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UNITED STATES OF AMERICA
DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

OPEN SESSION

Annapolis, Maryland
Wednesday, September 27, 2006

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Phone (703) 519-7180 Fax (703) 519-7190

1 PARTICIPANTS:
2 AFEB Board
3 DAN G. BLAZER, M.D., M.P.H., Ph.D.
4 Duke University Medical Center
5 JOHN DAVID CLEMENTS, Ph.D.
6 Chairman, Department of Microbiology and
7 Immunology, Tulane University School of Medicine
8 WILLIAM E. HALPERIN, M.D., M.P.H. Chair,
9 Department of Preventive Medicine University of
10 Medicine and Dentistry of New Jersey
11 EDWARD L. KAPLAN, M.D.
12 Department of Pediatrics University of Minnesota
13 Medical School
14 TAMARA D. LAUDER, M.D.
15 Physical Medicine and Rehabilitation Ministry
16 Medical Group
17 WAYNE M. LEDNAR, M.D., Ph.D.
18 Vice President and Director Corporate
19 Medical Eastman Kodak Company
20 RUSSELL V. LUEPKER, M.D.
21 Mayo Professor of Epidemiology Head, Division of
22 Epidemiology School of Public Health University of
23 Minnesota
24 KEVIN MILES MCNEILL, M.D., Ph.D.
25 State Epidemiologist, Mississippi
26 Department of Health Clinical Professor of
27 Preventive Medicine, University of Mississippi
28 School of Medicine
29 MARK A. MILLER, M.D.
30 National Institutes of Health
31
32

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1 PARTICIPANTS (CONT'D):

2 MICHAEL D. PARKINSON, M.D., M.P.H.
3 Executive Vice President Chief Health and Medical
4 Officer Lumenos

5 GREGORY A. POLAND, M.D.
6 Director, Mayo Vaccine Research Group
7 Translational Immunovirology and Biodefense

8 MARY LOWELL LEARY
9 Professor of Medicine Mayo Clinic and Foundation

10 NICOLAAS P. PRONK, M.D.
11 Health Partners Center for Health Promotion

12 ADIL E. SHAMOO, Ph.D.
13 Department of Biochemistry and Molecular
14 Biology University of Maryland School of Medicine

15 JOSEPH SILVA, JR., M.D.
16 Dean's Office School of Medicine University of
17 California

18 DAVID H. WALKER, M.D.
19 Department of Pathology University of Texas
20 Medical Branch

21 Board Consultants

22 JACQUELINE ANN CATTANI, Ph.D.
Director, Center for Biological Defense Department
of Environmental and Occupational Health College
of Public Health University of South Florida

PIERCE GARDNER, M.D.
National Institutes of Health

Ex-Officio Members

MARK H. BROWN, Ph.D.
Director, Environmental Agents Service Office of
Public Health and Environmental Hazards Department
of Veterans Affairs

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1 PARTICIPANTS (CONT'D):

2 J. TODD WEBER, M.D., F.A.C.P.
3 Captain, U.S. Public Health Service Director,
4 Office of Antimicrobial Resistance National Center
5 for Infectious Diseases Centers for Disease
6 Control and Prevention

7 ELLEN EMBREY
8 Deputy Assistant Secretary of Defense Force Health
9 Protection and Readiness

10 Board Staff

11 COL. ROGER L. GIBSON, Ph.D., D.V.M., M.P.H.
12 Executive Secretary Office of Assistant Secretary
13 of Defense for Health Affairs Preventive Medicine
14 Liaison Officers and Consultants

15 CDR. DAVID C. CARPENTER, CFMS
16 Assistant Defence Attache - Health Affairs
17 Canadian Defense Liaison Staff (Washington)

18 LCDR. TOM LUKE, MC,
19 USN Deputy Director, Preventive Medicine and
20 Occupational Health U.S. Navy Bureau of Medicine
21 and Surgery

22 LCDR. ERICA SCHWARTZ, USPHS
Preventive Medicine/Epidemiology Consultant U.S.
Coast Guard Headquarters

CDR. DAVID L. MCMILLAN,
MC., USN. Preventive Medicine Officer
Headquarters, U.S. Marine Corps

LTC. WAYNE HACHEY
USAMC Program Director, Preventive Medicine and
Surveillance Office of Assistant Secretary of
Defense for Health Affairs

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1 PARTICIPANTS (CONT'D):
2 COL. PRISCILLA BERRY
3 USA MC Medical Staff Officer Office of Assistant
4 Secretary of Defense for Reserve Affairs
5 COL. MICHAEL SNEDECOR
6 USAF, MC Chief, Preventive Medicine Department of
7 the Air Force
8 CAPT. DR. RICHARD JOHNSTON
9 USMR4 British Liaison Officer British Embassy
10 MAJ. RANDY SMITH
11 MS, USA Joint Staff Action Officer Joint Staff
12 Preventive Medicine
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1 P R O C E E D I N G S

2 DR. POLAND: Good morning, everybody. I
3 think we'll get started. We've got a pretty full
4 day's schedule, so please take your seats.

5 Ms. Embrey, would you please call the
6 meeting to order?

7 MS. EMBREY: Yes. As the Designated
8 Federal Official for the Armed Forces
9 Epidemiological Board, a federal advisory
10 committee to the Secretary of Defense which serves
11 as a continuing scientific advisory body to the
12 Assistant Secretary of Defense for Health Affairs
13 and the Surgeons General of the military
14 departments, I hereby call this meeting to order.

15 DR. POLAND: Thank you. I do want to
16 recognize our distinguished guests. Major General
17 Joseph Kelley is here; Rear Admiral Paul Higgins,
18 and Captain Neil Naito.

19 It is an open session this morning, so
20 before we begin, we'll go around as we did
21 yesterday and have the Board and distinguished
22 guests introduce themselves. That will be

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1 followed by Colonel Gibson making some
2 administrative remarks. So, Ms. Embrey, if we can
3 start with you.

4 MS. EMBREY: I'm Ellen Embrey. I'm the
5 Deputy Assistant Secretary of Defense for Force
6 Health Protection and Readiness, and also the
7 Designated Federal Official.

8 MGEN. KELLEY: I'm Joe Kelley, the Joint
9 Staff Surgeon.

10 MS. MacDERMID: I'm Shelley MacDermid,
11 Co-Chair of the Department of Defense Mental
12 Health Task Force.

13 DR. CATTANI: Jackie Cattani, Professor
14 of Public Health and Director of the Center for
15 Biological Defense at the University of South
16 Florida in Tampa.

17 DR. CLEMENTS: John Clements. I'm Chair
18 of Microbiology and Immunology and I do vaccine
19 research at Tulane University School of Medicine.

20 DR. WALKER: David Walker, Chair of
21 Pathology, University of Texas at Galveston.

22 DR. SILVA: Joe Silva, Professor of

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1 Internal Medicine, University of California,
2 Davis.

3 DR. LAUDER: Tamara Lauder, Physical
4 Medicine and Rehabilitation, Minocqua, Wisconsin.

5 DR. BROWN: I'm Mark Brown. I'm
6 representing the Department of Veterans' Affairs.

7 CAPT. JOHNSTON: Rich Johnston, British
8 liaison.

9 CDR. McMILLAN: David McMillan,
10 Headquarters, Marine Corps.

11 MAJ. SMITH: I'm Randy Smith, Joint
12 Staff, J4, Health Service Support Division.

13 [Audience introductions.]

14 CAPT. WEBER: Todd Weber, Centers for
15 Disease Control and Prevention. I'm the Director
16 of the Office of Antimicrobial Resistance.

17 LTC. STANEK: Scott Stanek, Preventive
18 Medicine Staff Officer, Army Office of the Surgeon
19 General.

20 CDR. SCHWARTZ: I'm Erica Schwartz,
21 Preventive Medicine Physician, Coast Guard
22 Headquarters.

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1 DR. LEDNAR: Wayne Lednar, Medical
2 Director for Eastman Kodak.

3 DR. PARKINSON: Mike Parkinson,
4 Executive Vice President, Lumenos, which is a part
5 of WellPoint.

6 DR. KAPLAN: Ed Kaplan, Professor of
7 Pediatrics, University of Minnesota in
8 Minneapolis.

9 DR. GARDNER: Pierce Gardner, Professor
10 of Medicine and Public Health at the State
11 University of New York at Stonybrook.

12 DR. PRONK: Nico Pronk, Vice President
13 and Executive Director of Health Behavior Group,
14 HealthPartners, Minneapolis.

15 DR. MILLER: Mark Miller, Director for
16 Research at the Fogarty International Center,
17 National Institutes of Health.

18 DR. SHAMOO: Adil Shamoo, Professor,
19 University of Maryland School of Medicine,
20 bioethicist.

21 DR. HALPERIN: Bill Halperin, Chair of
22 Preventive Medicine, New Jersey Medical School,

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1 and Chair, Quantitative Methods, at our School of
2 Public Health.

3 DR. LUEPKER: I'm Russell Luepker, and
4 I'm Professor of Epidemiology and Medicine at the
5 University of Minnesota.

6 CAPT. NAITO: Neil Naito, Preventive
7 Medicine, representing the President of the
8 Uniformed Services University.

9 RADM. HIGGINS: Paul Higgins, the
10 Director of Health and Safety of the Coast Guard.

11 COL. GIBSON: Roger Gibson, Executive
12 Secretary, Armed Forces Epi Board.

13 DR. POLAND: I'm Greg Poland, Mayo
14 Clinic Vaccine Research Group, Rochester,
15 Minnesota.

16 COL. SNEDECOR: Mike Snedecor, Chief of
17 Preventive Medicine, Air Force Surgeon General's
18 Office.

19 [Audience introductions.]

20 COL. GIBSON: A few administrative
21 announcements. Attendees, make sure that you sign
22 in on the sign-in roster for today. We have a

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1 federal advisory requirement to have a roster, a
2 report of the attendees. Also, there's a CME
3 roster back there. There are CME credits
4 available for this meeting, so please sign up.
5 We'll talk a little later about the attestation
6 documentation that's available also.

7 This meeting is being transcribed as a
8 federal advisory meeting, so if you want to speak,
9 please speak clearly into the microphones and
10 start with your names, so the transcriptionist can
11 capture the information.

12 If you need taxis, see Karen -- raise
13 your hand -- or Carolyn. They'll help you arrange
14 for your taxis.

15 To the Board members, remember to
16 complete and sign your 1352's so we can pay you
17 for this meeting. And refreshments are available
18 in both the morning and afternoon sessions today.
19 We'll have a working lunch for the speakers, the
20 distinguished guests, the preventive medicine
21 officers, and the Board members. There is the
22 Officers Club across the street and restaurants

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1 downtown for the rest of you.

2 I guess that's it.

3 DR. POLAND: Thank you, Roger. The
4 first order of business is a question on emergency
5 blood transfusions. This question was brought to
6 the Board in part as a result of our response to
7 parallel issues involving the interval for HIV
8 testing in military service members. The
9 question, as articulated by Ms. Embrey, is under
10 Tab 6. Commander Libby will be the first
11 presenter. We'll ask everybody that's presenting
12 in this segment to please stay on time. Thank
13 you.

14 CDR. LIBBY: Good morning, members of
15 the Board. I'd like to thank you for allowing us
16 to present a question. The question is that we
17 request that the Board review issues associated
18 practice by physicians to collect blood products
19 in the field and transfuse under emergency
20 conditions in a combat environment, and provide
21 recommendations regarding optimal strategies to
22 minimize risk.

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1 In particular, the Board should consider
2 issues related to the risk for HIV and hepatitis
3 infections from blood products collected and
4 transfused in the field. That was the question.

5 Presently, up to date there have been
6 5,500 units of blood products that have been
7 collected and transfused under "emergency
8 protocol" in Operation Iraqi Freedom (OIF) and
9 Operation Enduring Freedom (OEF). In the practice
10 of collection and transfusion, fresh whole blood
11 and apheresis platelets will continue to support
12 aggressive hemostatic resuscitation techniques.

13 The collection of fresh whole blood is primarily
14 occurring at the echelon segment, on echelon I and II
15 levels. Apheresis, platelets are collected only at the
16 10 Combat Support Hospitals (CSH) in Baghdad and also at
17 the 332nd Expeditionary Medical Supports (EMEDS) in Balad.

18 Also of note is, the Army has established a
19 protocol to establish a Blood Support Detachment, and with
20 it whole blood collection capability as well as platelet
21 and apheresis collection capability. There is no
22 testing capability with this unit.

1 On the slide it shows the number of
2 blood products that were transfused up until July
3 of '06. These are the products transfused, not
4 the number of patients that were transfused.
5 Whole blood transfusions, about 3,400 have been
6 transfused, and platelets, approximately 1,900.

7 And I have the percentage breakdown.
8 About 62 percent of the whole blood was transfused
9 to U.S. forces. And typically the ratio of
10 transfusion between U.S. forces and coalition or
11 host nation has been about 30, with the exception
12 of the whole blood transfusions. Of those
13 transfusions, about 36 percent got transfused to
14 the U.S. And all the platelets collected in
15 theater is not tested.

16 These are the numbers that show the
17 actual numbers of patients that were transfused.
18 The total number of patients transfused with whole
19 blood is 641, and of that 347 were U.S.
20 Platelets, 701 patients were transfused, and of
21 that 274 patients were U.S.

22 The blood donation steps that we have to

1 protect the safety of blood supply over there is
2 twofold. One, we ask medical screening type
3 questions and review medical history to prevent
4 transmissible disease from the recipient, identify
5 folks at risk, and also infectious disease
6 testing.

7 The donor history questionnaire, there
8 are several things that we look at that may
9 compromise some of our blood transfusion in
10 theater, issues like sensitivity or branding
11 indicators.

12 In other words, you wouldn't want
13 somebody from the unit -- or somebody from the
14 unit maybe asks -- you have a fellow soldier get
15 hurt and needs blood transfusions, and perhaps the
16 person doing the screening is friend of theirs.
17 They wouldn't want to be branded as somebody who
18 is has high-rise behaviors, so they may not ask
19 the person to answer the question.

20 Also, during emergency blood collection
21 there is a lot of emotion. There is motivation.
22 People want to save lives, and we want to donate,

1 give blood to our fellow soldiers. A lot of
2 pressure, pressure as a group to give to the
3 emergency blood collection, to donate.

4 In that time frame, if you're doing a
5 screening, they may have lapses in time frames,
6 when were they exposed to a high risk type
7 situation. Donor knowledge and understanding of
8 risk at the time. They're focused on saving
9 somebody. They may not be quite focusing in on
10 the risk that they may present to that recipient.

11 And also the competency of the blood
12 collection folks, the people that are actually
13 doing the medical screening. At the third echelon
14 levels a lot of those folks I know are fully
15 trained, very competent to do this. Our concern
16 is what happens at the second echelon level.

17 Infectious disease testing, the Food and Drug
18 Administration (FDA) requires the following: Enzyme
19 Immunoassay (EIA) testing, Hepatitis B Surface Antigen
20 (HBsAg), anti-Hepatitis B Core (HBc), anti-Hepatitis C Virus
21 (HCV), anti-Human T- Lymphotropic Virus (HTLV) I and II, and
22 anti-HIV I and II; Nucleic Acid Testing for HIV 1, NCV,
23 and West Nile Virus, and they're still including syphilis.

1 In the situation in Southeast Command (SECOM),
2 they usually collect a sample retrospectively and ship
3 it off to Wilford Hall or Fort Hood for their
4 FDA-licensed testing. Wilford Hall, the Air Force
5 has been able to do the NAT testing in addition to
6 the EIA testing.

7 In the field, what they have done in
8 order to prevent some of the risk, they have
9 adopted a Rapid Screening Test. We had a choice.
10 We went with the BioKit, manufactured in Spain.
11 It's not FDA-licensed. They're using it as a
12 screen for HIV 1 and 2, HCV, as well as HBsAG.
13 And this is in use at 322nd EMEDS and 10th CSH,
14 and the CENTCOM surgeon has recommended its use
15 throughout the Area of Operation(AOR).
16 Apparently the Marines at the Forward Resuscitative
17 Surgery System (FRSS), I understand, are still using the
18 OraQuick Advance screening for HIV 1 and 2.

19 The test kits that they use for screening,
20 for any screening type, are not currently available
21 commercially. There are several reasons for that but I
22 guess the main one is, in order to have a screening

1 assay be licensed, it's going to take a lot of money,
2 a lot of time for them to do that, so it's not
3 financially beneficial for the commercial entity
4 to develop a rapid screening test at this time.

5 A requirement was presented to Office of Naval
6 Research (ONR) to do a rapid screening test to be used
7 in CENTCOM, to be able to produce one that will
8 ensure safety. So they did sponsor a market
9 study, market surveillance, still ongoing, and
10 based on preliminary findings they issued a BAA to
11 move the process along and get it tested and
12 developed. However, they're telling us that it
13 could be a year before any funds can be applied to
14 this initiative.

15 This is some of the data from the
16 screening assays pulled from the facility at EMED
17 and as well as the CSH. I will say that the HBsAG
18 number there, I forgot to add the numbers, so that
19 number should actually be 1,552 HBsAG screening
20 tests performed.

21 And the last column here shows the
22 negative, our concern, which was negative and

1 which was the follow-on test result when it was
2 followed up. There was one HCV test that got
3 through, that was followed up, that was negative
4 although it was positive when tested
5 retrospectively, and for the HBsAG there was also
6 one.

7 These are the number of tests that were
8 screened prior to donation, and these were the
9 number of units to the right that were transfused
10 without any screening at all.

11 These were the test results from Fort
12 Hood for the Army, tests for the Army and the
13 Navy.

14 These are the retrospective testing, and
15 HCV is .11 percent. And this was using a donor
16 base of about 4,600 donations.

17 This was, I put this in there because
18 this is a comparison between the donors that we
19 see at CENTCOM compared with donors that we see
20 here in the U.S. Of note here was the issue of
21 retest. Positive incidence rates for the Continental
22 United States (CONUS) donors was 0.06 percent,

1 compared with the donors out of CENTCOM at 0.11 percent.

2 And this is unremarkable. This is the
3 comparison of HBsAG and HTLV. These are the
4 numbers that were derived from the Air Force EMED.
5 They tested so far 466 donors.

6 I put these slides just kind of to give
7 you a vision, to get an idea of what has been
8 going on in the past with whole blood
9 transfusions. Currently, the last data we have is
10 from July and August to September of this year,
11 and you're probably going to see a huge spike.
12 Things were extremely busy in CENTCOM, so this
13 activity, this process, the procedure to do whole
14 blood collection and transfusion data was probably
15 affected. His is showing the platelet
16 transfusions. This is a comparison of the data.

17 Post-transfusion follow-up, we have been
18 pretty good at following up the U.S. Active duty
19 but it has been very laborious for us to do that.
20 Civil service and government civil service,
21 anybody coming back that ends up in a military
22 facility, that is the group we have been targeting

1 and we have had follow- up for the testing. We do
2 nothing for coalition forces, nothing for the host
3 nation recipients.

4 We have the tools to do tracking.
5 Theater Defense Blood Standard System (DBSS), that's our
6 primary system we use for blood management, we only have
7 those at our blood supply units and blood transfusion
8 centers. We don't have those, we're not operating them
9 anywhere else at this point. The Joint Patient
10 Tracking Application, the Army Blood Program
11 Office has tried to apply this one in CENTCOM, but
12 I know they've been having problems getting
13 everybody on board to actually use this. I understand
14 they're not using Armed Forces Health Longitudinal
15 Technology Application (AHLTA) at this point to do tracking.

16 So it's the old system. We're using
17 Excel spreadsheets, which is termed the "Mother Of
18 All Spreadsheets." We get it in our office every
19 week. It has everybody who has been transfused,
20 the products. It has a lot of information for us,
21 and that's what we're using.

22 Here is the Health Affairs policy, and

1 this is the requirement for us to track patients
2 and do follow-up for infectious diseases. We try
3 to collect a pre-transfusion sample if possible,
4 then do follow-up at 3 months, 6 months, and 12
5 months, and this is voluntary.

6 At this point I'll end my discussion and
7 take questions.

8 DR. KAPLAN: Could you clarify for me,
9 please, the non-FDA approved test kit, the one
10 that's made in Spain. It wasn't clear to me how
11 that was used and the basis for using a non-FDA
12 kit.

13 CDR. LIBBY: The reason it hasn't been
14 FDA approved is that the company never presented
15 it to the FDA to be approved. The companies have
16 never presented any of those screening tests to
17 the FDA for approval of the tests for sensitivity
18 and specificity.

19 The kits are being used. The intent is
20 to do blood collection and then collect a sample
21 from the donor at the same time to do the testing.
22 Some of these kits, it only takes 5 or 10 minutes

1 to get a result from the kit, so it's a very rapid
2 test. So apparently they're trying to use these
3 prior to transfusion.

4 DR. KAPLAN: Can I follow up on that?
5 Does the fact that it's used in an emergency
6 eliminate the necessity for it to be FDA-approved?

7 DR. POLAND: Actually this presentation
8 was a little difficult for me to follow. Let's
9 step back a minute, and tell the Board what the
10 issues are and what the policies are in regard to
11 emergency transfusion. I think we have the sense
12 there are some conditions and some fractions of
13 blood that are not tested and some that are.

14 COL. GIBSON: One second. For the Board
15 members, if you look in your books, the Armed
16 Forces Epi Board produced a recommendation for HIV
17 testing. One of the assumptions -- that
18 recommendation is in your package -- one of the
19 assumptions was that emergency blood transfusions
20 were rare events -- 5,500 is not rare. So one of
21 the reasons this question came back to you all was
22 to look at the issue of HIV in particular, but

1 emergency blood transfusions occurring in theater
2 to save lives. We have a policy within DOD to not
3 use non-FDA -- to not use products that are not
4 FDA- approved. We also, if you're going to put
5 out a policy that says we're going to use a
6 product like that, there is a problem for DOD.

7 But what physicians and what commanders
8 do off-line with our policy is another issue. And
9 then you might clarify the part about testing.

10 CDR. LIBBY: The collection and
11 transfusion of blood under emergency conditions,
12 that's really like onesies and twosies throughout
13 the world. It's been a physician discretion to do
14 so, assuming the risks and presenting the data.
15 There could be 500 occurrences in the past, in
16 which case policy, DREGS policy and DREGS
17 guidance, you know, to ensure safety, like Colonel
18 Gibson said, you know, when you write policy and
19 you want folks to use an unlicensed kit, that
20 could be a regulatory issue with the FDA.

21 DR. POLAND: Did you imply in your
22 presentation that there are fractions that are not

1 tested?

2 CDR. LIBBY: Yes, in emergency
3 situations.

4 DR. POLAND: You indicated there were
5 different levels, Level 2 and Level 3.

6 CDR. LIBBY: Yes. On Level 2 they have
7 -- they do not have rapid screening assays at
8 Level 2.

9 DR. POLAND: And what is Level 2?

10 MGEN. KELLEY: Level 1 is the medic --

11 DR. POLAND: We need to be oriented as
12 to what you're speaking about.

13 MGEN. KELLEY: Level 1 is the care
14 that's provided by the medic in the field. Level
15 2 would be the collection points, the first time
16 that you have -- it's the corpsman in the field,
17 and the first time probably there's a Table of
18 Allowances on Level 2, although there are some places
19 that have supplemental and they do have some emergency
20 surgery capability, lifesaving capability there,
21 but it is not a hospital-type setting. Then Level
22 3 is your field hospitals. Level 4 is your

1 evacuating hospital like Landstuhl. Level 5 is
2 your complete medical system for that patient
3 which is back in the States. So it's all levels
4 of care.

5 COL. GIBSON: So, one other point. The
6 next briefing will be talking about trauma care
7 and will provide more detail on exactly what
8 you're talking about, why we're going things the
9 way we're doing them.

10 DR. POLAND: Mark?

11 DR. MILLER: I guess I needed to have
12 some clarification also about the indications in
13 the field for why blood is being used and whether
14 or not -- at what level of discretion is that
15 made, because this is really a risk
16 stratification.

17 DR. POLAND: Pierce? Board members
18 first, and then we'll --

19 DR. GARDNER: Two things. At the time
20 of recruitment, all of the recruits have the
21 baseline tests for everything on your list, I
22 guess, except perhaps for West Nile. Is that

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1 correct? Do we know their Hepatitis B and their
2 syphilis data at the time they're recruited?

3 COL. GIBSON: We'll go through the
4 policies on HCV and HIV and HBV a little later,
5 after --

6 DR. GARDNER: But I'm assuming that
7 these are basically all, the positives that are
8 showing up in the field are all post- recruitment
9 acquisition.

10 COL. GIBSON: Not necessarily.

11 DR. GARDNER: Not necessarily? Okay.

12 COL. GIBSON: Not with HCV, but yes, the
13 others. We have policies. We'll go over those.

14 DR. GARDNER: My other, perhaps you'd
15 explain to me, the majority of transfused patients
16 by a large amount are non- U.S., so these are
17 Iraqi basically personnel that are being treated
18 in our facilities, that are getting most of these
19 products. Is that what I get from it?

20 CDR. LIBBY: The blood products,
21 correct. But the percentage of the fresh whole
22 blood is slanted towards the U.S. About 80 percent

1 of the U.S. is getting the fresh whole blood, and
2 that's because their wounds --

3 DR. GARDNER: I didn't realize that our
4 military facilities were doing that much care of
5 the Iraqi casualties, but that's another issue.

6 CDR. LIBBY: Blood products overall are
7 going to the Iraqis.

8 DR. POLAND: And just to clarify, the
9 blood that is collected, is that blood only from
10 U.S. personnel?

11 CDR. LIBBY: That is the CENTCOM policy.
12 There have been exceptions.

13 DR. POLAND: And those are blood
14 products going into U.S. personnel?

15 CDR. LIBBY: They're all U.S., that's
16 correct.

17 DR. POLAND: Wayne?

18 DR. LEDNAR: Wayne Lednar. Did I
19 understand that you said that if there are
20 coalition force personnel who are transfused with
21 U.S. units, that there is no notification and no
22 follow-up?

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1 CDR. LIBBY: There is no policy that
2 would encourage --

3 DR. LEDNAR: That's an answer to a
4 different question. Is there in fact a
5 notification to some sort of medical chain of
6 command in the coalition forces of follow-up
7 information, so that those medical assets in the
8 coalition forces can do the appropriate follow-up
9 of their troops?

10 CDR. LIBBY: There is a mechanism in
11 place to have a liaison for CENTCOM in the --

12 DR. LEDNAR: And that communication does
13 occur?

14 CDR. LIBBY: Yes.

15 DR. POLAND: Joe?

16 DR. SILVA: Silva. Just very briefly,
17 you're going to do retesting at 3, 6 months, and
18 one other interval?

19 CDR. LIBBY: Yes, for HIV and HCV.

20 DR. SILVA: And do you have any data on
21 what that's showing, how many were missed in the
22 field?

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1 CDR. LIBBY: I don't have that data, but
2 I think if there was a positive we would have
3 known about it. I don't believe there has been.

4 DR. SILVA: That's comforting.

5 SPEAKER: Most of my questions were
6 asked and answered. You didn't mention it, but
7 I'm assuming that the more non-infectious disease,
8 mundane, typical tests for blood are also being
9 done, like typing, crossing, antibodies, etcetera?
10 Because it seems to me that would present a more
11 immediate risk than the longer-term infectious
12 disease risks.

13 CDR. LIBBY: There are various degrees
14 to testing done in OIF and the echelons, depending
15 on what the capabilities are. The echelons do
16 have a variation of testing capability in the
17 field.

18 SPEAKER: Okay. Thank you.

19 DR. POLAND: Russ?

20 DR. LUEPKER: It looked like only about
21 25 percent were being tested. Are all of these
22 transfusions given at Level 3, or is it at Level 2

1 as well?

2 CDR. LIBBY: Well, there's a mix of both
3 Level 2 and 3. What we've been seeing lately is
4 they have had an increase in whole blood
5 transfused at the Level 2's, we've seen over the
6 last couple of months, so it's shifting toward the
7 Level 2.

8 DR. LUEPKER: Do the Level 2 people have
9 access to testing kits?

10 CDR. LIBBY: They do now. They had
11 previous to -- this last couple of weeks it was
12 mandated that everybody use the screening test,
13 including Level 2's, that was available.

14 The only two sites that was using the
15 screening test was the CSH, 10th CSH, and then the
16 EMEDS in OIF.

17 DR. POLAND: Okay. Thank you. Next we
18 have Lieutenant Colonel Kurt Grathwohl -- I hope
19 I'm saying this right -- from Wilford Hall, the
20 United States Air Force Medical Center in San
21 Antonio. He represents a team of trauma and
22 emergency medicine surgeons engaged in dealing

1 with OIF and OEF casualties, and he will present
2 on advances in combat trauma care.

3 LTC. GRATHWOHL: I'm actually from
4 Brooke Army Medical Center but I do work at
5 Wilford Hall. I'm going to hopefully clarify some
6 of the things that you were just talking about in
7 my discussion, and what you will notice is that I
8 pared down the slide presentation to be more
9 germane to the particular war.

10 The things that we're seeing are
11 injuries that really have not been described
12 before and injuries that really are things that
13 have not been experienced before. And because of
14 that, we've had to actually change how we deliver
15 medical care.

16 There are a lot of people out here in
17 this group and many more, anyone involved in
18 delivering combat casualty care is actually
19 rewriting the book on how to manage trauma
20 patients. And what's really amazing to me, and
21 I'm going to quote Dr. John Holcomb, "We're not
22 waiting for the end, but are making changes in the

1 middle of the war."

2 And there are a lot of different
3 advances in combat casualty care, all the way from
4 development of trauma systems, going through the
5 trauma registry, to tactical care, including
6 tourniquets for every single soldier deployed;
7 implementation of new surgical techniques, damage
8 control surgery; and then what I'm going to talk
9 about is damage control resuscitation, hemostatic
10 resuscitation, specifically the delivery of whole
11 blood in the management of these severely injured
12 patients.

13 There are a lot of people that are
14 involved in this. Some of them are listed here,
15 from the 31st Combat Support Hospital, the 86th,
16 the 10th, and then of course the biggest proponent
17 of this is the trauma consultant and commander of
18 the Institute of Surgical Research, Dr. John
19 Holcomb.

20 So this is my gratuitous epidemiologic
21 slide for you all, and many of you have probably
22 seen this before. The reason why I bring this to

1 show you is that historically the killed in action
2 rate is about 20 percent, and that has decreased
3 in this conflict down to 12.5 percent. And that
4 is likely due to improvements in training with the
5 medics and control of hemorrhage on the
6 battlefield, that 25 to 35 percent of patients
7 that die out on the battlefield.

8 What's disturbing, however, is that as a
9 result of that and increased personal protective
10 equipment, patients that would otherwise have died
11 on the battlefield are now making it to the Combat
12 Support Hospital, and you'll see that the "died of
13 wounds" rate has actually increased slightly to
14 4.1 percent, over Vietnam and even World War II.
15 Well, the "died of wounds" rate really represents
16 the care that's delivered at the Combat Support
17 Hospitals, and so it really is our challenge then
18 to determine how we can affect change in that
19 small increase of patients dying of their wounds
20 after they arrive at our hospital.

21 This is data from the Armed Forces Institute of
22 Pathology (AFIP). This was 495 patients. They were

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1 subsequently evaluated for potentially survivable causes of
2 death, and you'll see that out of those 495, or 17 percent
3 were thought to have a potentially survivable
4 injury. There were 107 causes, and the majority
5 of those patients actually died from hemorrhage,
6 whether it would be a compressible region or a
7 non- compressible region.

8 I looked at the 31st and 86th Combat
9 Support Hospital from January of '04 to May of
10 2005, and you can see that only a small portion of
11 the patients that are being injured actually are
12 hemorrhaging to death, and that's about 5.4
13 percent. The target population is those patients
14 that receive massive transfusions, defined as more
15 than 10 liters of packed red blood cells or any
16 kind of blood component.

17 But the reason why that's important is
18 that those patients, the ones that require massive
19 transfusion, are the ones that are dying. Their
20 mortality is 25 percent, and that's where we're
21 focusing our attention.

22 A lot of people ask, well, why does the

1 casualty die after they get to a Combat Support
2 Hospital with a surgical team, which is a Level 2,
3 where they're getting surgery to stop the
4 bleeding? And the reason why is because their
5 injuries are so spectacular that these patients
6 are hemorrhaging and subsequently enter what we
7 call the bloody vicious triad or the triad of
8 death. They are coagulopathic, acidotic, and
9 hypothermic. And those patients are dying from
10 these severe metabolic, physiologic abnormalities,
11 not from surgical bleeding but from coagulopathy.

12 I don't know how many of you were taught
13 in medical school but I know I was taught that we
14 should use advanced trauma life support
15 principles, and really what they teach is that you
16 should infuse two liters of crystalloids in these
17 combat-injured patients, and then to replace their
18 blood loss, one cc of blood to three cc's of
19 crystalloid.

20 Well, if any of those patients are in
21 Class III or Class IV shock, you should actually
22 also replace their blood losses with red blood

1 cells. You should check their coagulation status
2 and then subsequently treat them with Fresh Frozen Plasma
3 (FFP) and platelets in dosage as required, or you can
4 empirically treat them with a ratio of 10 red
5 cells, 4 FFP, and a 6- pack of platelets.

6 The problem with that is, that probably
7 is completely incorrect for these severely injured
8 patients. What we've been taught is probably not
9 right, and I'm going to give you a couple of
10 examples of why that's not true.

11 Here is a bag of lactated Ringers, and
12 you can see right on the bag of lactated Ringers,
13 this solution is actually quite acidotic. What
14 have we done to patients who are suffering from
15 severe acidosis? It even says on the package that
16 it's not for use in the treatment of lactic
17 acidosis. Well, that's exactly what these
18 patients are all suffering from. But it's the
19 primary solution for resuscitation of these
20 severely injured casualties.

21 This is a study by Peter Rhee which
22 actually shows, if you're looking for the optimal

1 resuscitation fluid, that lactated Ringers,
2 hypertonic saline, Dextran and Hespan are all
3 potent deciders of an inflammatory response, which
4 is not a very good thing for these patients. And,
5 as a matter of fact, you can see that lactated
6 Ringers is responsible for activating neutrophils
7 more than any of the other resuscitative fluids,
8 which is essentially like keeping these combat
9 casualties endotoxic, which can't be a good thing
10 for them.

11 This is another compilation of studies
12 that looks into the adverse effects associated
13 with red blood cells, and there is emerging data
14 every day that shows that giving patients red
15 blood cells is probably not optimum. It's
16 associated with increased length of stay,
17 increased infection, and more importantly,
18 multi-organ dysfunction and even death.

19 This is a study from Basran that looked
20 at patients post-cardiac surgery, and this
21 associates the age of stored red cells with
22 morbidity and mortality. You can see that the

1 longer the red cells were stored, the worse their
2 function is and the more they are associated with
3 morbidity and mortality.

4 And this is an electron micrograph which
5 probably shows one of the reasons why. This is
6 what a red cell looks like on day one of
7 collection, and then after 21 days the red cells
8 are severely deformed.

9 As a result of the storage process
10 actually there are many things that occur to red
11 blood cells. There is inflammatory media release,
12 decreased 2,3 Diphosphoglycerate (DPG), and adhesion
13 aggregation which actually increases, paradoxically,
14 microvascular perfusion. And it's well known that stored
15 red cells do not do what is the intended purpose, and
16 that is deliver oxygen. As a matter of fact, they
17 don't do that, and it's associated with multi-
18 organ dysfunction and even death.

19 As an aside, just as a look at the over
20 5,000 units that were transfused at the 31st
21 Combat Support Hospital, the average age at
22 delivery was 27 days. Remember the shelf life of

1 this product is actually 42 days, and they were
2 transfused on an average of 33 days, so almost at
3 the end of their life span.

4 This is an actually more detailed look
5 at the resuscitative physiology, and I just want
6 to point out, it's a busy slide, but this is that
7 vicious triad. And what we know now is that the
8 very lifesaving interventions that we're trying to
9 give patients may actually be killing them.

10 And what I mean by that is, you can see
11 that packed red blood cells produce crystalloids
12 and colloids which are associated with their own
13 primary adverse effects, including cytokine
14 release, transfusional rate, and immunomodulation.
15 This also plays into the vicious cycle by actually
16 exacerbating coagulopathy, and it exacerbates the
17 acidosis as well as hypothermia.

18 And so what we now understand is that we
19 have to develop resuscitative strategies that not
20 only interrupt that but primarily treat the
21 acidosis, coagulopathy, and hypothermia. And so
22 things like whole blood and FFP and warming the

1 patient up are the primary ways to do that.

2 It turns out that historically speaking,
3 this was known back in World War I and World War
4 II. Hundreds of thousands of fresh whole blood
5 units were actually administered during both of
6 those conflicts, and you can see here the comments
7 by some of the people that were associated with
8 transfusing those whole units. It was responsible
9 for saving the lives of many soldiers in World War
10 II and in the Korean War.

11 And if you ask any surgeon who has
12 administered whole blood, they will tell you that
13 it's like a religious experience. The patient
14 actually clinically looks better and they do
15 better. Coagulopathic bleeding stops right in
16 front of their eyes. And so it really is an
17 important intervention.

18 The problem is that during the Korean
19 War hundreds of thousands of whole blood units
20 were actually wasted, and that's actually what led
21 to blood banking as we know it today. It was in
22 order to more rationally use blood products.

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1 So what I want to do is just spend a
2 couple of minutes giving you the rationale for why
3 so many fresh whole blood units are actually being
4 used in theater. We struggled with this as we
5 were trying to figure out how to best take care of
6 these severely injured patients.

7 And what we discovered is that really
8 whole blood probably is superior to stored blood
9 cells, and the reason why is because there is no
10 depletion of 2,3 DPG, so you actually do deliver
11 oxygen to the microcirculation. It doesn't
12 exacerbate dilutional coagulopathy like the
13 administration of red cells and crystalloids, and
14 it actually has been shown, both in animal and
15 human studies, to improve microcirculatory
16 hemodynamics and increase cardiac output.

17 And then when you start talking about
18 hemostasis and stopping bleeding, a unit of whole
19 blood is essentially proven to equal units of
20 pooled platelets, so much more effective. This is
21 a study by J.L. Sondeen with a group at the United States
22 Army Institute of Surgical Research, (ISR). They actually

1 looked at the different resuscitative fluids. And this has
2 been corroborated by several other studies, that
3 without a doubt, fresh whole blood in uncontrolled
4 swine model hemorrhage is the best resuscitative
5 fluid.

6 A lot of people that are blood bankers
7 and other folks will say, "Well, why don't you
8 just reconstitute whole blood? Logistically, that
9 would be better, etcetera."

10 Well, this is the problem. If you take
11 component therapy and reconstitute it, one unit of
12 packed cells, one unit of platelets, one unit of
13 FFP, and ten units of cryo, which is what you get
14 when you break it down, you actually get 660 cc's
15 of whole fluid, the hematocrit is actually 29
16 percent, there are decreased platelets, decreased
17 coagulation activity, and decreased fibrinogen, as
18 compared to one unit of fresh whole blood. So the
19 products are not comparable.

20 As we struggled with this whole process,
21 we actually started to develop a scheme with which
22 we could start to administer efficiently fresh

1 whole blood, and this is actually our massive
2 transfusion protocol that was developed in the
3 31st Combat Support Hospital, and I'm going to
4 talk a little bit about this in a subsequent
5 slide.

6 Our strategy was actually to transfuse
7 patients with O positive blood, if that were
8 available, thawed plasma, and a ratio of 1 red
9 cells to 1 FFP, and if platelets were available --
10 and you have to remember, platelets weren't
11 available at the Combat Support Hospital in
12 Baghdad until January of '05, and so whole blood
13 was actually used instead of platelets -- if they
14 were available, we would also give them in a 1 to
15 1 ratio, as well.

16 The whole blood trial would be initiated
17 as soon as a casualty required it, and the
18 clinical science is sometimes adverse,
19 particularly with massive transfusion, and then we
20 would start giving them fresh whole blood as soon
21 as possible, and we would continue that until the
22 patient stopped bleeding and they were

1 hemodynamically and clinically stabilized.

2 Just to give you -- you heard over 5,000
3 units of cold blood products, but just as of
4 several months ago there were over 3,000 units of
5 fresh whole blood. So one of the questions we had
6 and wanted to figure out, is the fresh whole blood
7 actually helping us?

8 And we went back -- this is Phil
9 Spinella -- to look at our massive transfusion
10 database, at 111 patients who were severely
11 injured, looked at a bunch of different variables
12 associated with mortality. And what we found is
13 that fresh whole blood is independently associated
14 with survival in the patients that were given it.
15 Survival ratio was 1.48 per unit of fresh whole
16 blood that was transfused.

17 We also went back and compared fresh
18 whole blood versus just those patients that got
19 component therapy, and you can see mortality in
20 the fresh whole blood cohort was 21.8 percent,
21 versus 32.9 percent in those patients that only
22 received component therapy.

1 Because of the low numbers, that's when
2 we started to see the significance.

3 We also wanted to look at if the ratio
4 of FFP to red cells made a difference, because we
5 have changed that strategy, and Matt Borgman and
6 Phil Spinella looked at that, and what they have
7 done is that if patients got 1 unit of FFP for 1.7
8 units of packed red blood cells, that actually was
9 associated with increased survival, as opposed to
10 if they got a ratio of 1 unit of FFP to 3 of red
11 cells, which was associated with increased
12 mortality.

13 They subsequently went back and then
14 looked at different ratios, and you see that as
15 you got more FFP, your mortality started to
16 decrease, and this is essentially the 1 to 1 or
17 less than 1 FFP to -- or more than 1 FFP to red
18 cells, and you can see mortality significantly
19 decreased. And that was all statistically
20 significant.

21 They also wanted to see if there was an
22 effect on the hemorrhage, and if you look at those

1 same groups of patients, you can see that
2 patients, as expected, stopped dying of their
3 hemorrhage because their coagulation was fixed,
4 and then this group down here that got more FFP
5 per red blood cells, they started to die of other
6 things -- multi-organ dysfunction and sepsis --
7 and so that's an interesting association, and
8 something we need to look into.

9 As a result of this we have coined a
10 term, the new term, "damage control
11 resuscitation," which truly has three primary
12 principles. The first principle is the use of
13 Tactical Combat Casualty Care concepts; permissive
14 resuscitation, I don't like the word
15 "hypertensive" resuscitation; and then the new
16 concept, hemostatic resuscitation, which is the
17 prevention and treatment of coagulopathy early on.

18 The overarching goals of hemostatic
19 resuscitation is, first off, avoid dilution of any
20 of coagulation factors by the indeterminate use of
21 crystalloids. And then restore coagulation and
22 intravascular volume by replacing blood loss with

1 fresh whole blood, because that's what patients
2 are needing, at the earliest available time or if
3 available.

4 And then aggressive treatment of all the
5 metabolic abnormalities that are exacerbating the
6 coagulopathy, so treating acidosis, treating
7 hypothermia, and treating hypocalcemia. And then,
8 finally, targeting all directed therapy for the
9 treating of coagulopathy, which included FFP,
10 cryoprecipitate, platelets, in the most optimal
11 ratios that we have figured out, about to 1, and
12 then Factor VIIa early on. And then the moment
13 they find out if that strategy now really
14 prospectively is working -- and I only have
15 preliminary data for you. This is from the 10th
16 Combat Support Hospital. There are 27 patients
17 that they treated there, and 252 patients in our
18 total massive transfusion database.

19 And what you can see, those patients
20 actually were a little bit more severely injured,
21 but using this sort of goal-directed therapy, they
22 were able to normalize their INR's. As expected,

1 those patients got fresh whole blood,
2 cryoprecipitate and platelets, but they also got
3 less crystalloid. And it's too early to tell, but
4 you can see that the mortality, the 24-hour
5 survival is essentially the same. Now there are
6 over 100 patients in this database, and we're
7 looking forward to seeing what the survival
8 benefit is from this strategy.

9 I want to shift gears a little bit
10 actually and I want to talk to you a little bit
11 about our fresh blood donation program, to clarify
12 some of those issues. All of the Americans in the
13 international zone were given a chance to become
14 whole blood donors, and we were able to screen
15 them for eligibility by a questionnaire. If they
16 hadn't already been screened, we also gave them a
17 questionnaire to look for high risk behaviors.

18 If those patients were able to donate,
19 we tested them for anemia. Interestingly, 5
20 percent of all the female donors were excluded.
21 And then that blood was typed and crossed and
22 subsequently transfused to the patient. While we

1 were doing our test, we got this process down to
2 less than 30 minutes. Now I understand that the
3 10th Combat Support Hospital has it down to less
4 than 20 minutes.

5 Unfortunately, there are risks
6 associated with the administration of whole blood,
7 both to the donor and to the recipient.

8 This slide shows that out of 370 whole
9 blood donors, 25 percent actually developed mild
10 anemia. The reason why that might be important is
11 because of performance issues associated with the
12 donation of whole blood.

13 And then to touch on the transfusion
14 reaction that was brought up earlier,
15 unfortunately this data is not entirely reliable
16 because of over-reporting and the nature of the
17 injuries. These patients all had pulmonary edema,
18 they all had pulmonary contusions, and they were
19 all febrile, just because of their severe
20 injuries. And so while we're trying to do our
21 best to report hemolytic transfusion reactions and
22 Transfusion Related Acute Lung Injury (TRALI), I don't

1 know that we can trust these numbers.

2 But the take-home point is that they are
3 relatively similar with the exception of two
4 patients. Two patients actually had fatal
5 transfusion reactions, and both of those patients
6 where the red cell was not in the threshold, so
7 that is potentially significant.

8 And then we struggled very much with
9 trying to minimize exposure to infectious
10 diseases, and so actually Major Bordeen is
11 responsible for finding that BioKit that's
12 produced in Spain and subsequently starting to
13 test patients for both HIV and Hepatitis B and
14 Hepatitis C. We were able to screen 462 of those
15 donors for HIV and then 406 of them for Hepatitis
16 B and Hepatitis C, and we actually did find two
17 positive HCV units. Those units were subsequently
18 not transfused and were discarded.

19 Now the test is actually -- it takes
20 about 15 to 20 minutes, and it's very
21 operationally relevant because of the time that it
22 takes, but of course it is non-FDA approved, as

1 mentioned.

2 DR. POLAND: Could I just ask a question
3 here?

4 LTC. GRATHWOHL: Yes, sir.

5 DR. POLAND: You were talking about this
6 graphic of verbal screening that you had. You
7 mean it failed with those two?

8 LTC. GRATHWOHL: No, those patients were
9 screened with a questionnaire. It was a written
10 questionnaire taken by the folks at the Combat
11 Support Hospital that were responsible for
12 collecting the blood, and if those patients did
13 not have high risk behaviors or if the
14 questionnaire was okay, if they subsequently went
15 on to donate, two of those patients that went on
16 to donate were found to have HCV positive. So the
17 blood bank --

18 MGEN. KELLEY: Were those two followed
19 up?

20 LTC. GRATHWOHL: No, sir.
21 Unfortunately, that's one of -- you'll see on the
22 next slide, since those units were discarded, they

1 subsequently weren't subjected to formal testing
2 at Fort Hood, so we don't know if that was a
3 testing false positive.

4 MGEN. KELLEY: But how about the
5 individuals? Were they --

6 LTC. GRATHWOHL: No, sir, not that I am
7 aware of. Maybe somebody from the Armed Services
8 Blood Banking Program, but I'm not aware of the
9 disposition.

10 SPEAKER: What was the question?

11 LTC. GRATHWOHL: Of those two donors
12 that tested positive for Hepatitis C by the rapid
13 screening, were they followed up?

14 SPEAKER: That individual was
15 prescreened. In other words, he wasn't donating
16 at that point. Prescreened, twice he was
17 reactive, and he's deferred, but he was EIA
18 negative. So he was deferred from the donor pool.

19 LTC. GRATHWOHL: We actually had two
20 patients show up, so we followed one, but the
21 other, no.

22 So the Armed Services Blood Program

1 started testing, and the data that I have is
2 through February 2006, so not quite up-to-date,
3 but 2,800 whole blood donors have been -- were
4 actually tested between May and February of 2006,
5 and the results of those include three positive
6 HCV, two HTLV, one inconclusive for syphilis, and
7 there were no HIVs and Hepatitis Bs. There since
8 has been one HIV, but that person subsequently
9 tested negative.

10 And this is just a table that shows the
11 potential effectiveness of this prescreening, and
12 so just to talk you through this slide, again 462
13 patients donated blood, and that blood was
14 screened for HIV prior to transfusion. None of
15 those were positive. 406 were screened for
16 Hepatitis C and Hepatitis B. Two were positive
17 for Hepatitis C, and subsequently discarded and
18 not transfused.

19 In this 2,831 patients is included the
20 462 and 406 patients that were screened for
21 Hepatitis B and C as well as HIV, and you can see
22 the results of that were the three. None of the

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1 ones that were HIV negative, though, were
2 positive; two for HCV, two for HTLV, and one for
3 syphilis was subsequently inconclusive.

4 DR. POLAND: Does this also mean that
5 only 406 out of the 2,800 were screened?

6 MGEN. KELLEY: Yes, sir.

7 DR. POLAND: And the rest of them were
8 not screened and transfused?

9 MGEN. KELLEY: Yes, sir. Absolutely.

10 LTC. GRATHWOHL: So obviously there is
11 continued risk with the administration of red cell
12 products, and so obviously we are looking into
13 other products that minimize the risk and that
14 have actually potentially even more resuscitative
15 properties, and there are several that are
16 currently either approved or there is ongoing
17 study to approve. That includes lyophilized
18 plasma or platelets, fibrinogen, and of course the
19 hemoglobin substitutes that you have previously
20 heard of.

21 So, in conclusion, fresh whole blood may
22 improve outcomes in severely traumatized patients

1 requiring massive transfusion. The use of fresh
2 whole blood as a part of damage control
3 resuscitation and hemostatic resuscitation is
4 increasing.

5 And because of that, there is an
6 increase also in the safety issues associated with
7 fresh whole blood transfusion, to include blood
8 donor anemia, but more importantly, I think, the
9 infectious disease issue. And so there are
10 several questions, some of which you have already
11 raised.

12 To articulate those, the first is,
13 should pre-deployment testing be performed? And
14 if we do do that, currently American soldiers are
15 not being tested prior to deployment -- correct me
16 if I'm wrong -- but they are screened every two
17 years, and so should they actually be screened
18 pre- deployment? Should testing be performed
19 during deployment? And then, finally, should
20 donors then be rapidly screened prior to
21 transfusion. Let alone the issues that were
22 brought up about follow-up of those patients that

1 subsequently have been made, or those patients
2 that have received transfusion.

3 So with that I would like to conclude,
4 and I would be happy to answer any questions.

5 DR. SHAMOO: I still didn't get my
6 answer to my question I wanted to ask, and that
7 is, the legal basis for using something non-FDA
8 approved is what? Other than the courage, the
9 moral courage of the surgeon who wants to do good
10 in an emergency. Is my understanding correct?

11 MGEN. KELLEY: I think Dr. Pearson
12 actually is intimately aware of the issue.

13 COL. PEARSON: Colonel Pearson from Fort
14 Detrick. There is a law on the books called 10
15 U.S.C. 1107, that requires that the DOD --
16 actually it states, it starts off, when the
17 Secretary of Defense requests or requires the use
18 of a non-approved product, that they will go
19 through certain steps.

20 Now, the issue here is, the Secretary of
21 Defense doesn't request or require these things to
22 be done, but we're taking things and making de

1 service members did receive products that were not
2 necessarily approved by the FDA and weren't
3 provided prior consent, and this is basically
4 going back and correcting some of those previous
5 things that happened, you know, 14 or 15 years ago
6 now.

7 DR. POLAND: I have the same issue on
8 that. On the civilian side, to my knowledge there
9 is no circumstance, there is no circumstance under
10 which this could be done.

11 DR. SHAMOO: That's correct.

12 DR. POLAND: Period. It doesn't matter
13 how many lives are at risk or that they were
14 certainly going to die if you didn't. There is no
15 circumstance under which it could be done.

16 So we're dealing, though, with a
17 different set of conditions and environment,
18 etcetera, and taking that into account, is there a
19 policy or anything on sort of at what level can
20 that be done?

21 DR. SHAMOO: None.

22 DR. POLAND: Because my response to this

1 will be centered around this. If we say to
2 ourselves that it is unacceptable that a single
3 unit of blood that's HCV- or HIV- infected be
4 transfused, if that is our policy, we have one set
5 of recommendations. If the policy is, we'll
6 minimize that to the extent possible, that's a
7 different policy and set of recommendations.

8 So maybe can somebody clarify that for
9 me?

10 MS. EMBREY: I think that that's the
11 reason why we're asking the question, because the
12 practice and judgment of the practitioners in
13 theater are dealing with this situation in this
14 way within the existing policy framework of the
15 department, and it is of sufficient concern that
16 this practice or policy is giving us pause, and
17 this is why we are seeking your guidance.

18 DR. POLAND: Let me ask Dan to make a
19 comment.

20 DR. BLAZER: I guess my thought is, I
21 mean, I certainly understand the situation.

22 I think I would be very hesitant as a

1 Board to somehow say this is okay. On the other
2 hand, I also would be very hesitant as a Board to
3 say it's not okay, to be quite honest, because I
4 think this is -- I think it's an ethics issue.

5 I think it's a much larger issue than I
6 think we as a Board are capable of responding to.
7 I think we've heard it. I think we understand the
8 nuances of the situation. But going beyond that,
9 I think it's going to be extremely difficult for
10 us as well. I don't think we can have the
11 discussion, quite honestly, that would permit us
12 to come to the kind of decision we need to.

13 DR. POLAND: Right. Go ahead.

14 DR. SHAMOO: I think I understand what
15 you're saying. However, this is what society
16 faces. It faces two things: A moral new paradigm
17 that forces us to change our laws and regulations,
18 or an immoral act that used to be legal and new
19 law was established.

20 So I think this is nothing new in our
21 society, that we are faced, and as a Board, or you
22 could get other people to, we have to discuss it.

1 We recommend, and then the country as a whole has
2 to change the law if they think it's a moral
3 imperative.

4 And I am sure the surgeons -- that's why
5 in my question I said this is morally compelling
6 to the surgeons to do what they are doing, and
7 they're taking a personal risk. Even though they
8 are in the DOD establishment, that doesn't really
9 remove the liability from them. So we have to
10 face it and we have to put the best policy we
11 think that's appropriate as a public policy.

12 COL. GIBSON: Let me put a couple of
13 things in context before we go forward. This
14 Board has the right to say we're not going to do
15 it and turn away the question, so you have that
16 right. However, as Ms. Embrey talked about, we're
17 in a situation here where there are things that
18 you all can do to help us, help DOD frame this.
19 If there are issues that you as part of this issue
20 don't want to address, then don't address those.

21 There are things that can be
22 recommended, recommending things like we have

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1 rapid tests commercially available in the United
2 States that can be used if they are FDA-approved.
3 And so there are issues like risk analysis that
4 this Board is very capable of addressing, and then
5 not address those issues which you don't want to
6 address.

7 We're providing policies for DOD. This
8 package on this question is quite thick, and there
9 are old policies that will be provided to whoever
10 the Chair decides to assign this to.

11 DR. MILLER: I think it would be useful
12 to make a distinction right away between something
13 which, when we use the term "FDA approved" versus
14 a product which actually never even went before
15 the FDA. And I'm not sure what we're dealing with
16 here because this might be a product which is
17 viable, just never went through the process, and
18 that doesn't mean it's not a good product.

19 So that's a very important distinction
20 to make. It might be FDA approved, and this is
21 just a set of circumstances that these individuals
22 are overseas and there hasn't been an opportunity

1 yet to go through that. That's my first point.

2 The second is, going back to what Dr.
3 Blazer was mentioning, there is an issue here of
4 omission versus commission, in terms of what we're
5 doing in the field, and whether or not we're
6 looking for zero risk versus allowing at least the
7 principles and guidelines and the judgment of the
8 clinicians in the field to make that decision of
9 whether or not to use lifesaving products, which
10 in the short term is extremely beneficial but
11 perhaps in the long term -- and who knows what
12 that may well be, because the risks of HCV
13 infection or HIV won't necessarily even play out
14 until 10 to 20 years or 30 years into the future.
15 It may be irrelevant.

16 So it really becomes an overall
17 judgment, and I would hate to think that this
18 Board would make a blanket recommendation against
19 the use of products which just inhibit the
20 clinicians in the field, rather than perhaps to
21 perhaps commission a study to look at the
22 potential judgment on the usage of these products

1 in the field, to get a better flavor of whether or
2 not they're being used appropriately, because I
3 think we could potentially cause a damaging
4 situation, and we've seen this in the case of
5 vaccines.

6 DR. GARDNER: Pierce Gardner. Just to
7 follow on, I can't imagine us taking a role that
8 would say that -- put the field physician in the
9 role of having to choose between following a
10 regulation and saving -- what he or she believes
11 is a lifesaving. That, for somebody who took the
12 Hippocratic oath, that's just not a situation you
13 want to put them into.

14 So I think that we have to allow that
15 judgment in whatever we recommend. Now, what we
16 can certainly do is try to make this every bit as
17 safe as possible by making sure the donors are
18 well-tested. So you suggested testing on
19 deployment. That seems like a no-brainer to me.

20 My question, I think, don't we, Roger,
21 when folks are recruited, don't we check out their
22 Hepatitis B status and HIV status? We have blood

1 at the time of the -- but then to do it again on
2 deployment, and then the other thing is to get the
3 kit ready.

4 And those are two things that will get
5 us down to minimum, minimum, minimum risk but not
6 ever to zero.

7 COL. GIBSON: We will go through the
8 policies for HIV, HBV, and HCV. Dr. Rubertone is
9 coming up. He will give us a look at the
10 incidence, prevalence, primarily of HIV, in our
11 population at the present time. I've got some
12 data on a study on HCV in our cohort, and we'll go
13 through the policies, issues, and nuances that are
14 -- Colonel Ruscio is supposed to come and do it.
15 If he doesn't, I will.

16 DR. GARDNER: Okay. I'm sure that HCV
17 is going to turn out to be the numerical issue,
18 and there again the incubation periods are very
19 long. Again, most of the time you choose to
20 transfuse and take the risk of a long incubation
21 problem.

22 COL. GIBSON: The other thing that Kurt

1 really didn't bring up in his talk, you know,
2 historically military trauma care has set the
3 precedent for this country, for the world, and
4 particularly American trauma care.

5 So what these guys are doing is out
6 there, really out there, the point of the spear,
7 and to hamstring them, which I don't think is our
8 intent -- our intent is to what can we do to make
9 it the best.

10 DR. KAPLAN: Kaplan. Maybe I missed it,
11 but it seems to me that the basis for the
12 discussion about FDA approval or non-approval,
13 I've not seen data from the Spanish test that's
14 non-FDA approved, that tells me -- the assumption
15 so far has been that it's 100 percent effective,
16 and we don't know whether the test is any good or
17 not, which may change the whole argument.

18 DR. POLAND: That point was made. We
19 don't know what's happening. Did you have a
20 comment?

21 DR. WALKER: I think, pragmatically
22 speaking, the data says that the rapid test isn't

1 eliminating -- it's not accomplishing -- it's
2 making you feel good that you're testing, but they
3 aren't finding any positives. It's really not an
4 important part of the decision.

5 I mean, I think it's really important to
6 know that by doing the retrospective testing, and
7 to keep looking to know whether there is an issue
8 arising of transmission of something, but in point
9 of fact the data says that the use of that test
10 isn't accomplishing anything.

11 MGEN. KELLEY: I think that that's two
12 points. I mean, you can recommend that DOD get
13 the FDA-certified test, but also the other point
14 is that the lack of retrospective testing, which
15 really is less than 20 percent, that's probably
16 unacceptable; that all of these should be
17 retrospectively tested. At least they need to
18 give the risk assessment to the person who
19 received that.

20 DR. POLAND: One final comment, and I
21 don't want this to be misinterpreted, but the
22 Board seems to be leaning toward, "Well, gee, in a

1 circumstance like that, don't take away any of the
2 options."

3 But remember that what we do in medicine
4 is, where we don't know, is subject things to --
5 we try to make our decisions on evidence, to
6 subject them to trials and find out. In the
7 history of medicine, many times things that were
8 dogma, that this is what you do, were not found to
9 be helpful. You've just reviewed a series of
10 those that turned out to be true. So I do want us
11 to pause a little bit, and the select subcommittee
12 will look into this, but I think we want to be
13 careful about first doing no harm.

14 Joe, you had a comment, I think?

15 DR. SILVA: No. I think I enjoy the
16 debate here. It is tricky. I think Dave made the
17 important point that I asked about, which is, we
18 need to get better follow-up and see what's the
19 error rate for this test out in the field.

20 DR. POLAND: There are clearly a number
21 of nuances actually in the question, because it's
22 sort of the point of the process that occurs.

1 DR. SILVA: Right. Until we find out,
2 administratively it's acceptable to demonstrate
3 activity. We don't have to do anything right now,
4 and let them go on their way and gather data.

5 DR. LEDNAR: Wayne Lednar. Just a
6 comment. As Colonel Gibson said, really the
7 world's best approaches to trauma care, especially
8 in the combat environment, have been generated by
9 the United States in its experience.

10 And I just think all of us on the Board
11 want to thank you for the presentation you gave,
12 because the scientific basis that you took us
13 through for the response in this very difficult
14 situation is very, very hard to do, not only the
15 pathophysiology and the science underlying it, but
16 really trying to take a data-based approach to
17 assembling the experience to date, and being very
18 up front with us about where the data is thin or
19 we don't know and there are questions. So in this
20 very important question I think you have served us
21 all really well, and wanted to thank you for doing
22 that.

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1 DR. POLAND: Another comment?

2 SPEAKER: Just one clarification.

3 Retrospectively, there are 600 donations that were
4 not tested for EIA during follow-up, so there were
5 600 donations that we couldn't account for for
6 testing. The rest we could. About 4,900 worth
7 were actually tested.

8 DR. POLAND: There were 240 that were
9 tested out of the 2,800.

10 SPEAKER: That was for the screening,
11 but they have been able to retrospectively -- they
12 always collect samples off the donors if it's
13 possible, and they ship it back to the U.S. to be
14 tested. So there were 600 donations that were not
15 followed up with EIA testing. Okay? Is that
16 clear?

17 DR. POLAND: Okay. Next is Colonel Mark
18 Rubertone, who will brief us on current HIV
19 testing policy and HIV incidence in military
20 service members.

21 COL. RUBERTONE: I'll actually hold my
22 briefing on the policy. I'm going to focus on HIV

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1 incidence in service members. I appreciate the
2 opportunity to come back and visit with the Board.
3 The last time was exactly four years ago at West
4 Point, so I will mark my calendar for 2010.

5 The outline I'm going to talk about
6 really has two major areas, one of which is HIV
7 testing in the active component, starting with the
8 definition of terms and then focusing on the HIV
9 screening and seroprevalence. And the second one
10 is HIV testing in relation to deployments, looking
11 at some of the intervals between test and
12 deployment, estimating HIV infections in
13 deployers, and looking at the first HIV positive
14 test following deployment.

15 I'm going to start off with just some
16 definitions, but it would be presumptuous of me to
17 lecture such a distinguished group, or for that
18 matter this esteemed body. But in terms of some
19 of the subtle differences between these
20 definitions, I will say that unfortunately these
21 terms are used fairly interchangeably in reports.
22 The difference there --

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1 COL. GIBSON: One quick second. His
2 slides are at the very back of this Section 6.

3 Sorry.

4 COL. RUBERTONE: No problem. In each
5 case you will notice that the numerator is the
6 same: It's the number of newly detected
7 individuals in a given year or a given period.
8 The change is in what's the denominator. So
9 seroprevalence is typically what the military
10 names in a report as the rate of infection, is the
11 number of newly detected individuals in a given
12 population divided by the number of individuals
13 that were actually tested in a given year. So
14 it's the number of positives over the number of
15 people.

16 Occasionally prevalence or a period
17 prevalence, as described for an event, is the
18 number of newly infected individuals divided by
19 the total number of serologic tests in a given
20 year, positives over tests.

21 Finally, the incidence rate, which is
22 rarely actually reported, is the number of newly

1 detected individuals in a given year divided by
2 the number of person years since the last negative
3 test, so actually tracking individuals from a
4 negative test over time, cumulative person-time,
5 and then positives over person-time.

6 So how do these three metrics look? If
7 you look at the top line just for a second, we see
8 that this top dark black line is what we call the
9 seroprevalence. That is actually a rate that is
10 often reported in reports on HIV. It has gone
11 down dramatically since the mid-'80s, and as you
12 can see since 1990, and now at least for the Army
13 is somewhere around 0.16 or so per 1,000 persons
14 tested in a year. So this line here is test
15 positives in a year over persons tested in a year.

16 The dashed line is the prevalence, and
17 that is the number of positives over the number of
18 tests per year, which may seem a little
19 counter-intuitive but it actually is a better
20 reflection overall, based on our policy of testing
21 fairly frequently in the military, to the actual
22 incidence rate.

1 The bottom line rates the incidence of
2 HIV in the active duty Army, the incidence in
3 cumulative person-time since last negative test,
4 in order to determine the number of positives, and
5 it is approximately 0.12 for the Army for the last
6 four or five years.

7 Turning to the upper line, this is just
8 the time, the mean time since the last prior test
9 of all of the tests in a given year. That might
10 be a little bit much to go into in a short time,
11 but basically we know the policy for testing in
12 the Army is to be tested every two years. On
13 average, and these are inconsistent, we are
14 testing about every 11 months. And with the war in
15 Iraq and Afghanistan, the Iraq war, for a couple
16 of years we have actually really been testing
17 pretty close to almost a year, a little over 13
18 months between tests. When the time, the mean
19 time approaches, when it becomes one year since
20 the last test, the prevalence rate actually does
21 become the incidence rate, because the person-
22 time of these individuals since their last test is

1 actually just a year.

2 When the mean time is higher than a
3 year, then that means that we're testing less
4 frequently, they accumulate more time and the
5 incidence becomes lower.

6 So at the risk of confusing you, the
7 remainder of the -- the numbers I'm about to
8 present for the military will be this line here,
9 the seroprevalence. Later on when I give you an
10 analysis of HIV infections in relation to
11 deployment, I will actually use the incidence rate
12 because that's how it was done.

13 This is the data for the last four years
14 for the active component, and I purposely left out
15 the reserve component because there are some
16 issues raised on HIV follow-up and testing.
17 Reserve component testing is a little bit more
18 difficult to present, so I stayed with the active
19 component.

20 This is the last four years of data. I
21 want to acknowledge the Navy and the Air Force for
22 providing the data. Actually I would be remiss if

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1 I didn't mention Roger Gibson. It took me -- I've
2 been working for years trying to get the Air Force
3 to send me positive data, unsuccessfully. It took
4 Roger three days. I wish I had called him sooner.

5 You will notice that each of the
6 services over the last four years have been fairly
7 stable, as you can see, and this next slide
8 actually shows some of the details behind those
9 numbers. This first column is the total HIV tests
10 that were done, and these are the total persons
11 tested, so people are tested fairly frequently.
12 It could be more than once a year or as often as
13 once a year.

14 This is the total number of HIV
15 positives for the different services for the
16 four-year period, and this here is the positives
17 per 1,000 persons tested for what we're calling
18 seroprevalence.

19 This middle column says approximately
20 what percent of the force was tested in a given
21 year. And the percent of total force tested seems
22 to hover around 60 percent, as you can see, except

1 for the Navy which tests 75 to 80 percent of its
2 force each year. The Army also tests
3 three-quarters of its troops.

4 I will now turn my attention to the HIV
5 testing in relation to deployments, and this first
6 slide describes the testing interval prior to
7 deployments to Southwest Asia, OEF and OIF. I'm
8 going to focus on the last four or five years
9 worth of data. This is in active duty U.S. armed
10 forces.

11 And, as you can see, in days for the
12 different services, most -- and this is the
13 average -- but most of the testing is done
14 actually within a one-year period, and in fact
15 within later years it's about six months prior to
16 deployment where we're seeing the HIV testing
17 done. And a lot of that is driven by the
18 retainment policy which calls for testing within
19 one year. Not all troops are tested every year,
20 but right now the majority are tested for HIV.

21 This is the cumulative percent of
22 deployers with HIV tests, and this basically says

1 that most of the services, the Army, the Air
2 Force, and the Marines and the Navy, the Army and
3 the Air Force, they start out at about 50 percent
4 of their force are tested actually within three
5 months of deployment. The Navy and the Marines
6 are a little bit lower within three months.

7 But by two years, which is the current
8 policy, virtually 100 percent of the force or very
9 close to 100 percent have been tested. Certainly
10 when you're out past 24 months, it is 100 percent,
11 so that everyone in the military does have at
12 least one negative HIV test.

13 This data seen on this slide is for
14 everyone combined, and what it shows is that about
15 50 percent of the individuals deploying had a test
16 within three months, another 20 percent had a test
17 within three to six months, another 10 percent had
18 a test within six to nine months, and you can see
19 the cumulative percent here is just like what was
20 shown on the other slide, approaching 100 percent
21 at 24 months. So most people are tested shortly
22 before deployment, which is actually in alignment

1 with policy.

2 So does this mean that there are or are
3 not HIV-infected individuals who are sent on
4 deployment? Well --

5 DR. POLAND: Mark, can I just ask, is
6 there anything peculiar to the group past 12 months
7 that might suggest their incidence would be higher
8 or lower? In other words, is there some reason
9 somebody is tested at 24 months and not at 12
10 months that goes to a greater or lower risk of
11 being positive?

12 COL. RUBERTONE: Probably lower risk.
13 The more frequently individuals are tested for
14 HIV, the higher the incidence rate in that
15 particular group. We call for testing as needed,
16 for testing that's risk-based. The group that's
17 tested out in the stream tend to be the lower risk
18 group, married, officers, and more senior
19 enlisted.

20 This slide just shows a hypothetical
21 estimate of HIV infection that you might expect to
22 occur in the force, actually an estimate of 150

1 HIV infections, and basically three components
2 emerge from this estimate.

3 First is the size of the population,
4 which is 200,000 population. The second thing we
5 need to know is the infection rate, and in this
6 case there is a bunch to choose from, all the way
7 from 0.08 to 0.20. The one in dark is actually the
8 Army current rate of 0.12. And the third thing is
9 the time in years between HIV test and the
10 deployment.

11 So, for example, if the average time for
12 test prior to deployment was approximately a year,
13 and we use the current Army rate, you would expect
14 to find 20 to 25 individuals that were undetected
15 at deployment in that population. Of course, as
16 you go out in time in years, the number goes up in
17 the population.

18 The obvious question is how to handle
19 the infected individuals who actually were
20 undetected when they began to deploy, and the
21 answer is we really don't know. They are
22 undetected. One way to know how many we would

1 deploy, would be to test everyone the day before
2 they deploy.

3 So the group made an analysis of HIV
4 testing in deployers. We tried to get a little
5 bit better handle on that. And this is Army-only
6 data, because I don't really have the Navy and Air
7 Force data to do the same kind of analysis.

8 I should tell you at the beginning, I
9 usually start with a slide that goes over, defends
10 my risk analysis, but I don't have really have the
11 time here. But I can truly say all of this data
12 comes from the Defense Medical Surveillance
13 System, which integrates data from various
14 sources, personnel data, medical data,
15 immunization, deployments, pharmacy and other
16 data.

17 Some of my technical folks were
18 impressed by how large DMSS is, and I would say
19 there are literally 1.4 billion records that
20 constitute the Defense Medical Surveillance
21 System. Of those records, about 480 million of them
22 are HIV tests. This goes back to about 1985. And

1 of those 48 million, we have about 40 million
2 which were associated with a serum specimen, and
3 we have those stored at minus 30 degrees Celsius.
4 We have the world's largest serum repository.

5 Moving on to this analysis, only
6 assumptions: First, that there is a uniform risk
7 among deployed forces. That's certainly
8 debatable, but for the purposes of this analysis I
9 didn't want to make negative assumptions on risk.

10 The risk that we used was the risk in
11 deployers comparable to the Army rate, and as you
12 can see, there are some differences in the
13 composition of the deployed forces and the Army.

14 The third assumption was that there was
15 no risk during deployment. Policy would lead you
16 to believe that there is little opportunity for
17 there to be risk behavior in this deployment. It
18 may not end up being a factor in the case, but for
19 the purposes of this analysis we have eliminated
20 deployment time in terms of being at risk.

21 The last assumption is that the
22 deployment roster that we received from the

1 Defense Manpower Data Center actually is accurate,
2 and that it reflects deployed service members and
3 deployment dates. I think it's a pretty good
4 assumption. It's not 100 percent, I'm certain,
5 but I think it's good enough for this kind of
6 analysis.

7 In terms of the analysis itself, we
8 looked at active component Army soldiers deployed
9 between 2001 and 2005, deployments to Southeast
10 Asia, OEF, or OIF. We used a background incidence
11 rate of 0.12 per one thousand person-years. Deployed
12 time, as I mentioned, was not counted toward
13 overall person-time at risk. And only sera tested
14 that actually had an infectious result were
15 included in the analysis.

16 This is a comparison of the demographic
17 and military characteristics of the deployed
18 soldiers relative to the Army as a whole, and in
19 general the deployed members tend to be young,
20 single males, a little bit of other race
21 ethnicity, a small difference in ethnicity. So
22 compared to the Army overall, looking at known

1 risk of single men, there is a slightly higher
2 proportion in the deployed group than in the Army
3 overall.

4 The results, turning to the expected
5 versus observed, number of HIV infections, we had a
6 total of 372,000 deployed soldiers during this
7 period. There went on 514,000 separate
8 deployments also during those months, over the
9 five-year period, and in fact they had 219,000
10 person-years at risk of developing any type of an
11 infection. This was both the time prior to
12 deployment and post deployment.

13 So typically some of them had an HIV
14 test prior to deployment, three months passed,
15 they deployed, they came back, maybe 30 days or
16 another couple of months occurred before they had
17 a post-deployment HIV test. So the time before
18 and after constitutes this person at risk, person-years
19 at risk. Seventy-five percent of the person-time
20 actually did occur in the pre-deployment period/
21 post-deployment period.

22 So what does this mean? If we apply the

1 0.12 per thousand person years at risk for HIV, we
2 would expect typically to discover 26 HIV-infected
3 soldiers at the time of their post-deployment
4 screening test. So that's just based on pure
5 assumptions in this analysis. What we actually
6 observed was 41 infected soldiers on their first
7 post-deployment screening test.

8 This is a listing of the 41 individuals,
9 a breakdown of the months since the months since
10 their last negative test in the pre time and the
11 months before their first positive test in the
12 post time. So, as I said, about 75 percent of the
13 total person-time overall is in the pre-deployment
14 period, and it's also true for the individuals
15 that came back and were first detected as
16 positive.

17 Most of the time that they were at risk,
18 so to speak, was in the pre-deployment period.
19 Overall, cumulative risk, they had long post-
20 deployment times before they were tested for HIV.

21 It's important to note that not all of
22 the pre- and post-deployment specimens are tested

1 for HIV, so anyone who is trying to look at the
2 policy of testing individuals within 30 days of
3 return from deployment or within a year of
4 deployment for a pre- deployment specimen, you
5 really can't make those assumptions or conclusions
6 off of this slide. This just talks about those
7 that actually were tested for HIV.

8 And when you look at the overall policy,
9 most individuals are within the two- year window.
10 Anyone past this line in cumulative amount of pre-
11 and post-time would officially be outside of the
12 Army's testing policy of every two years.

13 It means a few individuals here went a
14 month longer, less than a month outside, although
15 there are a few individuals who were six months
16 remiss. Particularly there is one individual who
17 went for a full 39 months prior to deployment for
18 his last HIV test, and then he had no
19 post-deployment time because he tested positive.
20 This person certainly, I would say, fell through
21 the cracks.

22 So what are the conclusions, whether

1 further study is needed? Well, certainly the
2 overall risk in deployers may not be comparable to
3 Army. As we saw, deployers, higher number male,
4 single, more at risk, and their risk might be a
5 little higher than comparable Army.

6 Risk during deployment may not be zero.
7 I didn't point it out, but we had three cases
8 where an individuals tested negative within a
9 month or days before deployment and tested
10 positive within days after deployment.

11 Now, they certainly could still have
12 become infected prior to deployment and just
13 tested negative in that sort of window of still
14 being negative for infection. So we don't know if
15 the risk during deployment is zero.

16 The last one that I think worthy of
17 study, deployers may actually engage in risky
18 behavior close to beginning and end of deployment
19 period, and they may actually be at higher risk of
20 infection than they normally would be otherwise
21 because of the deployment.

22 I just want to provide some

1 acknowledgements to some of my co-workers, in
2 particular John Brundage, Captain Halverson, and
3 Ellen Wertheimer. Also, for data from Data
4 Services, Captain Tasker and Lieutenant Colonel
5 Sjoberg, for providing the data for the Navy and
6 the Air Force.

7 And that's the end of my talk, and I'll
8 take your questions.

9 [Applause.]

10 DR. POLAND: Joe?

11 DR. SILVA: Nice presentation. Silva.

12 In those 41 cases, how many of them knew they were
13 going to be HIV positive? They had no way to
14 know?

15 COL. RUBERTONE: I have no way to know
16 what they knew, but this was their first reported
17 HIV positive test, so according to official
18 records they were HIV negative when they deployed,
19 and positive upon their post- deployment test.

20 DR. LEDNAR: Wayne Lednar. Nice
21 presentation, Mark. Two questions: One is,
22 obviously from a transfusion risk point of view,

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1 HIV is an important agent but not the only one.
2 Are there data to suggest that over time, like
3 you've shown for HIV since the mid- '80s going
4 forward, that the seroprevalence of other
5 blood-borne transmissible agents of concern has
6 also changed in the same way? Would we expect
7 that the risk factors that are shared, for
8 example, with Hepatitis C, might show curves for
9 Hepatitis C seroprevalence that would follow that?

10 MGEN. KELLEY: Yes. We don't do regular
11 testing for other infectious agents. I don't have
12 information on the number of diverse cases over
13 time. But in terms of routine testing data
14 available, we don't have that.

15 DR. LEDNAR: The second question is kind
16 of a practical one about during the time of
17 deployment, is there opportunity to leave the
18 theater, not return to home station, but in fact
19 get some R&R in a place where you could engage in
20 risky behaviors but for this purpose you're still
21 within the deployment time frame.

22 MGEN. KELLEY: I'll defer that to

1 Colonel Stanek from the Surgeon General's office.

2 LTC. STANEK: This is Lieutenant Colonel
3 Scott Stanek from the Army Surgeon General's
4 office.

5 At least for the Army, who goes over
6 there for a year, the soldiers who are deployed
7 are allowed two weeks of leave, during which time
8 they return -- actually most go back to the United
9 States. So certainly during that two-week window
10 there is ample opportunity for them to engage in
11 risky behavior.

12 DR. MILLER: Miller. Related to that
13 question, actually you had a very nice
14 presentation. You showed some interesting
15 differences between the services, and one service
16 which had noticeably higher rates was actually the
17 Navy, and I'm curious whether or not the
18 circumstances of their deployment, that they are
19 on ships and then are given R&R, is there any
20 relevant testing which is done after the R&R
21 activity.

22 COL. RUBERTONE: Well, I don't know the

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1 answer to that question, whether they are
2 specifically testing after potentially risky R&R,
3 but I do know -- maybe Captain Tasker knows if
4 their high rates are related to being in high risk
5 areas during deployment.

6 DR. HALPERIN: A sort of fundamental
7 question I don't understand. If someone is HIV
8 positive and asymptomatic, they can stay in the
9 military?

10 COL. RUBERTONE: Yes, they can. Until
11 they are medically unfit to be in the military,
12 they can remain in the military. There are some
13 HIV-positive individuals who have been in the
14 military for over 15 years.

15 DR. HALPERIN: If someone is HIV-
16 positive, are they retested for HIV?

17 COL. RUBERTONE: That's a good question.
18 I believe they should be, and the reason so is
19 because oftentimes troops are sort of marched down
20 to the testing place, especially young troops, and
21 you wouldn't want to single anyone out and say,
22 "You don't need to be tested." So even though

1 DR. PARKINSON: Yes, Mike Parkinson.
2 Just an observation which is striking is that a
3 policy of the department administered through the
4 services appears to be followed, which is the
5 periodicity of testing and the fact that it's
6 actually coming down to be one to two years and
7 it's actually effective, so I think that should be
8 noted as a kudo because it's not easy to do and
9 it's been a long time coming. So that's -- your
10 data is very compelling there.

11 The second thing it does, I think, in
12 advancing our dialogue as we go through this, is
13 it helps frame for me, you've got a major
14 technological or practice innovation in the field,
15 that probably a Med-Net is the right thing to do.

16 Secondly, now we've got a strategy
17 where we can begin to parse out the known
18 transmissible blood-borne agents and do some type
19 of risk stratification. And HIV fits very nicely
20 into one that to my read is, yes, while you can't
21 minimize all risk, it's certainly down there where
22 in a deployed force of 140,000 troops it's getting

1 pretty much down there.

2 So then it helps me frame, okay, where
3 do I want to go with Hepatitis B, with Hepatitis
4 C, with other types of issues, and the
5 availability of such things as rapid diagnostic
6 testing and/or accelerating FDA approval and/or
7 whatever. So this was very helpful in the
8 construct, I just wanted to feed that back, in my
9 personal view.

10 DR. POLAND: Joe?

11 DR. SILVA: Silva. I think many of you
12 know this but some may not. A new triple
13 combination HIV pill came out about, what, five or
14 six weeks ago, Atripla. It's once a day, and it
15 looks just -- you know, people with this disease
16 literally can take one tablet, probably suppress
17 it. Burdens of resistant bugs yet to be
18 determined, but it looks like it's going to be
19 quite slow from the initial data.

20 COL. GIBSON: One point on HCV. There's
21 a paper in your package by Hyams, et al., and Dr.
22 Rubertone, that talks about the prevalence and

1 incidence of Hepatitis C in the military, over
2 21,000, came from serum repository data, gives us
3 seroprevalence, gives us incidence, and one thing
4 the Board might consider -- this paper was done in
5 2001, right?

6 COL. RUBERTONE: Yes.

7 COL. GIBSON: -- is if you really want
8 to know what is happening with HCV in the military
9 cohort, review it.

10 DR. POLAND: Mike?

11 COL. SNEDECOR: Mike Snedecor, Air
12 Force. A question for you: Does this testing
13 compliance data include the reserve components?
14 Because we know the Air Force Reserve and I
15 believe the Army Guard have been testing to a
16 five-year testing frequency, not the two-year.

17 And then a question for Roger: Are we
18 going to ask the Board about the conflict between
19 the two-year and the five-year recommendation,
20 between the reserve component and the active?

21 COL. GIBSON: We'll get into that. As
22 part of this issue, we'll sort of look at that.

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1 There's some nuances that we may have to offer,
2 yes.

3 COL. RUBERTONE: To answer your
4 question, it's not our policy to exclude any data.
5 We just include any tests that were done.

6 I just leave one last thing for the
7 Board to consider, and that is, although the
8 testing prior to deployment is very short, and
9 that is mostly driven by the treatment and the
10 test, the Army is about to separate out the
11 three-point testing from its HIV testing program,
12 and do not intend to do testing on all specimens.

13 DR. POLAND: Okay. Thank you. We're
14 going to have a quick presentation by Colonel
15 Bruce Ruscio on DOD's current policies relating to
16 HIV and Hepatitis B and Hepatitis C. Following
17 that we will take about a 10- minute biologic
18 break.

19 LTC. RUSCIO: Dr. Poland and Colonel Gibson
20 and Board members, Colonel Gibson asked that I take a
21 couple of minutes just to go over some of the policies
22 at the Office of the Secretary of Defense (OSD) level.

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1 I just captured the most current ones,
2 and from a policy perspective the interesting
3 aspect for you is going through and seeing
4 policies over the years, policy development and
5 how that occurred. And I did capture, in your
6 slide you'll see I captured the AFEB
7 recommendations throughout the years.

8 If we could look on the first slide,
9 Hepatitis B immunization, vaccination of new
10 recruits against Hepatitis B, about -- this is the
11 2000-2001 time frame. The services are in the
12 process of updating their session standards, as
13 DOD has updated its sessions of directed
14 instruction, and these should be incorporated in a
15 policy memo to the directorate.

16 Ms. Embrey's shop this year has updated
17 both the Individual Medical Readiness (IMR) directive
18 and that requirement as an IMR. It's a pass/fail
19 for initiating, having the Hepatitis B
20 vaccination.

21 Hepatitis C, the policy memo is still in
22 existence from 1999, and this is Dr. Bailey's

1 policy memo. And interesting about that I think
2 is that -- actually it's still working -- is that
3 individuals who are 35 years or older when they
4 are separated from the military, receive a
5 letter in their packet offering Hepatitis C
6 testing and then follow-up care, based on a
7 screening questionnaire. That's an optional, but
8 it's presented to all service members as they
9 prepare to leave the military.

10 HIV testing, this is the 2004 memo,
11 policy memo. This is the 24 months policy. That
12 has been incorporated into DOD and service
13 directives, and is, I think, resulting in less
14 questions we're getting about the testing, the
15 interval of testing.

16 As I mentioned, I included the AFEB
17 recommendations on the following slides, but the
18 IMR's, the 2004 memo is a result of work on the
19 AFEB recommendations. And then, as I mentioned,
20 6130.4 DoDi, the directive, and the services
21 directives are being updated consistent with the
22 policy memos.

1 I don't have all these memos here.
2 Those are actually just some of the
3 recommendations that, questions that have been
4 presented to the Board. You will note that here
5 it's just Hepatitis B and HIV.

6 DR. POLAND: One question: Are we sure
7 that the policy is two years, not yearly?

8 COL. GIBSON: The policy for HIV testing
9 in the military is careful testing, based on the
10 recommendation of this Board, every two years.
11 The policy for post- deployment blood collection,
12 serum collection, is one year prior to deployment.

13 The connection is that if you have an
14 HIV test within that period of time, within that
15 one year, you can use that HIV test to meet your
16 pre-deployment requirements. If you have,
17 currently if you have a post-deployment test or a
18 pre-deployment test that is HIV tested, which the
19 Army was doing, that meets your HIV requirement,
20 so there's a link there.

21 The only service that has a strong link
22 between HIV testing and pre-deployment testing

1 right now is the Army, and, as you heard from
2 Mark, that is being separated out.

3 These things were mixed together heavily
4 in years previous. The services were all over the
5 board, from five years to one year, as far as how
6 often they were HIV testing.

7 This Board took an approach based on a
8 set of assumptions, one of which was to let them have
9 emergency blood transfusions for rare events, and
10 said that HIV testing was based on the risk to the
11 service member from military hazards, not based on
12 the risk of an HIV-positive person to the service,
13 which is fine. The game has changed. So that's
14 one of the reasons this question came up.

15 DR. POLAND: Russ?

16 DR. LUEPKER: I realize it's not on your
17 list of presentations here, maybe you're not the
18 right person to ask this, but are we still
19 immunizing for anthrax?

20 COL. ANDERSON: This is Colonel
21 Anderson. Currently we are voluntarily
22 vaccinating against anthrax for people deploying

1 to high risk areas, Afghanistan and Iraq or Korea,
2 and then special units. That's currently
3 voluntary.

4 DR. POLAND: Pierce?

5 CDR. McMILLAN: I have a quick question
6 or a statement before we go to the break. I don't
7 want to hold everybody up.

8 Navy and Marine Corps have been looking
9 at this whole issue for quite a while now, based
10 upon the knowledge of the transfusions that are
11 occurring in theater, and trying to come up with
12 an administrative solution, since an engineering
13 solution that would appear to be some time off as
14 far as an FDA-approved quick test.

15 We are looking at trying to shift from a
16 universal walking blood bank to a more
17 pre-selected walking blood bank, to have people
18 actually go to the current blood donor systems,
19 Red Cross or military, donate blood within some
20 interval prior to deployment, being pre-identified
21 as troops being deployed by their donation, and
22 use them. We would use incentives if we need some

1 high value groups, such as rare blood types and
2 stuff, to get those people enrolled in the
3 program.

4 One of the key things that we have as a
5 question, I think may dovetail into what you would
6 be answering, is that issue of how long an
7 interval prior to deployment should we look at
8 getting that donation for a group with some degree
9 of controlled risk factors? So that's kind of
10 what we're looking at in administrative control.
11 That is some things that hopefully you all will be
12 able to look at as a way of kind of an interim
13 solution for an understanding that fresh whole
14 blood is going to be transfused in theater, what
15 can we do better up front to try to help reduce
16 that risk.

17 DR. POLAND: We'll take a 10-minute --
18 I'm sorry, Pierce.

19 DR. GARDNER: We're focused on HIV, but
20 in fact Hepatitis C is the more transmissible and
21 numerically larger problem, as I read it.

22 DR. POLAND: It's a growing problem in

1 civilians.

2 DR. GARDNER: Yes. So, Roger, you said
3 we don't deploy HIV-positive folks to theater
4 because of issues of blood transfusion. Is that
5 correct? If they're HIV-positive, they don't go
6 into combat.

7 COL. GIBSON: There's a multitude of
8 reasons why they don't go. One of them is the
9 walking blood bank. But if you know you're
10 HIV-positive, then it's real simple. You don't
11 want to donate.

12 DR. GARDNER: Okay. What about if
13 you're Hepatitis C? Do you get deployed?

14 COL. GIBSON: We don't test for
15 Hepatitis C.

16 DR. GARDNER: It seems to me that's
17 going to come up in our discussions. It's
18 numerically -- and what about if you're Hepatitis
19 B-positive?

20 COL. GIBSON: Hepatitis B positives,
21 because we screen, we know what's going on, and
22 we're immunizing those folks who do deploy. And

1 if we already know they're Hepatitis B positive,
2 we don't --

3 DR. GARDNER: What if you're chronically
4 infected? What if you're a chronic Hepatitis B
5 carrier?

6 COL. GIBSON: There are people in the
7 military who are chronic HBV.

8 DR. GARDNER: Do you get deployed?

9 COL. GIBSON: Yes, but they know that
10 they're not a risk to the walking blood bank
11 because they've been tested and they know that
12 they're a chronic carrier.

13 DR. GARDNER: Okay, so we do need to
14 discuss Hep B. Hep C, I mean.

15 CDR. McMILLAN: I'm not aware of a
16 program, at least for the Marine Corps/Navy, that
17 does a routine screening for Hepatitis B surface
18 antigen, so only if they're symptomatic, maybe,
19 would they be screened for that. But as a routine
20 we don't test for Hepatitis B surface antigen or
21 Hepatitis C.

22 COL. GIBSON: Marine Corps, they do that

1 -- I should preface that. When we instituted the
2 HBV vaccination program, that's when that started.

3 DR. POLAND: Okay. We will take a
4 10-minute break, reconvening at 10 to.

5 [Recess.]

6 DR. POLAND: If we could have members of
7 the Board take their seats, please, we will get
8 started. And the side conversations are a little
9 distracting.

10 Our next speaker this morning is Dr.
11 Shelley MacDermid, Co-Chair of a very busy
12 subcommittee now the AFEB, the congressionally
13 directed Task Force on Mental Health. I had the
14 opportunity to meet with Dr. MacDermid this
15 summer. I attended, I don't know if it was your
16 first meeting, as well as General Kiley at that
17 time, too.

18 Remember that this task force is engaged
19 in a very ambitious effort, preparing a report for
20 the Secretary of Defense on the effectiveness of mental
21 health services for military members and any
22 recommendations for improvement. As an active

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1 AFEB subcommittee, the task force will
2 periodically report on their activities to the
3 full Board.

4 Dr. MacDermid, thank you for coming.

5 DR. MacDERMID: Thank you very much. I
6 did not mention, when I introduced myself, what my
7 day jobs are, and so just for background I'll tell
8 you that I am a Professor of Child Development and
9 Family Studies at Purdue University. I also serve
10 as Associate Dean of Consumer and Family Sciences,
11 Director of the Center for Families, and
12 Co-Director of the Military Family Research
13 Institute. I'm not a mental health clinician, but
14 I have been doing research on military families
15 for the past five or six years and so was invited,
16 I assume, to serve on the task force in that
17 capacity, and was subsequently elected as co-
18 chair.

19 DR. POLAND: And Dr. MacDermid's slides
20 are at Tab 8.

21 DR. MacDERMID: I am following the
22 format that was requested for presentations to the

1 AFEB, so what I'm going to tell you about is how
2 the task force has been organizing its work, what
3 it has done to date, and what activities are
4 planning. My purpose is to share information
5 primarily about the process of the task force
6 because we all feel that it's too early to be
7 saying very much about the content.

8 As you know, the task force has 14
9 members. Seven are DOD and seven are non-DOD,
10 although among the non-DOD members there are
11 several who have experience with DOD-related
12 capacities such as work in the Veterans Affairs (V.A.).
13 One of the non-DOD members is a reservist, and so on.

14 There are representatives from each of
15 the Armed Services, as you know, and military
16 families as well as mental health and other
17 fields.

18 So the things I'll tell you about are
19 our organizational structure, the activities that
20 we've carried out to date, and the planned
21 activities.

22 If you recall the elements that the task

1 force is required to report about, there are 17,
2 with the last one being the famous "other things
3 as seem appropriate." The main content that has
4 gone into that is attention to guard and reserve
5 units. They were not specifically labeled in the
6 elements, but our reading of the elements is that
7 they would certainly be considered relevant to the
8 work of the task force.

9 We have divided the elements into four
10 groups, one group focusing on active duty, one
11 group focusing on continuity of care, one on the
12 evaluation of services, and one group focusing on
13 family-related issues. Task force members then
14 have divided themselves among these working
15 groups, and if you study this you will note that
16 each task force member, with the exception of me,
17 is serving on two groups. I'm serving on only
18 one.

19 Our goal is to try to make sure that
20 there is easy flow of information among the
21 working groups; that we don't become provincial in
22 our focus; and that it's easy for, at the end,

1 everybody on the task force to feel very in touch
2 with whatever recommendations are generated, so
3 we're not divided in terms of this group is
4 responsible for recommendations related to this
5 particular group of elements and nobody else gets
6 to say anything about that.

7 The activities, the full task force held
8 its first closed meeting on July 15 and in
9 Washington. We held our first open meeting last
10 week at Fort Hood, Texas.

11 As a back story I'll tell you that I
12 went away on a long-planned family vacation in
13 August for three weeks to French Polynesia, and I
14 came back to find that this task force had decided
15 that we really needed to visit many, many, many
16 more places than we had originally been talking.
17 And so I'll tell you a little more about the
18 travel schedule soon.

19 So there are closed meetings and open
20 meetings, and then the working groups, each group
21 meets by teleconference approximately every week.
22 In addition, there are support requirement updates

1 and discussions also approximately every week. So
2 I think the level of activity is high.

3 At the moment I would say that there are
4 two kinds of information-gathering going on. One
5 is, we have been trying to figure out who needs to
6 talk to us, who has the information that we think
7 we need, and can we get them invited so that we
8 can hear from them.

9 We also are requesting or providing the
10 opportunity for groups to provide us with written
11 statements if they wish to. So, for example, the
12 National Military Family Association might wish to
13 provide a written statement with their concerns.
14 We are sort of in the mode at this point of being
15 inclusive with regard to information, as opposed
16 to exclusive.

17 We have developed questions for the
18 military services, and those requests have gone
19 out. It's a long list of information that we have
20 asked for, to be able to try to get a good handle
21 on what the current level of needs are, what the
22 characteristics are, and so on.

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1 We also have developed a list of
2 questions for different groups that we intend to
3 ask on the site visits. So in these site visits
4 that I'll tell you about, our goal is to speak
5 with a certain set list of people, and then we
6 have a certain set list of questions that we hope
7 to ask to those people.

8 That is a guide, an instrument. The
9 goal is that we're trying to gather systematic
10 information on every visit, no matter who is on
11 that visit, so that we get a picture at the end
12 that we can do something with.

13 We also have begun to try to talk about
14 what should the report format be, how will we
15 define mental health, how will we decide what
16 recommendations, what the procedure will be for
17 recommendations to the Board. Those are
18 procedural issues that are important to do.

19 The site visits, basically what is
20 happening, what has already begun to happen, is
21 that almost every week for the next six months,
22 five months now, groups of task force members will

1 be on site at military installations almost every
2 week. A group is scheduled to leave tomorrow for
3 Asia. We had a site visit to Fort Hood last week.
4 We had a site visit to Fort Drum the week before.
5 We're visiting the San Diego area in October.

6 The feeling was that we're never going
7 to get a really good handle on the regional
8 variations and the service variations if we don't
9 get out there and talk to people.

10 At each site visit our goal is to talk
11 to the providers there, both on base and in the
12 community. Our goal is to talk with the
13 commanders there who oversee the mental health
14 services, as well as of course the installation
15 commander, to understand the patterns that they
16 are seeing.

17 And our goal also is to hold at least
18 one open meeting at each site that we go to,
19 because we don't want the task force to be eight
20 months of officers and Ph.D.'s talking to each
21 other. We wanted to create a pathway, so if an Enlisted-2
22 (E-2) had a burning issue and wanted to tell us about

1 it, they would have that opportunity.

2 And having been on one site visit now, I
3 think it's very important. We heard material from
4 a psychiatrist who had just returned three days
5 before from Iraq and was able to tell us about the
6 work that they had been doing. It was very
7 instructive. And we also heard from individual
8 members who were struggling, after a long period
9 of recuperation, continuing to struggle with their
10 own physical and mental health challenges, and I
11 felt that it was important that they had that
12 forum.

13 I neglected to include in the list here,
14 Washington is our next open meeting, and I forgot
15 to look up, but we're meeting in San Diego in
16 October and San Francisco in November, and in each
17 place we'll be touring facilities also, in an
18 effort to try to understand best practices and
19 things that are going on out there.

20 So that's sort of where we're at. The
21 information is now coming at us in a flood, and it
22 will take all of us to figure out how to focus it

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1 now into the elements.

2 COL. GIBSON: Just as a quick follow-up
3 for the Board members, we discussed -- Tom Burke
4 came to the last meeting, Dr. Burke, who is the
5 executive secretary for the task force, where he
6 provided the terms of reference, this whole group
7 of elements, etcetera. I neglected to put it into
8 the book. I'll send it to you by e-mail. For the
9 rest of you in the audience, if you're interested
10 in it, Google AFEB. That page has a banner on the
11 congressionally directed Mental Health Task Force,
12 so you can get all of the same information I'm
13 going to send to the Board members right there.

14 Jackie?

15 DR. CATTANI: Jackie Cattani. I was
16 just wondering if you have structured protocols
17 and instruments for these site visits, because
18 you're going to be collecting a whole lot of data
19 if you do so many, and it will be difficult to
20 manage if you --

21 DR. MacDERMID: Right. I would call
22 them, I think it would be fair to call them

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1 semi-structured. As I said, they're not surveys.
2 They are templates for trying to make sure that we
3 are consistent in the kind of information that we
4 gather.

5 We also have a format that we use for
6 after action reports, so that before the site
7 visit is concluded there's a report prepared that
8 tries to lay out what we think the key insights
9 were, and the team of course will sign off on
10 that, and then it's distributed to the rest of the
11 task force. So that's our intent, to try to
12 manage the flow of information so we don't end up
13 at the end with a 10,000-page question.

14 DR. BLAZER: As a member of the task
15 force, I do want to make a couple of comments.

16 First, I think it's going very well, but
17 to give you some idea of how this is going, those
18 of you who have ever served on an Institute of Medicine
19 (IOM) committee, I think the basic way this is rolling
20 out is very, very similar to what an IOM committee is,
21 in terms of collecting information, writing, vetting that
22 information, and coming up with recommendations.

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1 And I think personally, since I've done a lot of
2 IOM committees, as some of you have as well, I
3 think that is exactly the right way that this
4 should be going. So that, I think that's a very,
5 very good comment about it.

6 The second thing is that given what
7 we're seeing, I think it's important not just
8 structurally but conceptually that this task force
9 has been under AFEB, because prevention of mental
10 health problems is certainly one of the major
11 concerns, from where I sit, that the DOD needs to
12 be concerned about. And so we're not just looking
13 at treatment after the fact in this task force. I
14 think we're really looking at what can be done in
15 terms of prevention as well, so I think that's a
16 very positive statement.

17 DR. SHAMOO: I'm sure you have probably
18 contacted and/or will contact National Alliance
19 for the Mentally Ill. It's a very large
20 organization, and they have a Military Liaison
21 Committee, as a matter of fact.

22 DR. MacDERMID: Yes. NAMI is exactly

1 one of the kinds of organizations that we would be
2 interested in hearing from. We know that there
3 are far more such organizations that we would like
4 to testify or to provide information to us. So
5 the written statement model is our strategy for
6 making sure that we're open to what a variety of
7 groups -- for example, veterans service
8 organizations are another sort of class of
9 organizations that we're interested in.

10 DR. KAPLAN: Kaplan. You listed a
11 number of geographic locations. What provisions
12 have you made for pre-deployment, post-deployment,
13 and recruits in that mix?

14 DR. MacDERMID: That's something that we
15 still -- I think each time we have a meeting we're
16 kind of looking at how the list -- for example, at
17 the last meeting we realized we're just not doing
18 a good enough job yet of getting to guard and
19 reserve issues, so we're discussing if there's a
20 site visit that we might be able to add, to a
21 place where guard and reserve folks are in large
22 numbers, for example, Camp Shelby.

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1 Our visit to Fort Hood I think was very
2 instructive in terms of pre-deployment and
3 re-deployment because, as they pointed out, they
4 have had 200,000 of those in OIF.

5 So the kinds of things that are talked
6 about are obviously geographic location, what
7 service is it, what kinds of issues are they
8 dealing with in terms of high tempo, or particular
9 kinds of mental health facilities or programs, and
10 you can't go everywhere and do everything but I
11 think it's a really good list. We are constantly
12 talking about it, though.

13 There was a question over here.

14 DR. POLAND: Mike?

15 DR. PARKINSON: Yes, Mike Parkinson. I
16 think -- just contrast this with the surgical
17 presentation we just heard -- there's a real
18 possibility that you could emerge hopefully out of
19 this effort with some really useful new constructs
20 about how you define not necessarily mental
21 health, which is an unfortunate legacy in my own
22 view, but what does a fit and high-performing,

1 broadly defined, military member and family look
2 like?

3 How do you assess it? How do you
4 evaluate it? What's the best way to do it?

5 And as a framework for that I would just
6 offer, Dr. Pronk and I, Nico and I had the chance
7 to serve on an IOM committee, as you heard me
8 brief at one of our meetings, that talked about
9 what are the characteristics of a health work
10 force. Well, you can't measure it. You don't
11 really know if you've got it.

12 And we defined four contexts that are
13 very applicable to the -- what has to be a
14 high-performing military family unit, broadly
15 defined family definition. And that would be
16 healthy, productive, ready, and resilient.

17 And if you could use that, it might be a
18 useful framework, Dan and Shelley, as you go
19 forward, to look at that framework and say how do
20 you apply -- looking over here at Nico -- to see
21 how do you apply those things that can be
22 developed in a high-performing work force for a

1 high-performing -- because we say the military is
2 one family, it's not just the military member. So
3 there be little pearls in there you might want to
4 look at and flesh them out into something that
5 might be useful.

6 DR. MacDERMID: That certainly has come
7 through in our conversations with providers,
8 family issues and marital stability. They just
9 come up over and over and over again in what
10 people talk about, in terms of what they're
11 concerned about. That's the result of one site
12 visit, so it's not binding, but it certainly was a
13 big topic of conversation at that site visit.

14 There was a question. I'm sorry. I
15 just wasn't sure if you could see past that
16 column.

17 DR. BROWN: Yes, I'm behind this. Mark
18 Brown, behind the pole here, behind the barrier.

19 I was happy to see that you have Toni
20 Zeiss on your task force. She's somebody involved
21 with mental health care in the Department of
22 Veterans' Affairs, and that seems like a good

1 idea. And I was wondering if you have any plans
2 for looking beyond -- I mean, in a sense, if
3 you're looking at the overall issue of mental
4 health care or establishing the status of mental
5 health amongst people who have served in Iraq and
6 Afghanistan, separation from military service is
7 sort of an artificial barrier there, because these
8 problems go on and somebody then might seek care
9 from the V.A.

10 DR. MacDERMID: Right.

11 DR. BROWN: And I'm wondering if you're
12 thinking about that, if you're trying to look at
13 people who are separated from the military. And I
14 think that would be particularly important for the
15 reserve and guard components. Some of these men
16 and women are getting out pretty quickly after
17 redeployment. We know we have almost 600,000
18 veterans from Iraq and Afghanistan, who have
19 served in Iraq and Afghanistan, and are now
20 separated from the military and therefore V.A.
21 Health care.

22 DR. MacDERMID: The elements pertaining

1 to continuity of care deal largely with that
2 specific issue, so it's definitely something that
3 is on the radar screen.

4 What you might not know is that one of
5 the non-DOD members of the task force is a retired
6 V.A. official, so we actually have pretty good
7 depth, I think, on V.A. We have pretty good
8 expertise regarding the V.A. and the ability to
9 ask questions. And one of the reasons for going
10 to San Francisco is the opportunity to visit a
11 V.A. facility there.

12 MGEN. KELLEY: That's part of the
13 question I was going to ask. Are you visiting the
14 V.A. facilities?

15 DR. MacDERMID: Yes. You know, not --

16 MGEN. KELLEY: Yes, not all of them.

17 DR. MacDERMID: -- all of them,

18 certainly.

19 MGEN. KELLEY: There are a lot of them
20 that are co-located with military facilities.

21 DR. MacDERMID: Yes.

22 MGEN. KELLEY: And the second one, how

1 about on base, are you just staying in the medical
2 mental health arena or are you going out to the
3 chaplains, to the family support centers and all
4 that other stuff?

5 DR. MacDERMID: Yes. I mean, what
6 you're getting at is the fundamental definitional
7 issue about mental health. Is mental health about
8 clinical mental health and what happens when
9 people go to medical treatment facilities, or is
10 it about the larger system?

11 And after a long period of debate, the
12 definition that we adopted is one that is more
13 inclusive as opposed to exclusive, although
14 everyone gulped when we did that because we know
15 what it means in terms of -- well, if you don't --
16 in terms of how much work there's going to be in
17 the spring.

18 But Dan and I were just talking about
19 this, that we have developed this kind of diagram.
20 We're trying to map the mental health system. And
21 the reality from my perspective, not speaking for
22 the task force but from my perspective, when an

1 individual perceives themselves as having a mental
2 health difficulty, whoever they go to for help
3 with that de facto becomes part of the mental
4 health system, whether they're supposed to be or
5 not.

6 And I think a lot of what the task force
7 is going to end up talking about is not what
8 happens relating to the boxes that are part of
9 that system but about the arrows, and how does
10 somebody get to the right box? Because once
11 they're in the box, maybe things are quite good,
12 but how do you make sure that the people who
13 really need to be at a particular place get to it?

14 DR. POLAND: Dr. Lednar?

15 DR. LEDNAR: Wayne Lednar. I have a
16 thought. First, obviously, understanding the
17 needs of military members and the system that they
18 have to confront and navigate through is a
19 daunting one. I don't know if this is a thought
20 that's out of scope for the task force or not, but
21 --

22 DR. MacDERMID: That hasn't seemed to

1 worry us so far.

2 DR. LEDNAR: Well, I don't want to
3 induce scope creep, but following up on that --

4 DR. MacDERMID: I believe we're at scope
5 weep.

6 DR. LEDNAR: -- to follow up on Dr.
7 Parkinson's thought, I think you may come to some
8 important insights that from a civilian, corporate
9 point of view I would put into the category of
10 fitness for duty, in other words, a military
11 member's ability to be part of a unit, to perform
12 and accomplish their mission.

13 And as we think about this in our
14 environment, there are two aspects of fitness for
15 duty that don't get much attention but I think are
16 very important, very relevant to mental health.
17 The usual and customary fitness for duty is a
18 physical one. Are you strong enough? Can you
19 lift and bend and walk and climb, and all of those
20 aspects? That's only one of three important ones.

21 A second one is cognitive, and that is,
22 do you have the ability to continue to rapidly

1 receive, process, and act on complex, and in the
2 military sense, technical information that's time
3 sensitive.

4 And then the third is interpersonal.
5 Because none of us works alone, you've got to be
6 able to work as a team, as part of a unit. And I
7 think to the extent that the mental health needs
8 that you identify and the effectiveness or not of
9 the therapies that are applied, as they affect the
10 cognitive and interpersonal aspects of the
11 military member's fitness for duty, will be very
12 mission-accomplishing relevant.

13 So we may in fact have a circle of
14 impairment in our units that's really compromising
15 our mission possibilities. And you may have some
16 insights that you can come to in your --

17 DR. MacDERMID: I am taking notes and I
18 will distribute them. Thank you very much.

19 COL. GIBSON: One final comment, and
20 that is that for this task force, they have to
21 deliver -- I'm sorry? -- the task force has to
22 deliver the report to the Secretary of Defense on

1 the 15th of May. Congress gave them one year to
2 do this. That is a tremendous task, and they're
3 working their tails off, and the task force needs
4 not only our support but needs a round of applause
5 for all of the work that they're doing.

6 [Applause.]

7 DR. MacDERMID: Many people other than
8 me actually are doing the heavy lifting, so I will
9 convey your message.

10 MS. EMBREY: One last thought. I was in
11 a similarly unenviable position of being in charge
12 of a very fast-moving study or investigation or
13 whatever relative to sexual assault in the
14 military. I had 90 days, however.

15 I would like to give you a little bit of
16 lessons learned. One is, when you go to these
17 sites, you're doing so with the blessing and
18 support of the installation commander and the
19 leadership there. It's very important that before
20 you leave, you provide that installation commander
21 with feedback on what you found and what they
22 might be able to do to help them deal with their

1 current situation, sort of free advice, and to
2 thank them for their participation. They want to
3 know the good and the bad, and as long as you keep
4 it off the record and don't make it part of your
5 public -- you know, I think that's very, very
6 important. It was important to us.

7 Second, you need to concern yourself
8 with the privacy and the protection of information
9 that comes out in town hall meetings.

10 Third, we also traveled to a number of
11 locations, but they are in fact representative.
12 And it's important that you meet and identify with
13 the government officials, whether they're from Health and
14 Human Services (HHS) or the Centers for Disease Control and
15 Prevention (CDC) or the National Institutes of Health (NIH)
16 or wherever we are looking, identify the officials that have
17 responsibility for those programs and ask them to set a
18 framework for how they operate today and what this framework
19 of their management of these issues is, because you need to
20 know where the gaps are as you move out and evaluate that.

21 And involve them in periodic feedback
22 sessions so that they can understand what you're

1 seeing, because your report will be very high
2 level, and they will want more detail about how
3 they can get moving on making corrective actions
4 where you find the gaps.

5 Lastly, you have a small group, just
6 like I had a small group, and because -- and I
7 notice there's a lot of Officer-6 (O6) level type
8 expertise, which means they have a working knowledge and
9 they have a command knowledge, but they may not have
10 the top of the mountain knowledge or the bigger,
11 larger picture views.

12 And I think it's very important that you
13 hold sessions where you invite topic leaders in
14 and ask their advice about their topics during
15 your study, because those experts study those
16 topics for a living and they can inform you, as
17 you are informed by your study. And that would
18 require bringing in not only government officials
19 but private and academic experts, known leaders.

20 And I guess really that is all I have to
21 suggest, just from my personal experience, when
22 you have an impossible task and you're expected to

1 come up with the right answer.

2 I also have a point of contact in the
3 Pentagon for reserve component matters. I think
4 that that is a particularly important area of
5 inquiry, and it is also one where our reserve
6 community has to meet certain eligibility criteria
7 in order to seek care in our system. So you need
8 to know what those rules are, and they're very
9 complicated, and there are experts in the Pentagon
10 that can help educate you in that so you can
11 advocate that.

12 DR. MacDERMID: Thank you very much. I
13 am open to all the expertise I can get my hands
14 on. I won't be staying for the rest of the day,
15 but I think Colonel Gibson could pass along to me
16 the contact information. That would be great.

17 DR. POLAND: Shelley, again, thank you.
18 Thank you for the important work that you and your
19 team are doing. Thank you.

20 DR. MacDERMID: Thank you all.

21 DR. POLAND: We are next going to hear,
22 I think, from Ms. Embrey on the Defense Health

1 Board.

2 MS. EMBREY: Okay. I apologize for
3 moving quickly, out of order. I have to return to
4 the Pentagon for a meeting this afternoon, at the
5 time that I was scheduled to give this, so we
6 rearranged the deck chairs.

7 This presentation covers the changes to
8 the federal advisory committee management that has
9 gone on within the department and will affect the
10 Armed Forces Epidemiological Board. We are going
11 to institute the new policies and procedures that
12 will change how this Board does business. It's
13 behind Tab 13, for the Board, the slides.

14 To go over the background and bring you
15 up to speed on this, the department at Mr.
16 Rumsfeld's urging was looking at ways to improve
17 its business practices, and they were reviewing
18 federal advisory committees as part of that
19 process.

20 There is a single Committee Management
21 Official now that works for Mr. Rumsfeld, who
22 looks at all federal advisory committees, and they

1 undertook a review to determine how we would
2 improve. Standard practice in the department has
3 been to review these every two years, but in
4 previous reviews there had not been any kind of
5 recommendation that would have the kind of impact
6 that this recent review did.

7 So I think that their most recent review
8 found that there were several boards that were
9 operating without charters, and members that had
10 never gone through that appointment process that
11 involves a White House review.

12 When Colonel Gibson found out about the
13 review, he of course went straight to the
14 appointed reviewer and said, "Before you start
15 looking at us, what are you looking for?" And he
16 found out a number of things, and he briefed us in
17 preparation for that, and the Board actually
18 approved making several changes that you see here.
19 At the time, in preparation for the review, we did
20 not have bylaws.

21 And you can see on the slide here that
22 there was an impression, based on those documents

1 that were in place, that the AFEB was working for
2 the department instead of independent of the
3 department. And of course you all know that
4 that's not true, that you are highly independent
5 and you often chastise us, but you ask hard
6 questions and that's what we need. So we wanted
7 to make sure that that independence was reflected
8 in the documents.

9 So we revised our charter, you approved
10 it, we streamlined and developed good bylaws for
11 operating the AFEB. A mission statement was
12 developed, logos, everything, a new coin, the
13 whole works. You guys did it all. And that was
14 just preparing for the review.

15 Well, in February this year DOD
16 concluded its review and they came back with their
17 recommendations, and they recommended eliminating
18 or combining nearly half of the federal advisory
19 committees that were in place at the department
20 level, and the Armed Forces Epidemiological Board
21 was among that group.

22 The reviewers found three boards that

1 dealt with health issues in some fashion as part
2 of your overall mission. That would be this
3 Board, the Armed Forces Institute of Pathology,
4 which provides recommendations to that director,
5 and the Board of Governors for the Army Amputee
6 Patient Care Program at Walter Reed Army Medical
7 Center.

8 In the case of the amputee patient care
9 program, the board had been chartered but no
10 appointments had been made. So reviewers
11 recommended creating a new board that would
12 combine the functions of three existing boards,
13 and at the same time expand the mission of the new
14 board, and they recommended it be called the DOD
15 Health Advisory Board.

16 The three boards that were being
17 combined had very different missions and scope,
18 and initially when we looked at it, we really
19 didn't think this was a good idea. We thought it
20 was kind of stupid. However, the more we looked
21 at it, the more we thought, well, maybe this is an
22 opportunity rather than a challenge.

1 asked for our comments and opinions, and asked the
2 Board itself about their comments and opinions
3 about their recommendations. And you all
4 concurred, but you didn't like the name and you
5 recommended different names.

6 But essentially I think your major
7 message to the Washington headquarters was that
8 AFEB should be the template for the new board, and
9 that it would be an evolution of this Board with a
10 new name and a larger charter, an expanded charter
11 with more subcommittees. And I think that is
12 essentially where we have gone.

13 This is the good news. The bad news is,
14 the history and the great contribution of this
15 Board will lose its identity. The Armed Forces
16 Epidemiological Board will cease to exist, and the
17 long history that is associated with that will not
18 be lost, but we need to make sure that it isn't
19 lost. Just because we change the name, we need to
20 maintain visibility of the great accomplishments
21 of this Board in its previous iteration.

22 As of last week, we crossed the last

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1 hurdle in creating the new board. All of the
2 offices that had to concur with this transition
3 concurred with it, and it is now sitting on the
4 Secretary of Defense's desk. Since this was his
5 idea, we do not anticipate a problem with his
6 signature. So, therefore, we anticipate that the
7 board will actually be stood up in October, and it
8 will be aligned under the auspices of the
9 Assistant Secretary of Health Affairs within the
10 Under Secretary of Personnel and Readiness
11 organization of OSD.

12 A little bit of background on how the
13 missions will change. This is the three separate
14 missions of the three boards that are being
15 combined into the new board.

16 This slide shows the mission of the new
17 board. It looks, acts, and smells a lot like the
18 Armed Forces Epidemiological Board charter
19 mission. It's broad enough to drive a Mack truck
20 through. I think you could probably take just
21 about anything and tell us what we need to do, and
22 that's a good thing. I'm just giving you a chance

1 to absorb it.

2 Now, clearly this is what's in our
3 charter. If, after the board convenes, they want
4 to propose changes to this, they certainly can.
5 This is the charter going in.

6 The structure will have a much broader
7 number of subcommittees and a much broader number
8 of participants in the overall structure. You, as
9 the core board, may participate in the
10 subcommittee panels, but they will be separate
11 panels with separate individuals assigned to those
12 to study various topics. But in all cases or most
13 all cases, except for maybe congressionally
14 directed or mandated activities, the subcommittee
15 reports must come to the core board for
16 deliberation and approval.

17 This shows graphically what the Defense
18 Health Board, as the name has been determined to
19 be, and its potential subcommittees. Based on the
20 new charter, the board could form any kind of
21 select subcommittees and subpanels or task forces
22 to deal with special interest areas.

1 The board may also have several standing
2 committees. The Armed Forces Institute of
3 Pathology's Scientific Advisory Board that reports
4 to the AFIP Director will now become the
5 Scientific Advisory Board for Pathology and
6 Laboratory Services for all DOD.

7 And the Amputee Patient Care Program
8 board will become the Subpanel on Care of
9 Individuals with Amputation and/or Functional Limb
10 Loss.

11 Organization of the board will be
12 different, it will look different, and it will
13 have different command and control structures.

14 You will be an independent board, but
15 you will be supported by the Office of the
16 Secretary of the Defense rather than the Army.

17 This is the organization chart before
18 the transition. You can see a lot of dotted
19 lines, dotted and regular lines that cross
20 function. There is an opportunity for confusion,
21 which is why Colonel Gibson always has that look
22 on his face.

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1 [Laughter.]

2 So under the new structure it is much
3 more streamlined, makes more sense. Ultimately
4 the board will be appointed by and provide
5 recommendations to the Secretary of Defense,
6 through the Under Secretary, through Dr.
7 Winkenwerder, the Under Secretary to the Secretary
8 of Defense. And the board will receive questions
9 from the senior medical leadership of the
10 department or any other part of the department
11 that believes they have an issue that is germane
12 to your mission.

13 So, once Mr. Rumsfeld signs the
14 memorandum, this is the list of things to do. We
15 believe that we will have all of you -- well,
16 after the signature, there has to be a notice in
17 the Federal Register that we're going to
18 disestablish everyone, and we're going to announce
19 the establishment of the new Health Board and the
20 subordinate task force within it as a
21 subcommittee.

22 The charter, which has already been

1 written and is waiting, will be approved 15 days
2 later according to our time line, and since Roger
3 is involved, I'm sure that will happen at that
4 time line. The core members of the Armed Forces
5 Epidemiological Board will be appointed,
6 reappointed to the new board, and one member from
7 the Armed Forces Institute of Pathology board and
8 the board for amputees, one of each of those will
9 be appointed to the core board here. The other
10 members will be appointed to subcommittees of the
11 board as appropriate. The Mental Health Task
12 Force folks will also be appointed to the
13 subcommittee.

14 And the first board meeting in its new
15 capacity will be December 5th and 6th in
16 Portsmouth, actually near Norfolk, at the Little
17 Creek Naval Amphibious Base. At that meeting the
18 board will establish the subcommittees, rewrite
19 the bylaws, and take care of other administrative
20 business matters, in addition to taking on the
21 hard work of the questions we asked you.

22 I think it's very important, since this

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1 is an open to the public session, that we sort of
2 review the history, if you will indulge me a bit,
3 of the Armed Forces Epidemiological Board at its
4 last official session.

5 The group of people you see here are the
6 original members of the Board for the
7 Investigation and Control of Influenza and Other
8 Epidemic Diseases in the Army that was established
9 in 1941. Brigadier General James Simmons, in the
10 center, and Brigadier General Stanhope Bayne-Jones
11 on the right, recognized the need for civilian
12 medical advisors to combat infectious disease as
13 the Army prepared for World War II.

14 As students of history, they understood
15 the tremendous challenge of the military in
16 dealing with disease, and had learned their
17 lessons from World War I and the 1918 pandemic.
18 And through their leadership, the Board for the
19 Investigation and Control of Influenza and other
20 Epidemic Diseases in the Army was established.
21 They sought out the gentleman on the left, Dr.
22 Francis Blake, the Chairman of the Department of

1 Medicine in Yale University, to serve as the
2 president of the board.

3 In 1945 the board changed its name to
4 the Army Epidemiological Board. Then in 1949,
5 recognizing the evolving tri-service role that the
6 board was playing, it changed its name to the
7 Armed Forces Epidemiological Board.

8 So since 1949 you have a very rich
9 history of accomplishments and work that has
10 significantly changed the way we do business in
11 the department. You have been an invaluable
12 resource to the Department of Defense and its
13 leaders, and have had a marked effect not only on
14 us but on America and in fact on the world, and
15 this is just a short list.

16 Over 450 specific recommendations and
17 reports have been issued to the department where
18 we have taken positive action with respect to the
19 recommendations, and that's a major
20 accomplishment. And we thank you and your
21 predecessors for your service.

22 These two men saw the Board through a

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1 dramatic transition back in the 1970's when the
2 Armed Forces Epidemiological Board commissions
3 were disestablished. The Board faced sort of an
4 identity crisis. It went from commissioning its
5 own research, with a substantial budget and a
6 large number of scientists to the Board, into one
7 that provided advice and recommendations based on
8 available scientific evidence.

9 That was a particularly challenging time
10 and one that many did not agree was needed, but I
11 think that now in hindsight everybody agrees that
12 this probably was a good transition to make.

13 Dr. Benenson, the gentleman on the left,
14 he served the Armed Forces Epidemiological Board
15 and many of its commissions from 1966 through
16 1983. From 1970 to 1995, he was the editor of six
17 editions of "Control of Communicable Diseases in
18 Man," or CCDM. This little handbook has been
19 published by the American Public Health
20 Association since 1915.

21 Dr. Woodward, the gentleman on the
22 right, was appointed to the Armed Forces

1 Epidemiological Board in 1954, and he continued to
2 serve on the Board and was voted the AFEB
3 president in 1976, a role in which he served until
4 1990, with the exception of a period from '78 to
5 '80. During his term he wrote a history of the
6 Armed Forces Epidemiological Board entitled, "Its
7 First 50 Years: From 1940 to 1990."

8 Dr. Woodward was instrumental in
9 reporting the first cure for typhus and typhoid
10 fever during World War II, which earned him a
11 nomination for a Nobel Prize in medicine. Over
12 the years he received the Golden Apple Teaching
13 Award from the University of Maryland over a dozen
14 times, and the faculty award for outstanding
15 abilities as a teacher over 20 times.

16 His philosophy on medical science, as
17 well as any organization, was practical and
18 grounded in reality, and this is his quote: "The
19 strength of any enterprise, whether a business, a
20 corporation, a medical center, or a scientific
21 institution, is not its buildings, its plush
22 surroundings, or its modern laboratories. Rather,

1 it is the people who work within its walls.
2 Perhaps more than anything else, this is why the
3 Armed Forces Epidemiological Board, with its
4 system of commissions and advisory committees, has
5 been so successful."

6 And so now we're changing again, and
7 while infectious disease remains an important
8 issue, the Department of Defense recognizes the
9 important role of a health-related federal
10 advisory committee consisting of whole class
11 leaders who could play in other areas such as
12 occupational disease and health promotion. And
13 while continuing to base their deliberations on
14 the best science available and understanding the
15 military mission, the Board has succeeded in
16 making a positive difference in lives of millions
17 of service members, past and present.

18 Lately, the Board has been involved in
19 issues relating to mental health and clinical
20 management of trauma, topics far removed from
21 those the Board dealt with in the 1940's.
22 Tomorrow the Board will deal with, who knows what?

1 Maybe how best to deliver health care and improve
2 the quality of medicine here at home. I can't
3 help but think that those great leaders in
4 medicine who you just saw on the past slide would
5 applaud our efforts to see the Board continue to
6 grow and evolve, with an extended mission that
7 addresses the most critical health and medical
8 needs of the Department of Defense and its forces.

9 So the next time we convene, it will be
10 as new members of the Defense Health Board, and I
11 as its designated federal official.

12 [Applause.]

13 DR. POLAND: Thank you for that
14 comprehensive review. It is in many ways humbling
15 to review that history. For the new Board
16 members, I only suggest that you look at the book,
17 "The First 50 Years." It really is a Who's Who of
18 people who would have to -- particularly in the
19 field of infectious diseases, but even more
20 broadly than that.

21 And to sort of use a well-worn phrase,
22 we truly do stand on the shoulders of the giants

1 that came before us. As Ms. Embrey said, when you
2 read that history, it was often not without
3 benefit of a lot of almost sometimes conflict,
4 debate, and other mechanisms, and offered the best
5 efforts and the best advice that could be sought
6 at the time. So we really do have a big role to
7 fulfill.

8 Ed?

9 DR. KAPLAN: Kaplan. Thank you, Ms.
10 Embrey. I would suggest for your consideration
11 that in view of the history of this Board, that
12 perhaps you and Greg and Roger write, for lack of
13 a better term, an obituary, and that that be
14 published in one of the prominent journals. It
15 certainly is an important step, and the name AFEB
16 means a lot to a lot of people. I suspect more
17 people read the journals than read the Federal
18 Register, so I would offer that for your
19 consideration.

20 COL. GIBSON: There is a marketing
21 awareness. Before this Federal Register notice
22 comes out, we will be contacting the Congress and

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1 the medical organizations about what's going on.
2 I take your comment well, and I think it's
3 something we're going to do, but please don't call
4 it an obituary. We're moving on. We're not dead.

5 DR. KAPLAN: Well, I said for lack of a
6 better word.

7 DR. POLAND: Okay. I think a couple of
8 comments. Mike, and then Wayne.

9 COL. SNEDECOR: Colonel Snedecor. Ms.
10 Embrey, can you comment on the status of the
11 military liaison officers, what will happen to us?

12 MS. EMBREY: Actually the obituary will
13 be coming out in December.

14 My personal opinion is, that's up to the
15 Board. They are an independent advisory body, and
16 if they deem that they need your advice and
17 assistance on a routine basis, then I think there
18 will be an important need for you to continue to
19 attend their meetings. However, I defer to the
20 Board.

21 DR. POLAND: We look forward to being
22 courted.

1 [Laughter.]

2 DR. LEDNAR: Wayne Lednar. Ms. Embrey,
3 thank you for that. That was really very, very --
4 you know, it really touches all of our hearts, I
5 think, especially those of us who worked with a
6 number of these giants on whose shoulders we now
7 stand.

8 The thought I was having is, because
9 "The First 50 Years" basically is an important
10 documentation of the Board and its contribution
11 through 1990, it would really be a nice additional
12 piece if from 1990 until December of 2006 that
13 additional list of accomplishments and the
14 important contributions could also be documented
15 in some way, so that those 50 years from now can
16 reflect on all of this achievement.

17 DR. MCNEILL: Can I make just a brief
18 comment? I just have to say even though I've only
19 been on the Board a year, my recollections of the
20 AFEB go all the way back to the 1970's when I was
21 a preventive medicine resident at WRAIR, and I
22 remember we would all creep like little mice up to

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1 the war room and try to disappear in those big
2 armchairs around the periphery of the room while
3 we saw the likes of Dr. DeBakey and others
4 participate in these Board hearings.

5 And I can just tell you there are a lot
6 of people who have, myself included, have a lot of
7 deep emotion and a lot of deep respect for the
8 history of the AFEB. I do see this as progress,
9 but I agree that there's nothing wrong with
10 reliving a little bit of the past every now and
11 then, and I think the AFEB is a very worthwhile
12 organization, has a tremendous history. So I
13 wanted to say that.

14 DR. POLAND: Yes?

15 COL. PETRUCELLI: Petrucelli. If you
16 want to delegate or commission that history, the
17 Military History Department of the Uniformed
18 Services University would be a good choice.

19 DR. POLAND: Thank you for that
20 suggestion.

21 DR. SHAMOO: Since we're being
22 nostalgic, I was privileged to overlap 25 years

1 with Dr. Woodward at the University of Maryland
2 School of Medicine, and what all you said and
3 multiply it by a thousand, that's what kind of a
4 human being he was.

5 DR. POLAND: I will finish with just one
6 last comment. My very first meeting of the AFEB
7 back in '91 or '92, something like that, I was
8 privileged to have lunch with Dr. Woodward. I
9 was a young, fresh face on the Board, had a full
10 head of hair --

11 [Laughter.]

12 -- and truly was, I mean by several
13 decades, the youngest person on the Board. But he
14 gave me a piece of advice when I asked about the
15 importance of this committee, somewhat naively.
16 He said as long as the Board always keeps in its
17 focus the needs of the service members, that he
18 didn't see how we could go wrong. And I've always
19 remembered that about him and about his passion
20 for the Board.

21 Okay. We will move on, with that
22 historical context. We're going to have a very

1 high-level overview of the issue that has come to
2 the Infectious Disease Subcommittee, on
3 pentavalent Botox. The subcommittee had a
4 telephone briefing where we went through some of
5 the material you are going to see here in detail.
6 This will be a summary of that, so that the Board
7 understands that the question came to us and that
8 recommendations are being generated in relation to
9 it.

10 COL. GIBSON: The question actually was
11 presented to the Board at the last meeting in May,
12 and Dr. Poland at that time referred the question
13 to the Infectious Disease Subcommittee. Their
14 activities have already been ongoing.

15 DR. POLAND: We are at Tab 9, and you
16 can see the question and some of the slides.

17 COL. GOODE: Thank you, Dr. Poland, Ms.
18 Embrey, esteemed members of the Board. I have a
19 short time now to try to explain this.

20 On behalf of my boss at United States Army Medical
21 Materiel Development Activity (USAMMDA), I want to thank you
22 guys for taking on our question here. What I would like to

1 do is use that question to tell you a little bit about who
2 we are and what we do there, so that you can understand the
3 reason for this actual question.

4 We are stationed at Fort Detrick. It's
5 called USAMMDA, United States Army Medical
6 Material Developmental Activity. We were tasked
7 back in 2004 to stand up a DOD executive agency
8 for the implementation of force health protection
9 protocols. These are protocols that we use in
10 support of military operations. That's what we do
11 at Fort Detrick, just in the force health
12 protection.

13 Our mission is to provide products and
14 devices for our fighters out there serving the
15 nation.

16 Part of our job there at Fort Detrick
17 involves contingency protocols, and in our recent
18 review for this particular protocol Human Subject
19 Research Review Board had some concerns with the
20 data regarding declining immunogenicity and
21 potency testing for the Pentavalent Botulinum Toxoid (PBT).
22 There was a lot of data that was generated in support of

1 that. And so they asked us to help provide some
2 clarification on that.

3 Out of that meeting came two tasks: To
4 actually obtain the services of a subject matter
5 expert outside of DOD, and in that regard we
6 obtained the services of Dr. Janice Rusnak, who
7 was introduced earlier today, an internationally
8 recognized expert on botulism and the
9 countermeasures associated with it.

10 We were also tasked to actually present
11 this question to the AFEB Board because of your
12 expertise to help us handle this particular
13 problem. Also note that this particular protocol
14 that we have has been approved by the FDA, but
15 it's approved only for serotype A. And the CDC
16 also has a similar protocol that has been approved
17 since the early 1960's and which is being used to
18 provide protection for laboratory workers.

19 This particular slide right here
20 outlines the strategies of DOD, looking at
21 pre-exposure as well as post-exposure. For the
22 pre-exposure strategy, the only part of that we

1 have available currently the Pentavalent Botulinum
2 Toxoid. Recombinant Botulinum Bivalent, that's in
3 development, but it's not expected to attain
4 licensure, FDA licensure, until somewhere around
5 FY 12, and it's just for A/B.

6 Post-exposure strategy involves DOD's
7 Heptavalent Botulism Antitoxin, as well as a list
8 of items that are being done in CDC, but our
9 primary focus is on the pre-exposure.

10 A little bit about the product. The
11 product is a formalin-inactivated toxoid tested
12 for protection against serotypes A, B, C, D, and
13 E, and it has been used in laboratory workers
14 since 1959. It has provided potential protection
15 four weeks after the initial three-dose series of
16 the PBT at those time points outlined there. And
17 there is also a yearly booster that's given after
18 12 months.

19 The manufacturing history there is that
20 it has a long history going back into 1970, 1971.
21 Also that product was used to support the efforts
22 in the first Gulf War. Subsequent to that, new

1 formulations were formulated, primarily the two
2 current ones that you see up there, the PBP-003
3 and -004. They were made in the 1992 to 1995 time
4 frame.

5 The manufacturer of these particular
6 products is the Michigan Department of Public
7 Health, and currently now Bioport Corp.

8 This is just a snapshot, a summary slide
9 of the stability tests associated with this
10 particular product. What we're getting at here is
11 the actual Lot PBP-003, but you will note there
12 that for the chemical, safety and stability assays
13 it met specification for all time points.

14 However, there was a discrepancy between
15 the potency tests. As you see on the slide there,
16 we have two different types of tests we have been
17 using to assess the potency of this particular
18 product, the mouse neutralization assay as well as
19 the guinea pig challenge assay.

20 But as you will note on there, for the
21 mouse neutralization assay this particular product
22 passed for serotype A at all time points.

1 However, it failed for all these other time points
2 associated there, B, C, D, and E. However, for
3 the guinea pig challenge assay, it passed for
4 serotypes A, B, and C at all time points.
5 However, it failed with D and E.

6 This is a summary slide of the Lot
7 PBP-004, the same type of situation. You have a
8 little discrepancy with the mouse neutralization
9 assay. It was good for serotype A. However, it
10 has failed for all the other ones. And for the
11 guinea pig challenge assay it's a similar type of
12 conclusion. It's good for serotypes A, B, and C.

13 This particular slide here is a snapshot
14 of the actual animal resistance challenge with the
15 guinea pig challenge test, showing that even
16 though the mouse **neut** assay only showed it good
17 for serotype A, it was believed that it was
18 protective not only for serotype A, which is the
19 most prevalent form that you'll see out there as
20 well as the one that's seen as causing more
21 mortality and morbidity, and it's also good for
22 serotype B and serotype C. For this particular

1 test here we're looking at anything greater than
2 50 percent as being good.

3 Now, I told you earlier that there is a
4 CDC protocol out there, and that's the protocol
5 that's used actually in the United States Army
6 Institute of Research up at Fort Detrick as well
7 as throughout the country. What they noticed is
8 that with the primary series of immunizations,
9 with the three-dose series, they noticed that
10 after 6 months out to 12 months there was a
11 decline in the protective titers.

12 Because of that, they went back and they
13 introduced this study and gave a dose at months,
14 so you have one given at zero, 2 weeks, 12 weeks,
15 and 6 months, and then out to one year. When they
16 gave that dose at 6 months, it showed that they
17 had protective activity out up to 48 months after.

18 Because of that, what they did was, they
19 changed the CDC protocol to include that month
20 dose, so instead of a three-dose series it's now a
21 four-dose series. There is still a booster at 12
22 months and annually thereafter.

1 They are no longer collecting titers,
2 and also this particular protocol is no longer
3 considered to offer protection as a pentavalent
4 toxoid. That's just up front.

5 This slide just reiterates some of the
6 information I presented earlier, that it has good
7 protection definitely against serotype A, and that
8 for PBP-003 potency tests, it does actually have
9 some protection against serotype B. And as the
10 previous slide showed, it gives good protection in
11 animals, 100 percent for serotypes A, B, and C.

12 This is just a little note for
13 consideration, to take into account as you provide
14 us with your recommendation on the utility of this
15 product. It takes 6 months to confer protective
16 titers. There is no DOD vaccination plan or
17 policy in place to immunize the force. And there
18 is a lack of alternative therapies for the
19 foreseeable future, because the recombinant
20 product is just for A/B and will not be available
21 until FY 13.

22 So, in summary, the pentavalent Bot, it

1 provides protection against serotype A, possibly
2 against serotypes B and C. It does not provide
3 protection for D, E, F, as well as G. There are
4 seven serotypes. And the recombinant vaccine is
5 years away, and would only address types A and B.

6 I also should remind the Board that if
7 you find the product has utility, what population
8 would receive the best use from the product?

9 Yes, ma'am?

10 MS. EMBREY: How many courses --

11 COL. GOODE: Pardon me, ma'am?

12 MS. EMBREY: How many courses do we have
13 in our inventory?

14 COL. GOODE: We've got approximately
15 37,000 doses.

16 MS. EMBREY: Doses or courses?

17 COL. GOODE: Doses.

18 MS. EMBREY: And how many courses would
19 come out of --

20 COL. GOODE: There's three -- well, I
21 think that's 111,000, so there's 37,000 units that
22 we can take to our service members, the primary

1 series of three doses.

2 DR. POLAND: Questions or comments by
3 the Board?

4 I will comment that the subcommittee has
5 looked at this data. We have a draft set of
6 recommendations. The basic concept behind our
7 recommendations would be that there are no other
8 options here. We can certainly put aside the
9 post-exposure, so for pre-exposure there are no
10 other options.

11 And we'll basically formulate a
12 recommendation saying, you know, keep the vaccine.
13 We'll use it under certain circumstances until a
14 better vaccine becomes available in the next five
15 to seven years, something like that.

16 DR. MILLER: I'm a bit hesitant to open
17 up a whole can of worms on this vaccine.

18 I think there are some basic questions
19 here. The first one is the actual biological and
20 scientific issues of the vaccine itself. The
21 second is the pragmatic application of it, which
22 is a whole other question. And the third is

1 military policy and strategy, which I don't think
2 that's our role here.

3 So I think if one is being asked to
4 address the utility of this particular vaccine for
5 a public health measure, the three are
6 interrelated in some way or another, which raises
7 some complexities in terms of how we deal with
8 this particular issue.

9 From the scientific issues, I think
10 there is one thing I would raise right away. I
11 don't know how this particular schedule was given
12 in the first place, with the 14 day. If this is a
13 toxin-based vaccine, perhaps one might think --

14 SPEAKER: Toxoid.

15 DR. MILLER: Toxoid. One might think of
16 a longer interval. But again, that's only one
17 part of the whole question.

18 DR. POLAND: Okay. Thank you very much,
19 Colonel Goode. We appreciate it. Our plan now is
20 to have a working lunch, so Ms. Embrey, are you
21 still able to stay?

22 COL. GIBSON: She's going to do

1 Lieutenant Colonel Hachey's presentation, update
2 on avian influenza. Lunch is going to be over
3 there again. Board members come back and sit
4 here. Those of you -- sorry -- preventive
5 medicine officers, go over and get your lunches.
6 Those of you who wish to stay during the working
7 lunch and listen to the update on influenza,
8 please do. It should not take the entire lunch
9 period, and then you can break and go where you
10 need to go to get lunch.

11 DR. POLAND: We'll take about a 10-
12 minute break to get your lunch and then we'll
13 start again.

14 [Recess.]

15 DR. POLAND: Okay. Ms. Embrey will give
16 you a briefing on avian influenza, so if Board
17 members can come and take their seats we will get
18 going.

19 MS. EMBREY: It's at Tab 5.

20 DR. POLAND: Tab 5 is the slides.

21 MS. EMBREY: I'll pretend that I'm Wayne
22 Hachey. Wayne works for me. He is the specialist

1 on my staff, and he has been the focal point on my
2 staff, working with a wide range of experts in the
3 department to pull together what we're doing
4 relative to pandemic influenza.

5 Okay, where is it now? This is where it
6 is. 1997, the global H5N1 emerged in poultry and
7 humans. It's still mostly a bird disease. It has
8 spread through many more countries than it was
9 when it started. It's in over 60 countries.

10 Of most concern is its spread to Africa,
11 where they lack an infrastructure with which to do
12 diligent surveillance. That's of great concern,
13 both in animals and humans. We do have continuing
14 infections in humans, but it's rare. There have
15 been instances of human-to-human transmission, but
16 it is not readily transmitted and it is not
17 sustainable.

18 Of concern, however, is the growth since
19 October of last year, the incidence of human
20 infections in four countries in October of last
21 year, now in 10 countries, so it is still rare but
22 it's spreading.

1 Another important note, the Indonesian
2 strains are particularly difficult. They have
3 over a 66 percent mortality rate, and that's even
4 higher for those who are age to 39, and that's of
5 particular concern to the DOD population if it
6 does make the leap to a transmissible situation.

7 How has it changed? One or more places.
8 It doesn't seem to have any particular preference.
9 It goes across areas, but it's more prevalent in
10 the young, in the young, healthy population.

11 You can see we have two to eight per
12 cluster now, as opposed to two to three cases a
13 year ago. In every case, well, most all cases,
14 the individuals who have been infected lived with
15 or otherwise handled, for a prolonged period,
16 infected birds.

17 Human-to-human transmission, as I said,
18 has occurred, but it's not sustained and it's
19 usually a second order transmission in blood
20 relatives.

21 There was a retrospective study of the
22 poultry spread and how it went through a Cambodian

1 village with a confirmed human case, a death.
2 There were 42 household flocks that were infected
3 with the same strain. Two chickens from a
4 property adjacent to the patient's house were
5 confirmed, and 351 participants from 93 households
6 had prolonged, close contact with the poultry that
7 was suspected of providing the infection that
8 killed the individual. Of note is that none had
9 neutralizing antibodies to H5N1.

10 The U.S. risk is for birds at this
11 point. We are carefully monitoring the flyways in
12 the U.S. by the Departments of Interior and Fish
13 and Wildlife. They are routinely sampling birds
14 along those flyways.

15 They have identified low pathogenic H5N1
16 in swans that appeared to be healthy until they
17 died. I guess that's a good way to go.

18 The Department of Agriculture has a very
19 aggressive program for monitoring domestic
20 poultry, and each state is heavily engaged in
21 augmenting their infrastructure on that. The two
22 highest risks to the U.S. are illegal imports of

1 poultry from the endemic areas and also bird
2 smuggling, which is -- the only thing that is
3 smuggled more than those birds are drugs, so it's
4 a major concern to the Department of Agriculture
5 and to the nation.

6 With respect to the pre-pandemic vaccine
7 that's being developed through the leadership of
8 the Department of Health and Human Services, we
9 have a Vietnam 1203 vaccine based on the Clade 1
10 Vietnam strain. We, the Department of Defense,
11 have purchased 1.6 million doses, of which 1.2
12 million are bottled.

13 The current acquisition strategy within
14 the department is to acquire a portion of that
15 which is produced by the 2006-7 production runs
16 that three different manufacturers are engaging
17 with HHS on. There is still not a decision as to
18 which vaccine strain will be used during that
19 production. There's talk of Clade 1 and Clade 2
20 or just Clade 2. That decision hasn't been made,
21 but we have Sanofi Pasteur, GlaxoSmithKline (GSK),
22 and Novartis that are the three manufacturers who

1 are engaging in production of this vaccine for
2 2006.

3 We've identified the requirement for 6.1
4 million individuals to be protected in our
5 department. Given that the production right now
6 for the next six months is about 10 million doses,
7 we realistically don't expect that we're going to
8 get our requirement when the total national
9 stockpile just now tops 4.7 million doses in the
10 strategic national stockpile for the 330 million
11 people in our population, so we do have to share
12 with our interagency partners. We likely will
13 request, and I think we have formally put in a bid
14 for about 3.5 million out of the 10 million doses
15 that will be produced this next six months.

16 The last bullet here talks about GSK has
17 a proprietary adjuvant which actually has good
18 reactivity in a smaller dose, and that it shows no
19 problems. It also shows that with that adjuvant
20 you could get more doses out of the production, so
21 this is a very good sign. We hope that the
22 clinical trials continue to show promise.

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1 I'll talk a little bit about the Clades.
2 The Clade 1 virus was in Cambodia, Thailand, and
3 Vietnam. We called it a Vietnam strain.
4 Currently none of that particular strain has been
5 in circulation for the last six months.

6 The Clade 2 virus is in circulation, and
7 it's the one that's moving around the world.
8 There are six different sub-Clades. Three of them
9 are primarily responsible for the infections, for
10 the high death rates in Indonesia primarily, and
11 they are genetically similar.

12 It feels a little weird talking to you
13 about this, when you know more about what I'm
14 talking about than I do. So correct me if I say
15 something wrong, please, especially the DOD
16 people.

17 With respect to antivirals, the
18 department has revised its antiviral release
19 policy and use policy and it is currently in
20 staffing. We are including both Oseltamivir and
21 Zanamivir -- Relenza, I say Relenza. Relenza has
22 been on acquisition for some time but we don't

1 expect delivery until March of next year. That
2 will be added to our stockpile. Then we will have
3 both. And this, by the way, is consistent with
4 the recommendations that you've given us.

5 And you see the volume here in our
6 stockpile for Tamiflu. We have 520,000 courses, I
7 guess, of Tamiflu in a centrally distributed
8 stockpile for release during a pandemic to the
9 appropriate places. We also have 480,000 which we
10 have purchased and will distribute to the Military Treatment
11 Facilities (MTF's) for use during a pandemic, for local
12 distribution, for faster response. That further lends to
13 the distributed stockpiles around the world.

14 We have also spent some of our pandemic
15 influenza supplemental money from last year, \$8
16 million to buy personal protective equipment,
17 primarily for providers in in-patient and
18 intensive care situations at our MTF's. This \$8
19 million is projected to support 12 weeks work of
20 operations, which is essentially two waves worth.

21 And also we have spent \$24 million in
22 purchasing, through our supply chain, antibiotics

1 that we believe will be responsive to secondary
2 bacterial pneumonias. If you've studied the 1918
3 flu, you know that secondary infections were a
4 high cause of death, and since we don't know
5 whether or not it will be the same or different,
6 we have prepared just in case.

7 In terms of containment measures, we
8 were briefed by the NIH model for community
9 response, layered approach. We were significantly
10 influenced by that briefing, and we believe that
11 many of those principles need to be adopted in our
12 approach, and we have incorporated that
13 community-based response in our internal clinical
14 practice guidelines and release policies.

15 The next series of slides gives you an
16 update on where we are in the department relative
17 to the President's implementation plan of the
18 national strategy that was announced in November
19 of 2005. The national plan was released on May
20 2nd, and within that plan DOD has been tasked to
21 accomplish 116 specific tasks, 32 of which we have
22 the lead for across the federal government.

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1 Within that 32, within those -- What is
2 it? Let me add it up very quickly. 148 tasks.
3 Within the 148, 67 of them have been assigned to
4 Dr. Winkenwerder's office, and I as his Force
5 Health Protection and Readiness person, to launch
6 those responsibilities, and we'll go through those
7 quickly in just a minute. And we have the lead in
8 the Department of Defense for implementing 17 of
9 those 67 specific tasks to some degree, both in
10 support and lead.

11 Okay, so we have finished our DOD
12 internal plan and briefed it to the Deputy
13 Secretary of Defense in August. It has been
14 approved, but the more detailed concept of
15 operations and how the commanders are going to
16 integrate those plans as part of their ability to
17 perform their mission is not due until December of
18 this year.

19 So the granularity of how each of the
20 commanders will do this is not available to us
21 yet. They are finalizing it. They have working
22 at those plans for quite some time, but they did

1 have the opportunity to see the final DOD plan.
2 It would be a little hard for them to develop a
3 supporting plan if they didn't have the final
4 plan, so now they have their opportunity.

5 It's a very interesting case study. If
6 I had to find somebody at Harvard to do a case
7 study of how you do a national plan, a DOD plan,
8 and an internal operating plan all at the same
9 time, and have it all come out, I would like to
10 study this maybe five years from now. It would be
11 very interesting.

12 Okay. The national plan tasks where Health
13 Affairs (HA) is the primary lead, we had 3 month and
14 6 month suspenses, 12 month suspenses and 18 month
15 suspenses. I won't read these to you, because you
16 can read as well as I can. So what I will do is
17 let you absorb this, and if you have any
18 questions, I'm more than happy to answer your
19 questions.

20 The bottom line is, the department has a
21 series of very important things to do. You could
22 advise us in many ways on these topics. They are

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1 things that we were already planning to do anyway,
2 many of them, and although we say we are complete
3 in some areas, nothing is complete in the area of
4 public health. You are always reviewing,
5 revising, and updating. So I think it's important
6 for you to know, just because it says "complete,"
7 we're still working. We're always working.

8 Maintain a stockpile, we talked about
9 that. The important part, though, is consistent
10 with the requirements of the shelf life extension
11 program, and to make that equivalent to the way
12 the states are doing it.

13 That's the hard part. Rapid diagnostic
14 tests, a huge issue, a lot of money being spent to
15 develop that, very high priority. Education
16 materials, I spoke to this yesterday. A high
17 objective is to make sure that the messages are the
18 same and consistent from the federal government
19 all the way down to the public health
20 infrastructure at the state and local community.

21 Twelve month suspense, we want health
22 surveillance data reported in a consistent way so

1 that the nation has some good data. I think that
2 yesterday when we were talking on this topic, you
3 said the importance of doing this is an
4 opportunity, a good natural experiment.

5 Well, we need to set the parameters of
6 how we're going to collect that data in a
7 consistent way. I think you'll be hearing from
8 Ken Cox on our staff -- is he here? -- on how
9 we're organizing to do that, because it's quite an
10 integrated effort across the multiple activities
11 of surveillance within the department.

12 Eighteen month suspense. Make sure that
13 our laboratories are functioning and integrated
14 and provide the necessary support to improve
15 diagnostic methods, and to really rapidly identify
16 what we're dealing with, to help us build that
17 case definition that we need as soon as possible.
18 So we're beefing that up as part of our program.

19 Conduct a medical materiel requirements
20 gap analysis, basically make sure that our process
21 for procuring things, medically speaking, is
22 efficient and effective and moves quickly from

1 peacetime to wartime and return, specifically with
2 respect to the distribution of material necessary
3 to respond to the pandemic.

4 When you have scarce resources, how do
5 you make those choices work? What criteria do you
6 apply? If you haven't already distributed, how do
7 you distribute to spread your capabilities out?
8 An important piece of this, the ability to
9 support.

10 Procure 2.4 million treatment courses of
11 antiviral medication and position them, that we
12 have done. You can check that off. We just have
13 to keep doing it so that the shelf life does not
14 go away. We have to keep doing that.

15 It appears as though we have to do the
16 same thing twice here, so perhaps that's a
17 metaphor for an ongoing requirement.

18 I think it's important just at this time
19 to say that especially your recommendation on how
20 we come up with a vaccine policy relative to the
21 pre-pandemic vaccine was extraordinarily helpful
22 to us, and we have endorsed virtually all of your

1 recommendations in respect to that, and we've
2 actually added some, too. When we get that
3 policy, we'll share it with you. And I thank you
4 for your help in that, and all the others as well.

5 Okay, getting back to surveillance,
6 ESSENCE is an important piece of this but it's not
7 the only piece. Our labs, the work that's being
8 done in each of the services at their locations
9 around the globe, are an essential part of an
10 integrated surveillance capability.

11 Public Health Emergency Officers, you
12 got a briefing on how that policy was implemented
13 with appropriate guidance. Not everybody agreed
14 on the role and responsibility. Well, hindsight
15 is always 20- 20. Now, in the face of a pandemic,
16 having these Public Health Emergency Officers at
17 installations actually is a wonderful idea.

18 But the challenge for us now is making
19 sure that they get good guidance and training, and
20 that they're supported through a network that
21 helps them understand how to play and work with
22 other public health administrators. That's a real

1 priority for us now, and we are putting a lot of
2 energy in that.

3 DOD pandemic influenza watch board.
4 It's a watch board, which we build in many places
5 for information to the medical community,
6 primarily for others that need to go and get
7 information on the state of play, whether it's a
8 protocol, whether it's a protocol, whether it's
9 the spread of the disease in humans or animals,
10 other practices, links to other federal agencies.
11 It's a one- stop shop for the medical community in
12 the Department of Defense.

13 To improve our capacity, most of the
14 supplemental dollars we received last year went
15 into building these capacities. We are eons ahead
16 of most of the other agencies in building this up.
17 Fortunately for the department, we already had a
18 good footprint. Now we're just expanding and
19 improving that. And this will become an important
20 federal resource in informing about the state of
21 the disease in the world, in humans primarily.

22 This is hard. This one is hard, but

1 this gets to the issue of the community response
2 and the educational materials, and it really
3 highlights the importance of our Public Health
4 Emergency Officer and the staff getting not only
5 good, consistent policy guidance from the top, in
6 working with our line commanders, but also making
7 sure that that message gets translated all the way
8 down to the community level. And making a policy,
9 making sure people understand it and apply it, is
10 the hard part. So this is tough, and we'll be in
11 progress with this for a very long time.

12 This is the web site. We've got it in
13 the slides, so you don't have to write it down.
14 It will be going live in October. It will be --
15 you have to have a password to get on if you don't
16 have a gov mail e-mail address. Members on the
17 board, I'm sure we can give you access, so if
18 you're having trouble getting access to this web
19 site, let me know, and we'll make sure that you
20 get on.

21 It will have all these kinds of things,
22 and this is a snapshot of the front, the front

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1 face of the web site. And I'm sure it will
2 change. All of the web interface human factor
3 engineers are playing with it now, so this is what
4 it was last week.

5 So I'm here to answer any questions, and
6 Wayne, thank you for your attention.

7 [Laughter.] [Applause.]

8 DR. POLAND: Thank you for being able to
9 wing it. We'll probably have a few questions.

10 DR. LEDNAR: I'll try not to get
11 anyone's dander up. I guess a question, I think
12 it was one of the first six month items had to do
13 with sort of local hospital and MTF preparedness,
14 and I guess a couple of questions, if you know.

15 Do those thoughts -- at the local level
16 within the MTF, obviously they're focused on surg
17 capacity and treatment -- also take into effect
18 that at an installation they're there to support a
19 military unit or units that have missions to
20 perform, so in addition to sort of increasing
21 medical treatment to provide for, let's say, 30
22 percent of the force that will be ill, how they

1 are going to link to the continuation of the line
2 operations?

3 And part of that may be that some of
4 their staff might be pulled out of the MTF to fill
5 certain kind of operational billets, or just the
6 normal transfer of personnel within assignments.
7 If their plan is critically dependent on a person
8 with a critical skill, and in the process of
9 moving people around all of a sudden that's empty,
10 how to anticipate that and not just to be totally
11 overcome by it?

12 MS. EMBREY: It's a complex problem,
13 particularly in the department. The MTF exists to
14 provide force health protection for the department
15 forces and to preserve our ability to perform
16 their mission, and there is a significant amount
17 that's going on at DOD installations around the
18 country, so that's the first priority.

19 That said, if the MTF itself has got a
20 30 percent or 40 percent absentee rate, and the
21 assumption and the test is when we have a network,
22 where we can refer our ill patients to people in

1 the TRICARE network or hospitals and clinics in
2 the TRICARE network, well, they're going to be
3 affected as well.

4 So this again comes back to the
5 importance of that installation's Public Health
6 Emergency Officer whose major job is to identify,
7 with the public health infrastructure outside the
8 gate, how they're going to work together to
9 respond to this, and what is the importance of
10 economic drivers in the community and the
11 department's requirement to perform its mission.

12 And that's part of that local
13 community's plan, and DOD cannot be an island in
14 and of itself. It depends on that community as
15 much as that community depends on the department.
16 So that's where we need our biggest payoff for
17 preserving our ability and the community's ability
18 to sustain important functions during a pandemic.

19 DR. POLAND: Pierce?

20 DR. GARDNER: You mentioned that making
21 policy is easy and implementation is hard, and I
22 think it was particularly evident yesterday in the

1 presentation of the joint U.S.-Australian forces,
2 where we looked pretty disorganized in terms of
3 our communications and who was supposed to report
4 to whom. Even though we had a military situation,
5 we didn't have -- it should have been one of the
6 easier ones rather than one of the harder ones.

7 So I keep coming back to the idea of
8 whether we need a team of influenza special -- a
9 specialty team to go in with the imprimatur of
10 having special knowledge and epidemiologic
11 expertise that can be brought in on a rapid
12 response basis to help, rather than I think our
13 current idea is to train a whole lot of people up
14 to a fairly reasonable level, but I think that we
15 may need to have some specialty groups that can go
16 in and help out, and provide real expertise.

17 MS. EMBREY: That is certainly a concept
18 that we have been pushing, but if you look across
19 the community, the epidemiological community in
20 the Department of Defense, there are not enough of
21 us to have that many SWAT teams to go to all the
22 places that would need that during a pandemic.

1 DR. GARDNER: Yes. Well, I think we're
2 all agreed that unless we get in there early, the
3 horse gets out of the barn by the time we get down
4 the line very far. In a true pandemic, most of
5 what we do won't make much difference, but I think
6 we're all very focused on trying to be very
7 energetic at the beginning.

8 MS. EMBREY: Yes. I think in fact that
9 this gets back to the combatant commanders, and we
10 have several geographic commanders and we have
11 several functional commanders, and each of them is
12 to define a concept of operations that would
13 address the phases and how they would respond to
14 them.

15 And having a cadre, a SWAT team to go to
16 address and contain, is a very important part of
17 those plans. But, again, having it in a plan and
18 being able to do it are two different things, you
19 know. And the first part of that is to have
20 appropriate training that's specific to what we're
21 trying to do. And that, I think we've spent a lot
22 of time trying to make sure we get ourselves

1 organized about how we're going to accomplish
2 that.

3 DR. POLAND: Mark?

4 DR. MILLER: Miller. Perhaps you can
5 speak a little bit to the clarity of the overall
6 mission and plan, because I can see that there
7 might be a bit of a creep here. The goal of the
8 AFEB or the new Defense Health Board is to address
9 the issue of health care in the service, and the
10 ultimate goal of the service is to protect the
11 overall population, both domestically and perhaps
12 now internationally as well, because this is a
13 threat to all humankind.

14 There are certain things that the
15 service can do in terms of logistics and
16 operations that no other entity in the world can
17 do. So in the face of the issues of avian
18 pandemics, what is the prime mission of the
19 strategic plan here? Is it for the protection of
20 the health services, the forces? The protection
21 of the overall population?

22 Again, this might be more than we want

1 to address at this particular stage, but I think
2 it's a fundamental question.

3 MS. EMBREY: Actually, now that the DOD
4 plan has been approved, and we can certainly get
5 you a copy, but more importantly we can get you a
6 set of these slides that sort of try to summarize
7 the national strategic objectives, the
8 implementation of the plan, and there is a
9 distribution at the top.

10 The majority of the leadership
11 responsibility for the actions is really not with
12 DOD. The DOD is actually a distant supporter,
13 where the federal government wants to leverage DOD
14 infrastructure and expertise in the context of
15 their larger leadership.

16 The Department of State has the
17 responsibility for addressing local containment,
18 the protection of U.S. citizens and the movement
19 out of affected areas of the U.S. citizens, and a
20 strategy for working international partnerships to
21 improve the ability of the less fortunate
22 countries of the world to understand that they

1 have a problem and to contain it as quickly as
2 possible. So that's sort of a shorthand
3 description of State Department's role.

4 HHS has the same, except domestically
5 speaking, and the burden of trying to coordinate
6 and integrate the state public health
7 infrastructure planning and operations with the
8 federal, and to make sure that they dovetail
9 together in important areas. This international
10 stockpile and the acquisition program that goes
11 with that is in partnership with HHS and NIH, who
12 do the research.

13 So we, DOD has been working in nonstop
14 interagency meetings since a year ago, with the
15 State Department and with HHS and CDC and NIH and
16 the Department of Agriculture, on their big
17 taskings and then how we can help support them by
18 leveraging some of our expertise and resources.
19 Going in, our plan deals primarily with how we are
20 going to protect the DOD population at risk to
21 preserve our mission globally, and if we have any
22 resources after that, we will support those

1 others.

2 And the Department of Homeland Security
3 is the President's lead for pulling together the
4 global and the domestic into a response
5 preparedness mode, by leveraging their training
6 structures, their granting programs, to tie the
7 loose ends all together and make sure that we are
8 functioning together as a national program at the
9 federal, state, and local level.

10 Again, this is my interpretation of the
11 way it is, but we can get you a briefing.

12 DR. LUEPKER: If we microscope down to
13 the local level, presuming that there were a local
14 or regional epidemic, a lot of the practical
15 decisions are going to be made by local medical
16 directors and preventive medicine officers,
17 etcetera.

18 And it gets down to the devil in the
19 details. You know, how do you close the school?
20 Who do you let on the base? Who supplies the food
21 for the base? Are you going to share the -- know,
22 all of these practical, practical things that one

1 would hope would be played out before confronting
2 for the first time, at least played out
3 vicariously.

4 Yesterday we talked about scenarios, but
5 as far as converting the scenarios to actual local
6 training, is there an effort to do that?

7 MS. EMBREY: Well, the President's
8 strategy and the implementation plan calls for
9 coming up with practical, applicable training and
10 exercises of the plans that are in place, across
11 the multi-tiers of government and academic and
12 private industry. The most recent introduction of
13 the idea of a community response, layered
14 approach, when applied to a playbook with all
15 those players in a community sitting down and
16 actually training and exercising together,
17 actually will get you to where you're going.

18 But the curse and the beauty of this
19 country is that there is no one single authority
20 with respect to public health, so if you don't go
21 into it with a commitment to cooperation at the
22 community level, you -- we -- will not succeed.

1 So every community is being charged or challenged
2 to take this on before all the participants in
3 that community, whether it's private industry,
4 whether it's a government entity, whether it's a
5 public school, and then to work together to come
6 up with that practical application and how we're
7 going to address the specific core elements of a
8 response.

9 The national plan defines the core
10 elements of a response. What it doesn't do is say
11 how everybody is going to rally around that and
12 make it happen, and that's I think where the
13 President wanted us to go. But again, having that
14 idea and then making it happen requires resources
15 and attention, and in a time when our public
16 health infrastructures are already strained just
17 dealing with normal public health emergencies,
18 this is going to be a real challenge for the
19 country unless we force ourselves to pay attention
20 to it.

21 And as far as DOD is concerned, at our
22 installation level, that's where the Public Health

1 Emergency Officer is so important. It's that
2 person's job to interface with the public health
3 infrastructure and to address those specific
4 issues.

5 DR. POLAND: General Kelley had a
6 comment.

7 MGEN. KELLEY: If I could add something
8 to your briefing, there have been exercises at
9 very high cabinet level meetings that haven't been
10 publicized a lot, but there have been, and going
11 down there have been a number of exercises. And
12 at the tactical level and the ground level, with
13 other countries in specific, we have also had
14 exercises in how the military would interface with
15 the global World Health Organization in specific
16 countries, and so there is an exercise program in
17 progress.

18 I think that as Ms. Embrey talked about
19 the hierarchy of a national plan and then a DOD
20 plan, and she talked about the coming of the COCOM
21 plans, it will be very different how the people in
22 Europe respond to how the people who are in

1 South American or how the people who are in the
2 Pacific, which is likely to be the kickoff point
3 if there is a pandemic related to API.

4 And so those specific plans are done in
5 draft form for the most part, and now they're
6 making sure that they fit into the whole sequence
7 of plans. So those are being exercised on an
8 annual basis, but we're not fully up with that.

9 DR. POLAND: Okay. Thank you.

10 [Recess.]

11 DR. POLAND: If Board members would take
12 their seats, we're going to push on here.

13 Our next speaker is Colonel Ken Cox,
14 Office of the Deputy Assistant Secretary of
15 Defense for Force Health Protection and Readiness,
16 who will brief us on the Armed Forces Health
17 Surveillance Center. The Board has heard bits and
18 pieces about this over the last few meetings.
19 This will be our first full briefing on it. Dr.
20 Cox's slides are in Tab 7.

21 COL. COX: Thank you for letting me
22 brief you. I'll get started because I really have

1 a lot to go through here today.

2 The subject of the Armed Forces Health
3 Surveillance Center has come up in the past, and
4 the Board asked that we provide more data on the
5 background, how we conceptually are focused, and
6 where we're going in terms of establishing the
7 Center.

8 Certainly this group recognizes that
9 surveillance is important, so I am not going to
10 belabor that. I do want to spend a little time,
11 though, just making sure that you all understand,
12 since you have new members, what we mean by health
13 surveillance. That's a new approach for us, and I
14 just sort of want to pass that on.

15 We're using that to encompass what was
16 traditionally recognized as and frequently
17 referred to as medical surveillance. Those were
18 outcomes, diagnoses, tests and things like that,
19 but we also have a lot of concerns that you will
20 recognize, which are related to environmental
21 exposures, occupational exposures, and those
22 events that may or may not be related to such

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1 exposures.

2 So to finally integrate what has been,
3 at least within the Department of Defense, fairly
4 separate environmental surveillance and medical
5 surveillance programs, we would like to combine
6 those. We're concerned that you need to hear from
7 a comprehensive surveillance as to policy areas.

8 Of course that also opens up the
9 population, health events, and other things that
10 are related to conditions that aren't necessarily
11 diseases, and everything else.

12 Now, obviously we've done a lot of work
13 with surveillance in the past, and it has been
14 good work, but as the current status shows, over
15 the decades the services have developed along
16 their own paths when it comes to surveillance, and
17 that has sometimes resulted in some gaps. It has
18 also resulted in some special niches that are
19 exceptionally well performed.

20 But we're looking to establish a more
21 uniform consistency and standardization for at
22 least those areas that should be critical to

1 public health and preventive medicine, and so
2 that's what the needs part identifies. We felt
3 there was a little too much fractionation, and we
4 needed to have some way to bring together the
5 different activities across the DOD enterprise.

6 So to establish that objective we set up
7 a task force, and what you see on the next slides
8 are the results of that task force's work as they
9 tried to design something that would meet these
10 needs. So the vision is relatively standard, and
11 is probably not anything that people would object
12 to.

13 One thing that expresses a certain
14 difference, and again, along with this combining
15 health, environmental, and occupational into one
16 system, we always tended to focus of course on the
17 military population, the active duty and of course
18 the reserve components as well.

19 But, as more and more situations reveal,
20 it is the greater community that determines in
21 greater part the health of that military
22 component. And so we are trying to develop our

1 systems to allow us to have the same ability to
2 invest in the affairs of joint and intimately
3 related centers along with the military.

4 Of course, our resources are more in
5 developing or piloting programs to help or
6 contribute to what is disbursed to the military
7 and make sure that it's appropriate to the strain
8 that's in the population. So the mission are the
9 standard aspects of surveillance, what we would
10 like to do.

11 Now, this sort of starts from the bottom
12 up as a slide. What we're trying to do is work
13 from the single isolated events or geographically
14 restricted occurrences, outbreaks, whatever the
15 case may be, and in the past we would handle those
16 in many cases on a center-specific basis.

17 But when we fell short, it was being
18 able to aggregate them or follow them across the
19 enterprise, or comparing services and looking for
20 things that we could pass from one to the other as
21 methods of improvement. So we need to have this
22 full spectrum, tiered approach to epidemiologic

1 analysis.

2 And that leads, then, to the outcomes
3 that we would like to obtain. So informing
4 operations, we talked a lot about that previous
5 outbreak of pandemic influenza yesterday with
6 regard to surveillance activities. There is a
7 direct relationship there.

8 Readiness refers more to the in-
9 garrison side, preparedness, force health
10 readiness, individual medical readiness, fitness,
11 nutrition, and so forth.

12 Policy of course applies to all of this.
13 If we don't have data, we can't come up always
14 with the best and most appropriate policies.

15 And surveillance should inform research,
16 not necessarily be part of research, but a lot of
17 that connection to research often proves awkward
18 and strains tensions and has to be reined back in.
19 And this all has to support our national
20 strategies.

21 Now I have to apologize, I guess, to the
22 CDC. I was hoping that we would be perceived as

1 sincere flatterers as opposed to intellectual
2 pirates, taking the term "CDC model" in vain. But
3 the point is that we often feel in our
4 relationships, at least from the Health Affairs
5 level in the services, that it's very analogous to
6 the sovereignty of states and the challenges that
7 HHS and CDC face just from that standpoint.

8 There is a great deal autonomy, much of
9 it is open, because the situations are not
10 identical across the services, and they have to be
11 able to deal with unusual outpatient subgroups,
12 etcetera. But there is also a need for a certain
13 level of standardization, an ability to bring
14 things together and evaluate and validate the work
15 that's being done.

16 So the Armed Forces Health Surveillance
17 Center is sort of our microscopic version of the
18 CDC for the military. We try to and bring those
19 centers together, establish standards, and to
20 promote unity, to gather information from all the
21 services, share it back to them so they know what
22 is being done already next over that they may not

1 have heard about, and may not need to duplicate
2 because the work has already been done, or that
3 they can provide input to other components.

4 Each of the services have their own
5 public health systems, have had them for years,
6 and we'll show the differences between the goals
7 and responsibilities for the Armed Forces Health
8 Surveillance Center as opposed to the public
9 health centers of each of the services, who are in
10 turn supporting their service-specific
11 installations around the world as well.

12 I'll try to outline a little bit about
13 the specific functions and responsibilities. And
14 you should cross off that word because some of the
15 people get mad about the Ops Center. This was
16 meant to be generic in that first goal. I didn't
17 realize it was going to be such a red flag and
18 that it was being interpreted as an operational
19 military kind of center.

20 All we meant is that it's 24-hour
21 operations, and it's active and doing good, and
22 not that it's some kind of line command fund. So

1 it's more of a support and coordinating center.
2 That, as we have talked and as I have mentioned,
3 already much of this is to support these public
4 health centers and to provide services where
5 things can be centralized.

6 If we develop, such as with GEIS, a
7 program with each of the services supplying data
8 to the central archives, there is no reason for
9 that central place to not be able to officially
10 provide reports back and modeling trends for each
11 of the services. It will relieve them of that
12 particular burden so that they can invest their
13 resources in more specific things that maybe the
14 Center would not have the knowledge to handle.

15 The other place where there is a concern
16 about how to avoid duplication or who would be
17 responsible is when you have actual potential
18 outbreaks or an elevated outbreak at a specific
19 site, that we would be flying in and taking over
20 everything for the Center. Well, no. That's
21 still the primary responsibility of Air Force Institute
22 for Operational Health (AFIOH) and Army Defense Ammunition

1 Center (ADAC) and Center for Health Promotion and Preventive
2 Medicine (CHPPM), the service-specific public health
3 centers. When requested, we can consult and provide
4 assistance, just as the CDC does working through their state
5 offices and through the metropolitan areas.

6 And again, that sort of points out one of the
7 hopes of the Center, is that it will provide sort of a
8 career path to encourage and motivate people in public
9 health or preventive medicine, who will know, who will see
10 that they have places to go to expand their horizons,
11 provide them with a wider background than that
12 they might have had staying in one certain narrow
13 place. And so we anticipate encouraging the
14 services to send more people for Emerging Infections
15 Surveillance (EIS) training, and CDC, which usually is the
16 natural place for individuals with that kind of background
17 to go to get support, to send in specific teams for
18 investigations, etcetera.

19 Now, for the existing public health
20 centers it's more or less business as is, and what
21 they're doing now is what they would continue to
22 do, although there is an option for that to evolve

1 over time. Most of the services are looking at
2 this, trying to figure out what's the most
3 efficient way to do business.

4 So, as I've already mentioned, if the
5 services are willing to offload certain of their
6 tasks which could be just as effectively
7 accomplished at the Center level, then we could do
8 that for them. Those things that they feel are
9 very specific to their mission and operations and
10 they want to keep, they can.

11 Obviously there is always going to be a
12 balancing act with the total amount of resources
13 available in the Department of Defense for
14 preventive medicine and public health activities,
15 and we'll have to keep a close eye on that to make
16 sure that we're taking care of things properly.

17 Obviously there have been over the years
18 some very specialized programs, such as we're well
19 aware of the Department of Defense Global
20 Influenza Surveillance Program, where we work with
21 AFIOH, and with supportive work by Global Emerging
22 Infections Surveillance (GEIS), and other places have

1 all been monitoring that. None of that is going
2 to be shifting around. None of those resources
3 have been identified as moving to the Center.

4 I think it's important to understand
5 that we don't want to bring in anything more.

6 We're looking to fill the gaps in the
7 system, as I will point out later.

8 Now, there's always some questions about
9 other stakeholders, other places who perform
10 similar surveillance type activities, and so we
11 tried to list a few of them, just to make sure
12 that people recognize that we've thought about
13 them. And again it's not a question of trying to
14 establish a superstructure, an empire. taking over
15 lots of things and mashing them together.

16 Certainly Armed Forces Medical Intelligence
17 Center (AFMIC) has a critical role to play, and has
18 over the years, but their existing mandate is for
19 foreign information and they are not allowed to look at
20 domestic occurrences. A move is afoot to try and expand
21 that so that they can participate in the review of
22 domestic data and use that to get a more global picture.

1 As that evolves, we will evolve our
2 relationship with them as well, but in the
3 meantime they could be more collaborative in using
4 their international partners to help inform us as
5 we work with our deployed troops and things of
6 that nature, and we would be extracting what we
7 could to support others.

8 AFIP, again this is a number of open
9 ones which they maintain, but we certainly don't
10 anticipate that the medical examiners -- their
11 offices will move or maybe stay in place, but
12 we're not going to be standing up laboratories,
13 we're not going to have morgues, and we still need
14 all that work to be done by them.

15 What we would need, of course, is access
16 to the data, and what we could provide are
17 services that are not part of AFIP now, such as a
18 death certificate-based, very broad mortality
19 registry for the entire DOD, not just the active
20 duty service members, which is all they have the
21 resources to concentrate on.

22 So we can start to truly fill, again,

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1 some of those tough gaps that have been developing
2 over the years.

3 The Uniformed Services Health Sciences
4 University, of course that's a teaching mission,
5 and yet that's part of active duty health, so DOD
6 supports studies in epidemiology and part of the
7 training for the Master of Public Health program
8 and such, but we would support that from the
9 standpoint that we will have a lot of data that's
10 available for them. They would be providing,
11 obviously, teaching and oversight.

12 The rest of it I think is showing that
13 we have taken a careful look at things that we
14 don't want to duplicate, that we can't afford to
15 duplicate due to shortages. We have outside
16 agencies such as the V.A., the CDC, and the
17 developing parts of Homeland Security, where we
18 have to pay attention to them and learn how to
19 interface with.

20 What it looks like from a government
21 structure, it is relatively simple. Some might
22 recognize this as being at least mostly based on

1 the Armed Forces Institute of Pathology structure,
2 but there are some very significant changes,
3 primarily with the board of governors, who will be
4 very hands-on.

5 It's not just a figurehead, advertising,
6 marketing kind of place or a rubber stamp
7 endorsement. They will be actively determining
8 the strategic plan within which the Center has to
9 fit its goals and objectives. They will have to
10 approve a new business plan. They will be picking
11 the director. All of those things will allow each
12 of the services, since the council involves all of
13 the Deputy Surgeons General as well as the
14 principal Deputy Assistants for Health Affairs and
15 others to sit and have a say.

16 The executive agency, which is
17 tentatively aimed towards the Army, although there
18 hasn't been a final decision made yet, provides
19 the business support and a single site to handle
20 budgeting and all the things that are involved
21 over time. Since they have experience with that
22 in an administrative function, that seemed like a

1 good point that.

2 Again, it doesn't mean they determine
3 what kind of work to staff. That's provided by
4 the council.

5 And this is one we don't need to spend
6 any time on. It just shows how we have divided up
7 the traditional surveillance cycles into work
8 areas which would be the primary functions or
9 divisions of the Center. And this not an
10 exhaustive list, but it shows many of the kinds of
11 functions with respect to where each of those
12 areas will fall.

13 And so what are we trying to stand up
14 now? We have identified a provisional operating
15 capability which is based on a series of
16 memorandums of agreement that we're developing now
17 between three of the initial components of the
18 Center.

19 And those three are the Army medical
20 surveillance activity, what we were talking about
21 earlier today; bringing the Defense Medical
22 Surveillance System into the Center, which is an

1 obvious archive for DOD level activities, and it
2 includes the DOD Serum Repository; initially
3 brings in GEIS, the Global Emerging Infections
4 Surveillance and Response System, Colonel Erickson
5 and his group and all the work that they do; and
6 from Ms. Embrey's shop, those aspects of
7 surveillance that are done there, which is
8 primarily in the realm of deployed surveillance
9 because they've got the access to look at the
10 data.

11 Supported by, as you come back up,
12 standardization, there are other sites that do
13 point surveillance, such as the Air Force has to
14 do outpatient health, and our resources would
15 support all of the other affected commands. So if
16 NORTHCOM and others were looking for support, that
17 would give them a place to turn.

18 The obvious rest of that is to set the
19 stage for a true collocated initial capability,
20 where you would find all three of those sites
21 together, those three initial components together,
22 as well as some additional support and

1 relationships with CHPPM and AFIOH.

2 And once we have collocation, of course
3 we will choose some other synergisms, so depending
4 upon the resources, we can start to move things
5 around and grow programs, but till work pretty
6 much from a cost-neutral basis because there just
7 isn't money enough to go challenge here. We'll
8 bring things together based on what we have, and
9 still be able to evolve and fill in the gaps.

10 Now that doesn't mean there is never any
11 new money in the future. It means we have to
12 compete for it, though. We have to show the value
13 of it, and the best way to do that is by having
14 products that are highly visible and actionable
15 and result in a meaningful change that our
16 leadership can see.

17 So we are looking in a few years to have
18 some kind of collocated site, and that may be part
19 of this new unified medical campus that continues
20 to develop. We will finally have on-site
21 classified, so that Defense Medical Surveillance
22 System can have all the data that it's supposed

1 to have. Right now much of it is restricted
2 because of issues about classification and how
3 their system is monitored.

4 We will also finally be able to expand
5 more to other groups that we've talked about,
6 family members, those who have separated, that are
7 still being followed by the V.A., all critical to
8 look at downstream outcomes related to possible.

9 So this just summarizes what you get
10 that you don't have right now. Much of this we
11 have already talked about. What we would like to
12 get to, and again this is just plugging the gaps,
13 I think it's important for everybody to recognize
14 that putting together what we have now is not the
15 final answer. It makes steps and progress towards
16 being able to do that. We know that there are
17 gaps. We know about the confidence of the DOD
18 Mortality Surveillance Program. Our mission is
19 surveillance. This shows us where we would like
20 to be.

21 Our recruit surveillance, even though we
22 talk about it, niche-oriented. We looked at

1 febrile illnesses, we looked at certain kinds of
2 injuries, injuries that we don't capture in a
3 systematic fashion, health events that occur
4 during the training periods.

5 So all of those are things that we need
6 to work on to put them in perspective. We're
7 looking for cancer clustering. There's all kinds
8 of proactive surveillance work that we could be
9 doing and should be doing.

10 So where are we exactly? This has been
11 approved by the Force Health Protection Council,
12 that we should implement this, and so here is just
13 a list of the bureaucratic steps that we're taking
14 to accomplish that right now. Ms. Embrey has
15 asked that we complete these initial steps and be
16 able to announce it to the world on January 1st of
17 2007.

18 In the meantime, we're already at work
19 in the separate sites on a very loose, collegial
20 basis, we want to pull it in writing so that we
21 know it's going to continue. And another step
22 that's already underway, in the absence of these

1 formal documents, is that we're telling the
2 analysts from AMSHA they're moving, together with
3 the GEIS community, into a temporary leased
4 building. This is a military building. And
5 they're in the act of moving this week, or is it
6 next week? Two of the important components who
7 will be very closely working together. After they
8 have settled in and are spread out, they're going
9 to tell us how much room they have left on those
10 floors, and a couple of the people from Ms.
11 Embrey's office may be relocating as well.

12 So that's all that I have to provide at
13 this point, just in general showing where we are
14 in the implementation of this. Certainly we
15 welcome continuing comments and suggestions from
16 you, which I didn't highlight a lot, but you were
17 listed as an advisory body to the Center, as were
18 the Joint Preventive Medicine Policy Group for
19 operational preventive medicine issues, as well as
20 the Joint Environmental Surveillance Working Group
21 under the Force Health Protection Council.
22 Obviously we need to go through the usual process

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1 for presenting questions to you. It's not that
2 we're going to send you an e-mail one day and ask
3 for advice.

4 DR. POLAND: Thank you, on both counts.
5 I did have one question, and it's just sort of a
6 general question. Probably you don't have all of
7 the details yet. But how will this organization
8 interact with more long-term or very fine sorts of
9 information?

10 I mean, right now if there's an exposure
11 and a serology that can be done a month after that
12 and a definable outcome, you would be right on it,
13 but what about something that's five years after
14 separation? This almost certainly touches on the
15 V.A. system, I realize, but how would you look at
16 the effects of different exposures or
17 interventions or outcomes over a long period of
18 time?

19 COL. COX: That's one of the key
20 functions that this Center has to provide, because
21 it's an area that we have a great deal of
22 difficulty doing in service-specific channels.

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1 And so we are building relationships with the V.A.
2 already.

3 We are supplying them with more and more
4 information for people that are separating. We're
5 telling them who was injured, the medical
6 evaluation board and what the diagnoses are.
7 They're getting lists of who is separating, when
8 they will be coming out.

9 We find that environmental exposure
10 issues, such as something that occurred in theater
11 and then it's reported to us, and there are
12 concerns about a particular issue, and they are
13 separated whether or not they want to be, they
14 will have CHPPM since they are the archive for the
15 environmental surveillance data.

16 But the V.A. part is currently missing,
17 actually, since it's not a two-way conduit yet, as
18 Dr. Brown and others know. We're working on that,
19 but all the health information exchange right now
20 is basically one way. The DOD is trying to send
21 data through that, and there is a lot of work
22 being done on the International Military Information Team

1 (IMIT) side. Once we are able to provide data for these
2 people who are separated and there's a cohort in there,
3 we'll be able to see what the health outcomes are based on
4 their follow-up care in the V.A., but at this point we
5 don't have access to that information.

6 DR. POLAND: But it is a part of your
7 sort of thinking or your concept of operations.

8 Jackie?

9 DR. CATTANI: Yes. Cattani. I have a
10 question on the opposite end of the spectrum. You
11 listed outbreak, real time outbreak detection as
12 one of the objectives, and I'm wondering. I can
13 see the value of pulling all this data together
14 for mid-term, longer term studies, having data
15 from all the services, but I guess my question is,
16 what's your definition of real time? And what
17 sources, what surveillance system would you be
18 actually using to identify real time outbreaks?

19 COL. COX: In some ways we're further
20 along in real time than we are in mid- and
21 long-term. We have an integrated DOD- wide system
22 that's called ESSENCE, and this is capturing ICD-9

1 codes in predefined groupings by respiratory
2 disease and things like illness, fever, etcetera.

3 DR. CATTANI: Right.

4 COL. COX: It gets the data. For us
5 real time is 24 hours, sometimes 48 hours.

6 Some of that is changing as we implement
7 our new replacement for our legacy system. It's
8 moving faster there. But we have data from 24 or
9 48 hours later which is processed, and the same
10 data is what we share in the DOD with the CDC,
11 that feeds the DOD data for bioassays.

12 So, again, we're implementing the
13 working relationship with HHS and CDC on real time
14 outbreak detection using our latest system. Right
15 now it's only based on ICD-9 codes, and there's
16 some limited pharmacy data, but we're in the
17 process of expanding that to also give laboratory
18 work and other ancillary information. We are
19 already looking at that in office. The primary
20 responsibility is at the installation level, of
21 course, because they've got the picture, but we
22 are certainly there to back them up in

1 consultation.

2 DR. POLAND: Okay, Dr. Miller, and then
3 Dr. Brown, and then Dr. Lednar.

4 DR. MILLER: Miller. I assume that this
5 program has both a domestic and a foreign focus.

6 And the second issue, I'm very happy to
7 see that you are very inclusive in your term
8 "health surveillance," and you included
9 environmental. I'm not sure if you're also
10 including in that terminology the ecology of
11 different environments in terms of climatological
12 or water systems or situations which are conducive
13 for a certain vector populations.

14 So in terms of -- rather than looking at
15 disease or disease surveillance, or environmental
16 such as toxin exposure, I hope that you're also
17 including ecological niches for where potentially
18 your populations will be residing.

19 COL. COX: We are. Unfortunately, given
20 the time I didn't list all the things you laid
21 out. Obviously we're going to have to prioritize.
22 We're going to have make certain compromises until

1 we're up more, but vector population surveillance
2 is high on my list.

3 What we often laugh at, in terms of
4 prioritization, is how easy it is to obtain good
5 data about those sources. So animal health data,
6 in some of those we don't have Department of the Environment
7 (DOE) assistance, but we have places that get parts of that,
8 and so from the environmental side some of those ecological
9 things have fallen into that --water sampling
10 results from across the country. As well as you
11 mentioned it isn't just domestic, we do it also
12 overseas. These sites and any of our deployed
13 operations, all of that data comes back to us.

14 DR. POLAND: A couple of comments, very
15 short, and then we need to move on.

16 DR. LEDNAR: Wayne Lednar. A question
17 of scope. Some of the questions about health can
18 be framed around populations like active duty,
19 reserve, guard. Sometimes the questions of health
20 tend to be more facility or installation-oriented
21 in terms of the question that's asked or the
22 answer that has to be given.

1 So two things: One is, are you
2 including in your populations whose health you're
3 going to monitor, DOD civilian employees who work
4 on installations?

5 COL. COX: That is part of our
6 population we're talking about expanding. That's
7 one that we feel that hasn't always been as easy
8 to get centralized data. Steps are already being
9 taken for the civilians that we deploy.

10 If you mean apply the same exact
11 process, the general answer is yes, but it turns
12 out the connections haven't been there for the
13 data. The forms they're filling out
14 pre-deployment, post-deployment, may not always be
15 sent to repositories like they should.

16 The other side is, our patients have
17 always been integrated if they're in an identified
18 hazardous work environment. But We want the total
19 civilian deployed population, and that has come up
20 in our discussions about other sources, too.

21 If we can find the right data sources to
22 be able to bring them in, we feel that they should

1 be monitored the same way as we do our military.
2 The fact that we're converting a lot of military
3 to civilian, the fact that we're deploying
4 thousands of civilians over the years, only
5 emphasizes the importance of making sure that they
6 are caught in the same surveillance method we use
7 for active duty personnel.

8 DR. LEDNAR: The second question is, we
9 talked in a quick follow-on to an initial
10 description of the health of a group, is how does
11 it compare to some other group. You know, are we
12 seeing more, seeing less? Are we healthier or are
13 we sicker? And what are your thoughts on
14 developing that comparison reference capability to
15 put against what you're seeing in your
16 populations?

17 COL. COX: I don't think I have a quick
18 answer to that one. We have talked about that.
19 It's difficult. You have a healthy warrior
20 deployed. You double screen even the healthy
21 people. If things continue, should you look at
22 other military forces in other countries? Should

1 you look at national populations and try to tease
2 out the sensitive groups? I don't know, We're
3 continuing to work with that, and I suspect we'll
4 be looking for suggestions and advice on how to do
5 it.

6 DR. POLAND: Mark?

7 DR. BROWN: Thanks. I want to just
8 follow up on the point that you raised, Greg,
9 about sort of the long term health surveillance
10 issues that Dr. Cox's talk I think raises. And
11 for Department of Veterans' Affairs, I think at
12 this point because of our history with dealing
13 with these types of health questions of veterans,
14 we're committed to doing these types of
15 longitudinal studies.

16 We know we're going to get questions
17 from veterans, from Congress, from the media about
18 what are those who served in any particular
19 deployment, are they getting healthier or are they
20 getting sicker? If they're getting sick, from
21 what diseases? You know, questions about
22 reproductive health, questions about cancer and so

1 forth. And so we're committed to doing
2 longitudinal morbidity and mortality studies.

3 But of course we're dependent on that to
4 get the data, just for example, the identity of
5 these individuals who are deployed, for example,
6 from Department of Defense. And unlike earlier
7 deployments, for example, today we're in much
8 better shape.

9 I don't know if most people appreciate
10 how much better off we are now in this current
11 deployment, for example, to capture data about who
12 was deployed. DOD already regularly supplies us
13 with information about who was deployed, for
14 example, to Iraq and Afghanistan and separated
15 from military service, and we can begin to track
16 them and think about following things like
17 mortality and morbidity.

18 But we're also completely dependent, of
19 course, on DOD for information, as Dr. Cox
20 mentioned, about what types of environmental
21 exposures or ecological exposures or whatever,
22 occupational exposures, may have occurred, and I

1 think we're much better off in that regard, too.
2 I think we are getting this data. I mean, I think
3 everyone recognizes at this point, based on our
4 collective history, that we're going to have to do
5 this, and I think we're doing better than we have
6 in the past. I think that in the future we're
7 going to be able to answer the questions that we
8 know we're going to get.

9 DR. POLAND: Thank you. Warren, did you
10 have a comment?

11 SPEAKER: Just one. I'd like to make a
12 special plea for consideration of environmental
13 exposures and unique communities. The program
14 outlined certainly covers the broad aspects of
15 health surveillance, maybe with an infectious
16 disease emphasis. But certainly a number of DOD
17 communities, such as the diving community which
18 spans all three services, and the Navy's submarine
19 community, have unique issues and problems that
20 are going to need special attention to focus on
21 long-term health surveillance, that are certainly
22 going to be in addition to what we consider the

1 typical role of health surveillance.

2 COL. COX: The Center certainly looks to
3 identify gaps over time. We'll have to parcel out
4 if the service-specific, if the service centers
5 will all be responsible for that, or if they want
6 to pass that on to the Center. There's aviation,
7 there's all kinds of stuff.

8 DR. GARDNER: Just a brief comment.
9 This is wonderful, that you're doing this.

10 Modeling after CDC is a good idea, and
11 you'll certainly get lots of new sources of
12 surveillance data. And then CDC does not with its
13 Morbidity and Mortality Weekly Report (MMWR) as a
14 communication, but it really gets its glory out of its
15 epidemic aids and its ability to go in and investigate and
16 discover things. Do you have an act -- are you proposing,
17 are you going to limit yourselves to surveillance, or are
18 you going to have again the ability to go in and do
19 investigations when people seem to be having
20 trouble solving problems?

21 COL. COX: Initially the staff, they are
22 expected to be sources for the Center. It's not

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1 for us to say we're going to make every
2 investigation for every outbreak that's of
3 concern.

4 DR. GARDNER: When requested.

5 COL. COX: The services are to have that
6 initial responsibility, but one of the slides does
7 mention that if asked, we can support, so we would
8 augment the team. We would send one or two
9 people, EIS graduates or whatever specialty is
10 needed, depending on what it was.

11 It might not be an infectious disease
12 outbreak, although that tends to be the tenor that
13 I think would come sooner, especially if it
14 involved unique concerns about how that might
15 affect our operations. But it could be a cluster
16 of injuries that is just as important to
17 investigate, with kind of the same kind of
18 mid-term effect on operations.

19 So, yes, we would support the
20 investigation, but we would be requiring their
21 response initially.

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

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1 Appreciate it.

2 [Recess.]

9 DR. POLAND: We're going to take a
10 10-minute break here, but before we do that, if we
11 could have Commander McMillan come up to the
12 front.

13 It may not be well known to the Board,
14 but Commander McMillan will be retiring from the
15 Board and moving on to a new duty station. We
16 wanted to recognize this.

17 Presented to Commander David McMillan,
18 in deep appreciation for your outstanding
19 contributions as a Marine Corps preventive
20 medicine liaison officer to the AFEB. Thank you
21 for your selfless and dedicated support.

22 [Applause.]

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1 COL. GIBSON: And here is a plaque from
2 Ms. Embrey, also commending him for his
3 outstanding support, and an AFEB coin.

4 [Applause.]

5 CDR. McMILLAN: It's been a real
6 pleasure to be able to work with the members of
7 the Board. At least for me, I'm glad that I got
8 the last day of the AFEB one rather than something
9 that said anything else.

10 I'll tell you, I have been amazed. I
11 guess our senior Marine Corps leaders at least all
12 have to be speed readers and insomniacs, because
13 we get stuff filtered down all the time. Every
14 time the AFEB releases a new opinion, it comes
15 down from the top about what we are going to do
16 and how it will affect us and so forth. I don't
17 think they know what AFEB stands for, necessarily,
18 but they do know it's something that's familiar to
19 them and they've known it for a while.

20 [Applause.]

21 DR. POLAND: We number the coins, so if
22 they show up on e-Bay we know who -- We're going

1 to take a 10-minute break.

2 [Recess.]

3 DR. POLAND: We're going to change the
4 order a little bit, related to travel plans. The
5 next speaker will be Dr. Lednar. He'll provide an
6 update on the AFEB's report to DOD on the
7 traumatic brain injury issue. As he will discuss,
8 we already requested and received a series of
9 briefings on Traumatic Brain Injury (TBI) at our last
10 meeting in the spring, and subsequently decided to provide
11 comments and recommendations on the department's
12 approach to prevention, clinical management, and
13 control.

14 I think Wayne's report is under Tab 12.
15 This session is open to the public.

16 DR. LEDNAR: Thank you. What you have
17 is a copy of the actual report of our Subcommittee
18 on Occupational and Environmental Health to the
19 question about traumatic brain injury that was
20 addressed to the Board. I'm not going to read
21 this to you, but I'd just like to give you a
22 couple of highlights, from the subcommittee's

1 point of view, a couple of highlights of what's in
2 the printed recommendation.

3 Number one, the Board went out and,
4 since there was an issue, the Board, again with
5 Colonel Gibson's leadership, identified expertise
6 across DOD and came back. And Commander McMillan
7 in particular, I think, had conversations with us
8 emphasizing how important TBI as an issue was in
9 operations in the Marine Corps. While there as a
10 question in the hands of the Board, I think really
11 it was the Board that formed the question.

12 The actual inputs to the process, we had
13 several briefings that were given over a number of
14 AFEB meetings, and on the basis of all that input
15 and really a number of things, Dr. Lauder I think
16 really helped frame the issues she wanted to focus
17 on.

18 So just a couple of points about the
19 document, the recommendations that are here.
20 Number one is prevention, very, very important.
21 Clearly it begins with the preparation of the
22 units, aspects of body armor, of tactical

1 operations. And again, there was a lot of work
2 before these recommendations occurred, in the Army
3 and in the Marine Corps, to try to anticipate this
4 issue and to reduce the impact of this on the
5 deployed force.

6 Going forward, the second recommendation
7 is that this is an issue that needs to be
8 supported by policy, and it's a multi-pronged
9 activity that needs to occur. Some of it is in
10 prevention. Some of it is in clinical evaluation.
11 Some of it is in screening sessions, pre- and
12 post-deployment.

13 Very importantly, while there is obvious
14 concern with severe brain injury, the concern of
15 the subcommittee is that there is moderate and
16 mild traumatic brain injury for which we have
17 large scientific gaps. We don't know a lot about
18 it in terms of evaluation, follow-up, and certain
19 gaps in between.

20 We also realized that to get better at
21 this across the services, it was not the subject
22 of this task to fix this. Rather we feel it is

1 our recommendation to all four, to recommend the
2 formation of a consensus panel across the
3 services, including the Department of Veterans'
4 Affairs, to really take these questions and issues
5 and to create a plan going forward. So that
6 really is probably one of the most important
7 aspects of this entire recommendation.

8 And as the committee, the subcommittee
9 did its work independently, it has been very
10 helpful to have input from other activities, but
11 they are a reminder to us all that there are
12 ongoing clinical care requirements for brain
13 injury of our service members, and clearly this is
14 going to require the health care system, whether
15 it's in DOD or the V.A., to ensure that the access
16 to clinical support is there for them.

17 So just in sort of a wrap-up sense, I
18 want to thank Dr. Lauder, Dr. Halperin, Dr.
19 McNeill, and especially Col. Gibson for his
20 leadership on this issue.

21 COL. GIBSON: One comment, if I could.
22 These recommendations were received by Dr.

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1 Winkenwerder and endorsed wholeheartedly by him.
2 I was at a meeting where he literally took me
3 aside and quoted some of this.

4 DR. POLAND: I want to add my comment to
5 that, that this was a high visibility issue.
6 There was a lot of press, politicization about it,
7 and you guys took a dispassionate look at it. And
8 so it's an example, again, of the AFEB providing a
9 product to DOD Health Affairs that I think has
10 been helpful to them.

11 The other point to make is that is it
12 has also influenced the Defense Science Board in
13 some of their thinking about what needs to be
14 done. So sometimes these have even more
15 far-reaching implications than we realize. So,
16 Wayne and Tamara, thank you very much.

17 Tamara, did you have a comment?

18 DR. LAUDER: Wayne just did a nice job
19 of thanking all of us, but I think that we should
20 thank Wayne, too, because he really had the
21 foresight to think that this was something that we
22 should pay attention to. And while we all worked

1 together to put it together, it really was Wayne
2 and I'm sure Roger that came up with the idea to
3 look at this. So I just want to make sure you get
4 credit.

5 [Applause.]

6 DR. POLAND: Wayne, thank you. Okay,
7 the next speaker is Colonel Mike Snedecor, Chief
8 of Preventive Medicine, Office of the Air Force
9 Surgeon. He will present the results of Chlamydia
10 screening in Air Force men, and his slides are
11 under Tab 11.

12 COL. SNEDECOR: Thank you. Good
13 afternoon. I'm not the PI for this study. I
14 didn't write the study. I've just done some
15 preliminary analysis of this.

16 I became aware of the results of this
17 study late last week, so I asked Roger to throw
18 this in because I thought it would be informative.
19 After having a chance to look at this over the
20 weekend, it looks like it may be a little less
21 useful than I thought.

22 To give you some background, the study

1 looks at several bases, eight bases, again
2 screening males and females 25 and under for
3 Chlamydia annually. You'll see further on that
4 they weren't screening everyone every year. These
5 were measured against eight bases that only
6 screened females every year, which is the standard
7 recommendation.

8 Here are some of the outcomes they
9 looked at, looking at the males, they looked at
10 these two different types of bases, females at two
11 different types of bases, and looked at health
12 outcomes of both of those groups.

13 Here are the studies, April 2002 to
14 March 2005, the two groups, and we looked at
15 people at those bases. If they moved off of the
16 base -- we tracked them when they came onto the
17 bases, and if they would then move off the bases,
18 then they were left out of the study group. We
19 only counted them in the exposure group if they
20 were at the base, so that we knew that they were
21 only in the exposure group, the exposure time,
22 when they were at the base. So if they left and

1 went to another base, they were taken out. I
2 think that explains that.

3 So of the males, 44,435, here are the
4 health outcomes. These are the health outcomes
5 that they looked at. This is the comparisons:
6 Infertility, orchitis/epididymitis, urethral
7 stricture, prostatitis. You can see it looks like
8 there were no statistical differences between the
9 two groups. These are males who were at the bases
10 where they were screened annually for Chlamydia,
11 and compared to males who were at bases where they
12 were not being screened annually.

13 DR. POLAND: And these are the outcomes
14 in those that were not, compared to the --

15 COL. SNEDECOR: These were outcomes in
16 both of those groups, so males outcomes, these
17 specific health outcomes in males in both groups,
18 compared to each other.

19 COL. GIBSON: And your control group was
20 what, in the ratio?

21 DR. POLAND: These are outcomes in the
22 people screened or not screened?

1 COL. SNEDECOR: These are screened;
2 those are the not screened.

3 DR. POLAND: Okay.

4 COL. SNEDECOR: There is actually a
5 higher incidence of prostatitis in people who were
6 not screened.

7 DR. POLAND: Yes, but none of them are
8 significant.

9 COL. SNEDECOR: Right.

10 DR. MILLER: No significant differences.

11 SPEAKER: You've got at least one that's
12 borderline because it's 1.8, so that certainly
13 suggests it's a borderline.

14 DR. MILLER: I agree.

15 SPEAKER: But is that a screening effect
16 or is it --

17 SPEAKER: I think we don't know.

18 COL. SNEDECOR: Exactly, because we know
19 that in the bases that were being screened they
20 were probably screened much more frequently than
21 the bases that weren't.

22 SPEAKER: So we don't know the number of

1 tests that were looked at on the non-screened
2 bases versus the number of tests for males that
3 were tested at the bases that were screened.

4 DR. POLAND: Maybe you just answered it.
5 How many were screening and how many were
6 non-screening?

7 COL. SNEDECOR: If you look in your
8 binder there's a more detailed report. That may
9 be in there, but like I said, I'd have to read
10 that myself. I can't answer it because I really
11 didn't do the analysis.

12 DR. MILLER: Are all these health
13 outcomes of those individuals who also had
14 Chlamydia?

15 COL. SNEDECOR: Yes, I believe so.
16 Actually I don't know. I don't know.

17 SPEAKER: And were they treated?

18 DR. POLAND: Look, it's a little
19 confused. We don't really know where we're at.

20 SPEAKER: Let him finish.

21 COL. SNEDECOR: That's what I was
22 saying. After looking at the slides over the

1 weekend, I -- here's a couple of graphs. You can
2 see this is on the left, that is, the grayish line
3 is the proportion or percentage of males screened
4 at the screened bases. The red line is the
5 proportion of tests submitted that were positive.

6 And then on the right is the proportion
7 of tests submitted that were positive at the
8 non-screened bases, which were essentially
9 probably symptomatic males coming in for a test,
10 which is really not the same thing.

11 So you can see that supposedly the males
12 that should have been being screened annually at
13 their health assessment should be close to 100
14 percent, and it's really only 40, maybe close to
15 50 percent.

16 DR. POLAND: Remember, in the non-
17 screened, if I can read that, 15 to 25 percent of
18 them were positive?

19 COL. SNEDECOR: Since they weren't being
20 screened --

21 DR. MILLER: You have a priori positive.

22 COL. SNEDECOR: Right. Again, this is

1 not -- these were just tests that were submitted
2 at bases that submitted them for diagnostic
3 purposes, really weren't submitted as part of a
4 health assessment screening program.

5 Young females, 11,000 enrolled. Those
6 health outcomes, we looked at Pelvic Inflammatory
7 Disease(PID), infertility, and ectopic pregnancy.
8 Once again, not significant.

9 Personally, I don't put a lot of -- I
10 wouldn't put a lot of emphasis on these health
11 outcomes, since they're often years down the road
12 and occurring after many other things.

13 My interest in this study was
14 reinfection rates, and I believe there's a slide
15 that looks at that.

16 DR. WALKER: This does not consider
17 whether the test was positive or not. This is
18 just a ratio --

19 COL. SNEDECOR: These are just health
20 outcomes in the population.

21 DR. POLAND: It's a little misleading to
22 characterize it as a study. These are similar

1 pieces of data that are sitting out there, and
2 they're almost passively trying to make
3 comparisons, from what I can see here.

4 I'll come back to this point because
5 it's relevant to what our December missions were
6 in terms of design and study to actually get at
7 this issue. These are descriptive pieces of data
8 that were not necessarily collected concurrently
9 or anything like that. They just happen to be
10 discrete pieces of data that are being compared.

11 COL. SNEDECOR: I'm pretty sure these
12 are health outcomes in the people that meet the
13 enrollment criteria for the study.

14 DR. SHAMOO: That's not what the author
15 says.

16 COL. SNEDECOR: These people were at the
17 bases during the time period and were being
18 screened or not being screened.

19 DR. SHAMOO: The author says that a
20 retrospective study was conducted between -- a
21 retrospective cohort study. They're claiming it
22 is a study, in the paper and the progress report

1 by the main author, Jill Trei.

2 COL. SNEDECOR: This isn't just looking
3 at the Air Force in general. This is directly
4 related to the population I described at the
5 beginning. These are women or men at these bases
6 where the screening is either going on annually or
7 not going on annually, who were at the bases
8 during the time period, met the enrollment
9 criteria.

10 Here is a similar graph. This is
11 looking at the females at the screened bases and
12 non-screened bases, and then percent positives of
13 the tests submitted at both the screened bases and
14 non-screened bases. It's a little hard to see.
15 The percent screened at the screened bases was
16 higher, and the percent positive tests were
17 slightly higher.

18 The dotted red line is the percent
19 positive tests at the non-screened bases. You can
20 see it's a little bit higher than the non-dotted
21 red line or the solid red line. That's the
22 percent positive test rate at the bases where they

1 were screening the males.

2 So it is slightly lower, and you can see
3 there was something to learn in the last year, but
4 it's not as impressive as we would like to see at
5 a base where they're also screening the males.
6 But you can also see that they're only screening
7 half of the population of women. It's the
8 mandated annual assessment, and if the requirement
9 is to screen everyone yearly, they weren't in
10 compliance.

11 DR. POLAND: Questions?

12 DR. BROWN: Yes. My recollection from
13 when we had this discussion last about Chlamydia
14 screening -- I don't know, a year ago or so, and
15 so everyone was not around I guess the last time
16 this came up -- a suggestion had to do with the
17 possibility, the hypothesis that you could prevent
18 reinfection rates by screening men for Chlamydia.

19 COL. SNEDECOR: Right.

20 DR. BROWN: And so I guess my question
21 is, does this study, did they take that into
22 account? Were they trying to investigate that?

1 It was a preventive approach to prevention.

2 COL. SNEDECOR: That was the idea.

3 DR. POLAND: It looks like diagnosis and
4 case findings, not screening.

5 COL. SNEDECOR: No, the idea behind this
6 was to do universal screening of men and women
7 under 25 at these bases, with the idea that you
8 would not only screen the asymptomatic females,
9 you would also screen the asymptomatic males --

10 DR. BROWN: Right.

11 COL. SNEDECOR: -- so that you would
12 basically wipe it out in the population.

13 You wouldn't have reinfection.

14 DR. BROWN: I guess my question is, was
15 that what they were trying to get at eventually?
16 Is this study going to address that suggestion?

17 COL. SNEDECOR: This study was hopefully
18 going to show that would have been the effect. If
19 you compared it to the bases where you weren't
20 screening the males, you would see much lower
21 positive screening rate the next year and the next
22 year, because the males we being screened and not

1 reinfected the females. And you don't see that.
2 But I can also see they weren't screening
3 everybody.

4 And you could also postulate that the
5 women were having sex with people who were not in
6 the Air Force and on base, in that age group, and
7 so if you weren't screening them, they were being
8 reinfected by other people.

9 DR. GARDNER: But even then, your last
10 slide, you showed that on the bases where
11 screening of the males was going on, the solid red
12 line is lower than when it wasn't going on, or
13 your dotted red line by a little bit here, which
14 supports at least, with all the flaws we've just
15 talked about, the idea that if you screen the men
16 -- I assume they're treated when they're found to
17 be positive?

18 COL. SNEDECOR: I think you can assume
19 that, yes.

20 [Laughter.]

21 DR. GARDNER: That you would reduce the
22 transmission to women. At least you could -- it's

1 a small bit in the right direction on that slide,
2 I think, isn't it?

3 COL. SNEDECOR: Right. I mean, it looks
4 like there may be some small benefit.

5 DR. PARKINSON: Sometimes I feel myself
6 a little bit back in residency or grand rounds and
7 kind of methodologically pimping a little bit, and
8 I've got to apologize that, not for me but for --
9 because what had happened here is, a commander
10 tried to do the right thing. In other words, we
11 are actually going to go out and we're going to
12 randomize eight bases where we do male and female
13 compared to ones that are not, but it's only
14 active duty in the periodic health assessment,
15 right, Mike? It's not every woman who comes
16 through the clinic door who's a beneficiary.

17 COL. SNEDECOR: Right.

18 DR. PARKINSON: So the notion that you
19 could demonstrate recurrent infection rate
20 reductions by selectively picking -- if you
21 happened to be an active duty member who was
22 having relations with another active duty member,

1 that's a great theory. In reality I think it's
2 probably unlikely, both because of the community
3 and because of the fact that spouses who are not
4 active duty service members, male or female, are
5 not going to be screened under the protocol.

6 So the question that I've got is, is it
7 possible -- because the hypothesis is still valid
8 if you can keep track of those people over time to
9 some degree. To the degree that you have a cohort
10 of 20,000 people at one point in time, were 85, 90
11 percent screened -- which is great -- both males
12 and females?

13 It may be that for the normal clinical
14 course of diseases like ectopic pregnancy,
15 infertility, these things are much longer term
16 anyway than you're likely to see in a two or
17 three-year cycle. So I think if you could
18 maintain that cohort, there might be some good
19 things that you could do going forward to look at
20 it.

21 Number two, there's probably a lot of
22 other questions could be answered once the primary

1 investigators present. And number three, I guess
2 on a very simple note, how do you define
3 infertility in someone who has just been screened?
4 I mean, how was that even defined for the case
5 definitions at endpoint?

6 Because typically you've got to have
7 certain age criteria, multiple times of trying to
8 be pregnant.

9 So, I mean, there's all sorts of stuff
10 we need to get at, but that's my reaction to it.
11 But let's not curse the darkness, let's light a
12 candle. There are some good things here, I think.

13 COL. SNEDECOR: This is the cohort.
14 They are individual people. They were tracked. I
15 was pretty insistent, when I helped her design
16 this study, that she go down to the individual
17 level, not just look at this as a study of a base.
18 Let's look at the tests on the basis of the
19 people, not just charge through here.

20 Let me move through here, since it's
21 getting late. There is one other slide I'd like
22 to look at. This is on a person level, the

1 percent positive. The percentage of being
2 positive once was 11 percent at the screened
3 bases, 10 percent at the non-screened bases. Then
4 of being positive two or more times, it was 2.4
5 percent at the screened bases and 1.8 percent at
6 the non-screened bases, which I thought was
7 interesting.

8 I will let you know that they did screen
9 more, they did give more tests, which implied that
10 they were screening more, at the screened bases.
11 That's my read to that, but I thought that was
12 very interesting, that at the bases where they
13 were screening men as well, women were getting
14 more -- had a higher percentage of being infected
15 by the virus.

16 That's basically it. So she was looking
17 for input on if you had suggestions for how she
18 might better analyze this data, like you're
19 saying, Mike.

20 DR. POLAND: It's probably a little hard
21 for the Board to comment on that because we
22 haven't seen this write-up. We can't review it

1 just quickly, on the fly like this.

2 But in the December recommendations that
3 were sent to Dr. Winkenwerder, you were concerned
4 that there be a well-designed study to look at
5 this. I don't know whether or not this meets
6 those criteria. And there's a small group of us
7 that are going to meet, I think. I'm trying to
8 remember who all is involved. Myself, Dr. Silva
9 --

10 COL. GIBSON: Dr. Parkinson.

11 DR. POLAND: -- Dr. Parkinson.

12 COL. GIBSON: Dr. Silva hasn't gotten
13 back to us whether he was going to participate in
14 the study design or not for this.

15 DR. SILVA: That's fine. I haven't been
16 home.

17 DR. POLAND: So we'll endeavor to do
18 that.

19 COL. SNEDECOR: I'm sure she would love
20 to have you look over the study design and what
21 she has found and provide --

22 DR. POLAND: What I don't know is where

1 we are with the compliance with the current DOD
2 policy. Has that moved at all in terms of
3 screening in each of the services?

4 COL. GIBSON: This is Colonel Gibson. I
5 can discuss that. Your letter to Dr. Winkenwerder
6 was well received. He wanted to know why we
7 couldn't monitor the Chlamydia testing, why a
8 disease measure was not being monitored.

9 He assigned this to the Air Force's
10 Population Health Center as a task for them to
11 come up with a method of monitoring, and he also
12 tasked - Dr. Ben Diniega got the task. Dr. Diniega
13 was then tasked to go to NQMP to address your
14 second issue, which was to decide a well- designed
15 study to look at several of these points, the
16 impact of screening.

17 In particular, the reason this came up
18 again was that Colonel Underwood brought some
19 data, just DMDC, non-person-level data that really
20 brought into question whether screening for
21 Chlamydia at basic training had a valid -- the
22 reason that question came up was, we knew from a

1 2001 audit to the AQ&B that our compliance rate
2 with Chlamydia screening on an annual basis for
3 high-risk females was 30 percent.

4 So the issue was, can we improve
5 compliance, monitor that, and then in the face of
6 that look at the value added from improvement in
7 screening? The Navy is doing it. The Marine
8 Corps is doing it. Air Force has just started
9 doing it, and the Army has not, so we had an
10 opportunity to do an experiment and look at this,
11 and see if there was truly value added in that.

12 Test them once in basic training and
13 they're good to go for the rest of their lives?
14 Not if we don't have a well-designed reproductive
15 health program for both men and women throughout
16 their military career.

17 DR. POLAND: Joe?

18 DR. SILVA: Silva. I think everyone has
19 seen the new results from the cervical cancer
20 vaccine, and I don't know where DOD has gone in
21 terms of providing that. It does have a
22 tremendous impact.

1 COL. GIBSON: As a member of the Joint Preventive
2 Medicine Policy Group (JPMPG), this issue came to the
3 JPMPG, and they recommended across the board that we use --
4 that we start using Human Papilloma Virus (HPV) vaccine,
5 mandatory for recruits, offered to all active duty females
6 under the age of 26, included in the TRICARE benefit.
7 That policy is now being signed off in concurrence
8 across the services, Health Affairs policy.

9 There are some issues, I understand,
10 about putting it in the TRICARE benefit -- you're
11 shaking your head no. Was that fixed?

12 COL. SNEDECOR: I don't think so. I saw
13 something the other day that said once it becomes
14 basic policy --

15 COL. GIBSON: This came up last week,
16 It's going to happen. It just won't be quite as
17 timely as we thought it was going to be.

18 DR. POLAND: Just one little thought on
19 that. Oh, sorry, Russ.

20 DR. LUEPKER: You attempted not to have
21 an ecologic study but in fact, as you point out,
22 you don't know who is having a relationship with

1 whom. You just know on some bases males and
2 females were screened, on other bases just females
3 were screened.

4 So really the next step would be a
5 nested case controlled study where you actually
6 ask the females who were positive, versus those
7 who were negative, whether the relationships were
8 with men, specific men who were screened or not
9 screened, and then you might be able to get to the
10 issue of whether a relationship with a man who has
11 been screened is a preventive factor for a woman
12 getting Chlamydia.

13 DR. SILVA: Or a woman, a sexual
14 relationship with a woman.

15 DR. LUEPKER: Or it could go the other
16 way.

17 DR. SILVA: From California.

18 [Laughter.]

19 DR. POLAND: That's a different reason.

20 Okay. Thank you, Mike. Colonel Gibson
21 has a few administrative remarks and then we'll
22 adjourn.

1 COL. GIBSON: Don't forget your
2 attestation statements for evaluations for your
3 CME's. We want to give those credits out if we
4 can. And thanks again to Carolyn and Karen for
5 their support here, and Ms. Jean Ward for what she
6 does back home.

7 [Applause.]

8 And we'll see you in December.

9 DR. POLAND: The last meeting of the
10 AFEB, to be continued in December as the Defense
11 Health Board, is adjourned.

12 [Whereupon, at 2:55 p.m., the meeting
13 was adjourned.]

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ANDERSON COURT REPORTING
706 Duke Street, Suite 100
Alexandria, VA 22314
Phone (703) 519-7180 Fax (703) 519-7190