

UNITED STATES OF AMERICA
DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

OPEN SESSION

Frederick, Maryland

Wednesday, March 8, 2006

ANDERSON COURT REPORTING
706 Duke Street, Suite 100
Alexandria, VA 22314
Phone (703) 519-7180 Fax (703) 519-7190

1 PARTICIPANTS:

2 AFEB Board

3 DR. FRANCIS A. ENNIS
4 Director, Center for Infectious Disease and
5 Vaccine Research University of Massachusetts
6 Medical School

7 DR. GREGORY C. GRAY
8 Professor, Department of Epidemiology College of
9 Public Health, University of Iowa

10 DR. EDWARD L. KAPLAN
11 Department of Pediatrics University of Minnesota
12 Medical School

13 DR. TAMARA D. LAUDER

14 DR. WAYNE M. LEDNAR
15 Vice President and Director, Corporate Medical
16 Eastman Kodak Company

17 DR. LEON S. MALMUD
18 Herbert M. Stauffer Professor of Diagnostic
19 Imaging Professor of Medicine, Dean Emeritus
20 Temple University School of Medicine

21 DR. KEVIN MILLS MCNEILL
22 State Epidemiologist, Mississippi Department of
Health Director, Mississippi Public Health
Laboratory Clinical Professor of Preventive
Medicine University of Mississippi School of
Medicine

DR. J. GLENN MORRIS, JR.
Professor and Chairman Department of Epidemiology
and Preventive Medicine University of Maryland
School of Medicine

DR. MICHAEL N. OXMAN
Staff Physician, Infectious Disease Section
Medical Service, Veterans Administration Medical
Center

ANDERSON COURT REPORTING
706 Duke Street, Suite 100
Alexandria, VA 22314
Phone (703) 519-7180 Fax (703) 519-7190

1 PARTICIPANTS (CONT'D):

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

4 DR. GREGORY A. POLAND
5 Director, Mayo Vaccine Research Group
6 Translational Immunovirology and Biodefense Mary
7 Lowell Leary Professor of Medicine Mayo Clinic
8 Foundation

7 DR. ADIL E. SHAMOO
8 Department of Biochemistry and Molecular Biology
9 University of Maryland School of Medicine

9 DR. JOSEPH SILVA, JR. Dean's Office, School of
10 Medicine University of California, Davis

11 Board Consultants

12 DR. JACQUELINE A. CATTANI
13 Director, Center for Environmental and
14 Occupational Health College of Public Health,
15 University of South Florida

15 DR. PIERCE GARDNER
16 National Institutes of Health

17 Ex-Officio Members

18 DR. MARK BROWN
19 Director, Environmental Agents Service Office of
20 Public Health and Environmental Hazards Department
21 of Veterans Health

21 MRS. ELLEN EMBREY
22 Deputy Assistant Secretary of Defense Force Health
Protection and Readiness

1 PARTICIPANTS (CONT'D):

2 Board Staff

3

DR./COL. ROGER L. GIBSON
4 Executive Secretary Office of Assistant Secretary
of Defense for Health Affairs

5

CDR. DAVID C. CARPENTER
6 Assistant Defense Attache - Health Affairs
Canadian Defense Liaison Staff

7

LCDR. ERICA SCHWARTZ
8 Preventive Medicine/Epidemiology Consultant U.S.
Coast Guard Headquarters

9

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

11

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

14

COL. MICHAEL SNEDECOR
15 Chief, Preventive Medicine Department of the Air
Force

16

COL. PAULA UNDERWOOD
17 Representing Lt. Scott Stanek Preventive Medicine
Staff Officer

18

CAPT./DR. RICHARD JOHNSTON
19 British Liaison Officer British Embassy

20

21

* * * * *

22

ANDERSON COURT REPORTING
706 Duke Street, Suite 100
Alexandria, VA 22314
Phone (703) 519-7180 Fax (703) 519-7190

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

2 (8:04 a.m.)

3 DR. POLAND: Good morning, everybody.
4 If the Board Members would take their seats, we
5 will get started here. Mrs. Embrey couldn't be
6 here this morning. Col. Cox is going to be our
7 designated Federal official and will call the
8 meeting to order.

9 COL. COX: Yes, official mouthpiece is
10 one of my other many duties. As the Acting
11 Designated Federal Official for the Armed Forces
12 Epidemiological Board, a Federal Advisory
13 Committee to the Secretary of Defense, which
14 serves as a continuing scientific advisory body to
15 the Assistant Secretary of Defense for Health
16 Affairs and the Surgeons General of the Military
17 Departments, I hereby call this meeting to order
18 -- all in one breath.

19 DR. POLAND: Thank you, Col. Cox. If we
20 could now, I would like to go around the table and
21 have the Board and our guests introduce
22 themselves. If you would state clearly your name

ANDERSON COURT REPORTING
706 Duke Street, Suite 100
Alexandria, VA 22314
Phone (703) 519-7180 Fax (703) 519-7190

1 and where you are from, that would be helpful.
2 Can I start with Dr. Lauder at the end, and we
3 will weave our way our way around?

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

6 DR. GRAY: Greg Gray, Professor of
7 Epidemiology, University of Iowa.

8 DR. SILVA: Joe Silva, Professor of
9 Internal Medicine, University of California at
10 Davis.

11 DR. PARKINSON: Mike Parkinson, Chief
12 Health and Medical Officer, Lumenos.

13 DR. KAPLAN: Ed Kaplan, Professor of
14 Pediatrics, University of Minnesota.

15 DR. OXMAN: Mike Oxman, Professor of
16 Medicine and Pathology, University of
17 California-San Diego.

18 COL. SKVORAK: I am Col. John Skvorak,
19 the Deputy Commander here at USAMRIID.

20 DR. MCNEILL: Mills McNeill, State
21 Epidemiologist, Mississippi Department of Health.

22 COL. GIBSON: Roger Gibson, Executive

1 Secretary, Armed Forces Epi Board.

2 DR. POLAND: Greg Poland, Professor of
3 Medicine and Infectious Disease, Mayo Clinic
4 College of Medicine, Rochester, Minnesota.

5 DR. MALMUD: Leon Malmud, Professor of
6 Medicine and Nuclear Medicine and Radiology,
7 Temple University School of Medicine,
8 Philadelphia.

9 DR. SHAMOO: Adil Shamoo, University of
10 Maryland, School of Medicine, Professor of
11 Biochemistry and Bioethics.

12 DR. ENNIS: Frank Ennis, Professor of
13 Medicine, Microbiology, and Molecular Genetics,
14 University of Massachusetts Medical School.

15 DR. CATTANI: Jackie Cattani, Professor
16 of Public Health at the University of South
17 Florida.

18 DR. GARDNER: Pierce Gardner, Professor
19 of Medicine/Public Health at Stonybrook Medical
20 School.

21 DR. BROWN: Mark Brown from the
22 Department of Veterans Affairs.

1 DR. POLAND: Please remember to pull the
2 mics down toward you, so that they can catch.

3 CDR. MCMILLAN: David McMillan,
4 Preventive Medicine Officer at Headquarters,
5 Marine Corps.

6 LCDR. SCHWARTZ: Erica Schwartz from the
7 U.S. Coast Guard, Preventive Medicine Liaison.

8 COL. RUSCIO: Bruce Ruscio, Clinical
9 Program Policy, Health Affairs.

10 LTC. HACHEY: Wayne Hachey, Post-Op
11 Protection and Readiness, Health Affairs.

12 COL. UNDERWOOD: Paula Underwood, Deputy
13 Functional Proponent for Preventive Medicine,
14 Office of the Army Surgeon General.

15 COL. SNEDECOR: Mike Snedecor, Office of
16 the Surgeon General for the Air Force, Chief of
17 Preventive Medicine.

18 CDR. KASOWSKI: Eric Kasowski, Special
19 Staff Officer for Pandemic Influenza Planning, the
20 Navy's N3 Staff.

21 CAPT. JOHNSTON: Richard Johnston,
22 British Liaison Officer, Department of Health.

ANDERSON COURT REPORTING
706 Duke Street, Suite 100
Alexandria, VA 22314
Phone (703) 519-7180 Fax (703) 519-7190

1 MAJ. KILIAN: Dennis Kilian, Action
2 Officer, Director of Logistics, the Joint Staff.

3 LCDR. LUKE: Tom Luke, Population and
4 Preventive Health, Bureau of Medicine and Surgery.

5 DR. POLAND: Thank you all very much.
6 Col. Gibson has some administrative remarks before
7 we begin the morning session.

8 COL. GIBSON: Attendees, please sign the
9 roster outside, if you didn't do so on the way in.
10 Please make sure that we get you recorded as
11 coming to the meeting. This session is an open
12 meeting. It is being transcribed. As you speak,
13 when you go to the mic, please make sure that you
14 turn the mic on, so that we can capture all of the
15 information. The restrooms are located outside
16 and to the left. For Board Members, please
17 remember to complete and sign your 1352, so that
18 Ms. Ward doesn't yell at me anymore. Refreshments
19 will be available in both the morning and the
20 afternoon sessions today, and we will have a
21 working lunch here at USAMRIID for the Board
22 Members, Preventive Medicine Liaison Officers, and

ANDERSON COURT REPORTING
706 Duke Street, Suite 100
Alexandria, VA 22314
Phone (703) 519-7180 Fax (703) 519-7190

1 the speakers. Our next Board Meeting is May
2 23-24. It is the third Tuesday and Wednesday of
3 May at Tripler Army Medical Center in Hawaii. The
4 tentative agenda includes an update on DOD
5 vaccination and a question to the Board on dental
6 exam frequency. One other thing, the CME forms,
7 we get CME credit for this meeting. Please sign
8 the CME roster. We will pass it around. The
9 forms that you need to fill out are also
10 available, so we will get you credit for this
11 attendance. I think the credits for this session
12 are 5.23, something like that.

13 DR. POLAND: Thank you. Our first
14 speakers this morning are Ms. Linda Canas and Cdr.
15 Kevin Russell, who will set the tone for the
16 morning by briefing us on DOD Influenza
17 Surveillance. The slides on all the
18 influenza-related briefings are under Tab 5. I
19 will ask all the speakers for the morning and
20 afternoon sessions to please stay on time. If it
21 looks like you are starting to run over, I will
22 hold my hand up high with all fingers extended,

1 indicating you have five minutes. The Board will
2 need time to have adequate discussion of each of
3 the topics. We do ask people to stay on time.
4 Thank you.

5 MS. CANAS: Good morning, Cdr. Russell
6 and I are here to present the DOD-GEIS Influenza
7 Program to you. While we promise not to tap
8 dance, we will do a tag team on our program. I
9 will be presenting the Air Force at Brooks
10 City-Base in San Antonio, our surveillance
11 program, at which we have a surveillance-based
12 program, and Cdr. Russell will be presenting his
13 population-based program. So everyone understands
14 how our program works, our oversight is by
15 DOD-GEIS in Washington, and together the
16 epidemiologists and the laboratory work on who the
17 sentinel sites should be, based on mission and
18 location and where we might be able to encounter
19 new forms of influenza. The epidemiologists make
20 sure the Public Health Offices at each site know
21 how the program is run, and the laboratory makes
22 sure they are provided with all the supplies.

1 Then the Public Health Officer collects samples
2 according to a case definition, which is a fever
3 of 100.5 degrees or higher and a cough or sore
4 throat. Those samples are then submitted to our
5 facility, and we do conventional laboratory
6 virology. We are not so interested in whether or
7 not they have flu but in the actual virus. The
8 rapid tests are not performed at our site,
9 although we may often have the results from the
10 submitting site. We ask that they send us their
11 negatives as well as some of their positives to
12 keep up with what might not be picked up with the
13 rapid tests. We want the virus to look at, and we
14 are also now concentrating on getting an isolate
15 as soon as possible. So, the molecular work, the
16 onsite PCR, is becoming more important. Once the
17 samples get to our lab and we get an isolate, we
18 treat these as clinical samples in our site. The
19 day they come in is the day they get set up. As
20 soon as we have an isolate or an answer, we put
21 that into our computer system, and it goes back to
22 the submitting site as a patient report. In

1 addition, there is a weekly report that the
2 epidemiologists put out that summarizes what is
3 done at each site and overall. In addition to the
4 DOD reports that are put out, we also communicate
5 regularly with the CDC. All of our laboratory
6 results are given to them on a weekly basis, so
7 they are incorporated into their report. In
8 addition, selected isolates are submitted to them,
9 so they can compare what we are seeing at our
10 sites with what they are seeing globally. We also
11 do molecular sequencing, and all of that is shared
12 with them, so they don't have to duplicate our
13 work. All of this goes together to help in making
14 the vaccine decisions. This is a general overall
15 map of what influenza surveillance is taking place
16 today. The green areas represent National
17 Influenza Centers around the world, and there only
18 has to be one for the country to be colored green.
19 This map doesn't give any kind of indication of
20 how dense the centers are. The blue areas
21 represent where, in addition to the National
22 Influenza Centers, the DOD Program is present;

1 and, in addition to what CDR. Russell does and our
2 lab does, this also represents NAMRU-2 and
3 NAMRU-3. In the white areas, there is no
4 influenza surveillance that is routinely conducted
5 and submitted back to the World Health
6 Organization. The red areas represent those areas
7 where only the DOD sites are available, and we are
8 the only ones that are submitting samples. To
9 summarize what we have done this year, this graph
10 represents the fact that we have a case definition
11 for influenza, and that is generally what we
12 isolate. But, in addition, we are going to get
13 other viruses. As you know, there are a lot
14 circulating at the same time. This has been an
15 Influenza A year. It has been a rather steady
16 year. It is still going on. We haven't seen much
17 of a decrease in our samples or our isolates yet.
18 The vast majority of what we are getting is H3N2,
19 consistent with the vaccine strain that has been
20 proposed for next year. There is seeming to be an
21 increase in B at this point. I can't tell if it
22 is going to be something that the season will tail

1 out with another realm of B. We are seeing B at
2 sites where we were seeing A, but it has been
3 mainly an A year. It is important, and it is
4 becoming more and more important, if it is not
5 flu, what is it? Where we concentrate, we get the
6 paraflus and RSVs and the adenoviruses, and I
7 would add that the Air Force is getting very few
8 adenoviruses at the recruit center at this point
9 in time. We are trying to concentrate more on
10 those more esoteric respiratory viruses -- the
11 Chlamydia Pneumoniae, the Bordatella Pertussis.
12 This could become more important. If it is not
13 flu, what is it? This map summarizes over a
14 period of time from 1998 and on. The red and
15 yellow bars above represent the Flu As in each
16 season, and the Bs are in blue below. The
17 take-home message here is that every season is
18 just completely different. You just cannot
19 predict from one season to the next. If you look
20 over this year, we seem to be much lower. It
21 hasn't been an overwhelming year. But, in our
22 lab, that is in large part due to our

1 epidemiologists who worked very hard to regulate
2 what our site sent. We have increased our number
3 of sites. We are up to 42 now. If they all sent
4 every specimen that walked through the door, we
5 would be truly overwhelmed. So they are working
6 very hard that they send us a representative
7 sample of 6 to 10 per week, and that is helping us
8 a lot in the laboratory. We are still continuing
9 to see the same percentage of isolates. So, this
10 year is steady, and it hasn't started to decrease
11 yet. As you can see from the 2003 year, that can
12 change from one week to the next. It was very
13 dramatic right before Christmas in 2003, and then
14 it was over. What have we done with this program?
15 Since 1998, we have sent to CDC over 903 isolates.
16 Occasionally, they will come back to us and say,
17 one is of particular interest, and could we send
18 the original sample? As you are aware, our
19 isolates have been grown in tissue culture, and
20 that is not a candidate for a seed virus for the
21 vaccine. Since we do keep our original samples,
22 we can send that to them, and they can test it for

1 the possibility of using it as a seed virus. In
2 1999, the A/Panama was, in fact, the seed virus
3 for the vaccine and was in that vaccine for four
4 years. That is dramatic, and we like to tell that
5 story. But I think that perhaps our biggest
6 impact is the fact that while we may not always
7 have the seed virus, in 1999 in the Peruvian
8 cadets, we isolated the H1N1/New Caledonia, which
9 is still in the vaccine. At that time, it had
10 only been seen in New Caledonia, and the program
11 said, okay, it is traveling; we have to pay
12 attention to it. In 2004, there was an outbreak
13 in Nepal, and the samples there in July of that
14 year were consistent with what become the
15 A/California vaccine that we have this year. We
16 saw it very early and were confirming again that
17 the A/Fujian had shifted or drifted, and we needed
18 to pay attention to it. Again, this past summer
19 at July at Luke Air Force Base in Arizona and in
20 Nepal again, there was an outbreak, and this time
21 it was a B. It was not at all similar to what was
22 in the vaccine this year, but it did match what

1 was in the Southern Hemisphere vaccine, the
2 B/Malaysia. That is what we are now seeing
3 throughout our South American isolates. Having
4 picked up Honduras from CHPPM-West this year as a
5 sentinel area, we are getting a lot of the
6 B/Malaysia. This has been incorporated this year
7 into our Northern Hemisphere vaccine. Of course,
8 we are very into sharing this information. We
9 have a weekly web site that goes up. Anyone with
10 dot.mil access can access this. It is on EPI-X
11 every week. We are working on getting it on the
12 CDC, a link from the CDC web site, and even from
13 the Pandemicflu.gov web site. If there is anyone
14 here that wants it just sent to you automatically
15 on Wednesdays, you can see me or Ms. Angie Owens
16 in the back, and we can just put you on our
17 address list, so that it is sent to you each week,
18 and you can have all the updates of what we are
19 seeing. Of course, now we are concerned with what
20 is coming. We need to be ready. We are a flu
21 laboratory, so we have to be prepared. We have
22 sentinel sites over in Asia in Thailand, so we

1 have received samples in the past. One of them
2 came in from a soldier ill after culling chickens
3 in an avian-infected area. That did get our
4 attention. We are going back to the basics. If
5 we are going to be looking for what is now a rare
6 event, we have got to have quality specimens.
7 Throat swabs are what we have been accepting, but
8 for molecular work, we really need nasal washes.
9 We are looking at providing our sites, at least
10 some of them, with prepackaged nasal wash kits, so
11 that they can easily collect these samples and get
12 us samples. Of course, collecting the samples and
13 getting them, this is probably the biggest road
14 block in the program -- shipping samples, so that
15 we can actually isolate the virus. We have to get
16 viable viruses. We have had a Fed Ex contract for
17 a long time, so they just have to put our number
18 on there and ship it to us. We are in the process
19 of adding DHL to that. There are several areas of
20 the world that only have DHL access. Soon,
21 hopefully, as we have the numbers for the
22 contract, but we just don't have some papers

1 signed to be able to use them. The other thing we
2 are looking at are shipping containers that don't
3 require dry ice, so that we can maintain a
4 constant temperature. Dry ice is a real roadblock
5 in many areas of the world. These boxes are still
6 only good for minus 20, which is just a big no-no
7 for viruses. So we are looking at the cold chain.
8 We also want to do a viability study. In the
9 literature, there is very little, except keeping
10 samples at minus 70. We are finding that we do
11 quite well if they are kept cold, and I would like
12 to do a real study to be able to prove that. This
13 is especially important in deployed areas. They
14 don't have access to dry ice. We are not actually
15 their priority in what they do. If we can make it
16 simple for them to collect the samples and get
17 them to us with our contract, in a box that they
18 don't have to worry about dry ice, then we can
19 provide public health information back to them,
20 which makes it more valuable for them to
21 participate and also have what is going on in that
22 area of the world. That is one of the areas where

1 we are the only ones collecting samples. The
2 other thing we are working on right now is to make
3 sure each of the public health sites know what
4 they should do if they have an event that is
5 suspicious for avian flu. We want to make sure
6 they have the supplies on hand and they know where
7 they are going to send them, whether that is
8 Landstuhl or Cairo or to us. So, they know and we
9 know. That is a challenge, of course, because the
10 people are constantly changing. Being able to
11 keep up with who is in charge and making sure they
12 know is something we are trying to work on, if
13 there is some way that we can make that more
14 institutionalized, so they have that onsite and it
15 doesn't get lost with each person changing. What
16 are we doing right now? We do have a BSL3
17 Laboratory. It is not large, but it is available.
18 We have done an exercise if we should get a sample
19 of interest and what we would do. We would carry
20 that through to telling the CDC. We would send it
21 to them. They even played that game with us and
22 sent a message back and said, your package has

1 arrived in good shape. We do plan to prescreen
2 any sample that comes in. It is not our intention
3 to purposely culture any sample that might contain
4 H5. It is a BSL3 plus organism. We can screen
5 for the Flu A/B universal, which would tell us any
6 virus that is there, in addition, specifically for
7 the H5/H3/H1, and we will be looking at the H7 and
8 H9. We now do hemagglutinin and neuraminidase
9 sequencing, so that we can tell, even though it
10 may be an H3 virus that we are seeing everywhere,
11 perhaps it has changes in the antigenic structure
12 that would make it look like it is a drift away
13 from or even a shift away from what we have seen.
14 We share this with CDC, and they are very good.
15 We don't always know, just because there are
16 changes, if they are important. So we would point
17 out to CDC, we have seen these changes, and then
18 they will let us know what they are seeing, if it
19 is something that has been important. That is
20 what happened with the B/Malaysia in Nepal. They
21 said that was a change, and that was important,
22 and they were looking at it, and asked for some of

1 our original samples on that. We did send a
2 person to AFRIMS in Thailand this past year, so
3 that they could work with the rapid instrument and
4 be able to prescreen samples onsite there. There
5 is a team going to Peru next month, and there are
6 possibilities of other sites that we would be
7 working with. We have increased our sites this
8 year. We are up to 42 sites. We are especially
9 working on the deployed sites, as I said, so they
10 can have regular shipments. Our laboratory is a
11 reference laboratory, so they have the capability
12 of sending us other clinical samples besides just
13 these flu samples. It has worked very nicely and
14 made it more cost-effective to be able to send
15 other samples. Any of the sites, they can send
16 chlamydia or hepatitis, as well as the flu
17 screening. This is the central laboratory
18 contract, so that has worked very nicely. As I
19 said before, we do put out weekly reports. We try
20 to be as visible as possible, so people do know
21 what is going on with us, and we can interact with
22 other groups. We continue to do the sequencing.

1 We are doing a lot more of that this year,
2 focusing of course on the overseas samples. While
3 the Flu Mist was not a big issue this year, it is
4 an attenuated virus. It will be picked up by any
5 of the rapid tests. We haven't encountered it
6 yet, but there is a possibility it could actually
7 grow in cultures. If we get a virus from a person
8 who has been vaccinated with the Flu Mist, we can
9 sequence and tell if it is the wild type virus or
10 the Flu Mist vaccine. One of the things we
11 constantly stress is that fever is part of the
12 algorithm when they collect the samples. We have
13 shown several times that if fever is not there, it
14 is not going to be flu. That will be especially
15 true with this Flu Mist because, while people may
16 feel achy and not well after receiving it, they
17 don't have fever. Again, the sequencing is
18 important in identifying what happens. We have a
19 form that we ask be submitted with each of the
20 samples. It has been hit or miss in the past.
21 Again, our epidemiologists have been tireless in
22 talking to the sites. It is online now. They can

1 fill it out online, where we get more of a history
2 of the patient with each of the samples that are
3 submitted. I will now turn this over to Cdr.
4 Russell.

5 CDR. RUSSELL: Thank you very much,
6 Linda. I appreciate the opportunity to discuss
7 with the AFEB the Naval Health Research Center's
8 contributions to the DOD-GEIS Influenza
9 Surveillance. It has been a real honor and
10 pleasure, working with a fantastic Air Force
11 project in their surveillance. As discussed by
12 Ms. Canas, the contributions by the Naval Health
13 Research Center are largely in population base,
14 and that is where we try to keep our focus, as
15 their focus is on global influenza hunting. The
16 primary populations that we are doing this in
17 include U.S. Military Basic trainees at eight
18 different recruit training sites. There are some
19 very strong reasons why this is important
20 surveillance, which I will get into briefly in a
21 moment. We have staff at seven of these eight
22 training centers, so that contributes to the

1 strength of this. We are not depending upon
2 individuals at those sites to collect samples for
3 us. We have staff there that collect the samples
4 and collect the numerator and denominator data for
5 us, so we can follow rates over time. We have
6 also been involved for about four years in
7 surveillance onboard ships, specifically out of
8 the West Coast or in the Third Fleet out of San
9 Diego. That has been phenomenally successful, and
10 I will share some of those results. Also, in the
11 last two years, we have been doing surveillance in
12 clinics that are along the California-Mexico
13 border. This is in collaboration with the CDC and
14 the Public Health Department in San Diego, and we
15 have had some very good results from that which
16 have contributed to the public health. We perform
17 both molecular and bioculture testing on samples
18 received at our Naval Respiratory Disease
19 Laboratory. We do do molecular front end now that
20 is CAP-approved and under the CAP umbrella. That,
21 which is molecular positive for influenza, goes on
22 to culture because, as Ms. Canas points out, we

1 need that viable virus. All negatives also go on
2 to culture. The bioculture testing involves,
3 again like the AFIOH program, a variety of other
4 viruses including the para-influenzas, intravirus,
5 and adenovirus. Of all influenza isolates that we
6 do get, we then do the HAI subtyping, and we are
7 PCR sequencing all of those samples at the current
8 time. I will talk about that briefly also. We do
9 quite a bit of training in molecular influenza
10 diagnosis, providing that to a variety of other
11 labs, not only shipboards that have the realtime
12 PCR capability but EPMUs are getting increased
13 requests and, in collaboration with AFIOH, are
14 using our resources to provide training. This is
15 a map quickly showing the breadth of our coverage
16 within active duty populations. Obviously, the
17 United States is a highly covered country for
18 influenza surveillance. I will point out quickly
19 why I feel this particular surveillance is so
20 important. The blue stars and the yellow stars
21 are where we have influenza surveillance. It is
22 either for influenza-like illness or what we call

1 Febrile Respiratory Illness. Since such a large
2 percentage of respiratory illnesses in our
3 recruits is adenovirus, we do prefer the Febrile
4 Respiratory Illness terminology rather than the
5 CDC's ILI. We also do pneumonia surveillance
6 which can be influenza, as you all know, at those
7 sites. The strength of this surveillance is the
8 fact that these are highly vaccinated populations.
9 Therefore, any breakthrough that we notice in this
10 active surveillance and this relatively real-time
11 laboratory processing is going to be important.
12 We want to follow those breakthroughs of the
13 current vaccine formulation. Shipboard, likewise,
14 highly vaccinated populations, but they are
15 exposing themselves to places throughout the
16 world, and we are getting that information. From
17 our basic trainees, in just this influenza season,
18 we received nearly a thousand samples through
19 February, and 784 of those were the results at the
20 time I wrote this slide last week or a week and a
21 half ago. Right now, we have 32 that have been
22 positive for influenza. So these aren't big

1 numbers compared to the AFIOH program but
2 incredibly important because we want to know how
3 many of those people are breaking through the
4 vaccine and if we are seeing increasing trends in
5 escaping the vaccine coverage. You see the
6 distribution of these influenzas is across our
7 recruit training camps, not a lot clustered in any
8 one site. This is the important point, that only
9 two cases were vaccinated for greater than 14
10 days. All others were unvaccinated or vaccinated
11 in the time period where we wouldn't expect that
12 vaccine to be getting coverage. We have not seen
13 any Influenza B in our recruits yet, but we
14 continue to monitor, and we will see if, as Ms.
15 Canas has found, influenza starting this season,
16 is Influenza B. This is the information that we
17 provide in our weekly information newsletters that
18 go out to all of the sites and interested parties.
19 It also is posted on the EPI-X. This information
20 here is what is important. What we are monitoring
21 in the last few years is those that are positive
22 for Influenza A but have been vaccinated greater

1 than 14 days. This is now updated with quite a
2 few more samples as it is a real document and is
3 updated weekly. But we still have only had 2 out
4 of 32 now samples that are among those that are
5 vaccinated -- so, again, showing good coverage
6 this influenza season in all highly vaccinated
7 populations in the DOD. This has been published
8 showing this type of surveillance and how it can
9 contribute to some idea of vaccine effectiveness
10 for any given year. We continue that each year.
11 We also have developed a PCR technique. Ms. Canas
12 mentioned sequencing can be used to differentiate
13 between a Flu Mist and wild type influenza
14 strains. We have developed a simple PCR technique
15 that can do this and is submitted for publication
16 right now. The strength of this is it is a lot
17 easier to do and a lot quicker, and it is
18 important for our surveillance because, even
19 though fever is an important aspect of the cases
20 that we acquire, and as Ms. Canas pointed out the
21 Flu Mist is unlikely to cause fever, fevers are
22 still caused by other viruses in our settings. If

1 they received the Flu Mist within three weeks or
2 so of that febrile illness, it could result in a
3 false positive with molecular testing, and we need
4 to be able to decipher which is wild influenza and
5 which is the vaccine. Moving real quickly to our
6 shipboard surveillance, you see a variety of ships
7 out of the Third Fleet that we have been involved
8 with and some outbreaks on ships as well. In
9 starting this surveillance, I noted that there had
10 been a lot of surveillance on ships for syndromic
11 febrile illness but very little on our shipboards
12 that was laboratory supported, really looking at
13 the pathogens causing the illnesses there. I
14 didn't know if adenovirus on our ships, a similar
15 crowded population, might be as important a
16 pathogen as it is in our recruits. I didn't know
17 in starting this surveillance, but what I found
18 out is very interesting. Very little adenovirus,
19 you see here the orange is just a couple
20 adenoviruses that we find now and then, and they
21 are not recruit serotypes in general. What we did
22 find is that the yellow here is a good percentage,

1 up to half almost of the samples that we are
2 collecting from ships are Influenza A positive. I
3 have the virus. You see down here that each time
4 I get an Influenza A outbreak, it absolutely, in
5 every single case, has correlated within a week or
6 two of a particular port stop. So I know where
7 that virus came from. I know that it is infecting
8 our active duty populations and potentially
9 bringing that back to the States. Those have been
10 very important samples that we have been
11 analyzing. The CDC has been interested in these.
12 Starting last year, we started, like the AFIOH
13 program, contributing to the CDC. We submit them
14 our sequences. We submit them the viruses. From
15 those viruses that neutralize poorly, they have
16 asked for the original patient specimen, and we
17 have, again starting last year, provided that to
18 them. Our shipboard and our Mexican border
19 populations today have been the ones that they
20 have requested original patient's serum from
21 because they have had some divergence that the CDC
22 was interested in. Looking quickly at our Mexican

1 border population surveillance, this year only, we
2 enrolled 169 cases to date, and a very large
3 percentage of those were Influenza A positive, 66
4 percent. Here you see, in the purple line, the
5 Influenza A positive out of the samples collected.
6 So a very large percentage were Influenza A
7 positive during the surveillance. Within the San
8 Diego-Mexican border population, it has tailed off
9 considerably. One of the things we do, in
10 addition to contributing to the California public
11 health and kind of keeping an eye on what is
12 coming across the border to a place that has an
13 awful lot of active duty populations, is we
14 provide them the rapid test as well, a quick view.
15 It is a way of engaging the clinics. As we have
16 seen routinely, year after year, in a setting of
17 known influenza activity, we have a very high
18 positive predictive value but a very low negative
19 predictive value. All of these were rapid test
20 negative but were influenza positive. We
21 routinely find that with the quick tests, with the
22 rapid tests that we use. These are sequence data

1 that we provide to the CDC and analyze. As far as
2 this past year, we see within all three of our
3 populations -- the recruits, the ships, and our
4 Mexican border -- that they are more closely
5 associated with the Wisconsin which is next year's
6 H3N2 component than they are to the California.
7 Again, this is the type of information we are able
8 to do and provide to the CDC. So, as far as our
9 training in pandemic preparedness, I mentioned
10 that we are involved in training a variety of
11 different groups in the DOD. We provide rapid PCR
12 diagnosis, using the life cycler platform to ships
13 in the Third Fleet for these pathogens. H5, I do
14 not provide in this setting for obvious reasons,
15 but we really want to make sure if it is provided
16 that there are very strong SOPs in place in how to
17 deal with that information. Four large Pacific
18 fleet ships have been trained with this particular
19 capability. We have been training some EPMUs as
20 well and have new requests from EPMUs for training
21 and transfer of these reagents, and positive and
22 negative controls, again all supported by the

1 DOD-GEIS Program. I did have H5 capability in
2 EPMUs prior to the LRN H5 capability, and that was
3 in theater with the forward deployable Preventive
4 Medicine Units. As I mentioned, sharing of data
5 goes out, similar to AFIOH, in weekly newsletters,
6 and EPI-X, and we do share with the CDC this
7 unique population surveillance information. We do
8 have a BSL3 laboratory, and also in progress, a
9 new facility at our laboratory that has BSL3
10 capabilities under construction. So, again, I
11 thank you, on behalf of Ms. Canas and the AFIOH
12 Program as well, for your time. I think we are
13 both available for questions as time allows.

14 DR. POLAND: Thank you, Cdr. Russell.
15 Actually I have the first question for Ms. Canas.
16 You mentioned an important thing, and that is that
17 you ask each site to submit, I think you said, six
18 to eight representative samples. Can you tell us
19 what you mean by representative samples or how
20 those individual subjects are selected, because
21 that could very much influence what we see here?

22 MS. CANAS: We don't tell them which

1 ones. We just ask for that many of the people
2 they are seeing that do fit our case definition.
3 I don't know.

4 DR. POLAND: Case definition for
5 influenza?

6 MS. CANAS: For influenza.

7 DR. POLAND: I see. But that would
8 influence the question of: If it is not
9 influenza, what is it?

10 MS. CANAS: What is it?

11 DR. POLAND: You are seeing people on
12 the more severe end of the clinical spectrum,
13 probably.

14 MS. CANAS: I think that is probably
15 true. Our numbers are down this year, but our
16 percentages are up. So I think they are looking
17 more at not just sending everyone. We have in the
18 past had issues where, oh, you need to see what we
19 have, and they would overwhelm us with samples.

20 DR. POLAND: Col. Gibson?

21 COL. GIBSON: Just a follow-on to that:
22 If the issue of, if it is not influenza, what is

1 it, is becoming more important, is there any
2 consideration in changing your criteria for
3 sampling? And have you done any pilot tests or
4 pilot looks or sampling looks at your compliance
5 rates at various facilities?

6 MS. CANAS: Yes, the epidemiologists do
7 look at who participates, and they have gentle
8 discussions with them on what they are seeing, and
9 sometimes they are not seeing influenza-like
10 illness. So then that makes sense not to send
11 things. Our criteria, those are the issues that
12 we bring up at our annual meeting in how we handle
13 the program, and that will probably be a big
14 discussion this year.

15 DR. POLAND: Mike, Ed, and then Kenneth.

16 DR. OXMAN: Dr. Russell, what was your
17 isolation technique for flu, and how does your
18 batting average compare between PCR and isolation
19 rates?

20 CDR. RUSSELL: We use RMK cells, the
21 Rhesus Monkey kidney cells for our influenza
22 isolation. Samples that come in are processed

1 both in RMK and A549 cells, the A549 being more
2 sensitive to the adenoviruses, but we do do the
3 molecular front end. So in our CAP certification
4 process, we did a huge number, much more than CAP
5 required, around 2,000 samples that were processed
6 with both methodologies and a phenomenally good
7 correlation in the high nineties, both sensitivity
8 and specificity, between our molecular and our
9 culture techniques. That was a bit surprising to
10 us, but I think it speaks to the fact that our
11 molecular technique is not as sensitive as it
12 could be. It has really been to correlate with
13 what we have found is clinically relevant and
14 correlates well with our culture techniques. The
15 other reason that we didn't necessary expect that
16 is our samples are throat samples or throat swabs,
17 but in studies where we have done both nasal swabs
18 and throat swabs, there is very good correlations
19 between the two in our collection specimen storage
20 and processing methodologies.

21 DR. KAPLAN: I am sitting here,
22 wondering what is happening to the data. For

1 example, in the slide that you showed on positive
2 viral results by week and year, 2005, 2006, those
3 were lump data from all of the sites. The first
4 question: Do you have that kind of information
5 for individual sites?

6 MS. CANAS: That is what is published
7 each week. So we do have it by site and aggregate
8 weekly on our site. This is just, you are right,
9 a summary of everything.

10 DR. KAPLAN: So, can you tell us a
11 little bit about the conclusions that you have
12 reached? Are you able to pinpoint certain areas
13 that should get increased epidemiological
14 attention?

15 MS. CANAS: When there was a vaccine
16 shortage a few years back, it was valuable to say
17 we have flu starting at a particular site, and
18 perhaps that is where we should target the
19 influenza vaccine that we have. So we do have
20 that kind of information.

21 DR. KAPLAN: Currently?

22 MS. CANAS: Currently? We do have,

1 currently, by site, what they have been seeing
2 over the year by week.

3 DR. KAPLAN: And where does that
4 information go?

5 MS. CANAS: It is published on our web
6 site weekly. It is on the CDC/EPI-X, and we can
7 get you on it, so you get it automatically every
8 week.

9 DR. KAPLAN: What is the action? I may
10 be getting ahead of the story, but what is the
11 action? Something like a red flag runs up at X or
12 Y site, where does it go from there?

13 MS. CANAS: The local public health
14 officers get this information ahead of even what
15 goes out on the sites, so they know if they have
16 something they need to deal with at their site.
17 We do have teams. This is an epidemiology center.
18 If there is something happening, a team can be
19 sent to an area. If there is something going on
20 that is not influenza, I think there are teams
21 that can go out, so they can react to it.

22 DR. KAPLAN: I don't mean this

1 critically at all. I am just trying to understand
2 it. It is more of a passive reaction than an
3 active reaction to this kind of thing? I am
4 asking, what happens? How do we know that
5 something is going on, and who takes action about
6 it, with all the data that you are collecting?

7 MS. CANAS: Right now, the data is
8 collected. There hasn't been anything
9 particularly important to act on. One of our big
10 questions that we go through a lot is: If we do
11 get something, like an H5, what do we do with that
12 information? This is an important question.

13 DR. KAPLAN: Yes, I mean posting it on
14 the web site is nice.

15 MS. CANAS: Right, and that would not be
16 posted on the web site.

17 DR. KAPLAN: The second part of that
18 question is: When these data are actually put
19 together and analyzed, is there any attempt, by
20 your group rather the CDC, to collaborate with or
21 coordinate those data with other international
22 agencies or other countries around the world to

1 give us an epidemiologic idea of what is going on?

2 MS. CANAS: I believe that is left up to
3 the individual public health offices. I don't
4 know. Does anyone want to add to that?

5 COL. COX: This is Kenneth Cox. I can
6 try and address some of both of these questions
7 because I think part of the issue is that you are
8 seeing the laboratory-based surveillance and
9 asking what kind of action is taken from that, and
10 it wasn't really designed as an outbreak detection
11 system. What we have is our integrated system
12 includes our monitoring on a daily basis of the
13 outpatient health events in the influenza-like
14 illness category -- the ESSENCE Program, which I
15 think has been presented here in the past but
16 similar to CDC's BioSense. So, by monitoring
17 that, we are looking to see what is showing up in
18 the clinic and being diagnosed as influenza-like.
19 If we see spikes beginning or upward trends, then
20 we often go and check the laboratory data to see
21 if we have anything from that specific site or
22 from that region to give us an indication about

1 what the cause of those outbreaks might be. And
2 then, based on that, we reach out to those local
3 public health officers to make sure that they are
4 aware of the situation and see what actions that
5 they have taken. In isolation, the laboratory
6 system doesn't provide us with public health
7 actionable information, but as part of the greater
8 system, it does. Then there are some other
9 interactions and supplementary systems that
10 support that as well. The second question
11 regarding the global part, I am not sure I heard
12 all of that. Certainly, we share this
13 information, as you have heard, with CDC. We are
14 interacting with the BioSense people at CDC, and
15 they finally are arranging for us to be able to
16 see what our DOD data looks like that they get.
17 Then they look at it at BioSense, which has a
18 different set of statistical algorithms in its
19 analytical outbreak detection engine than our
20 ESSENCE system does. That gives us a way to
21 validate or invalidate the great number of false
22 positives that show up with these specifically

1 tuned systems that are overly sensitive to make
2 sure that we don't miss that outbreak of concern
3 that might be related to a bioterrorist attack as
4 well as a natural outbreak. On a global
5 standpoint, yes, there is some sharing at our DOD
6 research labs and places like NAMRU-3 at Cairo
7 which is identified as the Eastern Mediterranean
8 Regional Referral Office for WHO. That is an
9 obvious clear relationship there about how they
10 share. That same formal degree is not existing at
11 some of the other sites yet, such as NAMRU-2 in
12 Jakarta, but movement is being made in that
13 direction. And we have a fully integrated system
14 between CDC and our overseas labs where they are
15 starting to station CDC people in each of these
16 sites to make our liaison easier and to share the
17 information.

18 DR. KAPLAN: Just to follow on about
19 that, my question may be totally inappropriate,
20 and if so, I apologize for it. The reason for
21 this is, as Cdr. Russell described for us, the
22 shipboard surveillance. If you knew that there

1 was an outbreak in Country X, and there was a plan
2 for the Navy to send ships to Country X for call
3 or what have you at that point, what I am getting
4 at is, is there a way that that could get back to
5 say, think about this whole thing?

6 COL. COX: There is. I won't say it is
7 a perfect way, but an example is every year, we
8 have a Cobra Gold exercise in Thailand. In
9 preparation for that, we are looking at the data
10 that has been collected in advance of that to
11 decide if there is going to be unique medical
12 risks that our people would face if they are there
13 to partake in an exercise. That involves the
14 Armed Forces Medical Intelligence Center and the
15 various sources that they have. It involves our
16 laboratory system and what we have collected. It
17 involves the WHO and their reports. That is all
18 looked at as part of the planning process before
19 we go anywhere. Now, I can't answer about the
20 Navy operations for a specific ship and whether
21 that would be transmitted to them and whether they
22 would change their port call based on information,

1 and maybe that is something Cdr. Russell can
2 address. But on these big joint things, they do
3 have a very set process where we look at all
4 available data, and we make an operational risk
5 assessment which includes a medical component.

6 DR. MCNEILL: I just wanted to make a
7 brief comment about how similar our surveillance
8 at the state level is to the global that you were
9 presenting, Ms. Canus, and that is this has
10 certainly been an Influenza A year. We have 40
11 ILI signal sites around our state that report to
12 us on a weekly basis. I think our case
13 definitions that we use certainly select for the
14 more clinically severe illness. So therefore, we
15 see a fairly high isolation or identification of
16 influenza from the submissions that we get, using
17 PCR. We have had 33 Influenza As so far this year
18 from I think we get about a 50 percent retrieval
19 actually from our submissions. We saw our first
20 Influenza B last week. I was interested in your
21 comment that our data very closely mirrors what
22 you are seeing globally.

1 DR. POLAND: Dr. Gray?

2 DR. GRAY: I just want to compliment you
3 guys. I know you see thousands of these specimens
4 every year, and sometimes you get no research
5 publications, but just know that you are playing
6 such a tremendous role in international
7 surveillance. I don't think you hear that enough.
8 I really like your design. You have a capability
9 not only to detect influenza from sentinel sites
10 but also in populations that are transitory. The
11 ships is a very novel idea, and we know that those
12 outbreaks can be very explosive. We have, in
13 addition, the breakthrough surveillance, which I
14 think is invaluable. So I want to commend you on
15 that. I like, also, that you are continually
16 improving your diagnostic capabilities. The news
17 that you both have BSL3 facilities in preparation,
18 and I know NHRC has got a new molecular diagnostic
19 capability in the Tiger System, is very, very
20 impressive for somebody who has followed
21 respiratory diseases. My one question is: How
22 will things change when H5 becomes more prevalent

1 and perhaps pandemic in North America?

2 MS. CANAS: Probably quite a bit. We do
3 have our own pandemic plan which we will screen
4 for. Everything will go into the BSL3 to rule out
5 H5 before we do any culturing. Like we said, we
6 will not purposely culture anything that we think
7 could be H5. We are an LRN laboratory. We have
8 the onsite LRN gatekeeper for the Air Force, so we
9 do have the CDC primers for H5 to be able to, if
10 we do get an isolate that we can show, we can also
11 do the up-front. We do have a plan in our
12 laboratory for diverting activities and personnel,
13 so that we would be doing influenza mainly. We
14 struggle with what it is going to mean. We are
15 stocking up on all kinds of respiratory
16 protections in anticipation. There is money
17 available now to improve our facilities and our
18 programs.

19 DR. POLAND: It raises another question
20 and that is for both NHRC and GEIS. Can you give
21 the Board sort of an order of magnitude look at
22 how many specimens you get, let us say, in a

1 season or a month, whatever is convenient, and
2 what is your maximum capability given the way you
3 are currently resourced?

4 MS. CANAS: That is a question we
5 struggle with, too. Of course, every season is
6 different. In 2003, we got 1,500 samples in
7 December, and my techs were on vacation for
8 Christmas. That is unusual. Right now, we are
9 averaging a couple hundred a week, which is very
10 manageable. To do culture, the way we are doing
11 it now, we say a hundred a day in my laboratory,
12 but we would be switching to molecular, and you
13 can screen many more up front that way. We have
14 talked in terms of thousands now. I think,
15 though, that the critical period is now. We
16 haven't picked it up yet. We are doing the
17 surveillance, and when we first start getting it
18 is a critical period. After a while, the testing
19 may not be the issue.

20 CDR. RUSSELL: If I can go back quickly
21 to Dr. Gray's question and comments, I knew he
22 wouldn't end his comments with an easy question.

1 It is something that DOD-GEIS, in our influenza
2 meetings held generally twice a year, struggles
3 with a lot. What are we doing to be ready? What
4 is our surge capacity? Are there SOPs to deal
5 with it? I might point out quickly that we don't
6 know what is going to happen with H5 when it
7 becomes a virus that is transmissible human to
8 human. Maybe it won't be a BSL3 plus agent
9 anymore. We don't know what the virus is going to
10 be like then. So, all bets are off. But we are
11 trying to be prepared with SOPs, with high
12 through-put capability, with surge capacity. To
13 that end, in answer also to your question, Dr.
14 Poland, NHRC, I believe, and we have moved to the
15 96 well format in processing our molecular samples
16 which allows a much, much greater capacity for
17 surge through put. With that molecular first
18 diagnostic capability, we estimate if we switch
19 all of our personnel over to dealing with an
20 emergency, then we could process in the thousands
21 a week. We can do a lot if we need to, and the
22 relationship contributes to that.

1 MS. CANAS: One of the other things that
2 is going to have to be addressed is, if the sites
3 have suspect samples, right now WHO is saying
4 those need to be shipped as hazardous goods. That
5 requires trained personnel and special packing
6 instructions, which is different than just sending
7 in a throat swab. So that is going to have to be
8 addressed also.

9 DR. POLAND: Dr. Silva and then Dr.
10 Oxman.

11 DR. SILVA: I also congratulate both of
12 you on accumulating these data and showing you
13 have capacity that you could reach and increase
14 it. What is your transit time on most of your
15 specimens? You take a sample, and what is the
16 usual travel time?

17 MS. CANAS: As I said, our laboratory is
18 a clinical laboratory with Fed Ex and soon DHL.
19 So ours is probably about a day or two for most of
20 them. Overseas may add another day to that. That
21 said, when we get samples in from Thailand and
22 South America, they may have stored those for

1 months with liquid nitrogen. But most of ours
2 come in fairly rapidly.

3 CDR. RUSSELL: Within the United States,
4 it is Fed Ex. It is overnight. Samples are
5 stored currently for up to a month. During the
6 influenza season, we like that to be no less than
7 once a week, and we are going to push that harder
8 this next year with supplemental Presidential
9 funds that are coming through to augment all of
10 our surveillance. Neither one of us have gotten
11 into the way our programs will change with current
12 Presidential supplementation, but there are
13 proposals on the table if and when that money
14 comes through for considerable augmentation to our
15 facilities and surveillance efforts. As far as
16 the shipboards, I think one of the strengths is
17 that they are collecting the appropriate sample at
18 the appropriate time. They are being stored in
19 minus 70 freezers or liquid nitrogen. The closest
20 we came to getting those samples before they came
21 back to port was a ship that was in Australia when
22 the Australia outbreak occurred last year.

1 Because it had tailed off, and there weren't
2 severe illness, we did not make a special effort
3 through the EPMU to get those samples. But if we
4 need to, we are plugged in to get those samples
5 right away. The appropriate samples were
6 collected is what I stress because, in general,
7 when the EPMU is kicked into a ship, often when
8 they get there, the epidemic is over and the time
9 to collect the virus has passed.

10 DR. OXMAN: I would like to also
11 compliment you on your attention to detail, which
12 is the key to this, in looking at your
13 sensitivities. In that regard, are you getting
14 any unknown spiked samples with H5 to see, to test
15 your molecular screening?

16 MS. CANAS: Are you asking if we are
17 getting H5?

18 DR. OXMAN: For example, are you being
19 sent any, they killed H5 spiked samples, so that
20 you know that you can break it up and have an
21 assessment of your sensitivity?

22 MS. CANAS: No, we are not.

1 CDR. RUSSELL: No, but in current
2 proposals, we would both be getting that killed
3 H5N for further work. We are both looking at not
4 developing tests but working with our resources to
5 validate tests that may be developed out there,
6 and that would be important.

7 DR. POLAND: Thank you very much. We
8 will move on to the next presentation which is Lt.
9 Col. Wayne Hachey who presented to us in December
10 at Ft. Bragg. He is here today with the DOD
11 Pandemic Influenza Preparedness Update.

12 LTC. HACHEY: Good morning. I will be
13 providing an update, now actually the third update
14 to the Board, that will cover both what is new
15 with avian influenza and DOD activities. This
16 slide depicts a laundry list of the countries with
17 confirmed avian disease. When we first had to
18 turn the slides in, the countries were listed in a
19 bold 28 font. Then avian flu kind of spread into
20 other parts of the globe, and we shrunk that down
21 to a 24 font, and we are now down to a measly 18
22 font with actually five more countries yet to be

1 added to this just over the past 48 hours. The
2 next thing will probably be back to that 28 font,
3 but it will be those countries without avian
4 disease. This is a chart that is provided by the
5 World Health Organization and gives you an idea of
6 who the potential culprits are. The dark colored
7 are those countries that have a disease in
8 domestic poultry, whereas the light kind of peachy
9 color are those countries with primarily just
10 disease in wild birds. You can see in Southeast
11 Asia and tracking on through, it looks like our
12 domestic poultry are the bad guys. In fact, the
13 recent outbreak in Nigeria is thought to be due to
14 some poultry that was brought in from China. Now,
15 in Europe, unfortunately, the wild birds do have
16 to take the rap for that. It does appear that the
17 transmission of disease is both by domestic and
18 wild birds. The question, again, that we asked
19 the last time: Is there a pandemic? The answer
20 is the same: So far, only if you are a bird.
21 What we are interested in is human disease.
22 Despite really widespread avian disease, the human

1 cases still are relatively low, less than 200
2 total cases. In the past week, we have added
3 another maybe three more to this and two more
4 deaths, but still, less than 100 deaths, despite,
5 again, avian disease that is stretching across the
6 planet. Human disease is primarily in Southeast
7 Asia with China and Indonesia still having active
8 cases actually each week; Vietnam, an occasional
9 case; Thailand and Cambodia; and more recently,
10 Turkey and Iraq. Thus far, there is still no
11 confirmed human-to-human transmission although
12 there are a couple instances where that is
13 suspect. But it looks like if you want to catch
14 avian disease or avian flu from another person,
15 you really have to go out of your way to do it,
16 whereas it is still not an easy transmission. All
17 recent cases have been associated with intimate
18 contact with diseased birds. A case in point was
19 the two index cases in Turkey where two children
20 who were playing with a severed disease chicken
21 head for about four to five days before they
22 developed symptoms; whereas the adults, who

1 actually slaughtered the bird, did not develop
2 disease. Human infections generally have been
3 associated, again, with massive doses of the
4 virus, and mortality has been somewhat of a mixed
5 bag with some cases being very suggestive of a
6 secondary bacterial pneumonia, other cases with a
7 whopping viral pneumonia. There has been a few
8 that mimic the outliers in the 1918 epidemic, the
9 folks that had the cytokine storm where they
10 presented to the clinic in the morning, and they
11 were dead by sunset. Then more recently, at least
12 in some of the pediatric cases, a coagulopathy
13 seems to be the primary presenting feature.
14 Interestingly, you see the same thing in cats, and
15 that coagulopathy has been reproduced in a feline
16 model. The problem is that we still have a
17 relative paucity of post-mortem data, that if you
18 were a double amputee, you could probably count
19 the number of post-mortem cases on one hand. So
20 we really don't have good, sound post-mortem data
21 to find out exactly what people are dying from.
22 But, nonetheless, H5N1 is spreading out of

1 Southeast Asia, and it is, again, due to migrating
2 birds and domestic bird traffic, which includes
3 both legal and illegal domestic birds being the
4 primary root but, again, wild bird migration also
5 facilitating the process. In particular the
6 spread to Europe appears to be caused by migrating
7 swans. That leads us to containment problems.
8 Now, in previous presentations, we outlined some
9 of the containment problems that exist, and
10 unfortunately, they still persist, but we now have
11 new containment problems. Surveys of countries
12 demonstrate a lack of comprehensive surveillance
13 or a response plan. That includes short term
14 plans like how do you cull, who do you cull, where
15 do you cull. One case, in point, is in Africa,
16 they were culling ostriches by actually shooting
17 them, which probably isn't the best approach
18 unless catching the ostrich is a factor. But,
19 interesting, the Ministry of Health wanted to come
20 in and test the cullers to make sure they hadn't
21 developed disease, and they all ran for the hills
22 and couldn't be found. When they were questioned,

1 they thought that, well, the ostriches had
2 disease, and we shot them. If we have disease,
3 are we going to be shot? So that does lead to
4 some problems as far as short term planning. As
5 far as intermediate planning, some concerns are
6 countries have no plans of how to repopulate their
7 poultry flocks after culling. And then, long term
8 plans, how are they going to fix their biosecurity
9 issues? In addition to that, there is poor
10 coordination between the Ministries of Agriculture
11 and the Ministries of Health. This results in
12 individual countries not really knowing what their
13 true capabilities are and more importantly what
14 their needs are. Other containment problems
15 revolve around the actual donors. Donor
16 coordination does need improvement. Multiple site
17 evaluations wind up hindering some host nation
18 responses. If a host nation is just barely
19 holding its head above water, having multiple
20 survey teams coming in to assess their needs and
21 capabilities, diminishes their ability to respond
22 to the outbreak. Then for countries who

1 essentially have their act together, it just
2 becomes a great annoyance to them, having the same
3 questions being asked by multiple teams. The good
4 news is that, through the Department of State, the
5 European Union, and the WHO, there are plans to
6 have a coordinated team integrated onsite that
7 will go in and do one assessment and then share
8 the information with all of the parties involved.
9 So actually there is a good fix in the system
10 there. The WHO has done a reasonably good job as
11 far as going in onsite and addressing the human
12 impact of the disease. However, the Food and
13 Agriculture Organization (FAO) does have some
14 problems. It lacks the capacity to provide a
15 rapid response or hands-on assistance and training
16 to the host nations. In that, too, there is a fix
17 in play though, again through the Department of
18 State and the European Union who are offering to
19 the FAO assistance, particularly with veterinary
20 resources. Now, it is not all bad news.
21 Recently, the experiences, particularly in Turkey,
22 show that Turkey is really the exception to the

1 region. In their outbreak, they had an excellent
2 response -- great transparency, everybody knew
3 what was going on. If they can actually get the
4 countries in that region to talk to one another,
5 Turkey will serve as a model for the region. Some
6 examples are that they are looking ahead to
7 control measures after repopulation of their
8 domestic poultry population and even long term
9 they are working with the WHO and the World Bank
10 to change their backyard poultry practices, so
11 that they actually do have biosecurity. Next is
12 our response here. As you all know, in November
13 of 2005, the National Strategy for Pandemic
14 Influenza was released. With that release, each
15 U.S. Government Agency was tasked to participate
16 in the National Plan and to develop individual
17 pandemic response plans, which leads us to DOD
18 activities. DOD has been an active partner in
19 U.S. Government pandemic planning efforts at
20 multiple levels, actually long before that
21 pandemic strategy was released. DOD is
22 specifically included in the National Pandemic

1 Strategy and is well vested throughout the
2 National Pandemic Plan which is due out at the end
3 of March. In fact, at least in the current draft,
4 there are over 29 specific tasks that DOD has the
5 lead or is in a supporting role. We have also
6 developed our own pandemic plan, and that, again,
7 is due out at the end of March. To help
8 facilitate that, Health Affairs released what
9 essentially amounts to the medical annex to that
10 plan, but was policy guidance, and that guidance
11 was reviewed by the AFEB Select AI Committee.
12 That guidance included just general pandemic
13 influenza guidance, clinical guidelines, pandemic
14 influenza vaccine guidelines, and some containment
15 measures. Also reviewed by the AFEB Committee was
16 our Tamiflu release guidance, and that, too, has
17 been released. The release authority is still
18 Health Affairs, and that would be contingent on a
19 declaration of a Phase 6 phase of a pandemic.
20 Now, we did recognize that that could lead to some
21 problems. When we are in Phase 5 or late Phase 4,
22 we would really like to get Tamiflu out there.

1 The Tamiflu was purchased as part of a large buy
2 through HHS, and HHS is currently negotiating with
3 the manufacturer to change the stipulation in the
4 purchase contract where we could use it before
5 Phase 6 for containment in, again, late Phase 4
6 and Phase 5. We are also working issues of
7 potential forward deployment of some of the
8 stockpile to facilitate a more timely delivery.
9 Within that guidance, we also have priority
10 groups. The first group is hospitalized patients
11 with PI and then use to preserve operational
12 effectiveness. In reality, these two groups will
13 really be getting Tamiflu simultaneously. So,
14 even though they are rank ordered 1 and 2, they
15 are really, in reality, both 1. Our current
16 supply is inadequate to treat all beneficiaries,
17 and we would be relying on the Strategic National
18 Stockpile to a small extent, particularly here in
19 CONUS. The Tamiflu currently is now 24 million
20 doses strong and is prepositioned in EUCOM, PACOM,
21 and CONUS. Although we have no pediatric
22 formulations, we do have pediatric compounding

1 instructions that are available. The question is:
2 We have got it now; does it work? Anecdotal and
3 animal data does demonstrate efficacy and
4 effectiveness for the treatment of current H5N1 if
5 it is used in a timely manner. If patient
6 presents, and he is bleeding from his eyeballs
7 from pandemic flu, Tamiflu probably isn't going to
8 work. But in those patients where it has been
9 provided early in the course, it does appear to be
10 effective. The other question is resistance, and
11 in fact, Tamiflu does have resistance with Type A
12 Influenza in about 4 percent of adults and in
13 about 20 percent of the pediatric population.
14 Basically, we used the data from Japan. Now the
15 good news is that resisting mutation results in a
16 virus that is either incapable of or has a
17 decreased infectivity, at least with the current
18 known mutation associated with resistance to
19 Tamiflu. So, if you want to decrease the
20 reproductive coefficient (R0), Tamiflu resistance
21 isn't necessarily such a bad thing. It might be a
22 bad thing if you are the person with the virus at

1 the time, but as far as population health, Tamiflu
2 resistance isn't quite as scary as the newspapers
3 might lead us to believe. The last thing, as far
4 as Tamiflu, is we are considering increasing our
5 stockpile. With that increase, it would allow us
6 to prophylax more active duty personnel and to
7 provide treatment for all beneficiaries. Another
8 antiviral that is in the neuraminidase group is
9 Relenza, and we do plan to purchase an amount that
10 represents about 10 percent of our total antiviral
11 supply. Some advantages to Relenza, at least
12 theoretically, are that it is alleged to have
13 little or no resistance or it is alleged to cause
14 little or no resistance, but it has not been used
15 for H5N1 to date. Some other problems are that it
16 is limited per the FDA for treatment only. So
17 prophylaxis, at least at this time, is out. It is
18 also contraindicated in those with a history of
19 reactive airway disease which lends to a problem
20 with many of our reservists and closeted
21 asthmatics who may be out in the field. And it
22 does require more education. You can't give folks

1 just a bunch of pills and say, take one of these
2 once or twice a day. It is a spin inhaler, so it
3 does require some one on one education. Anybody
4 who has tried to teach people how to use inhalers,
5 we all know that there are certain psychomotor
6 skills that are necessary that all individuals may
7 not have. The next thing is vaccine, and we now
8 have some 2.667 million doses of an avian flu
9 vaccine. This is based on a 90 microgram dose
10 requirement and is the 2004 Vietnamese Clade 1
11 vaccine strain. Now the problem is that it
12 currently has no cross reactivity to the Indonesia
13 or Clade 2 strain. So whether it would be useful
14 as a primer and a booster is really unlikely.
15 More than likely, at best, it may serve as a
16 decent primer. That 90 microgram dose requirement
17 may be decreased, pending some adjuvant and other
18 antigen sparing strategies that were presented
19 yesterday. Currently, it is in bulk storage. So
20 if the pandemic should hit tomorrow, it would take
21 about six weeks for a fill requirement. This is a
22 family tree of the H5N1 virus, courtesy of the

1 CDC, and down here we see essentially our parent
2 viruses with the two very distinct clades. This
3 particular strain here, the Vietnam 1203 strain,
4 is the one that our current vaccine is based on.
5 There are also some other manufacturers through
6 HHS that are developing other Clade 1 vaccines.
7 Yesterday, Secretary Leavitt mentioned that he has
8 approved at least the production or exploration of
9 a Clade 2 vaccine. MedImmune is also developing a
10 live attenuated vaccine for H5N1, although that is
11 all the data I have as far as their development.
12 The next component of DOD's response is
13 surveillance, and the Joint Health Surveillance
14 Center is now alive and well. It has been
15 approved by the Force Health Protection Council
16 and actually has money attached to it. This will
17 enhance DOD's situational awareness and
18 standardized collection, reporting, and analysis
19 of information. So, it essentially would be the
20 glue that hopefully will tie in all of our
21 surveillance activities into one uniform reporting
22 activity. Communication, we have added a trifold

1 information sheet that is targeting primarily
2 beneficiaries during Phase 5 and Phase 6, and what
3 it stresses is the non-pharmacological measures
4 rather than an over-reliance on vaccine and
5 antivirals. It includes such issues as social
6 distancing, handwashing, mask use if available,
7 and infection control measures. We are currently
8 debating whether this should be packaged with,
9 essentially, a little flu go kit with a sample of
10 some bottles of handwashing, perhaps a mask, a
11 thermometer, a temperature recording sheet. That
12 part is still to be decided, but the information
13 sheet is essentially a done deal and should be out
14 shortly. In addition to this, we also have some
15 public information pamphlets that are being
16 prepared regarding just poultry -- is your poultry
17 safe, and how to handle your poultry during a
18 pandemic. We still have our avian flu web site at
19 the deployment link and the DOD Readiness Watch
20 Board. The Watch Board, again, provides
21 comprehensive AI situational awareness. It
22 includes a current disease status, our

1 countermeasure status, and how much vaccine and
2 antivirals we have, antibiotics, PPE, and
3 ventilators. It also includes planning status,
4 status for current planning guidance, and also
5 offers the user a library of pertinent documents.
6 It is also beginning to include clinical guidance
7 for providers and labs, and this is where our
8 compounding instructions would be going. In
9 development, we are working on pre-pandemic
10 Tamiflu guidance for use in particularly Phase 4
11 and early Phase 5. We are working on Tamiflu
12 logistics during the pandemic phase to make sure
13 that we can actually get it from point A to point
14 B, to the end user. We are also developing some
15 entry and exit screening in conjunction with HHS
16 and the CDC. We are also developing clinical
17 tracking tools, using ESSENCE and CHCS. And,
18 lastly, we are developing clinical practice
19 guidelines. Any questions?

20 DR. POLAND: Thank you. Yes, there are
21 several of them. Let me start and then Dr. Gray
22 and Dr. Oxman. You mentioned sort of the

1 situation awareness and this Joint Health
2 Surveillance Center. Are those entities and
3 information available now? The Board has
4 particular interest in this through the Select
5 Subcommittee, and if so, maybe that is something
6 we ought to have the Board briefed on at our next
7 meeting. But are those reports being produced on
8 a regular basis now?

9 LTC. HACHEY: The Center has just been
10 approved, so it is not currently active but is
11 becoming one. I would say Col. Cox may be able to
12 give us a little better idea as far as that
13 timeline.

14 COL. COX: We expect, as we deal with
15 the budget right now, we are prioritizing. The
16 Center has been approved, and it is going to
17 consist of several primary components that are
18 working now. It is not that it doesn't exist, but
19 it doesn't exist as a co-located formal unit under
20 one commander kind of situation. GEIS will be a
21 component of the Center. The AMSA Group that has
22 been presented to you in the past for the Defense

1 Medical Surveillance System and Army Medical
2 Surveillance Agency at CHPPM will be the other
3 major component, as will my surveillance section
4 in Mrs. Embrey's office. And then there are other
5 participants from NIHAC, AFIOH, etcetera. That is
6 underway, and it will be at provisional operating
7 capability over the next two years until such time
8 as we can co-locate it at a new facility which
9 will be about Fiscal Year 2008. In the meantime,
10 though, work goes on. So, things like this
11 influenza report, it is not that the reports don't
12 exist, but they are not as seamless as we would
13 like, and it is a lot of manual bringing things
14 together by reaching out to these diverse streams.
15 We already produce a weekly surveillance update on
16 influenza activities and findings based on our
17 laboratory system, our ESSENCE system I mentioned.
18 All of those things go in the weekly update to Dr.
19 Winkenwerder, and it gets shared beyond there.
20 That is an extensive collaborative effort through
21 GEIS, the overseas labs, the AFMIC products, the
22 new National Biosurveillance Integration Center

1 that is being stood up under DHS, etcetera. So we
2 are all reaching out to each other. It is more of
3 a collegial and supportive role for one another,
4 and it is not formalized with memorandums of
5 agreement and set budget lines and such.

6 DR. POLAND: I guess there are two
7 things. One is maybe we can arrange to have those
8 reports sent particularly to the Select
9 Subcommittee. The second is who would be the
10 appropriate person in your estimation to brief the
11 Board at our next meeting on this?

12 COL. COX: I would suspect you are
13 looking at him.

14 DR. POLAND: Okay, good, we will plan on
15 that. Thank you. Dr. Gray?

16 DR. GRAY: I think, again, reiterating
17 the value of the DOD's contribution to
18 international surveillance, if I am not mistaken,
19 the isolate that they are planning to use in the
20 Clade 2 vaccine came from our lab in Indonesia,
21 again, just showing the value of that. I want to
22 commend what I see here, and it is just a

1 tremendously aggressive, well thought out plan in
2 handling this. Having some knowledge of our state
3 situation and not wanting to embarrass my state,
4 but to say that you are light years ahead of many
5 other organizations of similar population size,
6 and it is very, very commendable to see this. One
7 thing, and we have had the benefit of seeing the
8 plan in detail, the one thing that I think perhaps
9 that I haven't heard that might be something you
10 want to consider is the event when you have your
11 first introduction in a closed population, such as
12 a ship or a concentrated field unit, of H5N1. One
13 of the things you are going to want to do is
14 evaluate the close contacts. I don't know that
15 you have tremendous assets for those very
16 sophisticated microneutralization serologic tests.
17 I would encourage you to think about that. I know
18 you are training the labs in recognition of H5
19 with molecular tests but to think about acquiring,
20 there is a recombinant H5N1 that is low
21 pathogenicity. You have to get an agreement from
22 the CDC to use it. But you might be able to use

1 that -- it is BSL2 plus -- in developing these
2 assays at multiple sites in anticipation of the
3 introduction and the need to do serologic
4 evaluation of close contacts.

5 DR. OXMAN: I would like to ask an
6 extension of Ed Kaplan's question to Dr. Russell,
7 and that is, this is a fantastic rapid acquisition
8 of data with the shipping times and the online PCR
9 capabilities. You are talking about four or five
10 days to get reliable data on H5. Is there a plan
11 in place, or will there be, to get this, to make
12 this data the basis for action, for example, the
13 change in a planned port visit of a ship and the
14 deployment of Tamiflu?

15 LTC. HACHEY: I can't address whether a
16 ship's deployment would be affected. The COCOMs
17 are developing individual pandemic plans that may
18 or may not drill down to that detail. What we
19 have been struggling with just in the past month
20 is we have our Tamiflu stockpiles in those three
21 geographical areas, but how can we get it to
22 actually the end user, particularly if you are on

1 board a ship, for example, or if you are, for that
2 matter, out in the field. Those kinds of logistic
3 hurdles are currently being worked. Actually, the
4 Joint Staff has taken the lead in getting all of
5 the concerned parties together to come up with a
6 system where we can get Tamiflu to those more
7 remote areas in a timely manner. We don't have a
8 fix yet, but we are fairly close to that. One of
9 the initiatives we have now is increasing our
10 Tamiflu stockpile. What we plan to use that
11 increase in the stockpile for is to take, assuming
12 a 10 percent of our 30 percent is in the attack
13 rate, and preposition that 10 percent down to the
14 end user. So it is on the shelf, ready for the
15 provider to grab and to use when the declaration
16 is actually made.

17 DR. POLAND: Dr. Gardner and then Dr.
18 Ennis.

19 DR. GARDNER: Thanks. I would echo Greg
20 Gray's accolades for the overall program. I think
21 it has been spectacular. Our Subcommittee, I
22 think, had a little less enthusiasm for Tamiflu

1 and particularly getting down to the details
2 exactly of how it would be used in hospitalized
3 patients who already were sick for a few days but
4 with the idea of trying to prevent further spread,
5 and exactly how it would be used, and how it would
6 be used both in a preventive as well as a
7 therapeutic fashion. Those details aren't so much
8 in the plan, although I would applaud the listing
9 of non-pharmacologic means, social distancing and
10 handwashing and masks, as something that in a
11 practical sense would be easier to implement. My
12 question, and we really haven't talked about this,
13 has to do a little bit with: What is the
14 distribution of virus in bird tissue and what
15 about the alimentary tract of humans as a risk? I
16 have never really thought of influenza as
17 something that one ingests. What is the risk of a
18 bird that has been dressed and on the market
19 basically in terms of humans? Is this an
20 agricultural food issue, or is it something we
21 just have to worry about on the farms and in the
22 process of getting poultry to market?

1 LTC. HACHEY: Avian disease or avian flu
2 usually is primarily just a respiratory tract kind
3 of disease.

4 DR. GARDNER: Yes, all flu we think of.
5 That is my question.

6 LTC. HACHEY: But the H5N1 is rather
7 unique, unfortunately. You can isolate it in
8 avian respiratory secretions, avian droppings, and
9 probably more importantly, you can actually
10 isolate large quantities of the virus in avian
11 muscle, which is the problem as far as
12 consumption.

13 DR. GARDNER: That is my question. Then
14 assuming that one eats the infected chicken meat,
15 what is the effectiveness of being able to infect
16 the human by the alimentary route?

17 LTC. HACHEY: If you eat raw chicken
18 meat, then it may be quite effective; but if it is
19 cooked, then there is no risk.

20 DR. POLAND: Pierce, also, I don't know
21 the answer to the specific question of whether
22 this virus has been isolated from human fecal

1 matter, for example, but it is of interest that
2 diarrhea is a prominent feature of the disease
3 phenotype in humans.

4 DR. GARDNER: We never thought of
5 influenza of any sort in terms of alimentary or
6 fecal spread. It is occurring to me as a question
7 mark, and I just wonder what data we have on that.

8 DR. POLAND: We, also, I guess, have
9 reasonable data that ingesting uncooked duck's
10 blood of ducks that have been infected has led to
11 disease.

12 LTC. HACHEY: There has also been a
13 paper showing H5N1 isolation, I think in Japan,
14 from Chinese duck meat.

15 DR. GARDNER: So it is in the meat.

16 DR. POLAND: Dr. Ennis, CDRr. Carpenter,
17 and then CDR. Luke.

18 DR. ENNIS: Yes, this is something that
19 the Subcommittee brought up when we looked at the
20 draft document, the statement that the vaccine
21 that is available would not be effective against
22 more recent isolates. What are the data to reach

1 that conclusion?

2 LTC. HACHEY: Well, right now the
3 vaccine is based on, again, that Clade 1
4 Vietnamese strain. Thus far, there is little or
5 charitably little, some folks would say
6 essentially no cross-reactivity to Clade 2. Clade
7 2 is, essentially, the strain that we are seeing
8 Indonesia now, where the lion's share of the
9 fatalities are coming from.

10 DR. ENNIS: What are the data? People
11 are saying, what, based on what? What are the
12 data? Is it genetic sequencing? Is it
13 hemagglutination inhibition? Is it
14 neutralization? What are the data based on?

15 LTC. HACHEY: I believe it is
16 neutralization, but I would have to defer to the
17 vaccine folks.

18 DR. POLAND: It is actually been based
19 on two things, hemagglutination inhibition assays
20 and microneutralization assays.

21 DR. ENNIS: And what are the data? What
22 is the level of cross-reactivity or the absence of

1 cross-reactivity? This is very important because
2 this isn't shocking. One would expect decreased
3 reactivity with later strains of virus, two years
4 later. But to conclude that three million doses
5 of vaccine are of no value because there is
6 decreased reactivity, I think is a big mistake,
7 very unwise. I would expect decreased reactivity.
8 If there is not cross-reactivity, we should know
9 that. That is scientifically very important for
10 vaccine development, but we have been dancing on
11 this question since January 20th in that draft. I
12 have asked who has the data, and we still don't
13 have the data. We have a conclusion based on a
14 statement.

15 CDR. CARPENTER: Thank you, excellent
16 presentation. I will be happy to share with you
17 our DOD Pandemic Influenza Plan and plans for
18 entrance and exit screening as well as they are
19 developed. I wanted to let you know that Canada,
20 as well, has been stockpiling Tamiflu and now
21 Relenza. In fact, we started stockpiling Tamiflu
22 about two years ago, at least two years ago. Our

1 plan, initially, was to prophylax all active duty
2 personnel for a period of 90 days, that is, to
3 cover two 45-day waves. The problem is that this
4 didn't include reservists; it didn't include DOD
5 civilians; and it didn't include families. Of
6 course, this is now totally, certainly,
7 politically unacceptable, and I think that now we
8 are planning more to prophylax only key personnel
9 and treat. As well, we will have sufficient
10 medication to treat those who become ill. One of
11 the difficulties we are having in our DOD is that
12 we are having a bit of bun-fight with other
13 Federal Government Departments as to who has
14 control over the Tamiflu and Relenza stocks.

15 DR. POLAND: Thank goodness we don't
16 have that problem in the U.S. CDR. Luke?

17 CDR. LUKE: Sir, I was just going to
18 answer in response to the question about whether
19 this was strictly a respiratory disease or a
20 systemic disease. Clearly, we don't know what
21 H5N1 or a future avian strain which causes a
22 pandemic will cause clinically, but in our

1 analysis that we have been doing at BUMED about
2 the H1N1, Spanish Influenza strain, it is very
3 clear that this was a systemic disease. This has
4 been seen by neurological symptoms which were
5 defined as, what was it called, neurological
6 lethargica. Patients also experienced bilateral
7 adrenal necrosis, and patients also presented with
8 signs and symptoms which were very suggestive of a
9 DIC type of condition. So I think that we need to
10 be prepared for not only ARDS type of
11 presentations but also the MODS or the Multiple
12 Organ Dysfunction Syndrome that we see in SARS and
13 some of the other bioagents that are out there.

14 DR. POLAND: Dr. Shamo and then Dr.
15 Oxman.

16 DR. SHAMOO: Thank you. I realize there
17 has been only a few reports of avian flu in humans
18 in Iraq, but the highest concentration of our
19 troops are in Iraq, and they interact most with
20 the local population. But I heard nothing special
21 about whether we should pay special attention in
22 terms of surveillance of our troops or the local

1 population at all. I wonder if there is such a
2 program. Is there a need for such a program?

3 LTC. HACHEY: At the current time, we
4 are still in Phase 3 where getting the disease is
5 associated with, again, intimate contact with
6 diseased poultry. The area that the primary
7 outbreak occurred in, we do not have a high
8 concentration of at least U.S. troops. We had a
9 high concentration of Korean troops but not of
10 U.S. troops. So we did provide some guidance as
11 far as avoidance of obviously sick or dead
12 poultry, using just approved food sources, not
13 eating essentially raw chicken or coming in
14 contact with, again, diseased poultry. But other
15 than that, given the current transmission
16 characteristics of the disease, that is the extent
17 that our change in guidance included. Of course,
18 we always have surveillance for ILI, whether it be
19 due to avian influenza or just seasonal flu or
20 other respiratory pathogens.

21 DR. OXMAN: I would like to echo Dr.
22 Ennis' concerns about the verbiage we are using to

1 describe Clade 2, that if there isn't
2 cross-reactivity, it is not H5. The question I
3 have and we have had for months now is whether
4 that is an artifact of a low titer of antibody to
5 Clade 1, which would mean a 16-fold or an 8-fold
6 decline which is typical of significant drift, and
7 would essentially not register. So if your titer
8 is 1 to 80, and you have a 16-fold decline, then
9 you are not going to measure the cross-reactivity.
10 It is absolutely critical because, if it is just
11 antigenic drift, the Clade 1 vaccine may still be
12 extremely useful.

13 DR. POLAND: Dr. Gray?

14 DR. GRAY: I have just sent in a grant
15 in collaboration with NAMRU-3, and I wanted to
16 mention that they have actually assigned an M.D.
17 or at least an investigator to Iraq for the sole
18 purpose of influenza surveillance, and they are
19 setting up surveillance not only in humans but
20 also in animals.

21 COL. GIBSON: I want to make a couple
22 comments, a comment and a question. One, this is

1 just a point of clarification because we have a
2 transcribed meeting going on here. You called
3 the Subcommittee the AI Subcommittee. Well it is
4 the Pandemic Influenza Subcommittee, and I,
5 personally, think the difference is very
6 important. The work of this Subcommittee will
7 help with the issue of pandemic flu. Right now,
8 the 800-pound gorilla that we are dealing with is
9 AI, but hopefully, all of this planning, all of
10 this work, all of this preparation will transcend
11 AI into a good plan for pandemic flu, whatever the
12 strain. The question then is a question for the
13 group more than for you, Wayne. Has anybody seen
14 any information on the use of Cox-2 Inhibitors in
15 these Cytokine Storms associated with these cases?
16 CDR. Luke, you brought up the issue that this is a
17 systemic condition with Cytokine playing a huge
18 role. I just wondered if anybody has seen
19 anything in the literature. I haven't been able
20 to find anything so far.

21 CDR. LUKE: There was a study by, I
22 think, Otoloney. I will have to check the

1 pronunciation of that, but he has found that
2 topical cortical steroids have significantly
3 inhibited the respiratory signs and symptoms in
4 mice. Obviously, the question is whether or not
5 an inhaler, giving you a topical steroid, would
6 provide protection to your most at-risk organ in
7 your body, and that is relatively available and so
8 forth. I think that the AFEB should be advocating
9 studies on currently licensed products to
10 determine whether or not we can utilize those
11 efficaciously during a pandemic of influenza.

12 DR. PARKINSON: I am not a member of the
13 Subcommittee on influenza, but just listening to
14 this, I have a couple of concerns. First, is the
15 vaccine that we have effective or not? If that is
16 not resolved, I mean clearly that is a huge issue,
17 and if it is resolved, then let us document it
18 better. But, more importantly, coming out of the
19 anthrax experience, what is the policy planning
20 and practices that we would use to deploy that
21 vaccine, particularly, as I understand, it is not
22 FDA-approved, is that correct? Is that all

1 documented in the plan? I hope it is because if
2 the flag goes up, and we find it is even minimally
3 effective or hopeful, we had better not be
4 recreating the anthrax experience. So, lessons
5 learned, you know, fool me once, don't fool me
6 twice. Hopefully, that is all there.

7 DR. POLAND: John, do you want to make a
8 comment on that and then Dr. Ennis?

9 LTC. GRABENSTEIN: The H5N1 1203 vaccine
10 is not licensed. We have contingency plans. We
11 would prefer it to be licensed before we use it.
12 Should we proceed to Phase 5 or Phase 6 before it
13 is licensed, we have a contingency plan well in
14 place and detailed documents to use it under
15 emergency use authorization. DOD would also like
16 to go forward with HHS in using the product,
17 should that be appropriate. So we have a variety
18 of contingency plans. But just to address Dr.
19 Ennis' point while I have the mic, we have
20 requested the neutralization data from HHS. HHS
21 has agreed to provide it to us but has not done so
22 yet. So, we recognize the need to act on data as

1 well.

2 DR. POLAND: Dr. Ennis, go ahead.

3 DR. ENNIS: Thank you, John, and also
4 thank you for bringing us up to date on the
5 contingency plan. I personally think that the DOD
6 should be prepared to use that vaccine. Once the
7 cases start occurring, that vaccine should be used
8 unless there is definitive data that there is no
9 cross-reactivity and if there is nothing else
10 available at the time. One other point dealing
11 with the antivirals, I think the concept that
12 broader use of these antivirals, Tamiflu and
13 Relenza, can be accomplished without the likely
14 emergence of viruses that can replicate and be
15 hearty and robust eventually is a hope that is not
16 likely to happen. These viruses are very capable
17 of adapting, and I think, although they may not
18 appear, Tamiflu-resistant strains may not appear
19 to be as virulent now, they will become virulent.
20 I expect the same thing would happen to Relenza
21 and all other antivirals. It is just the nature
22 of the beast.

1 DR. POLAND: Thank you very much, Lt.
2 Col. Hachey. I am now going to give a report on
3 the Select Subcommittee. In the very beginning of
4 December, Assistant Secretary of Defense,
5 Winkenwerder, sent a memo to us, asking that the
6 Board form a Select Subcommittee to advise "the
7 Military Surgeons General, ASD Health Affairs, on
8 matters related to pandemic influenza, including
9 but not limited to providing recommendations for
10 optimizing influenza surveillance processes and
11 preparations for a pandemic." On the 21st of
12 December, I sent a memo back to Dr. Winkenwerder.
13 I have had two private teleconferences with him,
14 saying we agreed that pandemic influenza posed a
15 significant threat to Military forces and agreed
16 to form a Select Subcommittee. I want to point
17 out that we felt that it was, and I will read our
18 direct quote here, "extremely important to develop
19 processes and systems in order to respond to
20 pandemic influenza, regardless of viral type," à
21 la Col. Gibson's comment. To that end then, I
22 appointed a Select Subcommittee. I chair that.

1 The other appointees from the Board include Dr.
2 Gray, Dr. Silva, Dr. Oxman, Dr. Gardner, Dr.
3 Kaplan, and Dr. Ennis. We, subsequently, are
4 working to engage two members outside the Board --
5 Dr. Walter Dowdle who has huge public health
6 experience and Dr. Fred Hayden who has significant
7 expertise in antivirals, particularly influenza
8 antivirals. We have reviewed and made informal
9 comments on the policy for release of oseltamivir
10 during an influenza pandemic. We have reviewed
11 the preliminary influenza Pandemic Preparation and
12 Response Health Policy Guidance document from the
13 Department of Defense. We have had a face to face
14 meeting with Secretary Winkenwerder and each of
15 the Military Surgeons General with our Select
16 Subcommittee at the Pentagon, January 20th, I
17 believe it was. We have elected to begin our work
18 by outlining what we know about pandemic influenza
19 and particularly avian influenza as the most
20 likely immediate threat for a pandemic, what we
21 don't know, and what assumptions are being made.
22 That has led to a second document that has been

1 circulated among the Subcommittee that will
2 outline a series of, in particular, research
3 recommendations. What are the things that the
4 Select Subcommittee thinks need to be answered as
5 quickly as possible in order to inform both policy
6 and diagnosis, prevention, and treatment? We have
7 also heard from a number of the preventive
8 medicine officers. We have reviewed some
9 information papers that have come to us through a
10 variety of mechanisms. In particular, I want to
11 thank Col. Grabenstein in the MILVAX Agency for
12 information they have put together for us,
13 including the status of the H5N1 vaccine efforts.
14 A question has been brought to us about whether
15 pneumococcal vaccines would be of value in
16 thinking about policies for preparation against
17 pandemic influenza. So the Select Subcommittee's
18 work is still quite engaged. What time are we
19 meeting? After lunch, we will meet again to
20 consider our next steps. That, sort of, is the
21 basis of what we have done so far. I would be
22 happy to take any questions from Board Members or

1 from the audience. Please, Dr. Shamoo?

2 DR. SHAMOO: Thank you. Somebody
3 mentioned that if there is an emergency, they will
4 go through the emergency procedures. I presume
5 that is the emergency procedures as designated by
6 the FDA, and presumably also there is the plenary
7 power of the President. Is that the one you are
8 talking about or just the FDA without the White
9 House, the President actually signing? Regardless
10 of what the answer is, I am saying, shouldn't we
11 have a flowchart all ready, all the paper is done
12 and approved basically, if such and such a
13 condition, this way we have a day or two of
14 approval, rather than wait weeks? Let us learn
15 from the prior experience. That should be
16 incorporated in the recommendation.

17 DR. POLAND: To my knowledge, the only
18 office or the only individual vested with the
19 power to suspend the usual rules and
20 recommendations and allow an unapproved vaccine to
21 be administered is the President.

22 DR. SHAMOO: I understand.

1 DR. POLAND: In my personal opinion
2 here, I had the opportunity to brief President
3 Bush a year ago, and I found him to be extremely
4 engaged in understanding what was going on, both
5 with seasonal influenza vaccine shortages and with
6 this topic.

7 LTC. GRABENSTEIN: Dr. Poland, if I may,
8 the 1203 vaccine that exists was produced using
9 the licensed sanofi pasteur process, so FDA
10 considers it merely a strain change. It would be
11 readily licensable. The emergency use
12 authorization process, I mentioned, is set in law.
13 Either the Secretary of Defense or the Secretary
14 of Health and Human Services would sign,
15 essentially, a one-page declaration of an
16 emergency or a potential emergency. It goes to
17 the Commissioner of the FDA. The Commissioner
18 signs a one-page document. Those documents are
19 the only things that need to get done. The
20 100-page scientific document, essentially a
21 protocol, is done, well all but done. So we have
22 done the lion's share of the work. I don't mean

1 to diminish what would have to be done at the last
2 minute, but that is the extent of the contingency
3 planning I was referring to.

4 DR. POLAND: Thank you, Col.
5 Grabenstein. Other questions or comments? Also I
6 want to give any members of the Select
7 Subcommittee the opportunity to speak. Did I
8 fairly represent our work thus far? Any questions
9 from the audience?

10 COL. GIBSON: One comment, Dr. Kaplan
11 has done a yeoman's job of addressing the
12 pediatric issues associated with pandemic
13 influenza and has a draft document that is
14 circulating among the Subcommittee members.

15 DR. POLAND: Thank you. Very much
16 related to this, Maj. Dennis Kilian is here to
17 present a question to the Board on Southern
18 Hemisphere Influenza Vaccine for U.S. Forces. He
19 has provided slides, I believe. Do we have those?
20 They are the last part of it, yes, under Tab 5.
21 Maj. Kilian, go ahead.

22 MAJ. KILIAN: Dr. Poland, Board Members,

1 colleagues, on behalf of Lt. Gen. C.V.
2 Christianson, the Director of Joint Logistics, I
3 present you a question to the Board. This is the
4 agenda I will follow. Last October, at the AFEB
5 meeting at U.S. Northern Command in Colorado
6 Springs, Colorado, Lt. Cdr. Brian Tolbert, my
7 shipmate there on the Joint Staff, presented an
8 unclassified presentation on what the Unified
9 Command Plan is and how deliberate planning
10 processes happen. As many of you know, the
11 Department of Defense, through the Unified Command
12 Plan, or the UCP, divides the globe into five
13 geographic combatant commands listed here and four
14 functional commands, those being the United States
15 Transportation Command, U.S. Strategic Command,
16 U.S. Joint Forces Command, and U.S. Special
17 Operations Command. The critical point to take
18 away from this slide is every inch of the planet
19 is covered by one of the five geo COCOMs, and only
20 U.S. NORTHCOM is exclusively a Northern Hemisphere
21 COCOM. CENTCOM, through its apportionment in
22 Kenya, gets into Somalia and dips down into the

1 Southern Hemisphere. My boss, Maj. Gen. Joseph
2 Kelley, the Joint Staff Surgeon, hosts a Combatant
3 Command Surgeons Conference two to three times a
4 year. The most recent one was in December. A
5 substantive amount of the conference, as you can
6 anticipate, was dedicated to the DOD Pandemic
7 Influenza Planning Processes as specified to the
8 Combatant Commanders by a Joint Staff Planning
9 Order signed out by the Chairman. During these
10 discussions, U.S. Pacific Command raised a
11 question concerning the lack of a Southern
12 Hemisphere influenza vaccine. Geographically
13 speaking, U.S. PACOM is the largest of the
14 Combatant Commands with a large area in the
15 Southern Hemisphere, a.k.a the Pacific Ocean.
16 However, three out of the four geo COCOMs, as I
17 mentioned, have some Southern Hemisphere exposure.
18 It is worthy to note that U.S. Pacific Command has
19 a very aggressive influenza vaccine program, and
20 Admiral Hufstader's goal is to have 100 percent
21 influenza vaccination among all of the PACOM
22 apportioned forces or assigned forces. That way,

1 he can use that as a rule-out mechanism in case
2 there is a pandemic influenza outbreak of an AI
3 strain. On the 13th day of February, 2006, the
4 Joint Staff Surgeons submitted a question to the
5 Board concerning Southern Hemisphere influenza
6 vaccine for U.S. forces. The important part for
7 the AFEB to consider for these questions is to
8 anticipate a population at risk of approximately
9 10,000 service members per year. Gen. Kelley's
10 questions are: Are the common circulating
11 influenza viruses different enough to warrant
12 separate Northern and Southern Hemisphere
13 vaccines? As we understand it, about 6 to 7 times
14 out of 10, the vaccines have cross-reactivity. Is
15 there insufficient cross-reactivity between the
16 two vaccines to annually warrant DOD procurement
17 of two separate hemispheric influenza vaccines,
18 knowing that we live in a world of constrained
19 resources? Is it practical for DOD to annually
20 procure an FDA-licensed Southern Hemisphere
21 influenza vaccine? Again, the par for this is
22 10,000 service members. And what are the

1 consequences that DOD would face for not procuring
2 an FDA-licensed Southern Hemisphere influenza
3 vaccine? Dr. Poland?

4 DR. POLAND: Let me further frame this.
5 Thank you, Maj. Kilian. What our plans are today
6 is to hear the question, have some initial
7 discussion, some data will need to be gathered,
8 and then we will have a session on this and
9 respond to the question at our Hawaii meeting.
10 Maybe to start off, one of the things we recognize
11 we need is we will need to go back in time and
12 look historically to see what level of difference
13 there has been between circulating strains in the
14 Northern and Southern Hemispheres and differences
15 in cost neutralization between the two vaccines.
16 So we will endeavor to get that information for
17 the Board as a first step. Dr. Ennis?

18 DR. ENNIS: Yes, it is an interesting
19 question. I think, historically, and I haven't
20 been as active in this in the last 10 or 15 years,
21 but there has been one set of guidelines in the
22 WHO for the world, including the Southern

1 Hemisphere. The WHO, traditionally, would make
2 its recommendation. Has that changed?

3 DR. POLAND: That has changed.

4 DR. ENNIS: Okay.

5 DR. POLAND: I think that certainly used
6 to be the case, and now what happens is that they
7 deliberate. Just as VERBPAC for the FDA
8 deliberates on a Northern Hemisphere vaccine,
9 there is a deliberation about whether to make
10 strain recommendations for the Southern.
11 Typically, they have been the same or very close.
12 In the last few years, they have been divergent.
13 Perhaps, that is what is in part an answer to the
14 question. Dr. Oxman?

15 DR. OXMAN: The virology capital of the
16 world has been Australia which is in the Southern
17 Hemisphere last time I looked, and I think a quick
18 review of the last 10 years of the vaccine used in
19 Australia versus in the United States would
20 probably give a good answer to the question.

21 MR. DINIEGA: Ben Diniega from Health
22 Affairs. There has never been a licensed Southern

1 Hemisphere vaccine by the FDA. So somebody who
2 makes the Southern Hemisphere vaccine would have
3 to seek licensure here.

4 DR. POLAND: No other comments or
5 questions? Okay, thank you. I would like to just
6 point out to the Board that we are actually a
7 little bit ahead of time here. Col. Underwood is
8 going to be presenting an update on a
9 Streptococcal Infection Outbreak at Camp Leonard
10 Wood.

11 COL. UNDERWOOD: Thank you, Dr. Poland.
12 Col. Gibson had asked me -- I don't have a formal
13 presentation on this -- just to make a few remarks
14 about increased streptococcal activity at one of
15 our basic training posts, Ft. Leonard Wood, and
16 the intersection of that with a decrease in the
17 availability of Bicillin LA which we use at Ft.
18 Leonard Wood. Just as a matter of recap, within
19 the Army in our basic training sites, we use
20 Bicillin at Ft. Leonard Wood, at Ft. Benning, and
21 Ft. Sill. We do not use it routinely at Ft. Knox
22 and Ft. Jackson. We have not found the need

1 empirically to use it there. To recap what we
2 look at, at our basic training sites, we have the
3 acute Respiratory Disease Surveillance System, and
4 we get a weekly summary report for each of our
5 BCTs. Every week, we look at the number of ARD
6 cases that we have in our trainee populations, so
7 we have a denominator. We look also at what the
8 strep disease is, and our strep recovery rate for
9 Group A Beta-Hemolytic Strep. In that, there is
10 calculated the SASI Index, which I am speaking to
11 an audience that is very well versed in this and
12 knows it better than I do. That is the ARD rate
13 times the strep rate, and our trigger for knowing
14 that we have increased strep activity is when we
15 go over the threshold, which for the SASI Index is
16 25. If we exceed that SASI Index by two weeks in
17 a row, we know that this is evidence of increased
18 strep activity. Now couple this with the fact
19 Monarch Pharmaceutical which was the primary
20 distributor of Penicillin G Benthazine/Bicillin,
21 as the prime vendor in the Great Plains Regional
22 Medical Center was unable to supply the normal

1 quantities of Bicillin. Why was that? Because
2 Wyeth Pharmaceutical decided to discontinue
3 manufacturing of Bicillin. So we have an arena
4 set up here whereby we did go over that threshold.
5 The week of the 11th of February, we were at 28
6 SASI Index at Ft. Leonard Wood. The following
7 week, we were at 42, and we have a lack of
8 Bicillin. Several things occurred then.
9 Logistics came into play, medical logistics to go
10 out to a call to our other MedAcs and MedSyms to
11 see if we could garner enough Bicillin to get that
12 to Ft. Leonard Wood in light of this increased
13 strep activity. The other thing we did was we
14 consulted with the Preventive Medicine Consultant
15 for the Great Plains Region, Col. Forest
16 Oliverson. We asked him to get with the
17 Infectious Disease Consultant to the Surgeon
18 General who has briefly reported to the Board --
19 that is Col. Duane Hospenthal -- to make a
20 recommendation for an interim measure with the
21 lack or relative lack of Bicillin. The
22 recommendation was made that, in the interim

1 without sufficient Bicillin, the interim measure
2 would be azithromycin, 500 milligrams once a week
3 for four weeks for our recruits. This is the
4 measure that we have in place. It looks like the
5 firm that will be coming onboard or online with
6 Bicillin may not be able to completely have the
7 availability where it was until September of 2006.
8 Now, we have several things in our favor here, in
9 that as we come into spring, we are less likely to
10 exceed that threshold of the SASI Index. If it
11 had to happen in this timeframe, at least we are
12 getting into an era or a time, a seasonal time
13 where it is probably not as big a risk as it is
14 within the winter season. But that is the
15 scenario, and I know it has affected our sister
16 services as well. I think they have done some
17 similar things. I will probably turn that over to
18 Col. Snedecor to mention the Air Force.

19 DR. POLAND: Actually, before we switch,
20 can I just ask a point of information, so the
21 Board knows this? All of the recruits, at least
22 at the camps that you mentioned received Bicillin

1 on what sort of an interval? Then, do the other
2 services follow that same policy?

3 COL. UNDERWOOD: Well, let me go over
4 that, and this really goes back to the vagaries of
5 the different forts. Just a second here.
6 Historically, what Ft. Leonard Wood has done is
7 they have used it continuously since 1996. What
8 their pattern is, is that they find strep disease
9 within a company or a battalion of recruits four
10 weeks or more after the original prophylaxis, and
11 they administer another dose to the entire company
12 or battalion, but they administer that routinely.
13 Ft. Knox, of course, doesn't use it. Ft. Sill
14 uses prophylaxis for every trainee, and they have
15 done that since 1998. They also administer a
16 second dose if strep disease is found four or more
17 weeks after the original dose.

18 DR. POLAND: This particular outbreak
19 that you are talking about occurred in the face of
20 receipt of Bicillin among all of the recruits.
21 How long after that dose of Bicillin?

22 COL. UNDERWOOD: Well, the problem was,

1 of course, let me get back to the data here.

2 DR. POLAND: While you are looking for
3 that information, after hearing about this from
4 each service, I would also ask Ed Kaplan to be
5 thinking about some comments. He talked with me
6 on the airplane trip here. For the Board Members
7 that don't know, Dr. Kaplan is internationally
8 recognized for his work in Streptococcus and runs
9 one of the WHO collaborating centers. So after we
10 get that information, Ed, if you wouldn't mind
11 making some of the points that you told me about.

12 COL. UNDERWOOD: What we had, starting
13 out here in January and going back to when we
14 exceeded the threshold of the SASI Index, we were
15 running around 12.7, in January, to 15. And then
16 the week of 11 February was when we first exceeded
17 that SASI Index to 28.

18 DR. POLAND: When was that in relation
19 to their last receipt of Bicillin?

20 COL. UNDERWOOD: I don't have the data
21 on that.

22 DR. POLAND: Because I think that would

1 be important to know. Did this happen within a
2 few weeks -- I would doubt -- of receiving
3 Bicillin, or was this six weeks, eight weeks after
4 receiving it? And then, once it began to be
5 recognized, you mentioned two different SASI Index
6 numbers?

7 COL. UNDERWOOD: Yes.

8 DR. POLAND: Did that increase to 42?
9 Once it was detected, was another round of
10 Bicillin given?

11 COL. UNDERWOOD: Yes.

12 DR. POLAND: And that rate increased,
13 despite that?

14 COL. UNDERWOOD: What happened was they
15 requested, as I mentioned, MedLog to find
16 sufficient Bicillin, and let me give you some
17 dates on that. The 22nd of February, and let me
18 correlate this with the SASI Index. The SASI
19 Index was first reached the week of 11 February.
20 We noticed then that it was 28. On the 22nd of
21 February, Ft. Leonard Wood implemented their
22 emergency immunization plan to mitigate this high

1 strep rate when the index went up in the training
2 population. Two days later, on the 24th of
3 February, they received 1,200 doses from Monarch,
4 and Monarch, I believe, is the company that is
5 going to be producing Bicillin. Actually, Monarch
6 is going to be giving them limited amounts of
7 dosages of Bicillin until the shortage is
8 resolved, which is anticipated in September. Then
9 on the same day, this is the 24th of February,
10 this is when the Medical Logistics within Medical
11 Command conducted an emergency data call to the
12 other activities to locate excess stocks of
13 Bicillin. They located 4,800 doses of Bicillin
14 just within the Southeast Region. Tripler came on
15 board, and TAMSI and USAMSI also said they had
16 extra doses if necessary. So they took measures
17 when not waiting for a second breach of the
18 threshold of the SASI Index. But, of course, it
19 had already gone by the second week up to 42. Now
20 the latest information, I don't have the SASI
21 Index from this week, but from the 24th of
22 February, it was already coming down then. It was

1 29.3.

2 DR. POLAND: Col. Snedecor?

3 COL. SNEDECOR: We knew of the impending
4 Bicillin shortage. So they were planning ahead of
5 time to switch to oral antibiotics. Our
6 Infectious Disease Consultant actually recommended
7 either penicillin, oral penicillin or erythromycin
8 instead of azithromycin because they were
9 concerned about resistance development. But when
10 our training group was briefed that you can
11 perform a regimen of two pills a day or one pill
12 once a week, they said, why are you asking? There
13 were concerns over who would hold the medication
14 because the TIs can't touch it, they had to be
15 observed, and then what if they took the whole
16 bottle. So we switched to azithromycin, I
17 believe, a couple weeks ago when we ran out at
18 Lackland. As you know, we used to give everyone
19 Bicillin seasonally, and then in the off season,
20 we had a trigger as well. But after they
21 triggered two or three or four times in a row in
22 one month, they said we are just going to give it

1 to everyone. Our Febrile Respiratory Illness rate
2 just dropped almost in half and has maintained
3 there. I mean it is really unexplainable that
4 Bicillin could cut our Febrile Respiratory Illness
5 rate in half, but it has continued. So I guess it
6 is doing something there. We switched, and it was
7 a fairly planned for and smooth change.

8 DR. POLAND: So all the recruits get one
9 dose unless there is a threshold exceeded?

10 COL. SNEDECOR: Right now, they just get
11 one shot of Bicillin because our recruit training
12 lasts five weeks. So they get one. They don't
13 get any more. If they get spikes of additional
14 disease, which I don't think they have, I am not
15 sure what they would do.

16 DR. POLAND: Because this is also a
17 supply issue then, I would like to know what the
18 Navy and the Marine Corps and the Coast Guard are
19 doing.

20 LCDR. SCHWARTZ: At the Coast Guard, we
21 are not using Bicillin.

22 CDR. MCMILLAN: The Marine Corps has

1 used it intermittently. I think West Coast tends
2 to use it on a more continuing basis than East
3 Coast, and they have made provisions for the
4 shortage. They didn't use anything for a short
5 period of time, but then they went back to oral
6 agents initially with Pen-VK but then with
7 azithromycin.

8 DR. POLAND: Dr. Kaplan? Oh, sorry.

9 LCDR. LUKE: Sir, I am going to have to
10 get the exact specifics of what we are doing up at
11 Great Lakes. I know that there is a policy, but I
12 will have to provide that to you at a later date.

13 DR. POLAND: Okay.

14 CDR. RUSSELL: Dr. Poland, Kevin
15 Russell, Naval Respiratory Disease Laboratory, I
16 can speak to Great Lakes briefly and also point
17 out to the Board that, because of our respiratory
18 illness surveillance, we do have visibility on
19 penicillin usage throughout all the recruit camps
20 and keep a document that is certainly not as up to
21 date with the details that you are getting from
22 services but provides general up to date

1 information on the policy of whether or not they
2 use it and how often they use it, and I can
3 forward that to you. At Great Lakes, they use the
4 penicillin injection when available once, and that
5 is during in-processing. During shortage periods,
6 they resort to the Pen-VK. I would like to just
7 point the Board and other members here quickly to
8 a publication by NHRC, again reminding the group
9 that we do Group A Strep Surveillance at Military
10 treatment facilities, but the GAS is from
11 recruits. Our publication in 2003 -- Barosa was
12 the first author -- did note some site-specific
13 differences in erythromycin resistances, and
14 Lackland actually was the one that showed
15 significance in erythromycin resistance. Now,
16 quickly, Dr. Kaplan can speak to this better than
17 I, but the macrolide resistance don't go hand in
18 hand, i.e., erythromycin and azithromycin. So the
19 azithromycin has been a good alternative to
20 erythromycin.

21 DR. KAPLAN: Thank you. I don't know
22 how much time I have to cover 70 years of this.

1 This is a complex issue, and let me just respond
2 to several issues that Greg and I talked to.
3 First of all, with regard to supply, you are quite
4 right that Wyeth gave this up and sold it to this
5 outfit which then became Monarch. There has been
6 big question in the service about quality, not
7 just quantity, of manufactured penicillin. Having
8 personally tried and been stonewalled, there is
9 good data that Jim Bask (?) put together some
10 years ago showing that, in recruits, the levels
11 did not last long. Both Wyeth and Monarch have
12 stonewalled this question. There is serious
13 question in our minds as to whether this product
14 is what it was 50 years ago when Gene Stollerman
15 did the original studies. I would be very
16 cautious about this. Kevin Russell and I have
17 talked about this over a period of time, and I
18 don't think we need to go into detail at this
19 point, but this needs to be looked at, especially
20 when it is being used. Similarly Streptococcal
21 Disease in the Armed Forces goes back a long, long
22 time, as everybody here knows, including 27,000

1 cases of acute rheumatic fever in the Navy during
2 the Second World War and the Old Commission. I
3 would point out to you that this is not a disease
4 limited to Leonard Wood, which has an infamous
5 history anyway. If you look at the December issue
6 of the Medical Surveillance Monthly Report which
7 came in the mail just last week, Ft. Sill exceeds
8 one, two, three, four times the SASI Index in
9 October, November, and December of the present
10 time. So I think it is more widespread than just
11 at Leonard Wood. Those are the data which I am
12 sure you are familiar with that come here. I
13 think that deserved some information. The
14 question about macrolide resistance, as those of
15 you here know, in Europe, the macrolide resistance
16 now is about 40 percent in some countries. I
17 don't know whether this has been looked at. I
18 think Kevin has looked at this and has seen some
19 resistance, am I right?

20 CDR. RUSSELL: Actually, with the
21 particular outbreak at Ft. Leonard Wood, some of
22 the samples we got from there, which are not great

1 numbers and definitely the samples are clonal,
2 showed very high resistance rates, up to 80
3 percent. I haven't processed all of these, so
4 this is just a very cursory look. I don't want
5 that in a way to be taken as gospel at this point.
6 We are going to be processing more of these.

7 DR. KAPLAN: But it is enough to raise
8 your eyebrows.

9 CDR. RUSSELL: Very much so.

10 DR. KAPLAN: Yes. And so, I think in
11 the interest of time, that this is something that
12 does need to be looked at in more detail by the
13 Board and would suggest that however we put this
14 on the agenda for further investigation with the
15 Services, that we look at quality, quantity, and
16 resistance as well as epidemiology at this point.
17 Remember that it was in 1985 or 1986 when somebody
18 stumbled on the fact that there were 14 cases of
19 this strange arthritis on the ward at Ft. Leonard
20 Wood, which turned out to be 14 cases of acute
21 rheumatic fever when a preventive medicine team
22 was sent there. I would just make that

1 suggestion.

2 DR. POLAND: Col. Underwood also has a
3 comment to make, I think, about Hantavirus, right?

4 COL. UNDERWOOD: Yes, sir. Col. Gibson
5 motioned to me to talk about Hantavirus. Well,
6 since it happened at Ft. Bliss, my colleague has
7 something to do with this, too, as you will hear
8 from the information. What happened was on the
9 11th of February, a 24-year-old African-American
10 airman stationed at Luke Air Force Base died at
11 William Beaumont Army Medical Center at Ft. Bliss,
12 and he had severe pneumonia-type symptoms. At the
13 time, tissues were taken from that individual and
14 sent to labs for autopsy. Two weeks later,
15 USAMRIID, actually, discovered that the antibody
16 levels were very high for Hantavirus. So it turns
17 out that this was Hantavirus Pulmonary Syndrome,
18 and this led to a flurry of activity, as you might
19 imagine, by the Public Health Office at Ft. Bliss
20 and then with our colleagues in the Air Force.
21 Because of the incubation period typically being
22 about two weeks, it could be that this airman

1 actually was exposed at Luke before he actually
2 went to train at Ft. Bliss on the McGregor
3 training site there. We do know, from past
4 experience, that this was first discovered in
5 1993, called the Sin Nombre Virus in Spanish. We
6 know that means "no name virus." A variant of
7 Hantavirus, unlike the primary type which is more
8 kidney-related, this is, of course, pulmonary and
9 extremely deadly. It wasn't thought of in the
10 differential at the time the airman was seen. He,
11 essentially, had appeared within 24 to 48 hours of
12 this illness and then succumbed to this, quite
13 frankly, an otherwise healthy young man. I think
14 I will turn it over to Col. Snedecor for other
15 comments from the Air Force.

16 COL. SNEDECOR: Yes, the Army team
17 looked at the barracks at McGregor Field and found
18 that it was highly suggestive of a Hanta exposure.
19 There was easy access to rodents. There was food
20 in the barracks, old food. There were soiled
21 linens stuffed in closets. There was actually
22 some type of animal in one of the garbage cans

1 that the team didn't bother to identify. It was
2 clearly a place where he could have gotten this.
3 And there was ultraviolet light evidence of rodent
4 urine in the barracks. However, he became ill and
5 died 10 or 11 days after he arrived in the El Paso
6 area. Where he came from -- Luke is Arizona --
7 they also had Hantavirus there, and they had a
8 death in January in the area of the county where
9 he lived which was right off the base, Luke Air
10 Force Base. They looked at some of the training
11 sites. They are trying to track down now his
12 activity, his movements, and possible exposures
13 around his living environment. On the base, they
14 were security forces. They were training on the
15 base before they went to Ft. Bliss where they were
16 going to do more training before they went to
17 Iraq. One of their training sites is an abandoned
18 housing area that is fenced off. Usually, I think
19 they go in there and use it for like urban ops
20 training. Actually, the unit training mantra said
21 that each year before they go in there, they have
22 somebody come in and clean them out because they

1 have rat droppings and whatever in there. So that
2 is another potential site of exposure. We just
3 don't know right now. It doesn't appear that
4 there are any other cases. They have been
5 monitoring them quite closely at William Beaumont.

6 DR. POLAND: You said that was 6
7 February?

8 COL. UNDERWOOD: The 11th of February.

9 DR. POLAND: Okay.

10 COL. UNDERWOOD: The other thing I might
11 add is the CHPPM-West is going to be looking at
12 specimens, rodents for Hantavirus. Historically
13 and back in 1993-1994 timeframe at Ft. Carson,
14 when we looked at Pinon Canyon training film there
15 in Colorado, a similar study was done, although we
16 didn't have any evidence of human cases of
17 Hantavirus, and I believe they found a 20 percent
18 positivity rate in the rodents that they looked
19 for Hantavirus.

20 DR. POLAND: Any questions or comments?
21 Dr. Silva?

22 DR. SILVA: Yes. I am sorry for the

1 death of this recruit. California is still number
2 one in the Country, I think, related to this type
3 of pneumonia. We had three alone last year at our
4 center. The one thing you may want to tip your
5 epidemiologist off to, at least with this
6 particular strain of Hantavirus, almost all the
7 cases have a profound T cell cytolysis with a shift
8 to the left, profound. I mean like 40,000-50,000
9 counts, routinely. That has been a useful
10 epidemiological tipoff, when you are dealing with
11 an early pneumonia because pneumococcal pneumonia
12 probably does that, but this is a profound cytolysis
13 which is seen. Thank you.

14 DR. POLAND: Any other comments? Right
15 before our break, I would like to recognize a few
16 individuals. These are members of the Board who
17 are departing. Dr. Haywood, who is not here
18 today, has been a long term member. He actually
19 started on the Board in the early nineties and was
20 a member again from 1998 to 2002, and since 2004
21 has been a consultant to the Board. Sue Baker,
22 also a long term member, and she has sort of

1 repeated terms. Her last term was from 2004, and
2 recently she has had to step down from the Board.
3 Also, Maj. Dennis Kilian, our Joint Staff
4 Representative and Liaison, I understand, is
5 moving on, too. Dr. Greg Gray, now Dr. Gray is
6 not actually departing until June, but I
7 understand he won't be able to make the June
8 meeting, and so this will be his last meeting. If
9 we could have Dr. Gray and Dr. Kilian come up, we
10 would like to just do a short presentation. This
11 is our plaque, our coin, and a certificate of
12 appreciation to Greg Gray with deepest
13 appreciation for your outstanding contribution as
14 a consultant to the Armed Forces Epidemiological
15 Board and also for the drawing of infectious
16 disease prevention and control. I might just add
17 a personal note that I particularly appreciated
18 having Greg on the Board. He has a deep and rich
19 experience in the Navy. That experience, combined
20 with his international reputation as an Infectious
21 Disease Epidemiologist has served the Board very
22 well. I really think of him not only as colleague

1 but in a very real way as a brother, and I am
2 sorry to see him step down from the Board. Thank
3 you very much.

4 DR. GRAY: Thank you so much.

5 (Applause) I wonder if I can say
6 something.

7 Twenty years ago when Paula Underwood
8 and I were under Dick Miller and Joel Gaydos as
9 residents, one of the most frightening things was
10 to come in front of this Board and try to present
11 an idea. We realized that the wisdom and the
12 amount of knowledge that you had was just
13 tremendous. As Preventive Medicine Officers later
14 on and as residents, we came with fear and
15 trembling and anticipation of those things. Over
16 the years, I have really grown to respect this
17 Board, its service to the Country, the dedication,
18 the tirelessness of the Preventive Medicine
19 Officers, the contract staff, and all. So it is
20 just a tremendous honor to have been counted, at
21 least for four years, a member of the Board, and I
22 thank you very much.

1 (Applause)

2 DR. POLAND: Then also to members of the
3 Board who have been here a while, you have seen
4 Maj. Kilian many times. He has briefed us many
5 times and provided invaluable information to us
6 many times. I understand now he is being deployed
7 to Kuwait. So, we wish him the best of luck and
8 appreciate all the service and information he has
9 given us.

10 (Applause)

11 MAJ. KILIAN: For those of you in the
12 uniform, to paraphrase our past Army Surgeon
13 General, "See you on the high ground."

14 (Applause)

15 COL. GIBSON: We are at break. We will
16 be back in about 15 minutes.

17 (Recess)

18 DR. POLAND: Let us proceed with the
19 meeting here. We went a little bit longer than
20 anticipated. We are transitioning now into a
21 slightly different set of presentations. Our
22 first and next speakers are Maj. Do and Dr. -- I

1 hope I say it right -- Inae, here to present a
2 demonstration of AHLTA. The Board is probably
3 more familiar with the previous iteration of this
4 which was CHCS2. Hopefully, the speakers will
5 point out the reason for the name change.

6 MAJ. DO: Good morning, I am Maj. Do. I
7 am from the Information Management at TMA, the
8 Tricare Management Activity Office in Falls
9 Church, Virginia. I am an Internal Medicine
10 Physician who has been practicing at Madigan until
11 about two years ago when I left to do a fellowship
12 in Biomedical Informatics at Stanford. So I have
13 just recently joined TMA this past fall. For my
14 presentation, I will probably just give you a very
15 brief high level overview, and then I will turn it
16 over to Dr. Mark Hamra (?) who is a prior Air
17 Force Family Practice Physician, who has extensive
18 experience with its application. Also, since the
19 time is limited, we don't really have time for
20 questions, and it is not meant to be an
21 interactive session, but we will have contact
22 information at the end. So you can save all your

1 questions and just email them to us, and we can
2 address them for you. I will start off with
3 talking about some of the characteristics of our
4 enterprise, which is the Military Health System.
5 We serve about 9.2 million beneficiaries at 70
6 hospitals, 411 medical clinics, 417 dental
7 clinics, and we have about 132,000 employees. To
8 kind of get a sense, in any given week, we get
9 about 1.8 million outpatient encounters, 18,000
10 inpatient admissions, 104,000 dental visits, 2.1
11 million prescriptions, and 2,200 births. As
12 opposed to our civilian counterpart, we also have
13 to consider the care of our soldiers on the
14 battlefield. So we have about 255,000 outpatient
15 encounters in theater that are now stored in our
16 central theater database. How does AHLTA support
17 our enterprise? This slide depicts the life cycle
18 of an active duty member. You see on the left
19 here, he enters the Military. He trains and gets
20 deployed. He may get injured and get taken care
21 of in theater or possibly get evacuated in a brick
22 and mortar facility, and now to a sustaining base.

1 Eventually, he probably will leave the service and
2 get access to the VA care. At the core of AHLTA
3 is this large clinical data repository that
4 contains the medical records of all the patients
5 in the Military Health System, from the theater
6 side to our sustaining base. The CDR makes the
7 record available at all times to authorized users.
8 A patient can travel from end of the Country to
9 the other and have his record or her record
10 available at real-time across the Country to any
11 providers who use AHLTA. As of February, the
12 third of February of this year, we have 86
13 facilities that are using AHLTA at this time.
14 That is about 38,000 trained users. We have 14
15 million patient accounts that have already been
16 processed through AHLTA. To kind of get a sense
17 of the amount of computable data we collect at
18 this time, in a day, we get about a million
19 structured terms, 54,000 abnormal symptoms, and
20 50,000 abnormal exam findings. All of these data
21 that are collected can be fed into an application
22 that does surveillance and disease management and

1 population health management. This slide is kind
2 of a high level discussion on instead of relying
3 on diagnosis to evaluate a non-battlefield injury,
4 now we can look at the clusters or patterns of
5 symptoms that we collect in AHLTA. Now we can
6 adjust our treating environment. If we see a
7 cluster that is suggestive of heat injury, we can
8 start thinking about isolating the source of
9 natural infection to limit its spread, if we start
10 seeing these kinds of patterns. Or we can
11 consider countermeasures if we start seeing
12 symptoms or clusters suggestive of a biological
13 agent. This slide kind of shows our typical
14 workflow just to illustrate that the patient and
15 provider is only one part of the workflow. AHLTA
16 is part of all of the workflow, from the patient
17 checking in to the nursing assessment to the
18 education to when the patient checks out. It is
19 there to collect the information. I think at this
20 point, what you want to see is the live
21 demonstration of AHLTA. I am going to turn it
22 over to Dr. Hamra.

1 DR. HAMRA: Good morning. Dr. Inae
2 could not be with you, so depending on how this
3 goes, you can switch it to Hamra. We will wait
4 and see. What I brought is the training tool
5 version of AHLTA. Real quick, I will address your
6 question. Why was it CHCS2 and now AHLTA? I am
7 not at the level that discusses those kind of
8 things, but from my perspective, I will tell you
9 this. What we have is a core set of functionality
10 that has been funded for CHCS2 like questionnaire
11 upgrade, template management, pediatric growth
12 charts, wellness reminders. As that core set of
13 functionality is being rolled out, that is when
14 the name change occurred. I think it was kind of
15 the face of AHLTA is changing somewhat. Some of
16 the core functionality that is really useful, in
17 my opinion, is coming out, and I think they just
18 coincided. That is what I know about it. First,
19 I want to orient to the application. By clicking
20 on a patient, it loads that chart into CORE. We
21 have all the information that you typically find
22 in a patient's chart here on the left --

1 demographics, medications, their problem list, all
2 the things you normally find in a paper chart. I
3 am going to dig into a lot of these things because
4 I want to show you some of the structure text, how
5 it is used, and then I want to go into a second
6 phase where I show you some queries that can be
7 run on that data that we have done as test
8 projects. This is an SF600, an electronic version
9 of that. There is some information that is pulled
10 from the chart and auto-cited if you choose. You
11 can turn this off or leave it on. You can
12 customize it. The information about the patient
13 is pulled into the chart. You can review it here.
14 Screening and vital signs are typically done by
15 technicians. What I want to focus on is MEDCIN
16 and documentation at the point of care. What we
17 want to do is get down to that granular level,
18 symptoms, not just diagnoses but what the patient
19 complained of and also what questions were even
20 asked of that patient. We can do these things by
21 using structured clinical content. MEDCIN is
22 several hundred thousand uniquely identified terms

1 in context. What I mean by that, hypertension, if
2 you put it in here, it can be hypertension of the
3 patient or past medical history or past family
4 history of hypertension for a mother or father.
5 It is all in context. All that data is identified
6 uniquely and actionable or searchable later.
7 Obviously, with several hundred thousand terms,
8 there is stuff in here for anyone, but no one
9 could use it. What you have to do, there is a
10 couple of different ways to do it. We encourage
11 the use of templates. Templates can be created by
12 an individual. They can be created at an
13 enterprise level and deployed, as we do with the
14 Clinical Practice Guidelines templates where there
15 are standards of care that are recommended. How
16 these work is basically documentation of a few
17 simple complaints. You can free-text. You can
18 use structured content to do almost anything you
19 want in here. I did that for a reason, two
20 different ways. The remainder of the review of
21 systems was negative. As you can see, it starts
22 to write your note for you on the right. It is

1 legible; it is available. Past medical history
2 and physical exam are also available. So, using a
3 template is one way. The second way you can
4 document is through a diagnosis prompt. Now, all
5 these terms in MEDCIN are linked to one another
6 and associated with diagnosis codes. Let's do, a
7 good example is gout. If I go in and I type in
8 "gout," and I look at information from a past
9 medical history associated with gout. I don't
10 have a template built; I just search on the
11 diagnosis. You see alcohol; you see diuretics,
12 niacin. These things typically trigger gout. You
13 have tools available that allow physicians to
14 document the point of care in a structured way.
15 Now why do they want to do that? Because it is
16 different. It is easier just to write. Some
17 people type. What you do is you have to figure
18 out ways to make it useful to the person who is
19 doing that. Let us move on to assessment and
20 plan. We will get to the useful part in a minute.
21 I may have to open a new patient here. Like, I
22 said, this is the training system. This is

1 sometimes an issue.

2 DR. SHAMOO: Can I ask a question?

3 COL. GIBSON: Go ahead.

4 DR. SHAMOO: Are these real names?

5 DR. HAMRA: No, these are made-up names.

6 DR. SHAMOO: Okay, thank you.

7 DR. HAMRA: I apologize for the delay.

8 This hasn't happened in a long time. It is not
9 going to give me any. It is not going to give me
10 break.

11 DR. CATTANI: I just want to ask a
12 question while you are fiddling with this. How
13 does this interface with ESSENCE? Can anyone tell
14 me that?

15 DR. HAMRA: I can't.

16 COL. UNDERWOOD: I don't believe there
17 is any, well, ESSENCE takes information from
18 ambulatory visits which are in the SADR, which is
19 what CHCS2. When they enter that data, it feeds
20 the ambulatory visit. ESSENCE doesn't look at
21 inpatient visits but rather outpatient visits.
22 That is the connection.

1 UNIDENTIFIED SPEAKER: It feeds it?

2 COL. COX: No, it doesn't. ESSENCE is
3 just an interface. It works off of a dataset.
4 All of the outpatient data that is collected
5 currently from both CHCS and AHLTA is all put into
6 a single data repository. It is different names
7 than what they are showing you now because there
8 is a transition in process. It is just easy to
9 think of it as it all goes into one database.
10 ESSENCE then looks at that data, focusing only on
11 ambulatory visits right now but not just ICD-9
12 codes of visits. It also looks at pharmacy data
13 that comes in through a different stream. And we
14 are preparing to add on new modules in this next
15 12 to 18 months to look at laboratory orders and
16 results, x-rays orders and results, and chief
17 complaints from both emergency departments and
18 visits as well as primary care visits. It all
19 comes out of this integrated data system which is
20 the electronic health records for everybody. Once
21 we transition entirely to AHLTA, well, then that
22 is what ESSENCE will be using as its data source.

1 In theory, we could expand that to inpatient, but
2 there has been no value in that for outbreak
3 detection since it lags by 30 to 60 days usually
4 for final diagnoses, dictation, and all that. So
5 we focus on the outpatient.

6 DR. POLAND: Ken, is AHLTA just a way of
7 getting out the information that is already in, or
8 is this being used to input information?

9 COL. COX: AHLTA is for inputting the
10 information. This is what is occurring at the
11 point of care with the individuals coming in,
12 seeking treatment. And so, the healthcare
13 providers and the associated staff are putting the
14 data into the electronic systems, so it can be
15 accessed by these various tools for analysis.

16 DR. POLAND: It may be a little
17 misleading because we are having some problems
18 with it, but we use an electronic medical system,
19 I guess one question is: How easy is this for
20 somebody to use who is seeing somebody every five
21 or ten minutes?

22 COL. COX: It is one of those things

1 that has a learning curve, and there is always a
2 lot of resistance to changing from what you are
3 used to doing to something new, but we have been
4 using the system in the theater. That was
5 mentioned, the CHCS2-T, and providers that have
6 used it, come back, saying it is not so bad. I
7 don't know people who are using it right now. But
8 again, you have to remember, providers are that
9 way. Most providers don't like to change. There
10 is somebody over there who wants to say something
11 and doesn't agree with anything I am saying. So,
12 why don't you let him say it?

13 CAPT. JOHNSTON: There was a study
14 reported to the BMJ. It was about five years, so
15 it was older technology than this. It showed
16 that, typically, in an outpatient scenario, using
17 a computer to record the clinical data added about
18 two minutes to the consultation time, which added
19 up over the course of a clinic. It was actually
20 quite a lot of time.

21 DR. POLAND: Are you ready to proceed?

22 DR. HAMRA: Yes. I sincerely apologize.

1 I have never had it do this. Just to speak to
2 your theater for a second, I actually deployed to
3 Saudi Arabia to PSAB with theater and trained two
4 other physicians to use it, and we set up a little
5 network, and we didn't have a problem in theater.
6 The challenges within clinics, true, it adds time.
7 There is a steep learning curve, especially when
8 you are going from the natural language of writing
9 into this structured content which is difficult.
10 It doesn't read like we normally talk, and the
11 lists aren't always organized how you would
12 normally think about them in your head. One of
13 the things with that increased time is also it was
14 noted that there was increased documentation. You
15 have to remember that. The level and amount of
16 documentation that was done increased as well.
17 That might be why there was a little bit more
18 time. So it is give and take. Obviously, it is
19 not easy. It took me a while to learn to use it.
20 One of the interesting stats from the field, and
21 then I will get back to my failed demo here, is
22 that 67 percent of the primary care folks are

1 using nine or more MEDCIN terms right now today.
2 They are using templates, and they are using
3 structured text. Well, is 67 percent everybody?
4 No, but it is a lot. It is more than I actually
5 thought were using it from all the noise that we
6 get about how hard it is. So you have to look at
7 the data, too, and we can actually pull that
8 information. Not bad, a pretty good discussion,
9 it covered the lapse. Whenever you do an
10 assessment and plan after doing the documentation
11 and the SO, whenever you are in AP, you can give
12 someone a diagnosis. You can point and click
13 through ordering laboratory and medications,
14 tests, laboratory tests and medications. They are
15 associated with that diagnosis, and that is useful
16 in another way here in a second that I will talk
17 about. Disposition just takes the information we
18 were looking at and uses it to estimate a code.
19 This code is going to be off because I didn't even
20 do a physical exam on this patient, and that is
21 okay. But you can see here the structured text
22 listed. Once you have completed the encounter,

1 you can go back to the patient's problem list. We
2 see under pharyngitis, the patient has been seen
3 yesterday and again today. It lists the
4 encounters that were associated with that. If I
5 double-clicked on that, it would take me to the
6 actual text. You can see medications that were
7 given, lab tests that were done. You see how that
8 data, as you were doing it, is connected to
9 specific encounters and stored in an
10 encounter-centric way. What we did, Dr. Inae, the
11 guy who is not here, and myself, we took a set of
12 data from Langley, Portsmouth, Ft. Eustis, and
13 Seymour Johnson; pulled it onto a laptop in an
14 article database; and applied it to the CDM model.
15 Now, CDR is what we currently use, Clinical Data
16 Repository. That is where everything in the world
17 is going to, and it is stored in an
18 encounter-centric way. If you have John Smith,
19 and he has diabetes, and his A1C was done last
20 week, then that is stored in that encounter. If
21 you wanted to go search on it right now, you would
22 say, I want to know all my patients in this

1 population that have had an A1C. It would have to
2 go: John Smith, this encounter, diabetes. And it
3 would have to go: Mary Smith, this encounter,
4 diabetes. It is very time consuming; it doesn't
5 work. So, we take the data and we flatten it out
6 into what is called a CDM or Clinical Data Mark,
7 where now you have diabetes and all the patients
8 who have diabetes are stored right out here. It
9 is just a number. And all the A1Cs that have been
10 done are stored right over here. You can say,
11 show me all my patients with diabetes who have had
12 an A1C and tell me when. And, boom, you get it.
13 We took the data; we flattened it out; and we
14 started running some queries on it. Some of these
15 are a little boring, but it kind of leads up to
16 the useful part. You stick in the numbers. You
17 say, how many people in our dataset? How many
18 encounters were done, total? How many lab tests
19 were done? How many medications were done? And
20 these are the raw numbers that you get back, just
21 like that. What we used was business objects, so
22 this is not a front end that is meant to be in

1 production. This isn't what you would get. When
2 you hear about all the great data that is coming
3 from AHLTA, it is not going to look like this
4 whenever you are trying to run your queries, but
5 this is the same result. What we did was we took
6 different fields there on top. Say, you want to
7 know a clinic name, the diagnoses that were given
8 at that clinic within a time period, and how many.
9 Then your conditions are: I only want it for
10 Naval Medical Center/Portsmouth Family Medicine.
11 We ran the query, and we got it back. Number one
12 diagnosis is normal pelvic exam, about 900 of them
13 in our time period. It is just diagnosis coding.
14 Everybody can do that now. You can pull diagnoses
15 and see what the most common one is. The business
16 guys that we were talking to said, we want to know
17 what the beneficiary category is, like who is
18 being seen where. So, we did a query from the
19 first medical group where I used to work, and you
20 can see on the third line down, 13 percent of the
21 resources at Langley First Medical Group were
22 going to family members from the Navy. There are

1 Navy dependents being seen there. Now, the
2 business guys can fight over resources. In
3 talking to a group of OBs at a conference I was
4 at, I said, what would be cool to look for that
5 you can't do with a paper chart? One guy said, I
6 want to know all my patients, I want to know
7 everybody in the population who has an AFP and is
8 on Valproic Acid for high risk of neural tube
9 defect. Okay, so we ran the query: Who has had
10 an AFP -- 38,000 people in the time period we were
11 looking at. How many are on Valproic Acid -- 317.
12 Then with the click of a button, you can cross
13 those, as opposed to going down lists or looking
14 at it some other way -- 4. You can find those 4
15 people, and say, are you still taking your
16 Valproic Acid? You need to stop. Getting into
17 why the templates were used, I showed you the
18 templates and said we recommend things that folks
19 do. We can look at a group who had a central
20 hypertension. What were the questions asked of
21 people who had a diagnosis of a central
22 hypertension in their encounter? We ran a query

1 over the time period. Number one was chest pain.
2 You see cough down here at 1,500. So more
3 important than whether or not it was asked,
4 although that is important, you figure out why it
5 is important. You can have a group, like in
6 Saudi, and you say, we want to monitor this group
7 for GI symptoms to make sure the water is not
8 contaminated or whatever. We have five symptoms
9 that we want asked of every patient that comes
10 through the medical clinic. You can actually look
11 and see whether or not they are even asking the
12 questions because that is all it shows you. Was
13 it asked? The next question, was it positive? We
14 see the fourth going down is cough, 333 times for
15 hypertension cough. That was a complaint or was a
16 complaint or a symptom that was found. Are you
17 giving out too many ACE inhibitors? I don't know,
18 but it shows you how the data can be used for
19 these interesting queries. Say, you had a
20 syndrome that you were worried about, this was an
21 interesting one we brought up. Eighteen months
22 ago, you had a group of soldiers or sailors or

1 airmen somewhere, and you say, we are starting to
2 think there may have been something wrong there.
3 It might have been a syndrome, and we are worried
4 about these three symptoms. We want to know who.
5 You can do it this way. You can say: I want to
6 know everybody from that region that had at least
7 one of these three, any one of them. Or you can
8 say: I only want to know people who had all
9 three. It will pull back that information that
10 will give you, well, we call it a unit number
11 here. This is just the identified stuff. That
12 could be anything. That could be where they
13 currently are, any demographic you want. Eighteen
14 months ago, that group of Service folks, they are
15 now out of the Service, PCSed, moved all over the
16 place. Chasing their charts down would be a
17 nightmare to find out what kind of syndrome might
18 have been going on. But with this kind of data,
19 you could pull that in a relatively short period
20 of time. Now, this was an interesting one,
21 culture positive TB. We did this one on just
22 Langley and Seymour Johnson. We said, how many

1 positive TBs have there been? We ran the thing.
2 It said nine. How many in that same time period
3 received appropriate therapy -- four. You have
4 about five folks out there, running around, who
5 were either reservists in and out, or got their
6 prescription at a civilian pharmacy which is
7 perfectly fine. But I think we want to know.
8 Basically, for that small group, you can now go
9 out and see what is going on with the population.
10 There is this much TB. Well, has it been treated?
11 You just took it from nine down to five. It
12 seemed like useful information. That is the end
13 of the little games we were playing with data from
14 the CDM. Yes, sir, you have a question? I am
15 happy to take questions after that performance.

16 DR. POLAND: Col. Brumage, did you have
17 a comment?

18 COL. BRUMAGE: Yes, thank you. I want
19 to preface my statements here by saying that I
20 truly think AHLTA will be the wave of the future,
21 but in its current form, it has a number of
22 drawbacks. We are actually right now working with

1 AHLTA to create a template to be able to have a
2 Pandemic Influenza Tracking Database, using some
3 of the functionality that you just showed here.
4 It was mentioned before, that symptoms were able
5 to be queried, but that functionality does not yet
6 exist in AHLTA, and we have looked at that.
7 Recently, you had the 838 local cache upgrade to
8 the system, but it is still a very slow system,
9 and it has degraded the efficiency with which we
10 can see patients. I think what has to always be
11 remembered, too, is that the patient-physician
12 interaction depends on you looking and talking to
13 patients, and looking at their nonverbal cues and
14 being able to talk to them, whereas right now, a
15 lot of the attention is being paid to the
16 computer, unfortunately. I think it has degraded
17 the efficiency and effectiveness of that
18 patient-physician interaction. The original
19 purpose of AHLTA, from my understanding, its
20 original charter was to enhance medical readiness
21 among our active duty troops, and I don't think
22 that functionality exists yet, but I do think it

1 is the way to go in the future. You are right;
2 there is a steep learning curve with using the
3 system, but it is still too slow for practical
4 use. In fact, the five-minute visit is just not a
5 practicality. We have had to double the length of
6 visits, just to accommodate the use of AHLTA.

7 DR. POLAND: Let me ask Col. Gibson to
8 make comments, and then you can respond.

9 COL. GIBSON: I want to follow on a bit
10 with that. I just wonder how you respond to this
11 issue of acceptability. This comment that he just
12 made, I have heard from several clinicians so far
13 in demo sights and training where,
14 philosophically, they feel like they are treating
15 the computer rather than the patient. In addition
16 to that, because this becomes such an easy thing
17 to note, as you said, documenting that they asked
18 about cough, etcetera, I would rather, I guess I
19 don't take exception. I want to clarify. What
20 you have is documentation of cough; you don't
21 necessary know that the provider actually asked
22 the question about cough.

1 DR. HAMRA: Well, that is an ethical
2 issue.

3 COL. GIBSON: Yes, well, it is ethical,
4 but we have seen this before on the technician
5 side, in particular with the Post-Deployment
6 Health Clinical Practice Guideline, where it gets
7 checked that, no, this person is not here today
8 because of a deployment, and in fact, the question
9 was never asked on the technician side. I am not
10 getting into the ethics. I am just concerned
11 about the ease at which this happens. I am real
12 concerned. I am really interested in how you
13 would respond to the provider who says, I am
14 treating the computer; I am not treating the
15 patient.

16 DR. HAMRA: Yes, I will. I don't in my
17 mind, and maybe I am wrong, but I don't see the
18 difference between a pencil stroke and a key
19 stroke that is done incorrectly. If they are
20 going to check the box, and they didn't do it, or
21 they are going to hit the key saying yes, and they
22 didn't do it, I just don't see the difference.

1 But, with regard to that, it is true. I mean,
2 think about it. That is what I expected whenever
3 I got the system. I knew that I was going to have
4 to refocus because you are able to write in the
5 chart without thinking about the chart. Now, we
6 have this whole new business process, and you are
7 going to have to focus on it instead of the
8 patient, and it is hard at first. I am not sure
9 everybody can do it. I don't know. Maybe I
10 shouldn't say that. A lot of people have, the
11 silent majority, actually. We have the
12 information to prove it. I know people have
13 difficulty, and it takes some people longer than
14 others to get over it, to get that muscle memory
15 down, so that you know how to run a mouse and a
16 keyboard rather than write in a chart. The other
17 really hard part for me was the fact that it
18 didn't do things in the order that I was used to
19 doing them. And so, it is a risk-benefit ratio.
20 If I wanted the advantages of having an electronic
21 medical record, if I wanted to have that patient's
22 chart there all the time, then yes, it trained me

1 a little. You say, well, I shouldn't have to be
2 trained by this system. Everybody does. In the
3 civilian world, they realize it is a 20-80, that
4 20 percent of your business practices are going to
5 change when you adopt an EMR, based on some of the
6 stuff I have read. It is hard for docs to do that
7 kind of thing. But, you know, when I was sitting
8 there at Langley at 6:00, and I had a TCON to
9 answer, and all it said was please call patient,
10 and no chart, and the rec room is locked, I really
11 liked this. I could read my last note. I didn't
12 have to call the patient and go: "Yes, Ms. Jones,
13 this is Dr. Hamra. What did we do the other day?"
14 I hated that. There are advantages, and you get
15 over the pain.

16 DR. POLAND: Dr. Lauder and then Col.
17 Snedecor.

18 MAJ. DO: I think he brought up a
19 question or a comment about are we documenting
20 things that are not there? There are actually
21 studies that take a look at providers. They
22 videotape an encounter and then compare how much

1 of it are we documenting down. Without the
2 structured note, it is a mere fraction. Even with
3 the structured data, we are capturing more than
4 what we do, but still that is only a fraction of
5 that encounter that we actually do. I think, with
6 the system, we are doing better than without it.

7 DR. LAUDER: I am not trying to defend
8 this system because I don't know anything about it
9 and I have never used it, but I will say from
10 being a clinician and having worked in seven
11 different institutions that have all used
12 automated record systems, this same argument
13 happens in every institution, civilian included.
14 The same complaints: We can't look at the
15 patient; we can't pay attention to the patient.
16 And once everybody gets used to it, it becomes the
17 way you practice medicine. So, there are always,
18 I think, things that need to be worked out, but I
19 would agree that it is the way of the future.
20 There are just plain old some physicians that will
21 not adopt it, even in civilian institutions.

22 DR. POLAND: Yes, I might make a comment

1 about that. We have gone through this extensively
2 at my institution, and there are a couple of
3 interesting things. It turns out that this is,
4 for the most part, really a process of once you
5 build the database, taking it into a usability
6 lab, and looking at how users do it, and
7 reengineering based on that information, then a
8 set of validation studies. Then what we did is we
9 brought in a company called IDO. They are a
10 company built around innovation and realized the
11 solution to some of these issues is engineering.
12 It is real estate on the screen. It is where the
13 screen is positioned. Is it on a table or built
14 into a desk? And those are things that you can
15 take advantage of and pattern after the way health
16 care workers are already trained to do rather than
17 get them to adapt to something because it is off
18 the shelf technology. So, there are ways to
19 overcome this. I suspect nobody argues with the
20 utility of an EMR. It is how it is introduced and
21 how much usability and validation and innovation
22 is brought to the process of it. Let us sort of

1 move off that topic and on to the issues regarding
2 the actual database. Yes?

3 COL. SNEDECOR: I just want to comment.
4 At the Tricare Conference, Dr. Winkenwerder very
5 clearly said, we are past the point of no return.
6 We are going to use this. So, all the issues of:
7 Hey, it is too slow, it is too this, it is too
8 that -- well, we just have to deal with it and
9 move on. Our SG said the same thing at our
10 breakout. He said: Get beyond that. Stop
11 complaining about things you can't change. Let us
12 start moving forward. We are going to have to use
13 this. Let us just use it. I would comment that
14 there is some trouble in doing analysis on whether
15 a question was asked when you clearly have an auto
16 negative populate button, which only means that
17 they clicked one button and then all of the
18 questions became negative. You really don't know
19 if they asked that or not, especially when it is
20 so easy to just hit one button and everything goes
21 negative.

22 COL. UNDERWOOD: Thanks. I have a

1 question for the presenters, whether or not they
2 are looking at voice recognition methodology and
3 technology for populating these fields. Can you
4 comment on that?

5 DR. HAMRA: The answer is yes, we are
6 looking at that. NUANCE was at the Tricare
7 Conference and has recently changed some of its
8 functionality and has traction within Health
9 Affairs to look at that particular application.

10 MAJ. DO: There are several different
11 pilot studies that we are looking at right now.
12 Again, the structured data, for a lot of people it
13 is kind of unnatural, but it may not be express
14 enough to capture all the nuances and the
15 subtleties of what is in the clinical notes.
16 There will be a pilot project to take a look at if
17 we can preserve that and yet have some sort of
18 natural language and process beneath it. How much
19 data do we need to capture? We still need to kind
20 of look at that to still preserve that text, but
21 underneath it, capture some more structure,
22 something that we need to retain.

1 DR. HAMRA: I like the study because, if
2 it doesn't capture all the nuances of a note, then
3 maybe it needs to be improved upon, the content.

4 MAJ. DO: That is probably really more
5 important in the legal community when you have to
6 go back in a record to take a look.

7 DR. SHAMOO: Who has access to this
8 data?

9 DR. HAMRA: Nobody right now.

10 DR. SHAMOO: I mean later on. How are
11 you going to design a system by which you are
12 going to protect the confidentiality of that data
13 because it is going to be all over the Country?

14 DR. HAMRA: Those would be policy
15 questions, sir. I am a designer.

16 COL. SNEDECOR: That is already
17 addressed with the data mart we have right now.
18 There are very strict processes for who gets
19 access on what level, and I am sure that those
20 will be applied to this data mart as well.

21 DR. HAMRA: I should have said that
22 earlier. I apologize. The information that we

1 are looking at was completely de-identified. That
2 is why all you saw were numbers in those columns.

3 SPEAKER: (off mike)

4 DR. HAMRA: None of that was real.

5 SPEAKER: (off mike)

6 DR. HAMRA: Right, it was randomly
7 thrown in there, but it was set up to keep all the
8 data in place. All that was de-identified, I am
9 told.

10 DR. POLAND: Dr. Hachey, and then we
11 will get around to everybody.

12 LTC. HACHEY: Just to reinforce what
13 Col. Brumage had mentioned, one of the gaps that
14 we have as far as pandemic planning is we have all
15 of this preparation stuff that we are working on,
16 but when the pandemic actually comes, we really
17 don't have a good way of knowing in real-time what
18 works and what doesn't. Using a pandemic order
19 set like Col. Brumage is working on, we can
20 hopefully track, in at least near real-time, what
21 interventions are effective. Is a mask much
22 better than Tamiflu? Or is handwashing, is that

1 the magic bullet, or whatever? So, hopefully, if
2 it is constructed appropriately, we will be able
3 to track interventions with outcomes and get more
4 real-time data rather than waiting until the
5 pandemic is done and gone, and then say, oh, gee,
6 we coulda, shoulda.

7 DR. POLAND: Capt. Johnston?

8 CAPT. JOHNSTON: The system is quite a
9 lot. One of the enormous advantages of it is you
10 can actually measure how well people are complying
11 with things like chronic disease management,
12 hypertension. You can actually monitor it, and
13 that actually improves clinical management of
14 patients. There is, also, I have used the search
15 tools in a clinical scenario to look at everybody.
16 I was amazed at the number of people. For
17 example, we did a search on the number of people
18 who had hypertension measured during a routine
19 medical but had never been followed up. We
20 actually found that out by simply doing a search,
21 getting it to look through all the blood pressure
22 measurements and cross-checking to make sure they

1 had been followed up. We found quite a number of
2 patients in whom it just hadn't been noticed in
3 the process of a routine medical. I think that
4 sort of thing is what this system can empower you
5 to do.

6 COL. GIBSON: A quick question,
7 denominators, tying this to DEERS data, is it
8 within the data mart, the capability to get at
9 denominator data, so you can look at the
10 percentage of folks enrolled at this facility
11 between 17 and 24 years old, females who have had
12 a pap smear in the last year?

13 DR. HAMRA: Yes.

14 COL. GIBSON: Thank you.

15 DR. HAMRA: Our time is up, sir. We can
16 be excused.

17 LCDR. LUKE: Let me just ask, is it
18 acceptable to have a better system if it is a
19 slower system? That is what I want to hear from
20 Health Affairs because, in talking to the
21 clinicians that are my peers, this is costing
22 patient interaction time, and it is taking longer.

1 So, I just want to hear a very firm statement.
2 Hypothetically, would it be okay to see fewer
3 patients if you are using this system?

4 DR. HAMRA: No, I don't think so.

5 LCDR. LUKE: All right.

6 DR. HAMRA: But my question was this,
7 real quick, when you say it is slower, in what
8 way?

9 LCDR. LUKE: I am not saying it is
10 slower. It is when I talk to people, they tell me
11 it is slower.

12 DR. HAMRA: It helps, if folks when they
13 say, it is slower, if they determine whether or
14 not it is a connectivity issue or that they mean
15 they can't use the system because of structured
16 text or because they don't know how to type.

17 LCDR. LUKE: It is irrelevant from the
18 clinical standpoint.

19 DR. HAMRA: I understand, but not from
20 fixing the problem standpoint.

21 DR. POLAND: Okay, I am going to cut
22 this because the Board can't do anything about

1 that specific issue, and move on. Thank you. Our
2 next speaker is one of our own Board Members -- I
3 almost said Col. Parkinson -- Dr. Parkinson, who
4 will present on NASA Employee Health
5 Reengineering. Dr. Parkinson participated in an
6 IOM review of NASA, and the findings of that
7 review have important implications to a number of
8 issues that this Board has dealt with in the past
9 years. It also would be a nice segue, I think,
10 into the briefing following his on Preventive
11 Health Assessment Policy. Mike?

12 Thank you very much and good morning,
13 everyone. I just ripped out of my book the
14 Mission Statement of the AFEB which, again not to
15 remind this group, but it is "to maximize the
16 health, safety, and effectiveness of the United
17 States Armed Forces." I was privileged to be part
18 of a nearly two-year long effort, commissioned by
19 the Administrator of NASA, to do the same thing
20 for NASA. That is: We are a big organization.
21 We have 70,000 employees, 75 percent of which are
22 contractors. We spend a lot of money on health

1 care. We spend a lot of money on wellness. We
2 spend a lot of money on occupational medicine.
3 And we don't really know if we are maximizing the
4 health, safety, and effectiveness of NASA. We
5 would like a bunch of experts to come in through
6 this group called the IOM to help us determine how
7 we should do better. First of all, I applaud the
8 leadership of NASA for doing this, but as I
9 thought about it, now that I am on the Board, it
10 has huge implications not only for DOD but for the
11 company I work in, for the Fortune 100 companies,
12 and for every university that many of you work
13 for. That is, how do we become a high performing
14 organization, using what we know to be the science
15 of health promotion, disease prevention, and best
16 practice organization? So, today, what I am going
17 to give you is a very high level interview, mainly
18 for information, not for decision making, but for
19 you, if interested, to take back to your
20 organization and become an advocate for what is an
21 evidence-based approach to creating a high
22 performing organization. I will say at the

1 outset, conflict of interest, I do have a copy of
2 the actual report. It was produced by the
3 Institute of Medicine. My colleague, Col. Rick
4 Erdtmann, does get a little kickback for every
5 single edition that is sold. He is now at the
6 IOM. So, we will be helping Rick along here to
7 get a little better suit by selling one of these
8 books. Thank you, Col. Erdtmann, we appreciate
9 it. Tell your boss, the jacket is very nice. I
10 appreciate that. Let us have a little fun with
11 this. Very interesting, I put down the web site
12 if you want to download the information. The
13 report itself only costs \$24. It is well worth
14 the effort. I am not pushing it, but in one place
15 we have compiled probably 20 years worth of data
16 on: What is the evidence that you can improve
17 health and relate that to the bottom line of
18 companies? There has been a lot of rhetoric
19 around this issue for the better part of two
20 decades. This, in one place, brings together all
21 the evidence and 15 high level recommendations
22 which we would recommend be used by any

1 corporation, any organization in the Country. The
2 NASA Administrator was very generous with our
3 time. We, essentially, told him we wanted a
4 blueprint that, while it was for NASA, we could
5 apply it to any organization. He said,
6 absolutely, much of what we do at NASA is to take
7 things that we develop for space, and they are
8 civilianized. There is no reason why we shouldn't
9 use this template in much the same way. So, the
10 charge to the Committee was to review the existing
11 Preventive Health Programs. Why is it employees
12 don't use these programs? We have fitness
13 centers, and 3 percent of our people use them.
14 What are the things unique to the NASA environment
15 that maybe don't exist for IBM? How can you get
16 participation? What is the evidence that it
17 works? What is the roadmap to help us achieve a
18 highly performing workforce at a time when we are
19 downsizing, outsourcing, rightsizing, and have
20 more and more pressures 24-7 to have a healthy and
21 productive workforce? The core values at NASA,
22 not surprisingly, are very close to the core

1 values of the Military. Safety first, no doubt
2 colored by some of the recent experiences with the
3 shuttles. It is about our people, excellence, and
4 integrity. As you will see later, the core
5 values, though, get buried in the Mission
6 Statement somewhere, and you couldn't get to a
7 line manager who could articulate how his or her
8 job directly related to the core values of the
9 organization, a key first recommendation that you
10 will hear later. The same engineering culture
11 that has produced us putting a man on the moon
12 also has some downsides. NASA is predominantly an
13 engineering culture. If you can measure it, you
14 can improve it, Six Sigma. But it is not
15 necessarily a culture that leads to the warm and
16 fuzzy types of things that we might need to have a
17 highly performing workforce. Whatever culture is
18 in the organization, we have to notice that all
19 the things that it does well, it also probably
20 creates additional challenges, that cultural trait
21 in organizational ethos creates in the workforce.
22 They have led many of the areas in preventive

1 medicine and occupational health that those of you
2 with a background in our fields recognize. NASA
3 is organized almost like bases in the Military,
4 fourteen centers located around the Country. We
5 visited about 10 of them with in-depth two to
6 three day site visits, focus group interviews,
7 talking to the commander, the center director --
8 many of whom were former Military by the way -- to
9 get a feel for what went on there. In the culture
10 of safety, they said it is not good enough for us
11 to believe that we are safe; we want outside
12 certification. So, the VPP Star Certification
13 that they are very, very proud of and wear on
14 their sleeves is something that they show to the
15 world that we have been able to take civilian
16 standards and apply them to things that we know to
17 be important in the safety culture. We are going
18 to create a communication tool with a web site,
19 but like many web sites, it is very deep kind of
20 in the occupation health world. It is not really
21 accessed by line managers because it is not really
22 what we do. They didn't really see the relevance

1 to that. NASA has a very traditional
2 disease-focused approach rather than a health and
3 a population-based approach. Any one of America's
4 corporations, and I deal with them regularly now
5 for five years, have exactly the same things.
6 They are very concerned about controlling their
7 health care costs but have no indication
8 whatsoever that health care costs represent
9 anywhere from 30 to 50 percent of their total loss
10 productivity costs. NASA, when we talked to the
11 line managers, it was, how can we look at our
12 medical costs? By the way, FEHPP does not report
13 individual claims data to the various agencies
14 that use FEHPP. So, when you try to do what in
15 the civilian sector is being done all the time --
16 which is to disaggregate my health care costs down
17 to plant locations, so that I can become more
18 knowledgeable at a population basis about the
19 things we need to do to improve health and reduce
20 risk factors -- it is in a black hole in FEHPP.
21 So, NASA doesn't get that information, and they
22 certainly can't disaggregate it to the Johnson

1 Space Center or, for that matter, AIMS or Goddard
2 right down the street. The primary findings were
3 really pretty simple. Again, put your company or
4 your university in here. While there was an
5 Occupational Health Mission Statement that was
6 talking about the occupational health of NASA
7 employees, it was absolutely unlinked to the core
8 Mission Statement of the organization. By
9 studying best practice companies that have
10 implemented a majority or even part of what we are
11 talking about here, unless and until the health
12 and productivity of employees is in the core
13 Mission Statement of the company, it does not get
14 the institutional and managerial attention it
15 deserves. So, if you have got a good occupational
16 health program that is sitting still as a
17 stovepipe and it is not directly linked to the
18 bottom line productivity or performance or EPS of
19 the company, you are missing the leverage to move
20 forward as a successful company or organization.
21 The next thing is that the needs of the modern
22 knowledge base workforce are well beyond those in

1 traditional occupation medicine which is
2 characterized by: What are the things we must do
3 under OSHA, and what are the things we need to do
4 in terms of periodic health examinations and
5 risk-specific environments, which is very much out
6 of what? The safety and engineering culture. The
7 24-7, 365-day year, global communications that
8 were run are absolutely different from the
9 traditional occupational medicine backgrounds that
10 many of us were trained in. What is a healthy
11 workforce? Does every manager in your
12 organization know and understand that there are at
13 least four facets as to whether or not you have a
14 high performing worker or colleague? Healthy, I
15 can demonstrate that I have got the lowest
16 potential for immitigable risk factors, and it is
17 demonstrated year over year, and that I am
18 reducing risk factors over time. This is Dee
19 Ettington's work. Dee was one of the panelists
20 that worked with us. I have minimal illnesses,
21 disease, and injuries, the presentation we just
22 heard. How can I know at Langley Air Force Base,

1 that I have the minimal number of preventable
2 disease, injuries, illnesses, and deaths based on
3 the science? I should be able to know that down
4 to the unit level at NASA. How do I know that
5 someone at work is productive, not just present,
6 but they are actually high performing, and how
7 does that vary across the various disciplines in
8 my organization? So, at Bank One, if you are a
9 teller, it is very different than somebody who is
10 a manager. How do you know that a person present
11 at their desk, or for that matter working from
12 home, is a productive worker as opposed to a
13 present worker? Are they ready for the myriad of
14 challenges that are going to happen rapidly, and
15 they are going to happen more and more? Don't say
16 that you can run away from a 24-7 environment.
17 You have to be able to demonstrate and test, if
18 you will. You talked about the laboratory, Greg.
19 What are the ways we test the readiness of our
20 employees in all of our organizations at NASA or,
21 for that matter, at IBM or Intel? Then, finally,
22 we have got to be resilient. There will be

1 setbacks. How can we measure the resiliency,
2 bending but not breaking, when these things
3 happen? NASA, not surprisingly, is under
4 tremendous pressure to launch. It is under
5 tremendous pressure to make sure there is safety
6 beyond any reasonable engineering grounds of
7 safety to do what they have to do. How can we
8 make sure that we have all four of those aspects?
9 And we should be able to measure them as to where
10 we are, where we need to be, and where we are
11 getting there incrementally. If you look at this
12 grid, essentially, NASA and 99.9 percent of all of
13 our organizations are in the middle column, that
14 is, we measure whether or not Fred is at work. We
15 sometimes know how much money we spend per
16 employee per year last year on medical costs. We
17 certainly want to know about treatment and
18 evidence-based medicine. It is on an individual,
19 not population, basis. We talk about diseases and
20 not health. We tend to talk about risk factors
21 one by one, and we know that they don't travel one
22 by one; they travel in groups. We typically are

1 focused around the employer rather than the
2 employee. The employee lives their lives 24-7.
3 How do we look down, if you will, the longitudinal
4 aspect of Mike Parkinson as an employee rather
5 than the fact that he has a benefit, he has a
6 paycheck, and he has a medical benefit? We are
7 not taking the right perspective. Finally, we
8 certainly all suffer from segregated programs --
9 does this sound familiar in DOD -- as opposed to
10 an integrated system that really takes that
11 employee-centric approach. If we can move all of
12 our organizations over time from the current state
13 to the desired state, this was the goal of the
14 project. How do you move that organization with
15 15 recommendations towards the desired state?
16 This is an old and one of my favorite slides that
17 appears in the book, but we used it a lot in the
18 Air Force Surgeon General's Office to say that
19 that determinants of health are not medical. Very
20 little of medical care is determined by
21 traditional medical needs. All the things that
22 Stoddard talked about in 1994, now 12 years ago,

1 we keep learning again and again. Many of those
2 determinants of health and medical care are not at
3 all in the medical care system. They live in the
4 employer; they live in the community; they live in
5 the family; they live in the churches; they live
6 in our policies. If you just wanted to find
7 medical care costs as whether or not we do
8 evidence-based medicine with EMRS, we would miss
9 probably 70 percent of all health care costs and
10 all the attendant reduced productivity and
11 performance. I happen to like this slide because
12 this is how a lot of people make their living in
13 the outside world with stovepipe benefits. You
14 can see that, essentially, the challenge of having
15 an integrated health and productivity improvement
16 model is to take all of the disaggregated
17 stovepiped benefits, all of which absorb a
18 tremendous amount of resources after, typically
19 for every employer including NASA, the number one
20 cost is personnel. How do you begin to take a
21 longitudinal approach that looks at an integrated
22 approach to all of these things in a practical way

1 to help managers be able to do it? That really is
2 the challenge. First, you have got to get a clear
3 vision of what your organization needs to do.
4 Does your organization understand its mission?
5 Big question. We got very differing statements
6 from various managers at NASA as to what they
7 thought their mission was. So, the first thing is
8 do a vision gut-check and a mission gut-check, if
9 you will, for the organization. Job one in NASA
10 starts with the NASA Administrator. The NASA
11 Administrator and the Leadership Team need to
12 adopt a new vision for worker health, readiness,
13 and resilience -- notice those readiness and
14 resilience words -- that directly links to NASA's
15 mission, not the occupational medicine
16 directorate, not the chief medical officer's
17 mission, and include health as a core NASA value.
18 Only if you include health either in the Mission
19 Statement or as a core value will it get the level
20 of urgency it needs in the organization to make
21 sure that it improves over time. That is from
22 best benchmark companies. It is not consensus

1 opinion. It is from companies that actually do
2 it. They move it up the pecking order and chain,
3 so that they actually have to measure it, improve
4 it, incentivize it, and reward it. You have got
5 to then be able to say why a healthy workforce, in
6 direct verbs and terms, helps your organization
7 achieve that core mission on time, under budget,
8 and better than expected. You have got to be able
9 to demonstrate to the CFO and all the line
10 managers that it matters. This resonates very
11 well in an engineering culture like NASA. Don't
12 give me the fluffy stuff; give me the data. Then
13 you have to begin to build the data around that
14 healthy and resilient workforce to show that it
15 relates to the achievement of the earnings per
16 share. The next thing you have to do is take that
17 vision and put it into things that we in the
18 Military know very well. If it ain't in the
19 budget, if it ain't in the POM, policy,
20 programming, budgeting, implementation, ops,
21 evaluation, and management, it will last as long
22 as one person's influence in the organization.

1 NASA recently was going through a drill to do what
2 is called full cost accounting, meaning for every
3 major function, what is the total end to end cost?
4 You need to develop, essentially, what we used to
5 call in the Air Force, a human weapons systems
6 which is called our Air Force Personnel. What is
7 the full cost accounting for a healthy, productive
8 NASA employee, either a full time civil servant or
9 a contractor? You have got to be able to put it
10 in the planning, programming, budgeting process if
11 you are going to be able to manage it and approve
12 it. You have got to educate, educate, educate.
13 NASA managers at the line level have to own this
14 program. Very interesting focus group, we had so
15 much fun. I love engineers, a 55-year-old
16 engineer. One of our colleagues was doing a small
17 focus group at the Johnson Space Center about why
18 and how and were they aware of health and
19 productivity and the use of the fitness center.
20 She was urging him, and he just wasn't
21 participating very much, and finally said to him:
22 Well, Joe, what would happen to you because you

1 are not doing all the right things for your
2 health? If you came in one day and at your
3 console, you literally dropped to the console and
4 were dead as a doornail? He looked kind of
5 honestly at her and he said: Well, at NASA, we
6 have a word for that. It is called End Career
7 Progression for NASA Engineers. People there are
8 there forever, and it was kind of a
9 tongue-in-cheek approach, but you have to begin to
10 get on their terms to say to the NASA manager why
11 it is important to their bottom line and whatever
12 they define to be the productivity measure for
13 their particular unit. Obviously, effective
14 coordinated data-driven health programming policy
15 is what we talk about here all the time, but it
16 has got to be linked to that core mission. This
17 is a busy slide. I will leave it with you in the
18 book, but this is what Dee Ettington, who has been
19 studying large organizations like GM for 25 years
20 or more, has said. It is, integrated employee
21 total health management begins with, first, a
22 health risk appraisal. That is why it is so

1 important. In my current company, it is why we
2 pay people \$100 to do it. You have got to be able
3 to have then, acting on that information, an
4 integrated approach across all those stovepipe
5 benefits I showed you in an earlier spiderweb
6 diagram, to have an integrated way to improve it.
7 Let us quit fighting about which HRA is better. I
8 refuse to sit in any more of those meetings. HRAs
9 are HRAs to my read. By and large, if four or
10 five risk factors predict 70 percent of premature
11 death, illness, and injury, let us get on with
12 identifying and improving them. That was pretty
13 much the NASA Administrator because they, too,
14 were in the battle of the warring centers. AIMES
15 thought an HRA was better than the one they had
16 compared to the one at Johnson Space Center. They
17 were deep into the weeds of deploying technology,
18 and they did not have a business practice to
19 deploy it on, and they really weren't sure why
20 they wanted to have an EMR except the fact that
21 they needed an EMR. The next thing is what you
22 have to be able to do, once you identify people

1 with risk, is you have to have standardized common
2 risk-reduction programs across all 14 centers. If
3 you have to have it for those 3 or 4 for tobacco,
4 weight management, physical fitness and activity,
5 stress reduction, they should look pretty much the
6 same because they are our best practices for those
7 across all 14 centers. The one-off programs you
8 can't afford in a big organization that is
9 stressed for resources. Stand down your periodic
10 health examinations or at least cut them way back.
11 I will put on my old Military hat. We are
12 periodic health exam crazy. If you go into any of
13 our facilities, we do them all the time for a
14 variety of different reasons. We found it all
15 over NASA. More is better. Let us get everybody
16 in here and do it, and we are not really quite
17 sure what to do. Unless we can tie those periodic
18 health examination programs to an integrated risk
19 factor reduction program with data that feeds into
20 program evaluation and improvement, there really
21 is no reason to spend more money on health
22 examinations. Your data management is used for

1 four functions. I will give the credit here to
2 Nico Pronk (?) out of Health Partners in
3 Minnesota. You have to be able to have that data
4 for decision making, accountability, quality
5 improvement, and surveillance in longitudinal
6 analysis. That is true whether or not you have a
7 company with 300 employees like mine, or you have
8 a company of 170,000 like Northrop Grumman. Data
9 management, again, you are going to see some of
10 this in the Trainee Health Surveillance
11 Recommendation coming forward, but the data
12 collection, management, and reporting has got to
13 be standardized -- protocols, standards,
14 consistent data practices across all NASA centers
15 and longitudinal tracking over time. It is the
16 only way we know we are improving. A nice
17 framework, if you hadn't seen this -- I had not --
18 it is actually from the American College of Sports
19 Medicine, that talks about data in three different
20 kinds: Personal health management, what people
21 traditionally get from a health plan or their
22 payor, and population health management. You will

1 begin to see in a typical organization, including
2 DOD and including any of our other organizations,
3 there are data elements that live all across our
4 enterprises that are not integrated around that
5 line of sight, around the employee. To the degree
6 you can pull together some of these selected
7 elements and create a data profile, you can really
8 improve in very short time evidence-based
9 improvement programs to be able to get to health
10 and productivity maximization in your
11 organization. Of course, NASA, which does
12 research all the time should look at the 70,000
13 employees as a primary source of: How do we
14 improve our health and productivity from the data
15 that we generate ourselves? This, again, is
16 something that we try to do with the DOD. We do a
17 pretty good job of it. We could do a much better
18 job, I would say. If we get into the engineering
19 mindset, which is a core value of NASA, and the
20 health, fitness, productivity, and the readiness
21 of the troops, we can begin to use this type of
22 framework to increase that. The conclusions to

1 the NASA Administrator that you can make a major
2 improvement, using 15 recommendations to move
3 towards a healthier, more productive workforce.
4 Regardless of whether you are NASA or whether you
5 are any organization, the blueprint, the 15
6 recommendations -- it actually was chaired by a
7 colleague of Greg's at the University of Iowa, Dr.
8 Jim Merchant, who used to head NIOSH -- all of
9 this can lead to a healthy and productive
10 organization. In many cases, keep jobs in the
11 United States. In many cases, keep employment
12 period, because we are losing jobs dramatically.
13 My comments at the end, we have to move beyond
14 traditional medical costs to a total cost of
15 illness. Typically, what we find when we look at
16 the data is that the total cost of lost
17 productivity is one to three times greater than
18 the medical costs which are now consuming 16
19 percent of our GDP. It is absolutely huge, and it
20 is a huge iceberg that we typically don't track.
21 Ron Goetzel has done some excellent work when he
22 was at Medstat. He is now at Cornell. This is

1 1998 data. If for every single employee in 1998,
2 the total costs of benefits for that employee was
3 about \$10,000 -- that number is now about \$18,000
4 -- 50 percent of those benefits costs are the
5 medical care costs, but the other 50 percent are
6 things like turnover to train a new worker when
7 you lose one, absenteeism, presenteeism,
8 non-occupational disability, early return to work,
9 worker's comp. By a conservative estimate, by a
10 conservative estimate, 26 percent of those
11 dollars, 26 percent of \$18,000 for every employee
12 in the United States could be saved if we had a
13 modest integrated approach, using the IOM Report
14 as a guide, and that is modest, 26 percent.
15 Imagine how many jobs we could keep on shore if we
16 could get 26 percent more effective on \$18,000 a
17 year for a 70,000-person organization. No one has
18 done it. The challenge is big. But at least you
19 have a layout, both the vision and a blueprint to
20 get there. Back to the future. For those of you
21 who might remember an old Air Force slide, I
22 actually dusted this off. In 1998, when then Col.

1 Parkinson was working with some of my colleagues
2 here on the Board, we asked: Could we develop a
3 desktop model for our CEOs, which we called Wing
4 Commanders, to be able to look at for variable
5 inputs into their population at their base? If I
6 improve disease prevention, health promotion, if I
7 improve my care of diabetics, if I improve my
8 occupational health program, if I had the data
9 going in, and I differentially could put my
10 interventions, what would be the ROI to me, as a
11 Wing Commander, in terms of number of missions
12 flown, number of absenteeism days, a highly fit
13 and functional workforce? We went out and looked
14 at all civilian vendors in 1996 and 1997 and
15 actually tore apart their software because a lot
16 of individuals at that time were saying they had
17 the black box in the middle that could help you do
18 this. The report of this, for those of you who
19 remember, we called it EEpICAM because
20 epidemiology without economics is largely policy
21 irrelevant, I would argue, in most organizations.
22 You have to put it in dollar terms. What we found

1 was the software didn't really do what it said it
2 did because the data was not great enough in 1998
3 to say that, if you did this, I could lead there.
4 There was not enough RCT data or even case control
5 data, Grade II or Grade III evidence to use the
6 U.S. Preventive Services Task Force data to say
7 what worked. We are eight years later. There is
8 more data. But the Holy Grail is still out there.
9 I think the IOM Report can help us get there.
10 Implications for DOD? Our core values are very
11 similar to those of NASA -- integrity, service
12 before self, excellence in all we do. Those are
13 the Air Force's. All of our Services have it. We
14 have considerable inefficiencies of effort and
15 suboptimal deployment of resources. This program
16 could be used to inform those efforts, no matter
17 where we work. The challenge is considerable.
18 There are a lot of stovepipes. There are a lot of
19 egos. There are a lot of dollars. There are a
20 lot of invested political interests. But until or
21 unless we maximize something like this book, we
22 will leave at least 26 percent of the DOD budget

1 on the table -- it could be much, much more than
2 that -- not only to mention that but the fitness,
3 the productivity, and the performance of the
4 Services. Thank you for your attention, and
5 pursuant to any questions, I will say amen, and
6 pass the bullets. Dr. Poland?

7 (Applause)

8 DR. POLAND: I will say amen to what you
9 said. That was brilliant, wonderfully constructed
10 and said. Comments from the Board Members or
11 others?

12 COL. GIBSON: Thank you very much for
13 that briefing. I really enjoyed it. One question
14 comes with accessing the success of this sort of
15 innovative approach. I can see where even in the
16 face of a reengineering, an approach like this, in
17 the short term, productivity could in fact appear
18 to drop off. What I am getting at is under heavy
19 outside stresses, we can push people for a short
20 period of time to be highly productive, regardless
21 of improving their baseline health. How do you
22 assess this over time, or what do you think are

1 the proper timeframes after implementation of
2 something like this before you would measure
3 success?

4 DR. PARKINSON: I think what is
5 impressive to me is the dramatic return on
6 investment within three to six months. I think
7 that is a cop-out. This notion that it is too
8 hard to do because the payoff is two to three
9 years later is a very easy one. Tobacco cessation
10 policies, clinical tobacco cessations, the ROI is
11 within the first year, direct and indirect costs
12 to the employer and increasingly with data from
13 Kaiser, it is in the first year to the health
14 plan. No excuses, 20 percent of us smoke; get out
15 there; change your policies; get going. It is
16 leadership. What you begin to do is you start
17 with low hanging fruit of things that are both
18 clinically and shown to be effective in
19 productivity -- return to work policies. Do you
20 still have sick days in your organization as
21 opposed to just use your days in the organization?
22 Do you have disability management programs that

1 encourage and incentivize early return to work.
2 If you combine those all together, it is very,
3 very doable, Roger. So, I think that what we are
4 learning is it happens faster, it is quicker, and
5 it is more doable than perhaps we had been led to
6 believe in terms of 20-year long culture change.

7 DR. POLAND: Thank you, Mike, very much.
8 I am going to try to get us a little caught up
9 here. I will ask Ms. Lynn Pahlund -- I hope I say
10 it right -- from Health Affairs to provide an
11 update on DOD Preventive Health Assessment Policy.
12 I believe her slides are under Tab 9.

13 MS. PAHLAND: In addition to those
14 slides, you also have a copy of the policy, I was
15 told. Is that in your binder?

16 COL. GIBSON: It is in the back of Tab
17 9.

18 MS. PAHLAND: I am just going to briefly
19 speak on the fact that this policy that we are
20 going to discuss a little bit this morning is a
21 part of our DOD overall approach to assess and
22 intervene health status of individuals in

1 population along the Military life cycle
2 continuum. This is just one policy point. It is
3 an interim policy. We hope in the future to have
4 this embedded into a directive or an instruction,
5 but again, I want this to be viewed as just a part
6 of our overall approach to improving health status
7 in the Military. The policy was signed in
8 February, and it has been disseminated widely. My
9 telephone has been ringing off the hook. It is in
10 accordance with two of our very major directives.
11 One is our Health Promotion Directive, 1010.10,
12 and also in accordance with Force Health
13 Protection Directive, 6200.4. It is also in
14 accordance with the recommendations from this
15 body, September the 17th, 2002, when I brought a
16 question to you four years ago and asked for your
17 assistance in helping us to assess and intervene
18 in the health status of DOD individuals and
19 populations. We took all of your recommendations,
20 and they have been incorporated into this interim
21 policy. When someone comes into the Military, we
22 are asking in this interim policy that, as a part

1 of their medical approach into the Military
2 Service, they are given a Health Assessment Tool.
3 Now that tool has been called the HART. It is a
4 Health Assessment Review. In the past -- there
5 are a number of you in this room that are very
6 familiar with that instrument -- it used to be
7 called the RAP. I was involved in working with
8 Craig Hyams and the RAP maybe 7 or 10 years ago,
9 and now it is reemerging as another named tool.
10 The intent is to do what was embedded in the RAP
11 which is to give us that assessment of health
12 status, self-reported, as someone is coming into
13 Military Service, and then we are building this
14 process, so that we will be able to have this type
15 of information available at particular periodicity
16 across their service and then until we pass them
17 over to the VA. We are also asking that on an
18 annual basis, all service members are given an
19 assessment, and they will cover all of these
20 areas. We are trying to integrate self-reported
21 health status with a medical record review, and
22 also start pulling in those aspects of

1 occupational risks and exposures, and identify
2 health plans in the area of personal health, and
3 then also in occupation health; so that we can
4 assist the individual and provide the treatment
5 and health promotion programs for them; so that
6 they see health as something that they are dealing
7 on an almost day to day basis, and they are
8 becoming very aware of their own responsibilities
9 in the attainment and sustainment of their own
10 health status. This whole thing is being
11 developed so that the system is also assisting
12 this individual and populations in improving their
13 health status. We want the provider, of course,
14 to be very involved, but we are hoping that all
15 members of the health team are going to be
16 involved in helping individuals to assess and
17 improve their health status. The bottom line is
18 that the instrument, the HART instrument, is
19 available. We don't have all the pieces put
20 together yet of how we are going to deploy it.
21 The whole concept of doing a periodic health
22 assessment, again, should be embedded into costing

1 that already exists in the Services. We are not
2 asking the Services to see this as some separate
3 program. We are asking this to replace the
4 routine physical exam of every Friday at five
5 years or to replace what their existing
6 requirements are. If there are any kind of
7 concerns about implementation costs, we are asking
8 them to go to Tricare Management Activity to try
9 to identify how they can implement and stay on the
10 timeline, the aggressive timeline that we have
11 embedded into the policy. The Services are at
12 different places in the implementation of this
13 policy. The Air Force, I know, has been using
14 this concept for quite a while. The Navy is in
15 the process of rewriting their instructions, so
16 that they accommodate this interim policy. I have
17 been working with people in the Army who also are
18 looking at this to improve their way of assessing
19 medical health status. In the policy, it asks
20 that this be implemented within six months and
21 that they start reporting to different bodies
22 within the Department of Defense. I think it is

1 very important that we have this reporting
2 requirement in here because it will help the
3 Services identify where they are in
4 implementation, and it will help us identify areas
5 that might be causing problems and hopefully solve
6 those problems. Again, you all, I recognize quite
7 a few of you. A lot of you are very familiar with
8 the RAP, and you are very familiar with an
9 instrument we used to call the HEAR. This
10 concept, this instrument, this tool has been
11 around for quite a while, and we are having
12 difficulties in getting the IM/IT solution in
13 meeting Service needs for requirements that they
14 have to identify and intervene in health status,
15 to improve health status. We don't have this
16 completely implemented yet, nor do we have the
17 plan completed yet because the landscape, quite
18 frankly, keeps changing, but it is something that
19 we are working. As I said, the instrument is
20 available to the Services. We do want to make it
21 available to them online by March the 15th. We
22 don't have a full body of implementation

1 instructions for the HART, mainly because of the
2 IM/IT support considerations. As far as the PHA
3 program is concerned, we expect implementation by
4 all the Services by August the 1st. Again, as I
5 mentioned, we do require those reporting
6 capabilities from all the Services, so we get an
7 idea of how their implementation is going. In the
8 next step, we are in the process of trying to
9 complete an IM/IT implementation plan. This is
10 something that is not specific just to Health
11 Affairs or to the Service Medical Departments.
12 There are personnel issues. There are data
13 management issues. How do you access, store,
14 manage, and retrieve that information, so that it
15 is useful to the Services and useful to the
16 Department? So, that is where we are right now.
17 We have got the policy. The HART is an existing
18 viable tool. IM/IT is a question mark as to how
19 quickly we are going to be able to deploy it
20 fully. Are there any questions?

21 DR. POLAND: Questions? Mike?

22 DR. PARKINSON: Yes, thank you, Ms.

1 Pahland. This is a total force program or Active
2 Duty?

3 MS. PAHLAND: Active Duty and Selective
4 Reserves.

5 DR. PARKINSON: Just help me understand.
6 Selective Reserves, help me with Reserve and
7 Guard. Does it get used with Reserves and Guard
8 at all?

9 MS. PAHLAND: Does it what?

10 DR. PARKINSON: Does it get used with
11 Reserves and Guard?

12 MS. PAHLAND: Yes, it is going to.
13 Again, there are implementation issues, and there
14 are statements within the text in the body of the
15 interim policy that speak to the fact that if you
16 are covered by Tricare, what the process would be;
17 if you are not covered by Tricare, what the
18 process would be. So, the implementation aspect
19 to Reserves is a concern.

20 DR. PARKINSON: Right.

21 MS. PAHLAND: And this policy was built
22 with Service members. It took two and a half or

1 three years to develop this policy, and this was
2 built with a huge group of people from the
3 Services, and the Reserves were included in that.

4 DR. PARKINSON: I guess I am trying to
5 anticipate what has been going on for a decade,
6 and that is the delta between what will happen to
7 the Active Duty members and the Guard and
8 Reserves. I am just wondering, what is the
9 intent? Is the intent to make it uniform across
10 the Guard and Reserves? Is the intent to do it
11 less frequently with the Guard and Reserves? It
12 is premature to ask that.

13 MS. PAHLAND: We are asking for a health
14 status assessment on an annual basis. The HART
15 program itself has a huge number of questions. It
16 is almost too much to get into right now because
17 we don't have the final product. Right now, the
18 instrument exists, but who is going to use what
19 portions of those questions, that hasn't been
20 determined yet by the leadership in particular
21 organizations, but the HART as an instrument for
22 the Reserves will ask those questions. How do you

1 view your own health status? Do you smoke? Do
2 you use alcohol too much? There are core
3 questions that will definitely be used in the
4 Reserves. Those people for whom we have a
5 different allegiance and responsibility, the
6 questions will expand and contract as the Service
7 sees fit.

8 DR. PARKINSON: Thank you.

9 MAJ. KILIAN: It will be disparate
10 amongst the Reserves. They have to opt into the
11 Tricare Program as I recall. There is a Tricare
12 Program for Selective Reserves, and there is a
13 co-pay that goes with that, and that would cover
14 this one. The application across the Reserve
15 component force, National Guard, and the Reserve
16 Forces would be disparate.

17 COL. GIBSON: Dr. Brown?

18 DR. BROWN: Thanks. I work with Dr.
19 Hyams. He is going to ask me this question when I
20 go back. So, I want to just make sure I
21 understand this. It sounds like the HART is going
22 to do sort of multiple things. You are going to

1 use it to replace the function of the RAP, to
2 assess health of new recruits at accession, and
3 then you are going to use it, also the same
4 instrument throughout an individual's Military
5 care, is that correct?

6 MS. PAHLAND: That is correct.

7 DR. BROWN: When, as far as the part
8 that will fill the original concept behind the
9 RAP, that is to say to get the baseline data of a
10 new recruit, when will that be used? Because as I
11 recall, there was some discussion in previous
12 Board meetings about whether that would be the
13 MEPS or whatever before somebody actually shows up
14 to Boot Camp versus the original concept, I think,
15 was to use it literally at a new recruit's first
16 day when they show up at Boot Camp.

17 MS. PAHLAND: Right. Bruce Ruscio, you
18 can assist my answer on this one, but it is my
19 understanding that hasn't been completely
20 determined yet. I know Col. Ruscio is having a
21 lot of discussions with the MEPCOMS.

22 COL. RUSCIO: I can make two

1 verifications. The instrument is a varied
2 instrument. So, you have the HART-A, and you have
3 the HART-R. There is direct matching of the vast
4 majority of the questions across them, but there
5 are some differences as you would expect and would
6 be needed for accessions. That instrument is a
7 little bit different from the other one. I
8 briefed, I think last year, the AFEB along with
9 the MEPCOMS' Surgeon General. At that time, the
10 plan was to implement the HART-A at the MEPS
11 station after what is called inspect, so right
12 after the individual had raised his or her hand to
13 be in the Military. It was piggybacking onto
14 their automations process. What has happened, in
15 the meantime, is that the timeline on that
16 automation process has slipped significantly.
17 Given the policy implementation plan, we are now
18 relooking at the entry site for the HART-A. We
19 have had some emails and some discussion with the
20 folks in San Diego and the Air Force and the Army
21 on that.

22 MS. PAHLAND: Right, that has been the

1 problem all along. We have had the instruments.
2 I know Craig had the RAP, what was it, 10 or 12
3 years ago. On the HEAR, I started to work with
4 Maj. Jim Frazier (?), who is now a retired
5 Colonel, when I was at Region 1. So, the
6 instrument is alive and has been validated and is
7 acceptable. Again, there are many different
8 versions of it to meet Service needs or to meet
9 particular needs. The concept is that this group
10 of questions will exist, and there will be a
11 central data warehouse of this information, and it
12 can be viewed by these different groups, like
13 people that want to examine the medical problems
14 or strengths of people coming into the Military,
15 how long they stay, whatever, but to be able to
16 see someone before they enter the Military and
17 then all the way through to moving over to the VA.
18 This was my discomfort about giving a status
19 report on the HART program. We do have the PHA
20 policy which is a step in the right direction,
21 which again we have been trying to build for a
22 number of years. We have your recommendations and

1 your identification of the fact that we needed to
2 move along this trail back in 2002, but the IM/IT
3 pieces are a sticking wicket. In fact, on my way
4 up here, I was on the phone with one of the Deputy
5 Assistant Secretaries, with Dr. Tornberg, and we
6 were speaking to this exact issue because I didn't
7 want to make any kind of misstatement about where
8 we were on the implementation. There certainly is
9 leadership support of this. There certainly is
10 the existence of a viable tool. But the timeline
11 and the methodology of implementation is still
12 being developed. Hopefully, in the near future,
13 we will be able to give you something a little
14 more firm.

15 COL. GIBSON: Just before Dr. Parkinson
16 speaks, a quick point of clarification, more for
17 the transcriber than anybody else, HART stands for
18 Heath Assessment Reporting Tool, and then the
19 initial afterwards such as HART-A for accessions
20 is a point of clarification on the types of
21 different tools. Dr. Parkinson?

22 MS. PAHLAND: Right, and even further

1 clarification, there are about 10 different tools
2 that we are looking at. HART-A is the one that I
3 would equate to what the RAP used to be, but the
4 other ones are still in the identification phase.

5 DR. PARKINSON: I would just like to get
6 a reaction from Ms. Pahland and the Service reps.
7 Perhaps, we are solving too granular of a problem
8 here. Could we just come out and say by time
9 certain, six months after the person accesses, we
10 will have this information in the central
11 database, and allow the Services to solve to
12 whatever thing they want; as opposed to saying,
13 geez, they have enough time with the TIIs, do they
14 do it in secondary training school? Really, that
15 is probably not the level of granularity that we
16 want to get into beyond saying, we need to have a
17 baseline health status of self-reported
18 information that is standardized across all
19 Military members by time certain, and just a
20 reaction to that.

21 COL. SNEDECOR: Amen.

22 COL. RUSCIO: Essentially, I think that

1 is where we are headed now that we pulled it out
2 of the MEP station. There were some disagreements
3 between or issues related to individuals'
4 willingness to complete the form and the answers
5 on the form. This pulls us back out of there, out
6 of that MEP station or even the Basic Training and
7 provides an opportunity to relook at that and pull
8 back from it. I agree with that.

9 MS. PAHLAND: That is part of the
10 considerations that are going on. There is a work
11 group that is looking at these implementation
12 issues. Again, the majority of this is an IM/IT
13 issue. Where in the continuum are we going to be
14 able to best locate people, so that we can give
15 them this questionnaire in a setting that is not
16 going to prompt silly answers or irresponsible
17 answers, that they are not hurried, that they
18 don't feel like it is some sort of game that we
19 are trying to look into their mind? This is all a
20 part of this implementation structure that we are
21 looking at.

22 DR. POLAND: Col. Brumage and then any

1 other comments after him.

2 COL. BRUMAGE: A quick question, who
3 will be held accountable for the compliance with
4 this tool because, if it is not commanders, it
5 probably won't get done?

6 MS. PAHLAND: The policy was sent from
7 Dr. Winkenwerder to the Service Secretaries
8 because of that, to the M&RAs because this is a
9 system approach to trying to identify and
10 intervene with health status. That is why we are
11 going to have a reporting through several
12 mechanisms -- the Force Health Protection Council
13 which I think everyone in this audience is aware
14 of, and then also there is another group called
15 the MED/PERS Council which is chaired by Dr.
16 Jones, the Principal Deputy Assistant for Health
17 Affairs and the Principal Deputy Assistant for Dr.
18 Chu who has the oversight of Military personnel
19 policy. Does that answer your question or not?

20 COL. BRUMAGE: My last comment is if
21 commanders are not held accountable for the
22 information, they just won't comply with it. We

1 will be held accountable for the information, yet
2 with no authority to direct it be done.

3 MS. PAHLAND: Right, that is an
4 identified problem, and again that is part of the
5 implementation challenge that we have. That,
6 again, is why we have included the personnel areas
7 in the policy.

8 COL. COX: It is already a commander
9 policy, and it is already commander
10 responsibility. It is part of the Individual
11 Medical Readiness Reporting. It is one of the six
12 key elements. Commanders are already responsible
13 for getting these done. It is being inserted into
14 the BRRS which is the replacement for SORT. So,
15 it will be in the line's readiness score as well.
16 There can be plenty of commander attention to it.

17 COL. GIBSON: To follow up on that, if
18 you look at this memorandum, Assistant Secretary
19 of the Army, M&RA, Manpower & Reserve Affairs,
20 this is not a medical document, not a medical
21 policy.

22 COL. SNEDECOR: There is one issue I

1 would like the Board to address, and it was
2 briefly touched on when Mike did the NASA
3 briefing, and that is maybe we need to look at
4 some type of rationale for how often we assess and
5 what we do when we assess people. As I started
6 looking at what we are doing and what time
7 sequence, we are assessing our people to death,
8 but we are not using any type of risk assessment
9 that then says: Well, based on your risk, I don't
10 need to see you in a year. Maybe I can let you go
11 two years. Or based on your risk, maybe you need
12 to come a little bit more frequently. I had a
13 discussion with our dentist also this past week on
14 the same issue of what is driving this annual
15 dental exam, especially when I have been Class 1
16 for 15 years. Why do I need an annual exam each
17 year when all you do is basically look in my mouth
18 and go, okay, good to go for next year? One of my
19 issues that I have been trying to push is let us
20 look at or let us have somebody look at the
21 rationale for risk-based assessments, so that we
22 are not just doing this on some routine time

1 period that really has no basis other than
2 Congress told us to do it.

3 DR. POLAND: Okay, last comment.

4 COL. UNDERWOOD: Thanks, Dr. Poland.
5 This goes along really with what Col. Snedecor
6 said, and someone may have asked it. If this
7 policy is going to go by the standards of USPSTF,
8 just one that I can think of, off the top of my
9 head, that we are not in concurrence with, at
10 least at present, the Army does pap smears every
11 year in spite of what the USPSTF standards are.
12 So, there is a disconnect with that.

13 Yes, there is a variation for sure. We
14 are going to adjourn for lunch. Board Members,
15 Preventive Medicine Consultants, and speakers will
16 have a working lunch here. For the rest, as Col.
17 Gibson has mentioned earlier, there are multiple
18 restaurants in the area. We will reconvene for
19 the Board Members at 1:00 here for the Annual
20 Ethics Training. So, we are recessed until then.

21 (Whereupon, at 12:23 p.m., a lunch

22 Recess was taken.)

1 meeting. So, if you could use a microphone, I
2 would appreciate it.

3 LTC. MORNINGSTAR: Thank you, sir. I
4 want to pass around these sign-in sheets. Your
5 training belongs up to the Army Standard Conduct
6 Office. They have asked me to go ahead and do the
7 training. If I get you to sign in on these, one
8 on each of the small certificates, this will give
9 them proof that you in fact have attended
10 training, and it will prevent them from hunting
11 you down and giving you this training again this
12 year. Once again, we are here to learn about
13 ethics. The one thing I do want to say is this
14 year, the slides are slightly different, and we
15 were given a little bit more latitude to move the
16 slides around and streamline those that I do not
17 think are relevant to you all. I, in fact, have
18 deleted many, many of the slides. Many of them
19 are about Military balls or family support groups,
20 not relevant to you all. But there is some stuff
21 I would like to discuss with you again, and these
22 are them. We will talk about: Why Be Ethical,

1 The 14 Principles, The Conflict of Interest, Use
2 of Government Resources, and Personal and Official
3 Participation in Private Organizations. Those who
4 heard me last year, I don't know when I spoke with
5 you, where we were on the Darlene Druyun case, so
6 this may be an update to you. I want to talk to
7 you a little bit about the reasoning why being
8 ethical is so important. There is, first of all,
9 one level, the personal level. Everybody wants to
10 do the right thing. Everyone wants to be a
11 productive member of society. There is also a
12 pragmatic layer, though. All studies have shown
13 the Government is less corrupt, more efficient.
14 We will see in the case of Dragonlady, as you see
15 with her kind of looking at the computer, she is
16 the one who really screwed up the efficiency of a
17 lot of stuff, and we will talk about that a little
18 bit later. Of course, the final reason which is
19 my favorite reason, legal. If you don't act
20 ethically, even though it is not often done, there
21 are instances where you are taken away to jail
22 because of unethical conduct. I think in this

1 case, only a couple weeks ago, we have heard about
2 our Representative Cunningham from California, in
3 fact. Let me talk to you a little bit about these
4 two individuals and talk about how they impacted
5 their communities and, in fact, made things a lot
6 less pragmatic. The lady you see in the middle
7 there, in handcuffs actually, she was the
8 President of the Washington Teachers Union. It is
9 kind of an amazing case. When they finally caught
10 her, she had embezzled anywhere between \$2 million
11 to \$4 million from the account of the Teachers
12 Union. They were never able to ascertain exactly
13 how much she embezzled because she pulled the old
14 criminal trick of keeping no books as she was
15 embezzling. One of the things she did was she
16 ended up taking all this money, and she bought
17 furs and jewelry and expensive pictures. But one
18 of the things that she did, which was really
19 amazing to me, was she stopped paying the
20 insurance premiums for these retired teachers in
21 Washington, D.C. Many of these teachers who were
22 now retired, this was their only source of health

1 insurance. Because she was embezzling so much
2 money, she in fact just stopped paying their
3 premiums. It caused a huge mess. Eventually, the
4 National Teachers Union had to come and take over.
5 The lady you see looking at the computer there.
6 Her name is Darlene Druyun. Darlene Druyun is
7 really kind of an amazing person. I don't know if
8 you all have heard of her. Those from the Air
9 Force may have heard of her. She was the number
10 two Air Force Acquisition Officer. In fact,
11 immediately prior to her retirement from civil
12 service, she was overseeing and doing the
13 selection for a multi-billion contract, some tank
14 refuelers, if I remember correctly. Eventually,
15 this contract came down to two companies, Boeing
16 and Airbus. She, in fact, selected Boeing and
17 gave them such favorable terms that there was an
18 immediate cry, and Airbus immediately protested
19 the contract. As they started to unravel this,
20 certain things came out. They realized that when
21 she awarded this contract to Boeing, she had
22 already given this under the table agreement with

1 Boeing, that once I retire from the Federal
2 Government, I am going to come work with you. In
3 fact, that is what happened. They didn't know
4 this when they awarded the contract, but she
5 retired and kind of popped up six months later as
6 one of their VPs. So, this caused a lot of
7 problems. Amid an outcry, there was an
8 investigation. Once they started pulling the
9 string, they were like, oh, and she was
10 immediately fired from Boeing. The Vice President
11 she was working with from Boeing was immediately
12 fired. The contract was put in abeyance. That,
13 of course, was not the worst of it. As it was
14 going on, they started this Federal criminal case
15 against her. If you think about it logically, she
16 was this great acquisition person. She could
17 basically write her own ticket once she left
18 Federal Service. Why did she feel like she needed
19 to do a favor for Boeing? Well, it was because,
20 since many years before, she and Boeing had
21 accrued an impermissibly close relationship.
22 About five years before she retired, her daughter

1 got married, and she went to Boeing and said: How
2 about you give my son-in-law a job? Boeing was
3 like: Sure. Then she went to them later on and
4 said: How about you give my daughter a job? And
5 Boeing also complied in that case. Later on, when
6 her daughter was doing not so well in her job and
7 was in danger of being fired, she intervened to
8 ensure that her daughter kept her job at Boeing.
9 So, due to all of that, in the end she said: Oh,
10 I felt like I had to do a favor for Boeing before
11 I left. That was still not the worst of it. As
12 you start reading the newspaper, one of the other
13 things that happened was her Military supervisor
14 was nominated for his Fourth Star in a CINC slot.
15 He was, indeed, forced to withdraw his nomination
16 because there were questions as to whether he
17 properly supervised her. Beyond that, though
18 there was even worse stuff. The final thing that
19 I found was the worst was, as they put the
20 contract in abeyance, Boeing went to the U.S.
21 Government and said: You know, you told us we got
22 this contract. In reliance on that, we have stood

1 up this factory and we hired all these people.
2 There are all these people in Seattle now. What
3 are you going to do? We can't keep them sitting
4 them around forever. The Government was really in
5 a very tough position. In the end, I saw in the
6 newspaper, the contract will have to start out in
7 the beginning, re-awarded. That means, most
8 likely, all the people they hired in Seattle were
9 indeed fired because there was no contract at that
10 point. It started out with hey, can you do me a
11 little job? Do me a little favor by giving a job
12 to my son-in-law? And it ended up years later,
13 people, who don't even know her, getting fired
14 from their jobs. You see here that the issue of
15 ethics is when you have ethics, it is like a rock
16 being thrown in a pond. It starts out small, but
17 it ripples outward and impacts a lot of different
18 people. We are going to see what the Standard
19 Conduct Office did, which was very nice, was
20 reduce the ethics regulation. If you have ever
21 looked at it, it is quite extensive. It looks
22 almost like a phonebook. What they did was they

1 kind of shrunk it down and summarized it to these
2 14 Principles of Ethical Conduct. We are going to
3 go through them fairly quickly as kind of a
4 reminder. You are going to see that five or six
5 of these, one way or the other, have to do with
6 conflicts of interest, and that is what a lot of
7 primary issues are about. The first one they talk
8 about is "Public Service is a public trust,
9 requiring employees to place loyalty to the
10 Constitution, the laws and ethical principles
11 above personal gain." Secondly, you "shall not
12 hold financial interests that conflict with the
13 conscientious performance of duty." Also then, you
14 "shall not engage in financial transactions using
15 nonpublic Government information or allow the
16 improper use of such information to further any
17 private interest." And the fourth one has to do
18 with a gift. "An employee shall not accept as
19 [provided for by regulation], solicit or accept
20 any gift or other item of monetary value from any
21 person or entity seeking official action from,
22 doing business with, or conducting activities

1 regulated by the employee's agency, or whose
2 interests may be substantially affected by the
3 performance or nonperformance of the employee's
4 duties." "Employees shall put forth honest effort
5 in the performance of their duties." "Employees
6 shall not knowingly make unauthorized
7 commitments," that one is a little confusing. In
8 general, in the Military, in DOD, you have to be
9 authorized to purchase for DOD. You have to be a
10 warranted individual. Even those people who have
11 warrants, it is a permission slip, and the
12 permission slip says, I can buy and I can buy up
13 to X dollar amount. You may not exceed the extent
14 of your warrant. It is obvious that if you don't
15 have a warrant, you should not be promising to
16 purchase on behalf of the Government. "Employees
17 shall not use public office for private gain,"
18 another one that has to do with conflict of
19 interest. "Employees shall act impartially and
20 not give preferential treatment to any private
21 organization or individual." "Employees shall
22 protect and conserve Federal property and shall

1 not use it for other than authorized activities."
2 We will talk about more of that a little later.
3 You "shall not engage in outside employment or
4 activities, including conflict with official
5 Government duties." You "shall disclose waste,
6 fraud, abuse." You "shall satisfy in good faith
7 [your] obligations as citizen." This means that
8 you should be paying your tickets and paying your
9 taxes. Thirteen, you "shall adhere to all laws
10 and regulations that provide equal opportunity for
11 all Americans." And you "shall endeavor to avoid
12 any actions creating the appearance" that you may
13 be violating these ethical principles. These are
14 the 14 Principles. Yes, sir?

15 DR. POLAND: I am sorry to interrupt
16 you, but because for many members of the Board,
17 number 10 may be a particular issue. I know last
18 time a lot of questions centered around this
19 because of the level of expertise around the
20 Board, people may receive funding from
21 pharmaceutical companies to conduct clinical
22 trials, to be a speaker or a scientific consultant

1 to them. My understanding is, as long as that is
2 disclosed on that form that we have to fill out,
3 and as long as there is no -- and this is where it
4 gets hazy to me -- conflict of interest, we are
5 okay. Could you maybe elaborate a little bit on
6 that specific point?

7 LTC. MORNINGSTAR: Okay, sir. I think
8 this is the easiest way for me to think about
9 this. You have to think about yourself as having
10 two statuses. With most people in the Military,
11 it is easy to analyze. You have your official
12 status, and you have your personal status.
13 However, people who are scientists, in general,
14 your personal status is not just husband or wife
15 or daughter. You have an expertise, such that if
16 you retire from the Military tomorrow, you may
17 still be world's expert in Ebola or the world's
18 expert in HIV. The question is when you talk
19 about outside employment, are you talking about
20 employment in your official capacity, or are you
21 talking about your own expert private activity?
22 Those are two kinds of very different things. You

1 try to split them up right at the beginning. Now,
2 let me just give a quick sample about this. Most
3 things we run into a lot are people are invited to
4 come here or to go to conferences as speakers.
5 The question is: Should I go to this conference
6 in my official capacity or in my personal
7 capacity? There are upsides and downsides to
8 both. If you go in your official capacity, you
9 can go in a TDY or a permissive TDY status. The
10 Government will pay for you to go or you may
11 accept what we call 1453 Travel. That means an
12 outside Federal source can fund you. You will be
13 going then as a representative of DOD, Army or Air
14 Force or whatever, and you will be speaking for
15 that. Because you are on official duty, one of
16 the fallouts of that is, if at the end of your
17 speaking tour, they come to you and say, here is
18 an honorarium or here is a speaking fee, you can't
19 do it because you are speaking as part of your
20 official duty, and you have already been paid for
21 your official duty. That is what your normal
22 salary is. You cannot be paid twice for doing the

1 same thing. Let us look on the other end, though.
2 I forgot, there is one more aspect to being an
3 official speaker. If you are an official speaker,
4 one of the interesting things that came out
5 recently is in the Army side of the house. This
6 is the Army only. Up at the Army General
7 Counsel's Office, they have noticed a very
8 disturbing trend, which is that private
9 organizations out there realize they can invite a
10 lot of speakers from the Military or from the DOD
11 or the Executive Department, and they know if they
12 come as part of their official duty, they can't
13 take speaker fees. So, what they do is they
14 invite a bunch of these people who are great
15 experts, throw this great conference, and they are
16 charging people a lot of money to attend the
17 conference, essentially using Military personnel
18 and Military expertise as kind of a way to make
19 money on the private side. The Army's Ethical
20 Council has said, you may not be a speaker if the
21 registration fee is over \$300 a day, unless you
22 can further justify why it is a reasonable cost

1 beyond that. Here is one of the tags of going in
2 your official capacity.

3 DR. POLAND: I am sorry. I didn't make
4 it very clear. I am really speaking about the
5 SGE, so those of us employed by a private employer
6 who may do scientific consulting for a company but
7 yet are a member of the Board.

8 LTC. MORNINGSTAR: In that case, when
9 you look at your status, I will address the rest
10 of that later. If you look at the issue of if you
11 have an outside status, you sit on this Board but
12 you obviously have a life beyond this Board. The
13 question is: Can you still properly conduct what
14 you need to for this Board without it conflicting
15 with your personal life? For example, is it
16 possible that you sit on this Board, and this
17 Board is perhaps reviewing certain proposals, and
18 you are in a company who is submitting such a
19 proposal. If so, you should recuse yourself.
20 Sir?

21 DR. POLAND: That one does seem obvious.
22 The problem is, and I hate to push the point, but

1 I think it is a real point for several Committee
2 Members, it is a little hazier than that. You do
3 scientific consulting for a company that is
4 seeking to design a product, the nature of which
5 is it will be widely used, not specifically just
6 DOD, but DOD might have interest in it.

7 LTC. MORNINGSTAR: I think the main
8 thing you kind of have to fall back to, even
9 though sometimes the issue may be murky, the main
10 thing that a lot of these principles are trying to
11 protect against is a possibility that there is an
12 uneven playing field in the acquisition arena. As
13 long as you guys are not doing the purchasing, if
14 you are not the warranted purchasing officer, you
15 do not have the ability to impact the buying
16 itself. That is where a lot of the conflicts come
17 in. There is no actual way that I can give you
18 something and say, okay, you are always going to
19 be good, or you are not going to be good.
20 Everything is on a case by case basis.

21 MAJ. KILIAN: DynePort was here
22 previously in an open session. It would be

1 ethically wrong for us to invite them to a closed
2 part of the session unless it was to possibly go
3 down the line with MILVAX of a particular problem
4 or a particular aspect of the contract that
5 already exists with DynePort. If we were
6 discussing transferring of knowledge of the
7 antivirus vaccine out in a closed session with
8 only DynePort, then we might have a problem. We
9 would have to do that in an open session, allowing
10 Roche and whoever else was interesting in coming
11 into that open session.

12 LTC. MORNINGSTAR: Yes.

13 MAJ. KILIAN: If they chose to opt out,
14 that is fine. If DynePort were the only guys in
15 town that wanted to come, fine. But if we said
16 only DynePort is invited to this session, then we
17 would get in trouble.

18 COL. GIBSON: A point of clarification
19 for the Board Members, the charter, the Armed
20 Forces Epi Board Charter exclusively prohibits us
21 from dealing with issues associated with
22 procurement. If we do that, that is one of my

1 jobs, to make sure we don't cross that line. We
2 put that in the charter specifically to address
3 this sort of an issue.

4 LTC. MORNINGSTAR: Yes, sir. I think
5 the one that you guys may trigger, actually,
6 probably, is number three. It is the nonpublic
7 governmental information. Even though you guys
8 may not do the procurement, you may, through your
9 discussion, have very important information that,
10 if one vendor or one pharmaceutical company got it
11 instead of another, they may be able to utilize
12 it. Sir?

13 DR. KAPLAN: I was just going to say, We
14 talked about: Do we have enough Tamiflu
15 stockpiled? We need to get more. Or it needs to
16 be here, there, and the other. It becomes an
17 extraordinarily fine line. If you take it by the
18 letter, we did something, theoretically, we
19 shouldn't have done, except that it is the only
20 company producing the antiviral --

21 DR. POLAND: I understand the difference
22 there is we are not issuing a requisition. We are

1 not the writers of the requisition, saying buy 20
2 million more doses.

3 DR. KAPLAN: Yes, yes. Well, we told
4 them to, though.

5 LTC. MORNINGSTAR: I think the issue of
6 nonpublic interest, though, that might come up,
7 and feel free to email me thereafter.

8 CAPT. JOHNSTON: I think one of the
9 protections that you have is the limitation on the
10 duration of your tenure. I think one of the
11 reasons why it is limited is because this sort of
12 indirect influence you can have on procurement by
13 the guiding sound of your advice is much more of a
14 problem if you are working in a place for a long
15 period of time, and that is why they limit it.

16 LTC. MORNINGSTAR: I think this part is
17 probably most useful to you all, so if I don't, in
18 fact, get through all my slides, some of the other
19 stuff is probably not as useful as the discussion
20 here. Conflict of interest, there is a lot of
21 confusion in this area. People keep on saying:
22 What is conflict of interest? The basic rule is

1 you "shall not hold financial interests that
2 conflicts with the conscientious performance of
3 duty." This is the primary reason. If you have a
4 financial interest in the matter, it is assumed
5 that you cannot be entirely objective when
6 carrying out your official duty relating to that
7 matter. If you look at the next three bullets, it
8 says, the fact that the Federal employee is an
9 honest person is not relevant; if you don't even
10 make the final decision, that is not relevant.
11 All that is necessary for a conflict is that the
12 Federal employee participated personally,
13 substantially in the matter. Here is the test:
14 You participated personally, substantially, and
15 there is a real possibility you may gain or lose
16 as a result of the development in or a resolution
17 of that matter. This is one of those rules that
18 is fairly difficult. When you talk about the
19 language, it is fairly squishy, and when you try
20 to translate it to real life, sometimes it is
21 difficult. But most people, I have found when I
22 talk to them, they have a pretty good idea when

1 they are coming close to the conflict of interest.
2 They have been trained sufficiently. So, they
3 say: Okay, wait a second. I am dealing with this
4 specific subject matter. Maybe I should not be
5 buying stock or advising these people as
6 consultants. The one thing you want to be careful
7 of in the conflict of interest is there is an
8 issue about imputation to the employee. There are
9 certain people whose financial interests are
10 considered so close to those of yours, they are
11 basically considered your interests. Those are
12 your spouse; your minor children; if you are in a
13 partnership, those who you are in general
14 partnership with, because you guys have the same
15 financial liability and gain; an organization or
16 entity of which you are serving as an officer,
17 director, trustee, general partner, of employee;
18 and finally, an organization that you are seeking
19 employment with. I know that seems to cast a very
20 wide net. I think that most people have a good
21 idea of the last two bullets. The one that people
22 actually get a lot of times, and they don't really

1 realize, is the spouse piece of it, the spouse and
2 the minor children, because sometimes they think
3 that is a completely different issue. I have some
4 slides about use of Government equipment, having
5 to do with emails, having to do with computers and
6 cell phones. Is that of interest to you all? If
7 not, I will move on beyond that. Okay, let me go
8 ahead.

9 DR. BROWN: Board Members are considered
10 Federal employees when they are serving on the
11 Board?

12 LTC. MORNINGSTAR: Yes. This is the
13 main thing I would just about computers. I don't
14 know if you guys come with your own computers or
15 not, but if you are using a government computer,
16 there is only one slide here I want to show you.
17 Let me give you the no-no slide. The main rule of
18 thumb is don't use a DOD computer in a way that
19 would make the DOD embarrassed that they have this
20 information on their computer -- no obscene or
21 pornographic material, copyright infringement,
22 gambling, unofficial advertising, don't be using

1 the email to solicit other personnel for a private
2 business, or forwarding chain letters. Official
3 participation in private organizations or
4 non-Federal entities, let me ask you. This is
5 another area. I have tried to find stuff that
6 pertains to you, but maybe the best thing to do is
7 talking about working with non-Federal entities.
8 Give me a second here and let me look at this. I
9 think this part is possibly worthwhile to go
10 through because it will give you a delineation
11 when we talk about people's different status. The
12 status you really have to think about is when you
13 all are working for the Board, you do have the
14 status of being somebody who is an employee of
15 DOD. When you are not working for the Board, then
16 you are in your private status. We started
17 talking a little bit about providing speakers to
18 panel members. The one point I didn't get to
19 about that is you can be, you can go in your
20 official capacity, and you can also go in your
21 personal capacity. If you go in your personal
22 capacity, that generally is fine, but there are

1 limitations. You have to take leave. The money
2 you earn is really considered moonlighting. These
3 are for the Military members. And you generally
4 have to get your supervisor's approval to get
5 moonlighting.

6 DR. KAPLAN: May I ask a quick question?
7 If you are working for the Board, we are working
8 for the Board sitting here now, but we have a term
9 of appointment. Which is working for the Board,
10 both?

11 COL. GIBSON: Col. Morningstar can
12 clarify if I am wrong, but when you are on orders
13 as a special Government employee attending
14 something that was coordinated for you to travel,
15 for you to be there, for the Board, then that is
16 considered working. When you are not on orders,
17 since you are a special Government employee, you
18 are doing your thing, whatever that thing is. You
19 are not representing the Department of Defense.
20 You are not representing the Armed Forces Epi
21 Board. If you do that, please tell me. But to my
22 knowledge, I have not had any of our members do

1 something like that, go to a meeting and say I am
2 here representing the Armed Forces Epi Board, even
3 though you are not on orders and travel, etcetera.

4 DR. LAUDER: I am not sure if this is
5 the right time to ask this. It may sound like
6 kind of a silly, but it has come up several times,
7 and I am never quite sure what the right answer
8 is. It happens to me quite frequently, where they
9 are asking for volunteers to give up your seat on
10 the airline, and the airline ticket is being paid
11 for by the Government. What happens to that
12 ticket? And sometimes I am not given a choice.

13 DR. POLAND: Shannon?

14 LTC. MORNINGSTAR: Actually, if you do
15 that, the rule is if it doesn't prevent you from
16 being where you need to be, you are free to give
17 up your seat, and you can keep what they give you.
18 Actually, the travel rules are such now that you
19 can individually keep frequent flyer miles. That
20 is possible. The only thing travel-wise, I am
21 sure you guys don't do it. It is very hard
22 because we have cross-service here. I am trying

1 to distinguish out what is Army guidance and what
2 is DOD guidance. The Army's guidance is that to
3 have people come and travel around in first class
4 in very limited circumstances, the Sec. Army has
5 to actually approve those. Even business class,
6 very limited guidance about when you can travel in
7 business class. So, rule of thumb, when you work
8 for the Government, you should be traveling coach
9 class. When you go overseas, though, there are
10 some issues where you might be able to get
11 business class but you should clear it with your
12 ethics counselor. Yes, sir?

13 DR. POLAND: Just to clarify, our travel
14 arrangements are handled through this office, so
15 they are Government economy tickets. But multiple
16 members, because of their other life, get bumped
17 up into first class or business class, and that is
18 not a problem.

19 LTC. MORNINGSTAR: Yes, just remember it
20 is a status thing again. When you are on orders
21 for us, it is like you have to almost switch. You
22 are in a different status at that point. A lot of

1 things that we talk about here, the Joint Ethics
2 Regulation, some of them will apply to you
3 throughout, like the conflict of interest, because
4 you certainly don't want a conflict of interest
5 between what you are doing for this Board and what
6 you are doing in other aspects of your life.
7 Other things only trigger when you are on these
8 orders, such as the travel stuff. This part is a
9 little confusing. A lot of the issues that also
10 trigger is the issue of gifts. There is some
11 stuff. If I can think of the list right now, I
12 can tell you, like travel, gifts, use of
13 Government equipment, all these things only
14 trigger once you are on orders like that. Ma'am?

15 DR. CATTANI: Just one more question,
16 and I don't think this is an issue. Say, you are
17 on orders, and you receive your ticket from the
18 AFEB Office. Can you use your own miles to
19 upgrade that ticket?

20 LTC. MORNINGSTAR: Yes.

21 DR. CATTANI: Even though you are on
22 orders?

1 Yes, upgrades are okay, even upgrades to
2 first class. They don't care about that. The
3 only thing about the Military is we cannot sit in
4 first class in uniform. Let us kind of readjust a
5 little. Think of yourself as now being on orders
6 for AFEB. If you are on orders right now, you
7 should not be participating in the management of a
8 private organization. You may only participate in
9 the management of a non-Federal entity in official
10 capacity if authorization is received from the
11 Sec. Army and the DOD General Counsel. That is a
12 very, very high requirement. The only thing you
13 can do with a private organization is you can be a
14 liaison, as a member of this Board. What I mean
15 by liaison is think of yourself kind of as a tube.
16 The information is flowing through you. You
17 should not be making any decisions, basically, as
18 a liaison. Further stuff with liaisons, these are
19 the things. Liaisons cannot participate in the
20 management. You cannot be in a full time position
21 for any soldier or civilian employee. You must be
22 appointed. Here is another thing that is kind of

1 useful for us. Be careful about people who want
2 endorsements. This may be coming in a very
3 unusual way. Most people know enough, so that
4 they don't say: I am a member of the AFEB, and I
5 think you, Merck, are great. I think all DOD
6 should buy from Merck. Usually they don't do
7 that. That is, in fact, what they say. We don't
8 endorse. But it comes up in odd ways. For
9 example, as you see at MRMC we have a lot of
10 research projects. These research projects
11 usually involve private industry. It involves
12 DOD. It may even involve a school somewhere.
13 Usually, when people put these panels together,
14 and when it is done, they say stuff like: Oh,
15 everybody here did a great job. So, let us go
16 ahead and thank people. Well, if you are
17 Military, there are Military awards regs. If you
18 are a civilian, there are civilian awards regs.
19 The question is what do we do for people who are
20 contractors or private industry people? Usually
21 what happens is people write a letter, saying,
22 hey, so and so did a great job, and they helped us

1 out with this. You have to be very careful about
2 these letters. Once that little letter leaves
3 your hand, you don't know where it is going. The
4 worse case I have seen really was a contractor
5 actually had a letter of thank you from a general
6 officer, and he was very, he was a little too nice
7 in the letter. He was talking about what a great
8 organization this was, what a great job they did.
9 Well, what this organization did was they took
10 that letter, and they attached it to another
11 letter which they wrote to someone who sat on
12 Acquisitions of the Senate Armed Services
13 Committee, I think, to say: Hey, we are a great
14 company. Throw more acquisitions our way. So, on
15 one hand, this general officer was trying to thank
16 someone, not to endorse them, but it was then used
17 as a lobbying tool. You do want to be careful
18 about the issue of an official endorsement.
19 Sometimes, people are helping you, and you want to
20 say thank you, but you don't want to teeter onto
21 the other side. That is all we really needed to
22 know about that. Personal participation, I think

1 the main thing about personal participation, and I
2 probably don't need to go through all these
3 slides. The main thing I want to tell you about
4 personal participation is when you are on AFEB, if
5 you have a personal participation in a private
6 organization, that is fine. Just make sure there
7 is no conflict of interest there. That is another
8 one that goes all the way through. I tried to
9 streamline this. These are the slides that were
10 available this year. I tried to streamline them
11 to your needs, but I think a lot of it was still
12 superfluous. However, you seem like you have
13 special and unique questions, and they are
14 somewhat similar to the questions I get here at
15 MRMC. If you have other questions or other
16 discussions on these points, I certainly will be
17 willing to stay and talk to anyone about this.

18 (Applause)

19 DR. POLAND: One of the things our legal
20 counsel told us was that because certain members
21 of our faculty and perhaps of this Board are
22 visible and each organization sort of likes to

1 claim them, that when we give talks or anything
2 like that, we put up a disclaimer statement,
3 saying we are representing our personal views and
4 not those of, and then list the organizations that
5 we may have visibility with. Is that useful?

6 LTC. MORNINGSTAR: Yes. Yes, that is
7 useful, and generally there are a couple of things
8 involved with that. One is that there is usually
9 something that says, I am not endorsing you, but
10 they say it in a nicer way. Basically: I am here
11 to give a talk, but I am not endorsing this
12 organization. Another thing is it turns on what
13 you can use to present yourself. For example, if
14 you are going to speak, not as an official member
15 of AFEB but in your personal capacity, what can
16 you use. Can you still use the AFEB title? I
17 have actually never run into that. I would
18 suspect you probably cannot. For example, if a
19 Military person goes and speaks, but they are
20 speaking in their personal capacity, they cannot
21 use their job title. They can use their rank.
22 Their rank is considered part of their person, but

1 they cannot use their job title, not if they are
2 speaking in their personal capacity. These are
3 the two issues that you may see out there.

4 COL. GIBSON: My question is just to
5 make sure we get it in the record. Gifts, are
6 plaques gifts?

7 LTC. MORNINGSTAR: It depends. I know
8 that is like a weaselly lawyer answer, but, in
9 general. Let me back up a little bit. The issue
10 of gifts, you start out with this. Any item of
11 monetary value is considered a gift. However,
12 like all things written by an attorney, there are
13 several classes of exceptions. The first class of
14 exceptions is what we call non-gifts. They are
15 considered items of such minimal value, they are
16 not considered gifts. There is a list of them.
17 There is a list of them, and plaques are
18 considered non-gifts, and the reason is plaques,
19 although meaningful to the recipient, have almost
20 no resale value. However, if your plaque is made
21 from something extraordinary, if it is solid gold,
22 it is not a non-gift. That is why I said it

1 depends, because I have seen people try to say,
2 well, it is a plaque. No, that is a football
3 signed by Joe Montana. It is on a wooden stand,
4 but it has a resale value. So, I have seen people
5 do different things with that.

6 DR. KAPLAN: What about lunch today?

7 COL. GIBSON: To answer Dr. Kaplan's
8 question, lunch today, you are on per diem. That
9 lunch was a Government-provided meal. So,
10 therefore, we count it as a Government-provided
11 meal. That reduces the amount of per diem you get
12 for the day based on that Government-provided
13 meal.

14 DR. KAPLAN: Can I get a refund?

15 COL. GIBSON: No, even if you didn't
16 like the meal, I am sorry, that is it. That is
17 how we make sure that we haven't provided you with
18 per diem plus a meal. That would be unethical and
19 against the budget.

20 LTC. MORNINGSTAR: That is actually a
21 fiscal law issue, but it is true when there are
22 Army conferences. There is a Supreme Court case

1 that basically came down and said, the stand of
2 the Federal Government is that we say you have to
3 have an authorization to spend. It has to say,
4 you may spend, before you spend. If they are
5 silent on it, you can't assume the silence as an
6 authorization to spend. So, in essence, when we
7 have any kind of people gathering together, there
8 are all sorts of fiscal law issues about can we
9 spend on X, Y, and Z. It is kind of a very arcane
10 fiscal law area, but I am glad to sit and tell you
11 about food and pens and registration fees, too, if
12 you like.

13 DR. POLAND: One of the things that is
14 true for us in medicine and in science, and it may
15 be true in other fields, is that when you go to
16 speak, when you apply for a grant -- I am trying
17 to think of other things -- you typically include
18 a biography or bibliography. Is there any issue
19 in there in listing the positions that you have in
20 various organizations which include this DOD
21 Board?

22 No, sir. What you have to be careful of

1 is this, though. On the one hand, no; on the
2 other hand, if you are speaking in a private
3 capacity, you have to be careful because what they
4 may do, a lot of private organizations, depending
5 on which title sounds the best to them, they may
6 look through your biography and say, hey, this
7 sounds great. Then the next thing you know it is
8 Dr. So and So from the AFEB coming to speak to
9 you. It is like I am now speaking in my private
10 capacity as a doctor. So you do have to kind of
11 be careful because at some point you may lose
12 control. You just have to kind of really hold
13 their feet to the fire about that. Unless there
14 are any further questions, thank you very much.

15 (Applause)

16 DR. POLAND: Next on our agenda is a one
17 and a half hour session for the different
18 Subcommittee discussions. We will break into
19 those groups until, well, we will see how they are
20 going. We will reconvene no later than 3:00 and
21 potentially earlier than that. I guess what we
22 will do then, so we won't have transcription

1 services after this, is officially adjourn the
2 meeting, and we will have our own Subcommittee
3 meetings.

4 (Whereupon, at 1:40 p.m., the
5 PROCEEDINGS were adjourned.)

6

7 * * * * *

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

