 confidence by looking at several other sites as
18 well and put in an appropriate level of

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19 surveillance. I'm not sure what that would be,
20 how many bases, because again there is probably
21 quite a bit of heterogeneity in terms of the
22 practices. I'm not sure if jet fuel is normally

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98

1 used for burning things. In the State, waste
2 management is a complicated process. We have Tony
3 Soprano in New Jersey. We have all different
4 forms of waste management and without necessarily
5 looking at the long-term consequences because it's
6 easy to overlook those. So again looking at not
7 only environmental exposures but also the process
8 to restore confidence I think is something that we
9 should be attentive to.

10 DR. HALPERIN: We try to balance Tony in
11 New Jersey with the academic.

12 DR. POLAND: Thank you. One more
13 comment.

14 DR. LOCKEY: The relationship to
15 particulate matter, you're looking at PM 10 I
16 think.

17 LTC. SILVER: We're looking at PM and PM
18 2.5.

19 DR. LOCKEY: We spent some time on that
20 because you're dealing with paralysis perhaps,
21 your PM 10, even your PM 2.5 is going to mask any
22 of the ultra-fines in relationship to particulate

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99

1 number and surface area. So since you're dealing
2 with a complex environment, complex paralysis,
3 you're going to get ultra-fines given off and
4 there might be a carbon core with a heavy metal
5 with pH's on the surface. So I think one of the
6 recommendations is that you got to stratify the
7 particulates down to PM 0.1 ultra-fines or less to
8 see what is your real distribution of the
9 particulates in relationship to size.

10 DR. HALPERIN: Just very, very briefly,
11 this report is clear that it's not dealing with
12 the particulates or the metals so one of the
13 issues that I think Mark raises is absolutely
14 right, that the risk communications are going to
15 have to be coordinated with that because just to
16 talk about dioxin and some other chemicals and
17 ignore the fact that you've got the particulates
18 out there is not going to fly all that well and
19 it's got to be coordinated. Thank you.

20 DR. POLAND: Bill, thank you very much.

21 LTC. SILVER: May I make one more
22 clarifying point? The vast majority of the

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Page 88

1 particulate matter in that region is from blowing
2 sand. I just want to make sure that everybody
3 knows that. It's so bad some days that you can't
4 see 10 feet in front of you.

5 DR. POLAND: We really do need to cut
6 off here because we're starting to get late
7 despite starting a half-hour early. So let's
8 just take a 5-minute break if we can and then
9 reconvene.

10 (Recess)

11 DR. POLAND: A couple of things before
12 we go on that I want to be sure and clarify in
13 regards to the Joint Pathology Center. That will
14 be going to our Pathology Subcommittee, but I will
15 be asking for some volunteers and appointing some
16 individuals to that for the purpose of reviewing
17 the product of Dr. Kelley's committee. The second
18 thing is in regard to the posters that I
19 mentioned, I should probably clarify that we can't
20 have them on the inside where our meeting is
21 occurring and we'll have them on the outside as
22 they are and I just wanted to clarify that. I

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1 would also ask that for those of you who want to
Page 89

2 do that, and I do encourage it, that you just pass
3 them by Roger and his office first. The main
4 sensitivity I have is what I don't want from some
5 the visitors and others is commercials and
6 commercial kinds of posters out there. I wanted
7 to reflect the science of the military agencies
8 and of the individuals on the Board.

9 Our next speaker will be Colonel Robert
10 DeFrait es who is Director of the newly formed
11 Armed Forces Health Surveillance Center. Colonel
12 DeFrait es will discuss the center's mission and
13 structure. I want to add that the creation of the
14 center is the culmination of a long and difficult
15 struggle to centralize medical surveillance within
16 DOD and it's something that the Board has had
17 interest in over the years. There are a number of
18 issues that will probably come up at the end of it
19 and discussion will occur among some of the
20 Infectious Disease Subcommittee members at lunch.
21 So for the ID folks, I'd ask that we, no pun
22 intended, quarantine ourselves so that we can talk

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102

1 about some of those issues. Colonel DeFrait es?
2 COL. DEFRAITES: Thank you, Dr. Poland.
3 It's a great honor to be asked to speak and
4 address the Board. Some of the slides that you

5 have in your binders, I'll try to get through them
6 quickly and then leave a lot of time for
7 questions. This is what I'll cover today, the
8 background of the center and what was intended,
9 the concept, and then the current status such as
10 it is since it's been just recently officially
11 chartered.

12 The history here starts in July 2005,
13 though really the idea for a consolidated
14 Department of Defense Strategic Health
15 Surveillance Center clearly dates 2005. A lot of
16 the lessons from the first Gulf War and the need
17 to have some type of fairly comprehensive
18 surveillance system from an operational
19 perspective clearly predates 2005, but Ms. Embrey
20 formed a task force to develop a concept of
21 operations for an Armed Forces Health Surveillance
22 Center again to realign those strategic health

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103

1 surveillance capabilities that were scattered
2 within various agencies within the military
3 services and the Department of Defense. In the 6
4 months after the charter of the task force, the
5 CONOPS was developed and one of the key ideas was
6 that the center should be operated as an Army led
7 executive agency in a staged or phased approach of
8 formation and to start with using some of the

9 legacy or existing components of those
10 surveillance capabilities that existed within the
11 TRICARE Management Agency, the Deployment Health
12 Support Directorate, and some of the Army Medical
13 Department executive agency surveillance
14 activities.

15 In June 2006 the Force Health Protection
16 Council which Ms. Embrey chairs, a two-star-level
17 counsel, approved the concept of operations. In
18 the ensuing year some additional staff and
19 tweaking took place, but in May of last year the
20 CONOPS was signed off for OSD review by Dr. Chew,
21 the Under Secretary of Defense for Personnel and
22 Readiness. In the concept of operations, this is

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104

1 the division and the mission, and under that
2 vision statement you can see those descriptives of
3 information of relevance, timeliness, actionable
4 information, and comprehensive information, those
5 types of qualifies of information of what we do
6 with information that are common to all public
7 health surveillance activities. Again the idea
8 was to have this support available for all of the
9 armed forces, for the military and what were
10 termed military-associated populations, and I'll
11 talk a little bit more about what those might be.

12 Again, in the mission statement you can
13 see these other action words of acquiring,
14 analyzing, interpreting, recommending, and
15 disseminating information. Also a surveillance
16 methodology standardization, some approach to at
17 least have shared definitions of when we talk
18 about for example a traumatic brain injury, what
19 type of data when we're talking about rates of
20 traumatic brain injury or any other disease or
21 injury, to get some type of standardized approach
22 so that different parts of the organization can

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105

1 speak and can communicate accurately. So the
2 center was clearly given the mission to look at
3 methodologies for surveillance. The center would
4 be the focal point for sharing the products, the
5 expertise and information. Finally, what I've
6 started to embark on early on in the life cycle of
7 this organization is delineating those roles,
8 responsibilities, and relationships with the other
9 health surveillance organizations in the services
10 and other organizations that do things that the
11 center may not do, and I'll talk a little bit more
12 about one of those as we get closer.

13 This is germane I think to the question
14 that came up about policy for immunizations, for
15 example, but clearly in the idea of what the

16 center was envisioned to do, one way to look at it
17 is to look at what were those key outcomes or
18 actions that it was supposed to do and who are the
19 customers for that particular work. So for
20 informing operations in terms of existing or
21 ongoing health threats in operations, certainly
22 the Joint Chiefs of Staff and the combatant

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106

1 commands would be a key client. For readiness
2 issues in terms of individual medical readiness of
3 the force, that's a Title X responsibility that
4 the military services and the military departments
5 have for manning, equipping, and training the
6 force and clearly the individual medical readiness
7 is a service responsibility and having some type
8 of standardized approach for defining the
9 individual medical readiness is something that
10 Health Affairs and the services have been
11 interested in and certainly the health
12 surveillance information can help inform that.

13 For policy of all different types, and
14 again it's not just Health Affairs but also other
15 OSD policy offices, the information that's
16 generated by our Health Surveillance Center does
17 at least to plant the seed or begin the process by
18 which a requirement for a new immunization for

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19 example might be made. For researchers, and again
20 researchers are always looking for updated current
21 threat estimates of disease and injury trends
22 within the military, clearly the Health

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107

1 Surveillance Center would be involved in that.
2 And from a national and interservice federal
3 agency perspective or even international
4 perspective, we have relationships with the
5 Department of Homeland Security, DHHS, the Centers
6 for Disease Control, the VA, and World Health
7 Organization. I'll get specifically into WHO
8 because the liaison with WHO is with the Global
9 Emerging Infections Program which is part of the
10 Armed Forces Health Surveillance Center as it's
11 been rolled up under AFHSC. As far as looking at
12 the products, again you can look at this is just
13 the way the health surveillance and the
14 epidemiologists would look at life in terms of
15 stratifying or analyzing data by these aspects.
16 This is one of my favorite slides. It shows a
17 number of things. You can look at this and see a
18 number of things happening. For one thing, it
19 shows the multiple mutually supporting
20 relationship between the VA, research and
21 academia, the other national federal agencies, and
22 even states and metropolitan areas, because the

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108

1 data we have come from posts, camps, and stations
2 around the world and within the United States that
3 are parts of the communities. So we have a
4 relationship through those installations and again
5 the roll-up or the comprehensive nature of the
6 data we have allow us to support the work even in
7 the metropolitan areas. As I mentioned, the
8 unified commands, the combatant commands, the
9 deploy sites, the TRICARE management agency, and
10 through the service surveillance of U.S. Air
11 Force's School of Aerospace Medicine now their
12 epidemiology and their consultant service and risk
13 assessment programs are still extant, and again we
14 have a relationship with the Air Force and with
15 the Army at the Center for Health Promotion and
16 Preventive Medicine, the Navy-Marine Corps Public
17 Health Center, again working out the relationships
18 of what the AFHSC does and what these service
19 agencies still do is a work in progress.

20 The other thing I wanted to say about
21 this particular slide though is that you can see
22 it has mutually supported relationships. The

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Page 96

1 other thing you can see is that it looks you could
2 be pulled in many different directions on this
3 slide so you have to balance the needs of all of
4 these. Or it could be viewed as being trapped in
5 a web and you're waiting to be eaten up, so there
6 are a number of ways. It depends on what kind of
7 what I'm having depends on how I interpret that
8 slide.

9 Again from a public health perspective,
10 this is our functional organization. Right now
11 I'm working on how this functional organization is
12 actually going to play out in terms of a diagram
13 for command and control of the center, but again
14 as a data function for collecting, integrating,
15 and managing data, so we have certainly databases,
16 the Defense Medical Surveillance System is part of
17 our Armed Forces Health Surveillance Center, and
18 that's probably the largest single database that
19 we have along with the serum repository to manage.
20 But there are other data systems such as ESSENCE
21 (?) that's going to come into the fold. The
22 analysis function is very important in terms of

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1 making some sense of the data and again getting to
Page 97

2 where we're actually supporting operations through
3 dissemination of the information through reports
4 and a response piece in terms of how the Armed
5 Forces Health Surveillance Center helps to
6 coordinate public health response. That's going
7 to be a partnership with the Surveillance Centers
8 of the services and then on a national in
9 coordination with Homeland Security, DHHS, states,
10 and local entities, depending on what's
11 appropriate for our involvement.

12 I mentioned the phased approach from a
13 provisional center, to an initial operating
14 capability, to a future operating capability. The
15 provisional operating capability was viewed as
16 those pieces from existing agencies, the Center
17 for Health Promotion and Preventive Medicine, the
18 Navy, the Air Force, the Global Emerging
19 Infections Program, and Force Health Protection
20 and Readiness. This is part of Ms. Embrey's
21 staff. Right now as of February 28, the Center
22 for Health Promotion and Preventive Medicine has

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111

1 contributed the Program 30 which was their Army
2 Medical Surveillance Activity. The Global
3 Emerging Infections Program which you're quite
4 familiar with includes the DOD Influenza

5 Surveillance Program and the existing GEIS
6 programs. It's a total \$52 million per year
7 program. Then the Force Health Protection and
8 Readiness piece, we're still negotiating to see
9 how we're going to migrate that and that's a work
10 in progress.

11 It was envisioned that this provision
12 operation would be a split-based operation but
13 we're very quickly working to consolidate it
14 generally into a single location, but at least for
15 our analysts and our headquarters operations, it's
16 in a single operation. The initial operating
17 capability, this means within the next 8 months,
18 by the end of the fiscal year, we're really
19 supposed to have unity of command collocated
20 operations with 24/7 coverage. I'm still trying
21 to actually articulate what the 24/7 really means
22 in terms of what level of capability is really

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112

1 expected or needed at that level. Then we get
2 into the wider set of populations, and again, a
3 lot of our work is defined by the population for
4 whom we have the most relevant and useful data.
5 So starting with the Defense Medical Surveillance
6 System which is a very good set of data on that
7 active-duty population, those personnel who have
8 separated from active duty, again, some of whom

9 are in the VA system, some of whom are not, that's
10 a challenge. Then retirees and family members,
11 and again I'm negotiating with other organizations
12 who have a better handle on these databases. We
13 do get some medical outcome data on these other
14 populations but those populations are not nearly
15 as well defined as the active-duty population so
16 from an epidemiologic and a surveillance
17 perspective, it's not as handy a population to
18 deal with but we're working toward that. The
19 future, I'm not going to really spend much time on
20 that because the future goes beyond the horizon
21 and it could be anything and it's growing and
22 expanding your capabilities.

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113

1 Just a little bit more detail of what we
2 thought was potentially coming from these various
3 existing organizations, the Center for Health
4 Promotion and Preventive Medicine, the School of
5 Aerospace Medicine formerly known as the Air Force
6 Institute of Operational Health, some of their
7 expertise, Force Health Protection and Readiness,
8 and a big piece of this with the Joint Medical
9 Work Station, the Joint Patient Tracking
10 Application, MSAT (?), especially the JMEWS data,
11 they have access on the secure side to the data

12 that's generated within theater which is
13 classified as secret and one of our limitations of
14 our center now is that our particular building has
15 no access to secure data so right now all of the
16 data that's being accessed on the secure side is
17 in the Skyline Building with Force Health
18 Protection and Readiness so at least for the time
19 being we're going to be operating in two different
20 locations at least to get access to the -- data.
21 The Navy and Marine Corps Public Health Center has
22 some particular expertise developed with HL7 data

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114

1 (?) messaging with laboratory data that we're
2 interested in funded through the GEIS program.
3 Then the GEIS program in particular, their global
4 coordination and monitoring and emergency response
5 functions, the training functions, they fund the
6 surveillance programs by an entire worldwide
7 network of partners, the overseas laboratories --
8 respiratory illnesses at basic training sites and
9 -- mortality through the Armed Forces Medical
10 Examiner's Office. So the GEIS program being part
11 of the AFHSC brings a lot of capability.

12 This is interesting in the sense that
13 this is what we thought in the concept of
14 organizations is what the center will not focus on
15 and the idea of doing health care systems analysis

16 in terms of cost of care, bed occupancy, customer
17 satisfaction, medical management, utilization
18 management, disease management, quality of care,
19 and clinical research in terms of the -- comparing
20 particular treatment protocols was not considered
21 to be within the scope of the operations. So one
22 of the duties that I have as a professional

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115

1 director is to say if you don't do it, who does
2 and to make sure that we get that interface very
3 well defined. So number one, for better customer
4 satisfaction, if somebody calls me for that
5 particular -- at least I have one person or one
6 agency, the appropriate agency, to refer them to
7 with one phone call and not just say I don't know
8 how does that. So one of the things I did this
9 week was at Brooks Air Force Base, the Air Force
10 has developed a fairly robust population health
11 program, I forget what their name is now, but the
12 population health, and really a lot of this work
13 is their business. And again, there are other
14 organizations that do this too so I'm basically
15 going to improve my Rolodex capabilities to know
16 exactly who to refer. Then I think the next piece
17 will be how does this get better organized if it
18 needs to be beyond the scope of my particular

19 center.

20 Our current status of the center, as I
21 already mentioned, back in October to get a
22 jumpstart on things, there were a number of

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116

1 issues, very specific, very operational tactical
2 issues, dealing with an expiring lease on our
3 space for the serum repository in 2010 and also
4 our servers and part of our organization for the
5 Army Medical Surveillance Activity is on Walter
6 Reed's which is under the BRAC. So there are a
7 number of things that happen and General Pollack
8 as the Acting Surgeon General formed a provisional
9 AFHSC that merged the three Army Medical
10 Department executive agencies, the GEIS program,
11 the Defense Medical Surveillance System, and the
12 serum repository, and to start moving out
13 executing the task force draft CONOPS within the
14 limits of the Army at the time. This has now been
15 overcome by events, and on February 26 the Deputy
16 Secretary of Defense signed a memo that
17 established the AFHSC and now we're negotiating
18 with our other partners to get to our initial
19 operating capability by the end of the fiscal
20 year. This is where we are located now at 2900
21 Lindon Lane. This is right outside the Walter
22 Reed Forest Glen Annex complex on Lindon Lane. My

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117

1 office is here. We have two out of the three
2 floors of this building that belong to the AFHSC.
3 We have the analysts for the Defense Medical
4 Surveillance System, we have one Force Health
5 Protection and Readiness program analyst that sort
6 of migrates back and forth between the two sites
7 between Skyline and our office, and the GEIS
8 program is mostly located on the first floor. Our
9 serum repository is located at the Tech Road
10 campus which is about 5 miles away. And as I
11 mentioned, we still have our technical staff for
12 the Defense Medical Surveillance System and our
13 servers in Building 220 at RAMSEE at Walter Reed.
14 So part of the job of the director is to
15 consolidate these disparate scattered
16 organizations into one place. Just to refresh
17 your memory on the Defense Medical Surveillance
18 System as I mentioned, it's fairly comprehensive
19 for the active-duty population in terms of the
20 longitudinal data system to report medical events
21 and other sort of personnel relevant events linked
22 with the serologic data on the specimens that the

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Page 104

1 Board is well familiar with, the serum repository,
2 and so it's a very nice way to start a very, very
3 solid foundation, to start an Armed Forces Health
4 Surveillance Center in terms of data capability
5 which does need to be enhanced in the future. One
6 of the key products is the Medical Surveillance
7 Monthly Report which on purpose is modeled after
8 the Centers for Disease Control MMWR. It's
9 published on a monthly basis and there have been
10 100 issues of this published so far. The staff
11 does publish other articles. One of the things
12 Ms. Embrey really wants to see from the GEIS
13 program and from the Health Surveillance Center is
14 that we get more visibility in the peer-reviewed
15 literature.

16 One of our other key partners that I
17 didn't mention but came up before was the Military
18 Vaccine Organization, MILVAX. We have been
19 coordinating with them even before the ACAM 2000
20 vaccine was launched in February to assure that we
21 had the ongoing surveillance looks at the health
22 events associated that would be occurring among

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1 the cohort of service members who were receiving
Page 105

2 the new vaccine so that as we transition from the
3 Dryvax vaccine to the ACAM 2000 we could follow
4 the trends across time. As Colonel Anderson
5 mentioned, we're only in the second full month.
6 They started with ACAM 2000 exclusively on March
7 1, so we're only in the second full month, but
8 thanks to their foresight and preexisting
9 relationships, we had already started cranking
10 this back up before the transition. This is where
11 the serum repository is located. There is a
12 chance that we could get additional space within
13 this huge building and consolidate everything
14 here, so that's a possibility. We have about 43
15 million specimens on 8 million different
16 individuals collected since the late 1980s and
17 1990s and that's clearly a basis for a growth for
18 the Health Surveillance Center to do some more
19 ongoing surveillance using the serum repository.

20 Just a couple of words about the GEIS
21 program. For the Global Emerging Infections
22 Program, these are the infectious disease focus

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120

1 areas for the GEIS program, acute respiratory
2 disease, gastrointestinal disease -- infections
3 such as malaria, drug-resistant organisms and
4 sexually transmitted infections. The capabilities

5 that the GEIS program has focused have been in the
6 surveillance and detection arenas, response and
7 readiness, integration and innovation,
8 cooperation, and capacity-building. The modus
9 operandi of the GEIS program has been for the most
10 part building some innate capability within the
11 program itself but most of the funding goes to
12 external partners through an extensive network,
13 both what it's called, I think it's a great name,
14 they have two programs, the Influenza Program, and
15 they have something called EBI which is everything
16 but influenza which are the other things. But
17 both programs are operated very similarly in the
18 sense of coordination with Health Affairs and with
19 the combatant commanders around the world,
20 requests for proposals and funding of priority
21 issues within these areas.

22 Just a brief review of the GEIS program.

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121

1 It started in 1996 and the DOD's mission was
2 expanded. At the time it was a two-way street.
3 For the most part though the biggest emphasis was
4 that DOD would link arm in arm with other federal
5 agencies to combat emerging infections around the
6 world as part of a national effort. Again these
7 are the areas of surveillance training, research,
8 and response. Also though I think as part of that

9 and clearly fleshed out since 1996 was not only
10 what is DOD doing for emerging infectious diseases
11 around the world, but also what can the DOD GEIS
12 program do to assist the military health system in
13 terms of a force health protection mission for
14 emerging infectious surveillance and control
15 within the Department of Defense, so those two
16 missions of assisting the U.S. Effort for
17 worldwide partners as well as a force health
18 protection mission. This hasn't changed and this
19 is going to continue, but I want to point out one
20 thing in particular, that the DOD will strengthen
21 its global disease reduction efforts, again
22 global, and again particularly the President at

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122

1 that time pointed out the overseas laboratories.
2 I know the AFEB before the Defense Health Board
3 was very intimately involved with the support and
4 evaluation of the work of the Overseas Research
5 Laboratories and I'll say since 1996 the research
6 mission of those overseas laboratories has been
7 enhanced with the surveillance mission and now
8 some of these labs have about a fifty-fifty split
9 between the emerging infectious disease
10 surveillance mission and research.

11 This includes those countries in which

12 GEIS funded activities operate. Again, these are
13 not all operating out of Silver Spring, Maryland,
14 but through the worldwide partnership in 77
15 countries. This in particular since the flu
16 program started in 2006, we have a \$40 million pre
17 year DOD Influenza Surveillance Program that the
18 GEIS program operates and again through the
19 extensive network, it's an interesting combination
20 of military assets here. You see the overseas
21 laboratories of USAMUK in Kenya, NAMRU3 in Cairo,
22 NAMRU2 in Indonesia, AFRIIMS in Bangkok, and Naval

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123

1 Medical Research Command Detachment in Lima, Peru.
2 Those research entities are contributing their
3 part to influenza surveillance. A key piece, this
4 is the U.S. Air Force School of Aerospace
5 Medicine, but AFIOH is responsible for their
6 worldwide network of again collecting culture
7 specimens around the world and you heard yesterday
8 about the influenza strains that are contributing
9 to next year's vaccine and I believe, correct me
10 if I'm wrong -- but I believe the South Dakota
11 strain did come from one of the specimens that
12 AFIOH collected in a DOD beneficiary so that's
13 been a fairly routine occurrence. So this
14 surveillance network really is unmatched by any in
15 the world. The Centers for Disease Control has

16 nothing around the world like this. Where we're
17 expanding efforts, the area for expansion now is
18 going to be in Africa through AFRI COM. Colonel
19 Loren Erickson who is the Director of GEIS has
20 been very proactive and energetic in engaging the
21 combatant command surgeons and in particular with
22 the newly established AFRI COM.

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124

1 The other part of this slide I wanted to
2 point out is that not only do we have the research
3 laboratories, but also Landstuhl Regional Medical
4 Center in Europe, that's a medical treatment
5 facility, AFIOH 18th MEDCOM again is an Army
6 operational agency, and Naval Health Research
7 Center out in San Diego which operates the --
8 Respiratory Illness Surveillance programs on basic
9 training posts. One of the things in particular
10 that I viewed as very key is what were the
11 implications for the GEIS program now that it's
12 part of the Armed Forces Health Surveillance
13 Center and a couple of things I thought were true
14 is that certainly the vision and mission of the
15 GEIS program remains relevant and supportive.
16 GEIS headquarters certainly has a key piece to our
17 emergency response communication and coordination
18 functions. I mentioned the OCONUS laboratories,

19 and within the military health system, the
20 Emerging Infections Disease Surveillance, the --
21 Respiratory Illness Program, mortality work that's
22 done by the Armed Forces Medical Examiner's

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125

1 office, et cetera, that support will continue.
2 For the time being, the business process of
3 proposal submission and review and funding through
4 the network of partners will continue. The GEIS
5 website is still available and linked to the
6 AFHSC. We have www.afhsc.army.mil that is now the
7 AFHSC's website still operating and as funding
8 continues for the DOD's AIPi Pandemic Influenza
9 Surveillance Program, as long as that funding is
10 coming, we are going to continue to administer it
11 the way we have.

12 Again, one of the issues for me and for
13 the Force Health Protection Council who's my board
14 of governors is how to better integrate GEIS with
15 the other DOD surveillance programs and is one of
16 the key concerns of Ms. Embrey. Here are the
17 initial tasks, some are very bureaucratic in a
18 way, but we've got some paperwork to do in
19 updating some DOD directives and writing a DOD
20 instruction that helps us cement the Armed Forces
21 Health Surveillance Center as a DOD entity. We're
22 establishing the provisional operating capability,

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126

1 that's where I spend most of my time, because
2 these existing organizations have to continue to
3 do the work they've been doing. We're not giving
4 any time off so we continue to run. I've been
5 named the provisional director until next summer
6 and at that point there's going to be a
7 tri-service nomination process like we had for the
8 GEIS director where the future directors of the
9 AFHSC will be selected from tri-service nominees
10 and I'm supposed to provide a plan to achieve the
11 initial operating capability task to the Force
12 Health Protection Council by July 26. One of my
13 things as I mentioned earlier this week, I was
14 with the Air Force and I needed to work with the
15 Navy on how to transfer or at least make sure we
16 have the appropriate seams defined between what
17 the AFHSC does and what the services' surveillance
18 agencies will continue to do, namely, AFHSC is not
19 going to displace the function for example of a
20 Navy epidemiology team going aboard ship. There's
21 no way that I'm going to have people unless we're
22 invited, of course, and then we will come, but

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Page 112

1 clearly the service direct support functions are
2 going to remain with those surveillance agencies.
3 I think that's where I'll end and entertain
4 questions.

5 (Applause)

6 DR. POLAND: Nicely done. Thank you.
7 Questions?

8 DR. HALPERIN: As I recall the
9 organizational chart from yesterday that Colonel
10 Gibson and the staffing of the various committees,
11 I think that it's an odd match, but it's
12 occupational, environmental, and surveillance.

13 COL. DEFRAITES: Yes.

14 DR. HALPERIN: If that surveillance
15 means this surveillance, then we've got to figure
16 out a way to relate to what we've just heard and
17 figure out what our role is, whether it should be
18 ad hoc responsive or a visiting committee or what.

19 COL GIBSON: Let me address that if you
20 don't mind. Yes, it was an odd match we decided
21 as a Board to make that match. Historically we
22 had a requirement to do a review of GEIS.

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1 Obviously the Armed Forces Health Surveillance
Page 113

2 Center didn't exist at that point. But if you
3 notice the dates that Bob put up there, that was
4 just during the transition from the AFEB to here
5 so the decision was that we would not do a formal
6 obliged review recommendations to GEIS but to wait
7 until we were at a point where we had an Armed
8 Forces Health Surveillance Center and then talk to
9 ASDHA to codify a process, a formal relationship.
10 In addition to that, responding to the Armed
11 Forces Health Surveillance Center on an ad hoc
12 basis, that's part of our mission and we would
13 continue to do that if and when they asked
14 questions and want our opinion on either an
15 organizational issue or a technical issue relative
16 to surveillance. Does that answer the question?

17 DR. HAPERIN: Yes.

18 DR. POLAND: Joe?

19 DR. SILVA: Just a couple of quick
20 questions. Your monthly surveillance issue,
21 medical surveillance monthly report, can we get
22 access to that?

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129

1 COL. DEFRAITES: Yes. It's published on
2 the website.

3 DR. SILVA: It's on the website?

4 COL. DEFRAITES: But, yes, I'd love to

5 include all of the members. We do publish a
6 written paper copy.

7 COL GIBSON: Who on the Board doesn't
8 get it, because we've been sending it out. I've
9 asked Mark to send it to everybody.

10 COL. DEFRAITES: I think I've got
11 everybody's address. Isn't in the binder?

12 COL GIBSON: I asked Dr. Robitone to
13 include you on the distribution.

14 COL. DEFRAITES: You keep moving or
15 something.

16 DR. SILVA: Secondly, this serum
17 repository or other tissues, this is an incredibly
18 valuable resource. We have all kinds of people
19 exploring the genetics of man and other animals
20 and they're being posted in other countries where
21 they have excellent records like Iceland and it's
22 sort of protected. Can the civilian sector get

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130

1 entry to these samples for research?

2 COL. DEFRAITES: Some.

3 DR. SILVA: How do they do that?

4 COL. DEFRAITES: There is a process.

5 Generally, access to the serum repository is
6 limited to those proposals that meet several
7 criteria. One is an approved protocol with an
8 IRB, a military co-investigator to be named so

9 that there's some active-duty military co-
10 investigator who's actively involved in the
11 protocol. That's been our criteria up to now. I
12 think a lot of the operating characteristics of
13 the repository need to be reviewed, but that's
14 currently our approach right now.

15 DR. POLAND: It's only serum.

16 COL. DEFRAITES: It's just serum, yes.

17 DR. POLAND: So the genetics aspects are
18 difficult.

19 COL. DEFRAITES: There are some
20 proposals underway from USHUS (?) to look at what
21 genetic material might be available in the serum.

22 COL GIBSON: To quite Dr. Ennis, there's

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131

1 enough cellular filtrate at the bottom of those
2 tubes to do just about anything you want
3 genetically. I would comment that we talked about
4 this dioxin test -- serum repository. We ran
5 serum dioxins on a random group of 25 folks from
6 blood pre and post.

7 DR. LEDNAR: Bob, a really nice
8 description of this global network that you'll be
9 managing. My question is, as you're thinking
10 about the plan to operate this center, will that
11 include evaluating whether or not the

12 dissemination is reaching all of those places
13 throughout DOD that you'd like this information to
14 reach, that the action messages are clear and get
15 some feedback whether or not actions are
16 considered are implemented or not, and that the
17 products of the center from the eyes of the
18 customer are meeting the needs?

19 COL. DEFRAITES: Yes, I would be open
20 though to suggestions of how better to do that.
21 Right now I have no doubts of some of the readers
22 of the MESMA (?), for example, just to give you an

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132

1 example. I get phone calls and public affairs
2 officers get involved just about every month on a
3 regular basis and it's usually "USA Today," "Army
4 Times," and "Stars and Stripes" have questions
5 about articles or data they've seen in the MESMA.
6 So I know somebody's reading it and at least it's
7 getting somewhere. They're very good. And there
8 are a few others I get too. I am concerned about
9 who else might be reading it or not reading and
10 why and I'd be open to suggestions on how to do
11 that.

12 In terms of the other outcomes, I
13 mentioned all of these other clients or customers
14 of our products, for example, to generate policy
15 recommendations or to inform operations, the

16 feedback loop is indirect. I'm hoping that the
17 board of governors of the Force Health Protection
18 Council in their busy times, they have a lot of
19 things they have to do, but I'm hoping that that
20 venue, it's a two-star venue, the Deputy Surgeon
21 General, the Joint Staff Surgeon, and a few
22 others, at least a way to get entrée. But again,

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133

1 that's very close to the flagpole, very close to
2 the Beltway, and it doesn't answer your question
3 about the hinterlands. I think the partnerships
4 with these service surveillance agencies and their
5 reach and then the reach of the installations
6 helps to a great degree because the data we have
7 are generated locally.

8 DR. POLAND: Chris Ballard, and then
9 we'll move to Kevin.

10 COL. BALLARD: Just a couple comments
11 from a customer who's personally using the system
12 right now as I'm doing a thesis for my residency
13 on a population study, I want to piggyback that
14 the DMSS is an incredible database. Imagine doing
15 an historic population cohort or case control
16 studies on any medical diagnosis that's occurred
17 in the military over the past 15 to 20 years. You
18 streamline everything by having this database. As

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19 for the Air Force division, it's called PHSD, the
20 Population Health Surveillance Division. Sadly,
21 on a review when I was working at the DMSS, there
22 are only about 20 studies out on all of Medline

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134

1 that comment on anything on DMSS yet this database
2 has all of this historic data. One last comment
3 is unfortunately probably a little bit of a hole
4 in the database is if you want to drill down to
5 specific service specific populations, there's
6 difficulty getting data and the reason is that
7 once DMSS gets all the data, they convert all of
8 the ASFC's (?) or MOS's or duty codes to a DOD
9 general code. For instance, I'm doing my study on
10 fighter pilots and I can't pull the data from DMSS
11 because they do not have an Air Force specific
12 code for Air Force fighter pilots. It gets
13 combined with a few other pilots such as bombers.

14 DR. POLAND: Kevin?

15 DR. MCNEILL: I enjoyed your
16 presentation, Bob. I had the privilege to serve
17 on the recently published IOM report on the DOD
18 GEIS Global AIPI surveillance efforts. Actually I
19 was very surprised during the course of the
20 discussions how dependent the overseas laboratory
21 system has become on funding provided through the
22 DOD GEIS system to the extent that a very

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135

1 respected member of the group said that pretty
2 much the DOD funding was now the lifeblood of
3 these laboratories as a partial result of lower
4 levels of funding through their parent services,
5 primarily Army and Navy in terms of the overseas
6 labs. Frankly, looking at this on the surface,
7 this looks like a step away from the DOD level
8 organization that DOD GEIS is clearly now
9 recognized to be. It's becoming more of an Army
10 appearing organization under the CHIPM (?) and I
11 would like to know if there is any reassurance
12 that we on the Defense Health Board could get that
13 the current global medical surveillance mission
14 that is now being performed by DOD GEIS primarily
15 through the overseas laboratories will be
16 protected, will be appropriately emphasized, and
17 that this so-called ATM effect of collocating GEIS
18 with other programs, this was openly discussed at
19 the meeting in Bethesda in January, will not in
20 fact become a reality. I for one am very
21 concerned that we're about to lose a global public
22 health resource here in these overseas

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Page 120

1 laboratories. I think it's a sad day that these
2 laboratories have to depend on GEIS for funding.
3 I think that's the responsibility of the Army and
4 Navy medical R&D commands. Where are you guys?
5 But having said that, what's going to happen to
6 these labs?

7 COL. DEFRAITES: I see that Colonel --
8 DR. POLAND: I see that Colonel Jaffin
9 is here from MPMC. Just to reassure Dr. McNeill,
10 the oversight of the AFHSC is not from CHIPM. The
11 executive agency responsibility -- Army for the
12 care and feeding of the organization. The chain
13 of command goes back to Ms. Embrey and the Force
14 Health Protection Council's joint council is the
15 oversight body. I think that board of governors
16 is there to assure that there's a DOD mission
17 that's being preserved and it's not Army only. I
18 would say to its credit the Army has put up most
19 of the assets so far. That's one of the reasons I
20 went to see the Air Force this week too. There
21 are some checks in the mail from the Air Force.

22 MAJ. GEN. KELLEY: I think that it's an

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1 overall plan to get there and I don't think that
Page 121

2 there's any intention to decrease the surveillance
3 capability. As a matter of fact, the idea is to
4 centralize the surveillance capability so that
5 things like MILVAX when you're talking about
6 what's happening in the world has a single source
7 to go to to get the information. That works in
8 many different ways. The other services as Dr.
9 DeFrait es said were concerned that it was going to
10 be Army centric and they did not initially kick in
11 as much people and resources. But I think that
12 it's going and the idea would be to show its value
13 as a DOD resource and then the other services
14 could decrease their service specific requirements
15 for doing their own surveillance because you've
16 had a system in place that could tell you service
17 specific data but not have to have a separate
18 system for that service.

19 DR. POLAND: Mark and then the two
20 Mikes.

21 DR. MILLER: This is a related question
22 to Kevin's. You mentioned that GEIS is funded

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138

1 with influenza funds and that makes sense given
2 the rapidly transmissible nature of influenza and
3 other like viruses. I'm curious though about the
4 long-term funding and whether or not that's just

5 due to the flavor of the month type of funding or
6 whether or not there is long-term secure funding
7 for diseases such as influenza.

8 COL. DEFRAITES: The funding for GEIS
9 for the base program, that's the EB (?) program,
10 is stable through what we call the pom (?) years,
11 that's fiscal 10 through 15, at about \$12 million
12 dollars. The flu program right now was a
13 supplemental started in FY 06. That level of
14 funding for flu surveillance specifically is
15 locked in for FY 09. They're still discussing now
16 and still making decisions as to what the
17 appropriate amount is going to be through the pom
18 years, the fiscal years 10 through 15, and I have
19 not heard the final answer on what that number is.
20 These things get built up and then the decision
21 has to be made from a big perspective of which of
22 these enhanced programs do you need to maintain

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139

1 and at which level. I think the base program is
2 safe, is secure it looks like through the
3 foreseeable future, the flu program is still being
4 worked on in terms of what level of funding.

5 DR. POLAND: We're running about a
6 half-hour behind now and I'm cognizant of how many
7 of you have come up to me saying we got to move
8 along because of airplanes. So please very brief

9 comments and answers that can't be handled at the
10 subcommittee level which we're planning at lunch.
11 So if it's crucial, please go ahead, if not, hold
12 it.

13 DR. PARKINSON: Just a formal request
14 following Dr. Silva's comment. I think it's time
15 given the increasing federalization of our effort,
16 Dr. Cassell's attempt to get AHRQ and other
17 players involved, that we take a systematic review
18 of both the tissue repository and the serum
19 repository, their history, capability, current
20 operations procedures, and potential to advance
21 both the DOD and federal missions. I'll just put
22 that on the agenda. I think it would be a great

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140

1 time in the history of the DHB to do that.
2 DR. OXMAN: I'd like to point out
3 something and also question something. First of
4 all, because of the strength of the overseas
5 laboratories, the President tasked DOD with the
6 main responsibility for the whole country's
7 surveillance for emerging diseases, so not just
8 influenza, for emerging diseases although the
9 funding because of the timing came from influenza.
10 You mentioned when you presented to us a few
11 minutes ago that the future of surveillance in

12 GEIS would depend on what happens to that \$40
13 million. I for one had hoped that that would be
14 transitioned into a basic equivalent funding level
15 from DOD as a whole to underwrite that those gems
16 of the overseas laboratories which are really most
17 of the assets that we have outside the United
18 States in terms of surveillance for emerging
19 infectious diseases. So rather than have a
20 statement it depends on what happens with those
21 resources, that lifeblood of \$40 million, not just
22 \$12 million, depends on what Congress decides to

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141

1 do. I think there's a more important issue and
2 that is that DOD really needs to consider what it
3 will do to assure that there is a steady and level
4 funding that's independent of the flavor of the
5 month.

6 COL. JAFFIN: One of the things MRMC
7 very much acknowledges and appreciates is the
8 support for the overseas laboratories. We view
9 them also as real gems and unique assets that the
10 military brings to the table. Ms. Embrey has
11 been very involved at the Health Affairs level at
12 looking at how we can increase support to the
13 overseas laboratories. We have tried to increase
14 the pom slice for the overseas laboratories from
15 the MRMC perspective and working with the

16 Assistant Secretary of the Army for acquisitions,
17 logistics and technology, as well as AT&L within
18 the DOD to get more funding as well for them, and
19 also looking at other federal partners to try and
20 leverage that money as well. So we're very
21 actively looking for ways to fund them. In tight
22 money times unfortunately things get tough.

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142

1 DR. POLAND: I think we'll have to stop
2 there. Thanks, Bob, very much. The next briefing
3 is going to be Colonel Jim Neville who will bring
4 the Board up to date with changes in the Air Force
5 public health structure and I'm sure the Board
6 will see in this effort how this effort and the
7 AFHSC are aligned.

8 COL. NEVILLE: Thank you. Like Colonel
9 DeFrait es, it's an honor for me to be here and I
10 appreciate your allowing me a few minutes to go
11 through this reorganization. It's focused on the
12 School of Aerospace Medicine and what used to be
13 AFI which I'll describe a little bit more, an
14 organization one level higher.

15 Here is the outline. I'll first talk
16 just briefly about why this was done. It's
17 largely BRAC driven in a way. The Performance
18 Wing organization components, a little bit about

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19 the wing itself and then a quick summary. I'll
20 emphasize that the School of Aerospace Medicine
21 which is the organization I belong to now as
22 opposed to these others, and just a quick notes

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143

1 about USAFSAM.
2 The 2005 BRAC directed the creation of a
3 joint Aerospace Medicine Center of Excellence at
4 Wright-Patterson Air Force Base. It did not
5 describe how that Center of Excellence should be
6 organized so subsequent deliberations ended up
7 with the creation of a new wing in the Air Force
8 called the 711th Human Performance Wing. The idea
9 for this Center of Excellence was to use what's
10 been called the university model which I'll
11 describe in the next slide in a little bit more
12 detail. The university model combines education
13 and training, research, and what we're calling
14 operational consultation. Those three legs of the
15 triangle I suppose is the university model.

16 The organizations that were put together
17 to create this Human Performance Wing include the
18 Human Effectiveness Directorate of the Air Force
19 Research Lab, AFRL, formerly known as AFRLHE and
20 now it's AFRLRH, and now it's HPWRH and that's the
21 form science and technology organization. The Air
22 Force Institute for Operational Health which we've

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144

1 had has been disestablished or inactivated and all
2 the missions and resources rolled into the Air
3 Force School of Aerospace Medicine. So that
4 doesn't exist anymore and it's all USAFSAM now.
5 This is largely, but not exclusively DHP program
6 funded. Then a smaller Performance Enhancement
7 Directorate otherwise known as the Human
8 Performance Integration Directorate, maybe 20
9 folks or so, from Brooks is also part of this new
10 Human Performance Wing. The Navy Medical Research
11 Lab or parts of it from Pensacola are moving up to
12 Dayton, but a separate reporting chain, so that's
13 one reason it's going to be a Joint Center of
14 Excellence in Aerospace Medicine.

15 Just a little bit about the university
16 model again. These three main domains of work or
17 mission, research and development which again is
18 largely program six S&T but not exclusively S&T,
19 education and training which is historically the
20 mission of the School of Aerospace Medicine, and
21 operational consultation which has historically
22 been the focus of AFIOH. So generally AFIOH,

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Page 128

1 generally the School of Aerospace Medicine,
2 generally -- bring those all together and that
3 constitutes the wing. That doesn't mean that the
4 school doesn't do any consultation or research, it
5 doesn't mean that AFIOH didn't do any training,
6 but largely AFIOH, USAFSAM -- are all under the
7 same organization and each one of those missions
8 can be done more effectively and efficiently when
9 they're all in the same organization and all
10 feeding off each other, research feeding the
11 instructors, feeding the consultation consultants
12 and so forth. That's the theory, and we're pretty
13 excited about making that happen.

14 Of course, in the Dayton area is not out
15 in the middle of nowhere, there are a lot of other
16 Air Force certainly and other community assets
17 there that will be brought to bear to make these
18 things all work better, the Air Force Institute of
19 Technology which is an advanced degree scientific
20 educational institution there on Wright-
21 Patterson, the Air Force's major weapons systems
22 acquisition community is on Wright-Patterson, and

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1 of course the local community there plays a role
Page 129

2 as well.

3 Just a quick couple of slides on the

4 other two major pieces of the Human Performance

5 Wing, and then I'll talk more about the School of

6 Aerospace Medicine. This is the Human

7 Effectiveness Directorate, the AFRLRH it used to

8 be called, and their focus is on human

9 effectiveness, nonclinical, nonmedical kind of

10 research, but focusing on things like the

11 psychology of human decision making. They have a

12 pretty big investment in directed energy,

13 bioeffects, and counterproliferation technologies.

14 They're spread out between Brooks, Mesa, Arizona,

15 and Dayton. All of those mission are

16 consolidating at Wright-Patterson with the BRAC.

17 The other one, this is a smaller one, 10 to 20

18 folks headed by a pilot physician and that's the

19 Human Performance Integration Directorate. They

20 focus on assuring that the human factor is

21 integrated in acquisition programs, man-machine

22 interfaces and so forth, and the training and

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147

1 policy doctrine related to all that.

2 The School of Aerospace Medicine,

3 combining AFIOH and all USAFSAM into a new USAFSAM

4 or the really new USAFSAM. This is the vision.

5 The mission includes education and training of all
6 the Team Aerospace. The way we use that in the
7 Air Force is not just pilots and the flight crew
8 and medical issues related to them, but also the
9 nonclinical aspects of occupational medicine,
10 industrial hygiene, and public health, physiology,
11 those are all wrapped up in the aerospace in how
12 we use that term in that Air Force. So the School
13 of Aerospace Medicine instructs all those
14 specialties, enlisted and officer, and conducts
15 ongoing training for those specialties as well.
16 Our goal of course is to create a world-class
17 Center of Excellence that does all these things
18 and to make the transitions that we're undergoing
19 right now with the organizational changes as well
20 as the BRAC planning to physically move the
21 location from San Antonio, to Dayton, Ohio, to
22 make sure that the services that are provided to

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148

1 their customers and clients throughout that time
2 are transparent and maintained and take advantage
3 of this new organization of the university model
4 including research and operational consulting and
5 education and training to make all three of those
6 work better.

7 The next five slides just real quick are
8 the main departments of the Air Force School of

9 Aerospace Medicine. The Aerospace Medicine
10 Department focuses on the clinical aspects of
11 fliers. So the Air Medical Consult Service is one
12 of the main aspects of this department. When a
13 pilot or flight crew has any medical issue that
14 might be odd, not odd, maybe threatening to their
15 careers as aviators, they come to the school and
16 get that figured out. The history is that 80
17 percent of those people get returned to the
18 cockpit. They also field questions from flight
19 surgeons and others around the world with
20 questions related to the flying community and
21 health aspects of that. They do some education
22 and training in physiology and aeromedical

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149

1 operations that go on at the base level. And also
2 advanced training programs on aerospace medicine
3 are handled out of here.

4 The next department, International and
5 Expeditionary Education and Training at the School
6 of Aerospace Medicine conducts most of the
7 expeditionary medical skills training for the Air
8 Force including the critical care air transport
9 teams. There is CSTARS (?) which is
10 geographically separated locations in Cincinnati,
11 Baltimore, and St. Louis, where trauma skills are

12 polished before people deploy, so expeditious
13 medical training is managed out of the School of
14 Aerospace Medicine. This department also exports
15 courses to different countries and brings in
16 foreign nationals to go through training at
17 USAFSAM. In the previous slide, too, a lot of
18 aerospace medicine experts in a variety of
19 countries have been trained at USAFSAM. I can't
20 remember, but the number is something like 80 of
21 the other countries' surgeons general have been
22 trained at USAFSAM over the course of its history.

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150

1 The Department of Occupational and
2 Environmental Health focuses its efforts on health
3 hazard assessment, education, and training first
4 of all, and also consultation both receiving phone
5 calls if you will for questions as well as going
6 out to bases and sites to do work that's needed
7 for the Air Force. We also have the chemistry lab
8 and the Air Force Radiation Assessment Team that
9 are housed in this department. And of course,
10 24/7 phone calls for answering consults from
11 around the Air Force.

12 The Department of Public Health and
13 Preventive Medicine is where all the epidemiology
14 support goes and what we used to think of as the
15 Air Force's operational public health surveillance

16 hub is now in this department. We're calling it
17 USAFSAM because that's the organizational home,
18 but the Epidemiology Services folks, the clinical
19 reference lab is here, and the surveillance
20 program is placed here and a deployable
21 epidemiology team.

22 Then of course you have the Office of

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151

1 the Dean that takes care of all the school stuff
2 that needs to be done which is a fair amount of
3 work when you have 5,000 students rolling through
4 the school in any one year with a whole variety of
5 courses. I should probably know the numbers, but
6 there are several hundred courses that go on in
7 each year, and maintaining accreditation and so
8 forth.

9 Just a quick snapshot of the scope of
10 the Human Performance Wing. This is FY 06, I
11 don't have FY 07, unfortunately, it's roughly the
12 same in FY 07, maybe a little less, the bulk of it
13 of course is the Science and Technology Program
14 Six funding and this is mostly but not all DPH
15 funding. Almost 1,300 people that doesn't include
16 the extras, if you will, and quite a variety
17 separate operating locations including a couple
18 overseas. In mind there's a unique mix of

19 manpower skills that the school has. And MILCON,
20 military construction, which has been awarded last
21 week, sometime hopefully in May or June they'll
22 start turning dirt there at Wright-Patterson that

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152

1 brings all those organizations into the same
2 complex. There are still going to be some
3 operating locations separately, but the main bulk
4 of organizations will be in the same suit of
5 buildings which will be nice. It's a pretty large
6 effort there. And hopefully if all goes well that
7 building will be available May or June 2011, about
8 the same time that we have to depart Brooks. So
9 planning for that transition and the phasing of
10 all that is the challenge we're faced with right
11 now. It will be a nice new facility with labs and
12 the whole thing.

13 The vision of course, and I have
14 mentioned this before, is to be the world leader
15 in human performance defined broadly, the Center
16 of Excellence in Aerospace Medicine, collocating
17 all these functions will make it all work better,
18 state-of-the-art facilities, we're pretty excited
19 about that with altitude chambers, a new
20 centrifuge which may take a few more years to put
21 in place, but a brand new facility will be
22 exciting for us. Then we're trying to make all

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153

1 these transitions transparent to the customer and
2 I keep telling myself good luck because it's going
3 to be a challenge to do that. So this is all on
4 track. There are lots of details of course with
5 BRAC and that's not news if I say that, but it's
6 all working slowly toward fruition sometime in the
7 summer of 2011.

8 In summary, we feel this is a great
9 opportunity to enhance all three of those mission
10 areas I described. We're in the middle of trying
11 to work through some of the details of the
12 organizational structure which is no big deal, but
13 it will take some time to do that, and we're
14 looking forward to it. I think that's the last of
15 it, and if there are any questions, I'd be happy
16 to answer.

17 DR. POLAND: Just a little historical
18 note, I think the first human centrifuge was built
19 at Mayo Clinic in association with the predecessor
20 of the Air Force and the flight suit first
21 developed there.

22 DR. PARKINSON: Jim, a great

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Page 136

1 presentation. In many ways it's kind of back to
2 the future, bringing back in the public health
3 function of the School of Aerospace Medicine. Not
4 necessarily for immediate response, but just a
5 thought, the model of associating the
6 Wright-Patterson functions with a civilian
7 university seems to be if not a new model an
8 extension of a model that doesn't really exist
9 much of anywhere else in DOD. As we look for best
10 practice models when all federal agencies are
11 short of money and there's a lot of duplication,
12 when you got the VA that for years has had close
13 partnership with academic medical centers for good
14 or for ill, there may be some intellectual work in
15 here to say what does a best practice model look
16 like for a military-civilian-academic
17 collaboration based on either your experience or
18 experience going forward because clearly with
19 earmarks coming from Congress with directed DOD
20 money one way or another going to civilian-
21 academic institutions, we're kind of going there
22 de facto anyway through the will of Congress. So

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1 just a reaction and a thought going forward, maybe
Page 137

2 there is some work around the DHB to think about
3 what looks like a real model that you're building
4 as we speak or a desirable model that's out there
5 that hasn't been articulated yet because this is
6 different I think. Your reaction to any of that
7 would be welcome, but I think it's qualitatively
8 different.

9 COL. NEVILLE: I think it is different
10 than others and maybe that's one reason it was
11 designed that way. How to actually implement some
12 of the vision remains to be seen in my mind. I'm
13 not in charge of it all of course, but, for
14 example, how do we hire an officer into this
15 organization? Is that officer's time supposed to
16 be spent 20 percent teaching, 20 percent research,
17 60 percent consulting? Or is that person an
18 instructor and another person a researcher? I
19 think that's one detail of an example of how to
20 implement this thing when it gets to the
21 individuals and the expertise and whole career
22 field and so forth remains to be seen.

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156

1 MAJ. GEN. KELLEY: Mike, I'd just make a
2 comment. That's not a common concept, but it's
3 the model that's in place already at
4 Wright-Patterson. The medical center commander is

5 on the executive committee of the medical school
6 to ensure the integration of the programs. So the
7 programs are combined and I think that that move
8 will go easier because there's a model in place
9 that does that for the more typical clinical
10 specialties.

11 LTC. SILVER: Thank you for the
12 presentation. I think this is a move in the right
13 direction particularly if the Department of
14 Defense eventually wants to nourish good research
15 programs whatever its missions are. On the slide
16 on Office of the Dean, I would encourage you, one
17 critical thing that occurs in most universities
18 where there's active research is that the faculty
19 have to define who's qualified and also the
20 evaluation of faculty in terms of research. You
21 shouldn't join for 20 years support if you're only
22 doing one publication a year. So there has to be

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157

1 some conceptualization of targeting the faculty at
2 steps, maybe an academic entitlement, and the
3 concept is tenure, that you got to work in a
4 productive way, and others around the table have
5 survived the tenure system.

6 DR. POLAND: Thank you very much. We're
7 going to keep moving here. The last speaker of
8 the day is John Clements. He's going to provide

9 us with a brief regarding recommendations for
10 development of guidelines for the use of
11 convalescent plasma for pandemic influenza. You
12 may recall at the last meeting of the Board we
13 recommended that DOD pursue development of these
14 sorts of guidelines in the event of a pandemic and
15 since then our Pandemic and Influenza Preparedness
16 Work Group served as a forum for bringing together
17 experts to discuss how such guidelines might be
18 developed and John will update us on that and the
19 recommendations that are coming out of that.

20 DR. CLEMENTS: The operational phrase
21 here is brief. This is in fact a continuation of
22 a dialogue that we've been having a pandemic

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158

1 preparedness and this is one more option in the
2 arsenal of weaponry that we can bring to bear in
3 the event of a pandemic event. I'll just point
4 out, and I think we all know this but it bears
5 repeating in that when we think about pandemic
6 influenza we're not just talking about H5 although
7 we have discussed H5 extensively and it certainly
8 was on our minds as we were having this
9 conversation. So I always start with the bottom
10 line. It saves us a lot of time. The
11 Subcommittee urges DOD to consider development of

12 convalescent plasma therapy as part of the
13 national pandemic influenza plan and as an
14 important adjunct with other treatments. The
15 Subcommittee further emphasizes the development of
16 convalescent plasma therapy as a national effort
17 and the Department should co-partner in this issue
18 with our other leading national health
19 organizations.

20 By way of background, the cause of the
21 limited H5/N1 vaccine production because of
22 resistance to tamivir and other antivirals and the

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159

1 possibility that a different influenza strain may
2 emerge as a pandemic strain, the use of
3 convalescent plasma therapy and its application
4 for pandemic influenza were considered by members
5 of the DHB Subcommittee. This meeting took place
6 on February 5 and 6, 2008.

7 The rationale for us to consider
8 convalescent plasma therapy is that active-duty
9 personnel are at risk for exposure to natural or
10 bioterror infectious disease epidemics, and in
11 particular with respect bioterror epidemics, it
12 is entirely possible to engineer potential
13 bioterror strains around existing vaccines, and
14 there are other issues for which novaxins
15 currently exist. DOD has the capacity to collect,

16 produce, and transfuse large volumes of
17 convalescent plasma for military personnel and
18 convalescent plasma can be used with the DOD and
19 civilian populations. I would also point out that
20 this is not a new concept. Convalescent plasma
21 therapy has been used extensively in this country
22 and elsewhere for quite some period of time. It's

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160

1 been used successfully with scarlet fever, rocky
2 mountain spotted fever, pertussis, measles, mumps,
3 polio, influenza, and a variety of other diseases.
4 The NIH has ventured into this area as well and
5 has established programs in convalescent plasma
6 therapy for anthrax and also for H5, and we also
7 have the issue with immune globulin. So this is
8 something with which we have a great deal of
9 experience. It is a safe technology and we think
10 it has application as an additional component.

11 There were eight presentations to the
12 Subcommittee on February 5. Dr. Autoro Duval
13 gave us an historic perspective on the use of
14 convalescent plasma, serum, and blood products.
15 Dr. Luke then followed up with his blood products
16 for Spanish influenza and pneumonia. You will
17 recall that Dr. Luke did a very extensive and
18 highly regarded meta analysis of the use of

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19 convalescent plasma for Spanish influenza. Dr.
20 Enriat presented the national program to treat
21 Argentine hemorrhagic fever virus with
22 convalescent plasma. Dr. Trainer talked about

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161

1 human antibody responses after recovery from H1,
2 H3, and H5 influenza or from vaccination. And the
3 other possibility is that we can use plasma from
4 individuals who have been successfully vaccinated
5 and not just convalescent.

6 Dr. Lightman talked about observations
7 from the Transfusion Medicine Medicine Service at
8 the National Institutes of Health. Dr. Katz
9 talked about convalescent plasma production from
10 an industry perspective. We heard from Dr.
11 Williams about regulatory issues associated with
12 production and use of convalescent plasma. And
13 finally, Dr. Hoffman on clinical guidelines, data
14 collection and reporting, and IND applications
15 from the FDA.

16 That led to a series then of national
17 and DOD specific recommendations, and I'd just
18 like to talk about those very briefly. The first
19 national recommendation that there be someone, and
20 it wasn't the Defense Health Board, we kind of
21 tossed this back to Autoro Duval and to Commander
22 Luke to work on, publish a peer-reviewed article

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162

1 discussing alternative therapies for pandemic
2 influenza focusing on convalescent plasma therapy
3 with collaboration from members within DOD. The
4 article should provide established knowledge,
5 current gaps in knowledge, guidance and awareness
6 on convalescent plasma therapy to health care
7 communities at a national level.

8 The second national level recommendation
9 was the establishment of regional blood banks as
10 control points for plasma collection to ensure the
11 availability of plasma to individuals requiring
12 plasma therapy. The committee considered that the
13 existing regional blood banks would be the right
14 point for national level collection because they
15 have the facilities already in place.

16 The next recommendation was that DOD act
17 as a vested partner with other leading national
18 public health institutions to contribute to the
19 development of national standardized guidelines
20 for using convalescent plasma therapy as an
21 alternative in pandemic influenza, and would
22 further investigate applications of convalescent

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Page 144

1 plasma therapy for use with other infectious
2 diseases where no known alternatives existed. And
3 the final national level recommendation was the
4 identification of gaps in capabilities for plasma
5 collection, distribution, and tracking. In this
6 case we felt that DOD could work as a partner in
7 an interagency group to identify gaps and
8 capabilities for efficiently distributing and
9 implementing.

10 The DOD-specific recommendations, and
11 this goes back to something that we've talked
12 about as well, we have an issue with adenovirus
13 for instance for which there are no existing
14 appropriate vaccines. There are some in the
15 pipeline, but adeno is a moving target that the
16 DOD should propose and carry out research
17 initiatives for the purpose of providing data and
18 information about convalescent plasma therapy's
19 effectiveness against adenovirus, also determine
20 the logistical processes and appropriate equipment
21 involving treatment with convalescent plasma
22 therapy and much as we use the existing seasonal

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1 influenza immunization as a model for pandemic
Page 145

2 immunization, implementing this with adenovirus
3 would also give the DOD a way of establishing
4 processes and procedures that could be put into
5 place for other infectious diseases. The DOD
6 should identify gaps and capabilities within DOD
7 to effectively implement convalescent plasma
8 therapy within the services. Finally, that the
9 DOD should consider utilizing these guidelines
10 beyond pandemic influenza and implement
11 convalescent plasma therapy as an alternate
12 treatment for novel, natural, or man-made
13 bioagents or novel emerging biological threats in
14 future research and practices.

15 The conclusions of the committee, the
16 Subcommittee concluded that a national effort is
17 essential to explore convalescent plasma therapy
18 as an adjunct treatment. The DOD in its national
19 security role has a stake in ensuring that
20 guidelines and infrastructure are in place within
21 the department if use of convalescent plasma is
22 needed. And finally, the Subcommittee concluded

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165

1 that within the national context of an approach to
2 convalescent plasma therapy that DOD is not and
3 should not serve as the lead effort, that the DOD
4 has a vital stake and interest in acting as a

5 copartner with other national health organizations
6 such as CDC, DHS, and NIH. Then just the
7 disclaimer that in preparing these
8 recommendations, the Subcommittee engaged in
9 regular discussions and received a series of
10 briefings by experts from NIH, CDC, the National
11 Vaccine Program, Office of the FDA, DOD, among
12 others. So those were the findings of the
13 Subcommittee that met in February and our report
14 back to the Infectious Disease Subcommittee and
15 recommendations to the Board.

16 DR. POLAND: Thank you, John, and let me
17 publicly acknowledge, John, I couldn't physically
18 be at the meeting, I participated by
19 teleconference, and John masterfully ran what
20 turned out to be a very large meeting with a lot
21 of national interest in it. Again apropos of how
22 the Board will work, there are recommendations now

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166

1 coming back from the Subcommittee to the Board for
2 discussion and approval. They have been
3 previously circulated too. Comments?

4 DR. OXMAN: I think it's a superb report
5 and actually many of us have discussed it already
6 so if we don't spend a lot of time discussing it,
7 I'm ready for it to be adopted.

8 DR. POLAND: No other comments? All
Page 147

9 those in favor? I think we did it. I had some
10 minor grammatical and other comments on there, but
11 that was all. We did it. Thank you again, John.
12 Are there any other questions or comments? Russ
13 had a comment that I was going to ask him to make,
14 but are there any others so we can plan our time
15 here? Russ?

16 DR. LEUPKER: Just a quick suggestion
17 and thought. I think I like many of you here
18 picked up the paper this morning, the Tacoma
19 paper, and saw some of the very issues that have
20 taken this committee's time. We had a number of
21 presentations last year on suggestions and
22 recommendations for mental health services. I

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167

1 would like to hear some follow-up on what's
2 progressed since then because it hasn't gone away
3 as an issue obviously.

4 COL GIBSON: The Psychological Health
5 Subcommittee is standing up and literally Dr.
6 Cassells will make the nominations for those
7 members Monday. You heard from the Center of
8 Excellence on Psychological Health and TBI. What
9 you will hear the next time we meet is what they
10 got done, where they're going specific to
11 psychological health issues and the outcomes, not

12 only the due-outs, but the progress that the
13 department has made in the area of psychological
14 health which is what the department is using to
15 encompass the whole breadth of mental health
16 issues.

17 DR. LEUPKER: If you could add to that
18 list the issue of public health surveillance.
19 Essentially it seems like the controversy is about
20 a failure of public health surveillance to provide
21 accurate --

22 DR. POLAND: I don't know the details of

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168

1 this, but I would urge us, and it's not to
2 diminish the point made at all because it's
3 vitally important, but let's not rush to judgment
4 based on the media reports yet and get the full
5 details. As one said, we seem to have moved from
6 evidence-based medicine to medical-based medicine
7 in many aspects of our culture. But Bill and Russ
8 bring up an important point that deserves
9 additional work by this Board. Are there other
10 comments? If not, then for lunch we'll have the
11 ID Subcommittee eat together and have a
12 discussion. I want to thank everybody for their
13 participation and forbearance as I tried to move
14 the meeting along and keep us on track, so I
15 apologize if there's anybody that I didn't get to.

16 And I'll ask Dr. Kelly to adjourn the meeting.

17 SECRETARY KELLY: The meeting of the
18 Defense Health Board is adjourned. Thank you all
19 for attending. I appreciate all the presentations
20 and especially thank you for your support to the
21 Defense Health Board and everything that it means
22 to us in the Department of Defense. Thank you

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169

1 very much.

2 (Whereupon, at 1:30 p.m., the
3 PROCEEDINGS were adjourned.)

4 * * * * *

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