

BEFORE THE
UNITED STATES DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

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In the Matter of: :
ARMED FORCES EPIDEMIOLOGICAL :
BOARD - BOARD MEETING :
- - - - - X

Hill Air Force Base
Ogden, Utah

Friday,
February 24, 1995

The above-entitled matter convened for meeting
pursuant to notice, at 7:55 a.m.

BEFORE:

MICHAEL S. ASCHER, M.D.
Acting Chairman

APPEARANCES:

Board Members

- James R. Allen, M.D., M.P.H.
- Michael S. Ascher, M.D.
- John R. Bagby, Ph.D.
- Claire V. Broome, M.D.
- James Chin, M.D., M.P.H.
- Gerald F. Fletcher, M.D.
- Jack M. Gwaltney, Jr., M.D.
- Barbara C. Hansen, Ph.D.
- Meryl H. Karol, Ph.D.
- Lewis H. Kuller, M.D.
- Elisa T. Lee, Ph.D.
- Russell V. Luepker, M.D.

Dennis M. Perrotta, Ph.D.
APPEARANCES: (Continued)

Board Members

Gregory A. Poland, M.D.
William H. Schaffner, M.D.
David Schottenfeld, M.D.
Kenneth W. Sell, M.D.
Cladd E. Stevens, M.D.
Martin S. Wolfe, M.D.

Participants

Lieutenant Commander David Arday
Commander Gordon Clifford
Colonel J. Pitt Tomlinson
Colonel Robert Leitch
Colonel Francis O'Donnell
Captain David Trump

Presenters

Colonel Joel Gaydos
Colonel Malcolm Joseph
Colonel James Fleming
Commander W. Garry Rudolph
Lieutenant Colonel Sanford Zelnick

Audience Participants

Colonel W.H. Bancroft
Lieutenant Commander Gil Potter
Lieutenant Commander Patrick Kelley
Lieutenant Colonel Bruce Jones
Lieutenant Colonel Sharon Falkenheimer
Colonel Ben Diniega

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1 a lot to finish.

2 Okay. We will start this morning with
3 Colonel Gaydos on the adenovirus vaccine update.
4 There is a handout I believe that we have here.

5 COLONEL GAYDOS: Good morning. I am here
6 on behalf of the U.S. Army Center for Health
7 Promotion and Preventive Medicine, and I bring you
8 greetings from our commander, Brigadier General
9 Nancy Adams and the 800-or-so employees that we have
10 at the place that we affectionately call the
11 "CHPPM."

12 And we had some reservations about that
13 name when it was adopted last August, but we have
14 since found that it tends to bring a smile to
15 everyone's face, so we have decided to keep it. We
16 will shortly have a member of the Chaplain's Corps
17 on board working with some of health promotion
18 activities and we have decided that that individual
19 will officially be called the "CHPPM-Monk."

20 And on a serious note, we hope that
21 sometime in the near future that the Center for
22 Health Promotion and Preventive Medicine will have
23 the opportunity to host an Armed Forces
24 Epidemiological Board meeting.

1 A strong argument can be made for acute
2 respiratory disease being the single most important
3 cause of morbidity in the U.S. military, certainly
4 at military training centers.

5 It was in conjunction with this concern
6 that in December of 1941, the Department of War
7 established a board for the investigation and
8 control of influenza and other epidemic diseases,
9 and this board eventually became the Armed Forces
10 Epidemiological Board.

11 Over the last 50 years, the AFEB has played
12 a critical role in the control of acute respiratory
13 disease or ARD at our military training centers.
14 One of these control programs, our most successful
15 control program, is now in jeopardy, and that is the
16 adenovirus vaccine program. And my purpose this
17 morning is to appraise you of the current situation
18 with regard to acute respiratory disease in military
19 training centers and the adenovirus vaccine program.

20 Slide, please, Ben.

21 As you can see on the slide, live enteric-
22 coated adenovirus types 4 and 7 vaccines have been
23 successful used to control ARD in U.S. military
24 training centers since 1971. The Army and the Navy

1 have been routinely administering these vaccines.

2 Initially, these were administered from 1
3 October through the end of March. In 1985, the Army
4 and the Navy went to year-round administration
5 because we were having outbreaks occurring in the
6 spring and the fall.

7 About the mid-'80s, the Air Force, at their
8 basic training center in Lackland, elected to go
9 onto a surveillance program where they administer
10 the vaccine only when their surveillance program
11 indicates that it is needed.

12 The current situation is that from the
13 spring of 1994 until the present, adenovirus
14 vaccines have not been given due to production
15 delays at Wyeth. At the present time, adenovirus
16 virus vaccine is in the system and is being sent to
17 basic training centers.

18 Unfortunately, this was not a one time
19 occurrence and we are certain that we will
20 experience future production delays with regard to
21 the supply of adenovirus vaccines.

22 Next slide, please.

23 Adenoviruses were first identified in the
24 early 1950s. Something called "adenoid degeneration

1 agent" was recovered from surgically removed human
2 adenoid tissue. At about the same time, viruses
3 called "respiratory illness agents" were recovered
4 at the Walter Reed Army Institute of Research from
5 soldiers in basic training who were ill with acute
6 respiratory disease.

7 The adenoid degeneration agent and the
8 respiratory illness agents eventually were
9 designated "adenoviruses" and were associated with
10 the clinical syndromes of ARD, pharyngitis,
11 conjunctivitis, pneumonitis, and atypical pneumonia.

12 Through extensive studies that were done at
13 military training centers in the United States, and
14 through work that was done at the Walter Reed Army
15 Institute of Research, in conjunction with the
16 various organizations of the Armed Forces
17 Epidemiological Board, it was determined that at
18 some places, at some time, up to 80 percent of
19 military recruits developed adenovirus infections.
20 And it is commonly stated that about 20 percent of
21 these recruits would be hospitalized with acute
22 respiratory disease due to adenoviruses.

23 This 20 percent is actually low for some
24 places at some points in time. For example, in the

1 1960s at Fort Dix, New Jersey, in the winter time,
2 during an eight-week basic training cycle, 40 to 50
3 percent of the recruits who entered that cycle could
4 expect to be hospitalized at the Fort Dix Hospital
5 for an average hospital stay of three days due to
6 adenovirus acute respiratory disease.

7 It has been estimated that about 10 percent
8 of these recruits seeking medical attention had
9 radiological changes and the fever -- the clinical
10 picture was one of acute respiratory disease with
11 fever, malaise, nasal congestion, sore throat,
12 hoarseness, headache and cough.

13 In the pre-vaccine era, we saw hospital
14 admission rates for acute respiratory disease that
15 went into the area of five to eight recruits per 100
16 soldiers per week. Now at a place like a northern
17 Army training post, this would equate to around to
18 four to six, maybe even 800 admissions for ARD in a
19 week.

20 Some of you were a part of this, some of
21 you may remember stories being told of patients in
22 the hallways, of having to get tents in the winter
23 time and set up tents on the grounds of our
24 hospitals to accommodate our acute respiratory

1 disease patients. The impact on the medical care
2 system was incredible.

3 This situation also had a severe effect on
4 what we call readiness. And readiness is our
5 ability to respond to whatever we need to respond to
6 in a timely fashion.

7 If you could imagine a basic training
8 center, which is essentially a big training
9 business, that training center is tied into
10 recruiting centers, it is tied into transportation
11 centers, and it receives a programmed supply of
12 recruits. Those recruits come in through the gate
13 and they are expected to complete a program in six
14 weeks or eight weeks, or whatever the time period
15 is.

16 A certain number of those recruits will
17 become ill. A certain number of them will develop
18 injuries. A certain number of them will quit. And
19 so there is always some background of
20 administratively taking these people who can not
21 continue training, out of training.

22 Most of them we would like to recycle, we
23 would like to get them back into training because we
24 have already invested a considerable amount of time

1 and money in these individuals.

2 So if you can imagine a military basic
3 training post where we have a program supply of
4 recruits coming in, and we are having somewhere
5 between five and ten percent of those recruits being
6 hospitalized for an average period of three days per
7 week, and all of those who are hospitalized for
8 three days, or most of them, will probably have to
9 be recycled, which means that they will have to be
10 administratively held and inserted back into the
11 training program, then you might be able to imagine
12 an administrative nightmare of the greatest
13 proportions.

14 And we have had situations in the past
15 where we have almost had to stop the input of
16 trainees to these basic training posts. And all of
17 the basic training posts are tied in to other
18 training posts and they are tied in to operational
19 requirements in the units that are stationed in
20 Korea, the units that go to Somalia, the units that
21 go to Rwanda. And so once this system is severely
22 disrupted, the entire system becomes disrupted.

23 I believe that right now we have somewhere
24 around 35 different serotypes of adenoviruses that

1 have been identified. We have found that 60 percent
2 of our acute respiratory disease in hospitalized
3 recruits is the result of two serotypes, adenovirus
4 type 4 and adenovirus type 7.

5 Over time we have observed less frequently
6 types 3, 14 and 21 in hospitalized military
7 recruits. This problem was not a problem of the
8 U.S. military alone. Types 4, 7 and 21 have been
9 identified as causes of ARD in foreign military
10 recruits.

11 The situation I have been describing is a
12 militarily-unique situation. We have not seen the
13 extent of morbidity due to adenoviruses in civilian
14 populations that we have experienced in our military
15 populations. We have had reports of pneumonias and
16 eye infections in civilians and this primarily
17 centers around types 3 and 7.

18 In order to deal with the problem of the
19 ARD and the problem of the adenovirus-caused ARD,
20 vaccine programs were initiated about the same time
21 that the adenoid degeneration agent was identified.

22 This goes back to the early '50s. The first
23 vaccine was a bivalent formalin inactivated type 4
24 and 7 vaccine. This was a licensed vaccine.

1 When the vaccine went into large scale
2 production, problems occurred with variation in the
3 antigenicity of lots. Also, the vaccine seeds
4 became contaminated with the oncogenic SV-40 virus
5 and the SV-40 virus genome was incorporated into the
6 vaccine virus seeds. So the licensure of this
7 vaccine was pulled and work with this bivalent
8 formalin inactivated vaccine stopped.

9 Fortunately, that was not the only
10 adenovirus vaccine that was under development. Work
11 was being done on live, enteric-coated adenovirus
12 vaccines. It was determined that in adults
13 adenoviruses could be administered in an enteric-
14 coated form so that they did not infect the upper
15 airways, and the viruses would infect the gut, would
16 produce local antibody and would also produce a
17 circulating, neutralizing antibody with essentially
18 no side effects, and that this type of vaccine was
19 protective against acute respiratory disease due to
20 adenoviruses.

21 So the enteric-coated adenovirus vaccine
22 route was pursued, and it was a difficult route.
23 There were many problems.

24 Can I have the next slide, please?

1 Central nervous system inflammatory lesions
2 were identified in primates with type 4.
3 Researchers studied naturally-occurring human cases
4 and found no evidence that this was occurring in
5 humans so the work continued.

6 Adenoviruses were associated with
7 oncogenicity. Adenoviruses were associated with
8 tumors in hamsters, they were also associated with
9 oncogenic changes in a rat cell line, and these
10 changes were associates with types 3, 7 and 21.

11 Now, the tumors that occurred in hamsters
12 were related to a specific T-antigen. An antibody
13 was formed against this T-antigen. Using these
14 markers, and also using messenger RNA, a number of
15 studies were launched. These studies were done over
16 a period of several years, and the results of this
17 work eventually brought about a declaration from the
18 National Cancer Institute that adenoviruses were not
19 a cause of cancer in humans.

20 As I mentioned earlier, the type 4 and 7
21 vaccine campaigns actually got underway in 1971.
22 Subsequent to that, around the mid-'70s, we began to
23 notice that vaccine efficacy was not what we
24 expected it to be. We went back and found that

1 there were manufacturing problems and there was
2 solvent contamination of the vaccine which related
3 to the decrease in efficacy and this was corrected.

4 Next slide, please.

5 The sequence of events is that in 1971, we
6 initiated the simultaneous administration of
7 adenovirus type 4 and adenovirus type 7 vaccines at
8 our military training centers. A study of this
9 program was conducted in 1973, looking at the cost
10 of adenovirus ARD and the cost of the vaccine
11 program, and this resulted in a determination of a
12 cost benefit ratio of 1.56 in favor of the vaccine
13 program.

14 While we were giving the 4 and 7 vaccine in
15 the period 1975 and 1976, some of you may recognize
16 this as a period of swine flu and also influenza-A,
17 we also experienced adenovirus type 21 outbreaks at
18 some of our military training centers. These
19 outbreaks did not persist. This occurred over a
20 period of about two years.

21 In 1983, as I mentioned earlier, we became
22 concerned that we were seeing adenovirus outbreaks
23 at our military training centers in the spring and
24 fall, so we went from a period of administration of

1 1 October through the end of March to year-round
2 administration. As I mentioned, the Navy and the
3 Army adopted this program, and in the mid-'80s the
4 Air Force went to a program of following
5 surveillance data.

6 In 1985, we had another outbreak of
7 adenovirus 21. This was another self-limited
8 outbreak at Fort Dix. And in the back of our minds,
9 we have always had concern that we are going to see
10 another adenovirus come out someday, be it 21 or it
11 might be 11 or 14.

12 The program continued. We feel that we
13 have experienced great success with this program
14 from 1971 through the present time, and in the
15 spring of 1994, Wyeth, the producer of the
16 adenovirus vaccine, stopped providing vaccine to the
17 Army. And the vaccine was not provided until lots
18 again arrived at our Defense Personnel Support
19 Center a couple of weeks ago.

20 The current situation is that we don't know
21 very much about the ecological niche of adenoviruses
22 or adenovirus ARD in our military recruit
23 populations at the present time. This is a success
24 story where success was relished and there was

1 little done to look at changes that might be
2 occurring.

3 We do not know at the present time the
4 immune status of the recruits who are currently
5 entering basic training. The last time that a
6 serologic survey was done was in 1975 and at that
7 time we found that 42 percent of the recruits coming
8 in to Army basic training centers lacked antibody to
9 types 4 and 7. Now, this antibody prevalence is
10 consistent with what we were seeing back in the '60s
11 with the high ARD rates.

12 At the present time our Army ARD rates are
13 low. We have an adenovirus surveillance, we have a
14 surveillance system that Colonel O'Donnell discussed
15 yesterday. Over the past six months we have seen
16 only a couple of increases. At one of our basic
17 training posts back in October we saw an increase
18 that was due to strep. More recently, the last two
19 weeks in January, we had rates that went up to 1.6
20 at one of our basic training posts. These are ARD
21 admission rates, that's 1.6 per 100 per week.

22 We had a number of specimens that were sent
23 in to Eisenhower Army Medical Center, 33 specimens
24 to be exact. Out of those 33 specimens, we had

1 three or four that produced influenza-A, but we do
2 not know what the cause of that outbreak was.

3 We currently have being delivered to us
4 12.1 months of adenovirus types 4 and 7 vaccines.
5 This is based on prior usage where recruits coming
6 in to the post would receive the vaccine. So if we
7 continue that program, the vaccine that we are
8 receiving now will last us until the end of February
9 of next year.

10 And Wyeth has announced that in the event
11 that Wyeth continues to produce adenovirus vaccine,
12 that we can not expect to receive additional lots of
13 adenovirus vaccine on or about the 1st of March
14 1996. If, in fact, Wyeth continues to produce
15 vaccine, then they will provide us with another
16 production delay of indeterminate length prior to
17 giving us any more vaccine lots.

18 Now these are the concerns that we have.
19 We are concerned about the stability of the
20 adenovirus vaccine supply. I do not know all of the
21 details related to the production delay.
22 Administratively, it appears that the Defense
23 Personnel Center, Defense Personnel Support Center
24 may have not issued the appropriate paper work to

1 Wyeth in a timely fashion and that may have
2 contributed to the production delay that we
3 experienced.

4 Wyeth manufactures adenovirus vaccine in
5 between manufacture of lots of influenza vaccine.
6 Wyeth has had a concern that they have expressed to
7 the Department of Defense for a long time now about
8 the adequacy of their adenovirus production
9 facilities.

10 It is possible that federal organizations
11 such as the Occupational Safety and Health
12 Administration and the Food and Drug Administration
13 could come to Wyeth and tell them that the
14 adenovirus vaccine production facilities are no
15 longer adequate. Wyeth has extended to the military
16 the opportunity to sit down with them and discuss
17 the ramifications of this situation and the economic
18 aspects of this situation.

19 In looking at our surveillance programs, we
20 stepped up surveillance once we found out that we
21 had a production delay. Stepping up surveillance
22 meant sending out information to everyone about what
23 might happen with regard to adenovirus outbreak and
24 telling them that if their rates reached 1.5 we

1 wanted them to collect virus isolation impaired
2 serum.

3 We are doing virus isolation in the Army at
4 Dwight David Eisenhower Army Medical Center in
5 Augusta. We have totally lost our serologic
6 capability for adenovirus serology in the Army. And
7 we have not been able to locate any place in the
8 United States where we can send specimens to get
9 adenovirus serology.

10 Now, our data base on adenovirus serology
11 is imbedded in the neutralizing antibody studies.
12 Dr. Kelley at WRAIR has a number of sera that are
13 stored that were collected on recruits coming in to
14 the military. We can use these sera and we have
15 funds set aside to get the tests done. Dr. Kelley
16 is currently working with McMaster University in
17 Hamilton, Ontario to see if they could, and if they
18 will be willing to do antibody testing on the sera.

19
20 McMaster is working with adenovirus type 5
21 as a potential carrier for other vaccines. They use
22 a color-metric neutralizing antibody type of test
23 and the problem is taking what they are doing and
24 setting it up so that we can look at antibody to

1 adenovirus types 4 and 7.

2 Now, before I get into the discussion of
3 outbreaks, I will point out that we do not know
4 where we stand right now with regard to an
5 adenovirus vaccine supply. We have 12.1 months of
6 vaccine supply based on prior usage coming into the
7 system. So that means that if the Air Force holds
8 whatever volume they hold, and the Navy and the Army
9 continue to give adenovirus vaccine types 4 and 7 to
10 recruits who come onto basic training posts, then
11 that supply will last us until about 1 March.

12 We are concerned about this vaccine supply
13 because, if Wyeth is going to provide us with
14 another production delay, which they have assured us
15 they will, then we still aren't sure that Wyeth is
16 going to produce any vaccine in the future, so
17 perhaps we should go to a surveillance system and
18 hold the vaccine that we have and just use it when
19 the surveillance data indicates it should be used.

20 In the event that we do get into a
21 situation with an outbreak, and that outbreak occurs
22 sometime over the next one to two months, then that
23 outbreak will occur at an installation where the
24 recruits who have just walked onto the installation

1 have received adenovirus vaccine, but three, four,
2 five, six weeks worth of input of recruits will not
3 have received adenovirus vaccine.

4 If we go back in those situations and
5 saturate the post with adenovirus vaccine, then that
6 will diminish our 12.1 months' supply of vaccine. I
7 suspect that if we get into serious problems, that
8 we may very well go back and saturate the post where
9 we are having problems. But we are certainly
10 concerned right now about how we should manage the
11 supply of vaccine that we currently have on hand.

12 There is no specific treatment for
13 adenovirus acute respiratory disease. And if things
14 haven't changed too much with regard to the clinical
15 expression of adenovirus acute respiratory disease
16 and the transmission of this disease, and if
17 whatever unknown variables come into play and we do
18 have outbreaks, then we will probably see some or a
19 lot of what we saw back in the pre-vaccine era with
20 regard to basic training centers being disrupted and
21 having a problem with our entire system and having a
22 problem with our ability to respond when we need to
23 respond.

24 In the past, back in the '60s, some of you

1 in the room I am sure remember this, when we got
2 into these situations, we went back and relied on a
3 lot of empirical measures. We went back and said,
4 well, if we reduce crowding, if we reduce the space
5 between the recruits, if we hang sheets between
6 beds, if we increase the amount of make-up air in a
7 barracks, that this will reduce the potential for
8 transmission.

9 The people who are out there now
10 controlling at least our military training centers
11 and our barracks in the Army are not receptive to
12 these types of recommendations. We tend to use the
13 American Society for Heating, Air-Conditioning and
14 Ventilation Standards, at least those are the
15 standards we want people to use, as far as air
16 exchanges per hour, temperature and humidity.

17 In many cases, we are finding that the
18 insulation engineers are unresponsive to our
19 recommendations. The reason being that following
20 these recommendations very often results in
21 increased costs, because if you are in a northern
22 post in the winter time and you increase the amount
23 of make-up air coming into a barracks, you are going
24 to have to heat that air.

1 And these engineers have come back to us in
2 the medical community and said, no, we aren't going
3 to do that unless you can come back and provide us
4 with a good argument that these variables are in
5 fact related to an increase or a decrease in disease
6 potential in this community. If you can't do that,
7 then you are just asking us to spend money and we
8 don't see a good reason for doing it.

9 We are concerned about the vaccine supply.

10 We are concerned about our ability to diagnose
11 adenovirus acute respiratory disease and to conduct
12 surveillance. We have not determined yet what we
13 are going to do with our current vaccine supply,
14 other than the fact that we and the Navy and the Air
15 Force went back to the old system, the vaccine is
16 being given, or will be given to the recruits as
17 they come onto posts. And we are concerned because
18 the potential for outbreaks is still out there and,
19 again, we think we are going to have a lot of
20 problems.

21 That concludes my presentation.

22 ACTING CHAIRMAN ASCHER: About three or
23 more years ago, Wyeth came to the group to talk
24 about their problems with production, it was

1 regarding the facility as well.

2 Is that issue still hanging or is this a
3 repeat of the issue?

4 COLONEL GAYDOS: I believe it is the same
5 issue.

6 Colonel Bancroft, do you want to address
7 it?

8 COLONEL BANCROFT: Wyeth has had a contract
9 for the production of adenovirus vaccines for I
10 think at least five years, which was renewed, and
11 that contract is being fulfilled with this last
12 delivery of vaccine. And now we are in a situation
13 where we have, they have fulfilled their contract,
14 they are going to once again hold us hostage on a
15 production facility, as I understand it, and it is
16 now an acquisition issue with our command.

17 In the past, when the contract was being
18 negotiated, the Army took the position that the cost
19 of the production facility should be pro-rated into
20 the cost of the vaccine that we were buying and that
21 there should be no separate expense for a production
22 facility. I don't know if we can hold by that.

23 I would like to add one thing to what Joel
24 just described, and that is a good review. We are

1 facing a situation here which we have never faced
2 with adenovirus before. Adenovirus vaccines were
3 introduced to posts at a time when wild strains were
4 widespread on our basic training posts. And the
5 wild, we don't know what happened to the wild
6 strains. All we know is that we introduced more
7 live adeno 4 and 7 to the post than the vaccines,
8 and what we did is we suppressed the disease by
9 controlled enteric infections. But the viruses were
10 still there, 4 and 7, on every post and we kept
11 introducing them every time recruits came in.

12 Now we have a situation that Wyeth has
13 imposed on us that we have stopped introducing our
14 own virus and we don't know what has happened to the
15 wild strain. Now, a number of things could happen.

16 One is there won't be any disease because the wild
17 strains are not there, they have been replaced by
18 the vaccine stains and the vaccine strains aren't
19 there. The wild strains may come back, they may
20 have been there smoldering along, transmitted in
21 some of the non-immunized people all these years and
22 we may see outbreaks as Joel has suggested.

23 Or, what would be the worst situation, is
24 that, as Joel also said, would be some serotype

1 emergence and it takes over and fills the niche, if
2 you will, for which we have no vaccines.

3 And so we are facing an experiment of
4 nature in a sense that we never took with
5 adenovirus. Meantime, as we also said, we have no
6 research infrastructure for studying adenoviruses
7 anymore within our own laboratory system. We
8 stopped it. The problem went away. The problem was
9 solved with the vaccine.

10 COLONEL GAYDOS: Our laboratory at Dwight
11 David Eisenhower in August, prior to this last fall,
12 could not remember the last time that they received
13 specimens from basic training centers that resulted
14 in an isolation of adenovirus.

15 As of the end of calendar year last year,
16 they received five specimens all from one post, all
17 from Ft. McClellan, and these five specimens all
18 yielded adenovirus type 7. And, as I mentioned, the
19 other posts that had a respiratory, two respiratory
20 disease problems with the isolations of influenza-A,
21 that was Fort Benning. So it is interesting, we are
22 having some activity at two southern post right now.

23 DR. POLAND: Are there any foreign
24 manufacturers of the vaccine?

1 COLONEL GAYDOS: I am not aware of any.

2 Are you, Bill?

3 COLONEL BANCROFT: No, I think Wyeth is the
4 only one that has ever made these vaccines and they
5 have marketed to other companies -- other countries'
6 military forces at times, Canada and other places.

7 But it isn't an easy vaccine to make.

8 COLONEL GAYDOS: Yes, yes.

9 DR. LUEPKER: What is the shelf life of the
10 supplies that you have?

11 COLONEL GAYDOS: I don't know that. I
12 think that we have, my recollection is it is
13 certainly a year, but I don't, I would hesitate to
14 guess beyond that. And that's just based on the way
15 that I am familiar with the system working. I am
16 not familiar with, I don't know that we ever
17 accumulated any data on that, did we? I never saw
18 on data on extensive shelf life.

19 COLONEL BANCROFT: We have done stability
20 tests on tablets over the years, back in the days
21 when we had a laboratory base to do that. It was
22 required before licensure to monitor stability, and,
23 as I recall, you are probably right, the titer
24 stayed stable for year and then they start to drop

1 off.

2 ACTING CHAIRMAN ASCHER: I wonder if the
3 Navy, Captain Trump, would you come in on the issue
4 of whether this was coincidental, whether the loss
5 of vaccine availability was coincident with your
6 problem at Great Lakes or did you still have some
7 stuff around?

8 CAPTAIN TRUMP: No, we had run out of the
9 adenovirus vaccine at the same time. We don't know
10 what was, you know, what the underlying cause of the
11 increase we were seeing in just sort of general sick
12 call visits and respiratory disease in the total
13 population other than what, you know, ended up being
14 hospitalized.

15 ACTING CHAIRMAN ASCHER: Do you have any
16 specific comments from the Navy perspective or Mike
17 or anybody?

18 CAPTAIN TRUMP: We have essentially the
19 same concerns as far as we have been using the
20 vaccine, and especially in a place like Great Lakes
21 where, historically, respiratory diseases had been a
22 problem, a big concern, if we didn't have at least
23 the vaccine available for either emergent use or if
24 it is available, I am thinking of stock, we can

1 continue to use that as we have over the last ten
2 years.

3 ACTING CHAIRMAN ASCHER: Well, I think what
4 you said about finding out what the real problem was
5 vis-a-vis acquisitions is an important question.
6 But even if you solve that on a year-to-year basis,
7 we all know we are walking this knife edge, and so
8 keep us posted. It is going to be year-to-year it
9 sounds like. And your fallback position is
10 reasonable.

11 Dr. Gwaltney.

12 DR. GWALTNEY: I think, number one, this
13 should be given the highest priority status by the
14 military. This is not a trivial problem, and I
15 think you should make that clear in your own
16 discussions of this, make it is clear to whoever it
17 is important to be made clear to in terms of who you
18 have to go to get the resources to get this. And I
19 think the board should also recognize this as one of
20 the highest priority issues that we have dealt with
21 at least since I have been on the board.

22 There clearly is nothing that will disrupt
23 recruit training like acute respiratory disease.
24 Actually, I happened to be stationed at Fort Dix in

1 the early '60s so it clear, there is another
2 dimension to the problem which is very important,
3 which is the social, political aspect of these.
4 These young people come in, they immediately get
5 sick, they immediately go in the hospital. The
6 families call up by the hundreds. The kids lie on
7 the floor and have temper tantrums because they are
8 getting recycled in their training. And you can't
9 imagine the other part of the disruption in addition
10 to the fact that they are being recycle in their
11 training.

12 And this has been true in every war in the
13 United States that we have ever had, that acute
14 respiratory disease is the major cause of problems
15 in recruit training. So this is -- and it is
16 something we can do something about. So it is a
17 major, major problem and I think we should, number
18 one, just say that.

19 And it is really kind of inconceivable to
20 me that we have to sit here and even talk about it.

21 It seems to me that the people that are
22 responsible, if they have any education and
23 judgment, they should have been working on the
24 problem until now. We have been talking about it

1 for four years. So that's number one.

2 I think you could reasonably raise the
3 issue, has the ecology changed? Are the recruit
4 size populations smaller? Is the housing of the
5 recruits different? And is it possible that we
6 would not have it on the scale that was present in
7 the '60s now and could we just use the vaccine to
8 suppress outbreaks? That's another, that's one
9 option, and that might be reasonable to do that if
10 you had any funds to study it. But usually the
11 answer is we really don't have the resources to do
12 that.

13 So, the second option, of course, is to
14 just go on and continue like, doing something that
15 has been successful. But I strongly recommend that
16 we give this number one in the category of the
17 highest priority of problems.

18 ACTING CHAIRMAN ASCHER: If you would
19 submit a question or ask, as has been done in the
20 past by the Navy when they got a similar problem at
21 San Diego, where they were having trouble getting
22 the attention of their administration, if you were
23 to ask the board for a current statement on the
24 adenovirus issue, I think we would come back,

1 paraphrasing what Dr. Gwaltney said, highest
2 priority and a serious matter, and that would be
3 written probably between sessions. We could get
4 that to you. It would require laundering it through
5 the office and things but I don't see any problem
6 with that.

7 We did it for San Diego on a much smaller
8 scale, we could do it for you.

9 Yeah.

10 LIEUTENANT COMMANDER POTTER: I am not
11 familiar with the problems with production or the
12 technical aspects of it. I got involved with this
13 issue about last September when I got a call from
14 DMSB and I learned that from, it appeared to be a
15 problem of contracting at that time. DPSC had let,
16 had not written a new contract for production and
17 Wyeth as, as I can understand, not going to go start
18 producing something until they have a contract in
19 hand.

20 And, as it turned out, I talked with some
21 of the contracting people, not with the technical
22 people. Their impression was it was a problem not
23 of production but of contracting. We do have the
24 vaccine available now good for a year. The last

1 time I spoke with someone at DPSC, they implied that
2 they were going to go out for solicitation for bids
3 for production of this. Well, that seems kind of
4 strange since Wyeth is the only people that produce
5 it to start with. Why are you going to go out and
6 solicit?

7 But, from my impression, it is an
8 acquisition problem, a problem of contracting and
9 getting the contract written ahead of time so that
10 you can have the vaccine produced.

11 ACTING CHAIRMAN ASCHER: But Wyeth, as we
12 have heard before, is walking a fine line with FDA
13 and would love to leverage this into a new facility.
14 They wanted capital money to build a facility.

15 LIEUTENANT COMMANDER POTTER: I am not
16 familiar with that problem, but what I have been
17 told was the last problem was one of just not
18 getting the contract written.

19 ACTING CHAIRMAN ASCHER: Right. But don't
20 forget the one that is hanging over the whole thing.

21 Dr. Broome.

22 DR. BROOME: One of the alternatives being
23 considered for use of the current supplies is
24 outbreak control. Can you tell me, are there

1 options for rapid IF for adeno 4 and 7? It sounds
2 like waiting for sero-conversion is not what you do
3 to try to figure out what is causing an outbreak?
4 What are the time course of outbreaks, what is the
5 time to protection from the vaccine? You know, is
6 this a feasible strategy?

7 COLONEL GAYDOS: In the pre-vaccine era,
8 once the outbreak started, they generally started
9 very early in the basic training cycle and they
10 peaked at about the third or fourth week. We have
11 data to show that we were generally neutralizing
12 antibody titers that we associated with protection
13 at about 10 to 14 days. And we established a policy
14 of giving the vaccine as soon as the recruits came
15 through the door at the basic training center.

16 We found that we could not get good control
17 if we let them just randomly give that vaccine
18 within a period of a week after arrival. So,
19 essentially, what was happening was that the
20 recruits would come off the bus, walk in to their
21 first administrative point and someone would be
22 there and give them two tablets.

23 So it took us, it took us 10 to 14 days for
24 the antibody and once we got that at the beginning

1 of the basic training, then we began to see the
2 outbreaks stop.

3 I don't know what we have ever, that we
4 have any data where we have come into an
5 installation and, in the middle of an epidemic, and
6 saturated the installation or started giving the
7 vaccine at that point in time, as to how long it
8 took us to get control. Colonel Bancroft may have
9 knowledge of some of that.

10 With regard to the serologic studies, the
11 diagnostic capability, we are doing virus isolation
12 right now. We are open to anybody who has any
13 expertise or knowledge about the use of any other
14 tests that we could use that we be rapid diagnostic
15 potential. And Colonel Kelley has essentially
16 called around North America and we have not gotten
17 any help from anybody other than the group at
18 McMaster.

19 Pat, do you have anything to say about IF
20 or anything else?

21 I am not aware of anything out there right
22 now, or anything in the past, that we could take off
23 the shelf, that would help us to give us increased
24 diagnostic capability at the present time.

1 COLONEL KELLEY: The only group I have been
2 able to find that did a neutralization --

3 THE REPORTER: Would you come up to the
4 microphone, please?

5 ACTING CHAIRMAN ASCHER: He said the only
6 group he has been able to find is McMasters. I
7 might indicate that the California virus labs had
8 this capability for years. It is an orphan problem.
9 There's a lot of interest in the new strains being
10 characterized that come out of AIDS cases and we
11 have one scientist that works on it. He does
12 neutralization. He doesn't like to do it. But if
13 you call me, I could let you contact him and see
14 what capability might be able to transfer or to help
15 you with.

16 COLONEL KELLEY: It's a neutralization
17 assay?

18 ACTING CHAIRMAN ASCHER: He does all
19 adenovirus isolation, neutralization, plays around
20 with it and looking at new strains.

21 The thing will recombine, as Colonel
22 Bancroft suggested, we might have some very
23 interesting emergent organism out of this mix too
24 that, adenovirus X, which has been the story in AIDS

1 cases. They come up with characteristics of two
2 strains and then they have to give them a new
3 number. It has been growing.

4 Okay. We would like to move on and there
5 can be further discussion later if people want to
6 talk at the break or in the Executive Session.

7 Colonel Joseph, we are going to hear about
8 some databases in the DoD.

9 COLONEL JOSEPH: Good morning. I am
10 Colonel Malcolm Joseph and I represent the Office of
11 the Assistant Secretary of Defense for Health
12 Affairs, which is headed by Dr. Steven Joseph. The
13 Deputy is Dr. Edward Martin. The Director of our
14 agency is a Mr. Alan Andreoni, he is the Director of
15 Defense, Micro Information Management, and in that
16 agency there is an organization, relatively new,
17 named Medical Functional Integration Management.
18 Medical Functional Integration Management.

19 You have several handouts. I was given
20 very careful instructions not to bring skis but to
21 bring this information with me. One of the handouts
22 is an overview of the medical treatment facility
23 environment and the current automated systems which
24 we use in the MTS. There is also a brochure on

1 medical automation.

2 This briefing is the result of a request by
3 the board to Dr. Joseph and to Dr. Martin to
4 introduce the board to the automated information
5 systems that we currently use in health affairs.
6 This quotation by Dr. Eddy, "Physicians make
7 decisions about phenomenally complex problems, under
8 very different circumstances, with very little
9 support. They are in an impossible position of not
10 knowing the outcome of different actions but having
11 to act anyway."

12 It has only been very recent that
13 information technology has allowed for the
14 development of comprehensive health databases which
15 will help illuminate the areas of uncertainty in
16 medicine.

17 There are currently 128 automated
18 information systems in the military health service
19 system. Today, my goal is to highlight those
20 systems that allow reasonable access to databases
21 and those systems which we think will have some
22 meaning to the board members.

23 This slide depicts a subset of the current
24 information management strategic principles. One is

1 that the systems that are selected, that there will
2 be comparable performance measures across the MHSS
3 and the private sector. That the information
4 management to improve the understanding of how to
5 effectively and efficiently provide health services
6 so that informed choices can be made by providers
7 and beneficiaries, and that there be uniform data
8 sets, processes and technical standards.

9 One of the key initiatives currently is to
10 complete a DoD standard dictionary which will
11 include entities for all of the processes that we
12 use in the delivery of health care.

13 I handed out this slide which is an
14 overview of the current MHSS system architecture.
15 Currently, we have 8.5 million beneficiaries,
16 approximately 13,000 civilians, and the largest
17 health care provider network in the country. And it
18 is the goal that the use of automated information
19 systems will allow us to deliver better health care,
20 to do the right things, and to ensure that the
21 lessons that are learned by virtue of each clinic
22 visit, that we will be able to look at them from a
23 population-based epidemiological basis to assist our
24 researchers and our clinicians in improving the care

1 that is rendered.

2 A very significant ongoing effort currently
3 is the migration system selection process. As noted
4 initially, there are 124 systems and currently not
5 all the systems have inter-connectivity. They are
6 written in various computer languages. There was an
7 article recently in the "Harvard Business Review"
8 that stated, opened with a quotation that, "Strategy
9 and structure lead first" and that "the systems are
10 a result of the strategy and structure."

11 Part of what I think the group has heard
12 over the past day is that the structure and the
13 strategy in the MHSS is changing dramatically. And
14 I can also speak directly to the fact that our
15 systems are changing dramatically.

16 Our goal is towards an open environment
17 system, we call it plug in play. We do an object-
18 oriented analysis and design. Object-oriented
19 analysis creates standard entities and their related
20 characteristics and data elements.

21 During the development of an AIS system, an
22 analysis of the needed data elements is conducted.
23 Then consensus is reached regarding the standard
24 groupings of elements under objects. For example, a

1 physician examination could be considered an object.

2 Data elements would be auscultation of the lungs,
3 skin exam, etcetera.

4 There is an appendix that will provide more
5 detail related to the migration system selection.

6 The perfect database as defined by Dr.
7 Mitzmorris at the Office of Science and Data
8 Development would include these elements, and our
9 goal is to develop a perfect database for the DoD.

10 The automated systems that we think are of
11 some epidemiologic interest should be, our selection
12 criteria for choosing the systems we are going to
13 look at today, are systems, one, that we control
14 within the MHSS, they are population-based, they are
15 accessible, and they contribute to this
16 comprehensive or perfect database.

17 This is a list of those systems and we will
18 quickly walk through this list.

19 These are some additional systems which we
20 will not cover this morning. But currently there is
21 the preventive and occupational health, and in
22 occupational health, some of the systems that we
23 will not cover are the reportable database system;
24 the health risk appraisal system. We have future

1 systems that are being developed. A very key one is
2 the CEIS, or corporate executive information system,
3 which will access a computerized patient record
4 which we are currently developed.

5 The DMHRS system is a manpower system, it
6 standard for Defense Medical Human Resources. The
7 DMLSS system is a Defense Medical Logistics and
8 Standard Support System. And the CCEP is the
9 Comprehensive Clinical Evaluation Program.

10 The CHCS system is a system that is
11 probably most familiar to most military providers.
12 It is deployed at all of our major medical centers.

13 Its epidemiological importance is that it has a
14 primary data collection and storage. It has key
15 demographic data and has significant amounts of in-
16 patient and out-patient encounter data.

17 This slide demonstrates some of the various
18 interfaces, data access, timeliness and the name of
19 Dr. David Schroeder, who is the POC for CHCS. CHCS
20 is currently the backbone of our automated
21 information system network. And many of the systems
22 that will come online, one of the requirements is
23 that they interface with CHCS.

24 MHCMIS is a system that is less well known.

1 It is of epidemiologic importance because it has
2 access to detailed encounter-level data and it links
3 with multiple systems. One of the handouts
4 addresses MHCNIS.

5 These are the various databases which
6 MHCNIS links with, and we will just continue on to
7 the next one.

8 OHNIS. OHNIS is the Occupational Health
9 Management Information System. It is the
10 occupational health system that is currently used by
11 the United States Army. Yesterday you received a
12 briefing on the Phoenix system. Phoenix and OHNIS
13 have a great deal of overlap with respect to their
14 functionality and their data elements.

15 The Navy has a system called no NOHMS, the
16 Naval Occupational Health Management Information
17 System. What is important is that, with respect to
18 the strategy, the migration strategy is that the DoD
19 and the Services are committed to narrowing the
20 number of systems that we have to reduce overlap and
21 duplication.

22 In the future there will not be a separate
23 Army Occupational Health Management Information
24 System, Navy Occupational Health Management

1 Information System, and Air Force Occupational
2 Health Management Information System.

3 The process that I have been involved in
4 for several years now has specifically related to
5 occupational health and preventive medicine. I
6 anticipate that in the next 30 to 60 days, the Army
7 will be identified as the executive agent to migrate
8 this system, OHMIS, to the other services. This is
9 a tri-service effort and this initiative is
10 currently being staffed by the Surgeon Generals.

11 In addition to selecting OHMIS as the
12 migration system, and it will be called the DoD
13 OHMIS system, there is also another effort at which
14 we are developing a target system for preventive
15 medicine and occupational health to be used in the
16 military health services.

17 The role of the board, and of the various
18 consultants that are assembled today, with respect
19 to that development, I think is very important. We
20 have the opportunity to tailor, to handmake, to
21 customize a system that will meet any of the needs
22 that we identify.

23 This is obviously a slide that continues on
24 OHMIS and I think enough said.

1 Okay. The Ambulatory Data System is a
2 system that will be deployed in 1995. We think it
3 is important with respect to the data that it will
4 capture regarding the delivery of health care in the
5 out-patient setting. It will help us to determine
6 disease prevalent incidents, trend analysis and
7 practice patterns. It interfaces with many of the
8 other systems. The key interfaces are CHCS and
9 MHCMIS.

10 The RCMAS system is the Retrospective Case-
11 Mix Analysis System. It allows normative data
12 comparison within DoD to civilian norms. It
13 includes demographics, name, gender, race, etcetera,
14 and it generates several standard reports which we
15 think will be helpful with regard to epidemiological
16 research and analysis.

17 The RCMAS system also interfaces with many
18 other systems. CUN (phon.) activity is a
19 requirement for any of the systems that are selected
20 as migration systems.

21 This is CHAMPUS, which is I think familiar
22 to many of us.

23 Mike, bring that down a little bit. There
24 you go.

1 The CHAMPUS system is one that collects
2 information on the DoD beneficiaries who are outside
3 of direct health care system. CHAMPUS has many
4 interfaces, as with the other systems.

5 Next is DEERS. DEERS is the Defense
6 Enrollment Eligibility Reporting System. DEERS has
7 population data. DEERS is a system that will become
8 increasingly important with respect to our Tri-Care
9 effort, Tri-Care being the military management care
10 effort.

11 There is the Defense Blood Standard System.

12 This system was identified, to be brief, this
13 morning, to introduce the board members to a system
14 that has data which will be of importance in looking
15 at HIV and HIV-related issues, in addition to all
16 the issues related to the management of blood
17 products.

18 This is the Medical Expense and Performance
19 Reporting System. When we look at the collection of
20 data, data elements, the effort brings together
21 automated systems that not only include the
22 traditional health care delivery but also those that
23 are involved in the cost and management of cost.

24 Next slide.

1 We think that the databases can be used for
2 many purposes. They are currently used for public
3 health and surveillance, for epidemiological
4 research. And in the future, we anticipate that we
5 will use this information to develop performance
6 measures, outcome measurements, quality assurance,
7 improvement and continuous quality improvement and
8 also in Tri-Care managed care effort.

9 The next slide simply shows the output of
10 the MHCNIS fields.

11 I'll go to the last one.

12 We walked very quickly through ten systems.

13 There are 124. There is a document titled "The
14 Automated Information System Plan," AIS Plan, that
15 is a comprehensive document that lists all of the
16 124 systems. It lists the justification for those
17 systems. It will provide the board with some
18 historical background related to the systems. And I
19 will recommend that we provide a copy of that
20 document to each of the board members as you try to
21 determine what is the best role for the board in the
22 future related to this effort.

23 We have one more slide I want to show.

24 There is some migration in your handout. There are

1 some slides with arrows on them and I would like to
2 -- the effort that we are involved in currently at
3 DoD is taking those systems which are legacy
4 systems, and at the end is a glossary which will
5 explain those terms, take the current systems that
6 we have to see where we can reduce redundancy and
7 migrate selected systems.

8 Four years ago when this effort started, we
9 thought that we would be able to develop the target
10 system within a three- to four-year period of time.

11 For many reasons, that did not occur. In 1993, Mr.
12 Perry, who was then the Assistant Secretary of
13 Defense, he is now the Secretary of Defense, issued
14 a memorandum saying that, "While we continue the
15 efforts towards the target systems, let's choose a
16 system for migration." These systems will not be
17 funded. These systems will be funded. And we will
18 continue to look towards an open target system.

19 And I think that what I would ask the board
20 to do is to look at the entire pattern, but to focus
21 on the preventive health care and occupational
22 health. And, Mike, if you could find that
23 particular arrow, I would appreciate it. To look at
24 the systems that we have identified as legacy and

1 migration systems, to assist us in developing the
2 target system. This initiative has had a great deal
3 of interest by agencies outside of the DoD. NASA
4 has expressed interest. OSHA has expressed
5 interest.

6 We think that it is a tremendous
7 opportunity for those us in preventive health to
8 help develop a computer system that will allow us to
9 improve what we do, to make us more effective, more
10 efficient and to assist the military departments in
11 their key goal of readiness.

12 Thank you.

13 ACTING CHAIRMAN ASCHER: As was indicated
14 at the beginning of the presentation, this
15 presentation and others like it were solicited by
16 the board to try to understand this process. And
17 previously, Dr. Kuller and others had a very large
18 amount of input in the beginning of some of this
19 stuff, and we do not active subcommittee designated
20 to help you, and I don't think we need to at this
21 point, but I am wondering if Greg Poland would be
22 willing to kind of be a liaison to this area.

23 Is that of interest to you?

24 DR. POLAND: (Nodded in the affirmative.)

1 ACTING CHAIRMAN ASCHER: And if you would
2 then maybe check with Dr. Poland in terms of some of
3 your preliminary questions, and then if you would
4 like a little working group formulated to work with
5 him, I would very much appreciate it. It is
6 overwhelming to us all to see these acronyms and
7 things but it does fit together at some level, and
8 you are really encouraged to keep at it.

9 COLONEL JOSEPH: Thank you. Appreciate it.

10 ACTING CHAIRMAN ASCHER: Do we have any
11 comments on the system, or questions about the
12 presentation? Yes.

13 DR. LUEPKER: Just a comment and a question
14 here. You know I wasn't here when the board
15 recommended this. I think in all the systems you
16 have available, the need for consolidation is
17 apparent. The challenge though is great, and I can
18 see progress has perhaps been slower than you want.

19 The need for common records, common data sources is
20 very important.

21 I guess I would encourage you, and maybe
22 Dr. Poland, now that he has taken some
23 responsibility here, to think about how this
24 actually might be used. The promise, which goes

1 back several decades, of large databases improving
2 clinical care, I think has yet to be fulfilled. And
3 certainly, standardization is important in and of
4 itself, but if this consolidated database is to be
5 useful in advancing care, then this is the time to
6 begin to think about how that is going to occur.

7 ACTING CHAIRMAN ASCHER: Dr. Broome.

8 DR. BROOME: I guess I would look at it a
9 little differently. I don't see that collapsing
10 down to one database is either desirable or
11 feasible, and I didn't really hear very much about
12 efforts to promote common data elements, standard
13 variable definition, thoughtful issues related to
14 linkage. I assume you have SSN so that in fact you
15 are in pretty good shape to have a system of
16 databases which can be linked as appropriate for
17 needed analyses.

18 And, finally, in addition to these sort of
19 housekeeping issues, it seems to be the promise of
20 these is only realized if they in fact get analyzed
21 and used. And so I would think the board would be
22 interested in seeing a little more about exactly how
23 these public health surveillance applications or
24 epidemiologic studies are actually being realized to

1 take advantage of the data linkage potential.

2 ACTING CHAIRMAN ASCHER: Several years ago,
3 when one of these presentations was given, it was
4 clear that we had about 19 different systems, all
5 protecting their own turf, all in their own
6 languages. And the breakthrough was when people
7 realized that you can get through that by using
8 additional tools which will act as if the systems
9 are the same and will connect INFORMIX with SEQUEL
10 with ORACLE with all of the other, MUMPS, and that
11 sort of thing. So it is the secondary industry of
12 connectivity, but unless you have that dictionary
13 and at least one link, you are in real trouble.

14 You did mention the dictionary issue.

15 COLONEL JOSEPH: Yes, sir.

16 ACTING CHAIRMAN ASCHER: Do you want to
17 elaborate on that?

18 COLONEL JOSEPH: The data standardization
19 is the key piece of this undertaking. We have a
20 data standard acceleration group. And the intention
21 is that, as we put the pieces of the puzzle
22 together, and it has been slow and it has been
23 painstaking, that various other clinical entities,
24 functional people, users, will be able to come in,

1 look at what we have done, and add their piece to
2 the puzzle.

3 But the critical part of this is the data
4 standardization and the development of that
5 dictionary.

6 ACTING CHAIRMAN ASCHER: Dr. Hansen.

7 DR. HANSEN: As you will hear from my
8 report a little later on the injury working group,
9 we have actually been looking at some of the
10 possible uses of some of these databases. And I
11 agree completely with Dr. Broome's comments that we
12 have to think about the analysis before we think
13 about the data collection, because that will really
14 alter the way in which this whole process of
15 information improvement takes place.

16 We found, for example, that the reason a
17 record was set up is very important to understand in
18 order to understand why the record is structured as
19 it is, and why it is missing key elements. For
20 example, the medical records, the hospitalization
21 records, particularly, were structured for the
22 purpose, as I understand it, principally of
23 deploying the staff, how many nurses you need, how
24 many doctors you need, what kind of doctors you

1 need. And so the frequency was the thing they
2 needed. They needed to know how many fractures to
3 know how many orthopedic surgeons. But they didn't
4 need to know how many that fracture's number was of
5 the total.

6 So the whole issue of how to analyze the
7 data had not really been thought about for that
8 purpose.

9 And I think as we look toward supporting
10 the military, we need to think about the kinds of
11 questions that need to be answerable and then look
12 back to the database to see what needs to be
13 changed.

14 I am reminded of the issue of alcohol and
15 its involvement in injury. No dictionary and no
16 coding is going to help you unless you really think
17 out how you are going to actually use that
18 information in terms of the involvement of alcohol
19 in any injury, one way or another. But that gives
20 you at least a couple of examples from our
21 discussions of the kinds of concerns that we have
22 had about the databases as we have been trying to
23 use them to come to prevention recommendations,
24 which is really what I think the goal of these

1 information, at least many of these information
2 processes should be.

3 COLONEL JOSEPH: Dr. Hansen, I would like
4 to just follow up on your comments. One of the
5 reasons this process has taken longer than anyone
6 anticipated is that before we can automate anything,
7 we need to understand what we are automating. And
8 there are several references and texts, one that I
9 found particularly helpful is entitled "Re-
10 engineering the Corporation," it is a text that has
11 been on the best sellers' list for quite some time
12 now.

13 That re-engineering has proved to be very,
14 very difficult. And as we bring together various
15 working groups to try to identify what are the
16 important processes and how can we improve them, for
17 a system as large as ours, it has been difficult to
18 reach consensus.

19 DR. HANSEN: I am sure.

20 ACTING CHAIRMAN ASCHER: Dr. Stevens.

21 DR. STEVENS: That's okay.

22 LIEUTENANT COMMANDER JONES: You mentioned
23 that your candidate systems have to be under the
24 control of MHSS. It occurs to me that there are

1 several very important databases that are not under
2 the direct control but to which the medical
3 departments of the services contribute a great deal.

4 Those are the physical disability agencies who base
5 their physical evaluation boards on medical
6 evaluation boards. That may be an important source
7 of information, it is automated in at least one
8 service, it may not be in the others.

9 The other is in the area of workers'
10 compensation, which we have some input to and
11 understanding of, but which is, again, a system that
12 is not directly under your control but I think
13 deserves some consideration because of the important
14 implications.

15 COLONEL JOSEPH: Yes, sir. The issues are
16 right on target and my role is to serve as the
17 functional coordinator to ensure that we bring all
18 of the key elements and projects and programs into
19 the process.

20 Thank you.

21 ACTING CHAIRMAN ASCHER: Thank you very
22 much.

23 Dr. Stevens.

24 DR. STEVENS: This is not related to the

1 database issue, but something you said in your
2 presentation has jogged me a little bit. A look
3 back for HIV, I wondered whether somebody in a
4 future meeting could give us a little bit of
5 information about, I assume that it is for
6 individuals who donate blood and are found to be
7 positive where they were not positive before, sero-
8 converters.

9 I am looking back to the recipients of
10 previous donations. I wonder if sometime in the
11 future we could get some information about how often
12 that occurs, how big a problem it is in blood
13 donation in the military.

14 COLONEL JOSEPH: Yes, ma'am. We will
15 provide the information to the board.

16 ACTING CHAIRMAN ASCHER: We have some
17 schedule changes. A couple of announcements. We
18 probably want to stick with the break at 10:00, so
19 that we will get as far into the occupational
20 medicine package as we can and then break at 10:00
21 and come back and finish.

22 Colonel Leitch is unable to present today
23 because his slides didn't come in. I believe that
24 was --

1 COLONEL LEITCH: I apologize profusely to
2 everybody. Somewhere in Datapost or Fedex, I am not
3 sure who is to blame. It hasn't come in.

4 ACTING CHAIRMAN ASCHER: We will use that
5 time to discuss the hepatitis question in public, we
6 will have some opportunity to do that, and any other
7 issues about the Royal Family or anything else that
8 we would like to bring up.

9 (Laughter.)

10 ACTING CHAIRMAN ASCHER: Colonel Tomlinson
11 has a couple of other announcements.

12 COLONEL TOMLINSON: Yes. Those individuals
13 who have had some of the refreshments and have not
14 yet paid, that charge was \$2.00 for each day. So
15 those of you who maybe have not yet paid, if you
16 would pay Jean Ward, it is \$2.00 a day, \$4.00 for
17 the two days, that's for the coffee and the juice
18 and muffins.

19 Sergeant Harris and Colonel Falkenheimer
20 are actually holding the tab on that, so we don't
21 want to skip town owing them money.

22 Secondly, Sergeant Harrison and Colonel
23 Falkenheimer would like to take some candid pictures
24 of the AFEB and Action, so they may be doing that

1 for the rest of the meeting today.

2 And, thirdly, Jean Ward had heard that
3 there may be some delay of air traffic through
4 Chicago today, if anyone is going through, they
5 might want to check on your flight. That's it.

6 ACTING CHAIRMAN ASCHER: Okay. Do we have
7 the right sequence? Colonel Fleming is -- yes.

8 COLONEL FLEMING: Good morning. I am Jim
9 Fleming, a very new person to you folks. I have
10 just been named as the Occupational Medicine
11 Consultant. I have been asked to go ahead and give
12 a briefing to the AFEB on occupational health for
13 the Army.

14 I feel sort of like the definition of the
15 expert who comes from 50 miles away, go ahead and
16 tell you what you already know. I think you for
17 vindicating the fact that I am an expert, though I
18 don't really feel that I am.

19 Next slide, please.

20 Okay. This is the format for my briefing,
21 areas I will be covering.

22 Next slide, please.

23 This is our mission statement. Out of our
24 Army Regulation 40-5, which is the preventive

1 medicine regulation.

2 Okay. The objectives. Again, out of the
3 regulation, change essentially to assure that our
4 workers are able to go ahead and perform the work
5 physically, mentally, psychology, to protect those
6 personnel from adverse effects, to assure the care
7 and rehabilitation of our workers. Reduce the
8 economic loss associated with that, and to prevent
9 decreased combat readiness of our soldiers.

10 Okay. Briefly going through history,
11 occupational health in the Army has been a concern
12 since the Revolutionary War. There was a surgeon
13 who wrote a letter to General Washington about
14 hearing loss among artillerymen, so it has been
15 around for a long time.

16 It formally came into play in World War I
17 in the munitions industry as well as in the gas
18 production and gas protection elements of the war
19 efforts. In fact, that is where Dr. Hamilton became
20 involved in the munitions industry and the mortality
21 associated with TNT workers.

22 In World War II it has become even more
23 formalized, where, again, within our inordinance
24 areas where we looked at, again, the mortality among

1 the munitions employees and were able, due to
2 sanitary, increased sanitary protection, as well as
3 occupational health and industrial hygiene support,
4 to reduce mortality from about 24 per 10,000 down to
5 less than 5 per 10,000, and in a couple of year
6 period of time.

7 This was also the period of time where the,
8 what is now being known as the CHPPM actually
9 started, and that was the Army Industrial Hygiene
10 Lab at Johns Hopkins University and a very famous
11 and noted person has been responsible for that, that
12 was Dr. Ana Batchner, who has been part of the Army
13 community for many, many years.

14 Also, it is the first time at the Army
15 Surgeon General's office that there was an
16 occupational medicine consultant to go ahead and
17 work.

18 With the inception of OSHA, which came
19 around about 1970, and then also with the federal
20 government's coming under the OSHA Act, we sort of
21 formalized and straightened up our act even more.
22 That is when the DoD I-160-55, which is our
23 regulation that says, yes, you will go ahead and
24 follow all of the OSHA guidance, and also the

1 inception into the preventive medicine documentation
2 of AR 40-5 for occupation health support, as well as
3 the Army safety document AR 3 -- 385-10 which
4 supports that.

5 The other part of the history is our
6 military unique hazards. Unlike civilian
7 industries, where basically it is the work place is
8 a static environment, the Army moves, and so our
9 hazards move along with the soldiers. So, in order
10 to help control those hazards, or help protect the
11 soldiers, we need to go ahead and look at the army
12 materiel systems to go ahead and see how we protect
13 soldiers within those systems as opposed to in
14 static locations.

15 Next slide, please.

16 Our occupational health team consists of
17 basically these four elements. There are some
18 additional ones which I will talk about later. Our
19 industrial hygiene program, very strong.
20 Occupational health nursing. The first two at the
21 grass root levels are essentially the bedrock of our
22 program.

23 The occupational health PA's are fairly new
24 members of our team. They have been around for a

1 little over ten years. They mainly provide support
2 to the active duty soldier, and we utilize these
3 officers at large troop locations.

4 The occupational medicine physicians. Our
5 physician support ranges from general medical
6 officers and civilian physicians at the industrial
7 sites up to board certified occupational medicine
8 officers.

9 Next slide, please.

10 Just to give you a brief breakdown on the
11 Army, the new Army structure, I don't know how many
12 of you have seen this. Hopefully, you have already.

13 What you see there as MEDCOM used to be Health
14 Services Command but the structure goes deeper than
15 that. OTSG was really the controlling element of
16 the Army Medical Department. That is now changing
17 where they are now mainly an R staff function in
18 support of the Surgeon General to the Chief of Staff
19 for the Army.

20 The MEDCOM is where the power base has
21 moved to and that is a reality. And that is down at
22 Fort Sam Houston.

23 We also have, the HSSA's that you see up
24 here, are health service support agencies. Those

1 are regional commands that control all of the
2 medical centers and medical treatment facilities out
3 at the various installations. Currently these
4 HSSA's are co-located where our medical centers are,
5 essentially. And underneath them are the medical
6 treatment facilities, the medical centers, the
7 medical hospitals, as well as all the clinics that
8 fall within MEDCOM.

9 The CHPPM, you have already been, talked
10 about that. That is still the home of our
11 occupational medicine and the elements of the old
12 AEHA are still within that organization, and they
13 have some support elements underneath them are also
14 part of that.

15 The AMEDD center and school is our doctor
16 and training center and that is where I am currently
17 located within.

18 That is the structure of the Army. Now,
19 how does occupational health fit in?

20 The next slide, please.

21 at the installation level, as I mentioned
22 to you, the occupational health nurse and industrial
23 hygienist are our basic elements. We also have
24 general medical officers and, as I mentioned before,

1 the occupational health PA where we have large troop
2 concentrations.

3 At the regional levels, again, our
4 occupational health nurse. Usually the one at the
5 medical center is, also has double duty as the
6 regional occupational health nurse. The same thing
7 with the industrial hygienist, and we have placed
8 and/or are placing our board certified occupational
9 medicine physicians at all of the HSSA's. By the
10 summer, the only HSSA that will not have an oc med
11 physician will be at William Beaumont, and that is
12 our smallest one and we just do have the numbers to
13 go and support that at this time.

14 The CHPPM, again, the same elements they
15 had under the agency. A strong industrial hygiene,
16 occupational health nursing program, as well as the
17 occupational medicine physician program. And,
18 again, that is still home to the Army's occupational
19 medicine residence program.

20 At the MEDCOM level, again, as I mentioned,
21 the power base for the design, the structure, and
22 basically telling us what to do. We do have an
23 occupational medicine physician on staff there, as
24 well as industrial hygienist on staff.

1 At OTSG, the occupational medicine
2 consultant, myself, is no longer located there.
3 That has been, that is no longer a staff function,
4 it is only a consultant function -- I don't want to
5 say only -- but it is something that I do as an
6 extra duty. The industrial hygiene consultant is
7 still there, as well as the preventive medicine
8 consultant is still at OTSG serving on the R staff.

9 We also have occupational medicine
10 industrial hygiene support at our Army materiel
11 command elements at the headquarters level and at
12 the two of the subcommands, the industrial operation
13 command and chemical, biological defense command,
14 and we are considering trying to open up a position
15 at OSIA, the Overseas --

16 VOICE: Inspection.

17 COLONEL FLEMING: Inspection Agency. Thank
18 you.

19 Next slide, please.

20 Other than the four elements I talked about
21 earlier, we also have health physics officers who
22 support in the radiation health and safety, and they
23 are located at all levels of medical treatment
24 facilities up to the CHPPM level, life support, and

1 they are subject matters experts in that field.

2 The same thing with audiology, with hearing
3 conservation, and they are located at all those
4 levels.

5 We also have optometry at the CHPPM level
6 to provide occupational vision.

7 Our special emphasis areas that we are
8 looking at, and Colonel Joseph had a good talk on
9 OHMIS so I will just go ahead and mention it here.
10 The AMC-MEDCOM partnership program is a program
11 where the Army Medical Department is working with
12 AMC to handle additional support for the majority of
13 the civilians within the Army medical community --
14 Army community. And we, the Medical Department, are
15 not providing enough services, occupational health
16 services, to AMC. AMC is working with us to provide
17 the additional personnel.

18 Military Unique Hazards Program. As I
19 mentioned before in the history, we do have a health
20 hazard assessment program where we look at Army
21 materiel. This was started when we looked at Big
22 Bertha, that was a large howitzer that was found to
23 go ahead and cause not only auditory but non-
24 auditory effects such as pulmonary edema and

1 pulmonary hemorrhage and we looked at that piece of
2 materiel to go ahead and see how to reduce the
3 effects of adverse health on the soldiers, and we
4 were able to do that. We now look at all Army
5 materiel as it comes on line.

6 The Health Risk Assessment Program, also
7 centered up at the CHPPM, looks more at the
8 environmental concerns that the Army produces. This
9 goes everywhere from the depleted uranium on
10 training fields to looking at, we sent folks over
11 to, for the Kuwait oil fires to go ahead and look at
12 that situation. And we are also heavily involved in
13 the occupational medicine side, both in the research
14 as well as in the de-militiarization of the chemical
15 surety materiel.

16 Our last major emphasis area is on the
17 Civilian Resource Conservation Program, which is the
18 Army personnel's program for reducing the cost and
19 the number of civilian work injuries.

20 Next slide, please.

21 Special issues that we have, I started to
22 touch on these a little bit. Personnel
23 restrictions. We don't have enough people to go
24 ahead and do all the job. We don't have enough

1 funding to go ahead and get it all done. Our
2 industrial base, unlike the other two services, is
3 spread out. Our largest industrial base may have
4 about 3,000 personnel at this point in time. Most
5 of them are well under 1,000, and at last count, I
6 count I think at AMC there were still over 80
7 installations that we have to go and provide support
8 to.

9 So, again, it is a very spread-out
10 organization and we have to go and provide the basic
11 level of support to all of that.

12 The AMC-HSC Partnership Program is online.
13 There are some problems with that we are working
14 through.

15 Subject to your questions, that is the end
16 of my brief. Thank you.

17 ACTING CHAIRMAN ASCHER: Anything pressing
18 for this section, or should we go on to the next
19 one?

20 LIEUTENANT COLONEL FALKENHEIMER: I have
21 one question. Falkenheimer.

22 You mentioned you look at Army materiel
23 when it comes on line. I was wondering if you were
24 looking at getting in earlier in the acquisition

1 cycle, because once it is online, obviously, it is a
2 lot harder to change.

3 COLONEL FLEMING: Well, we actually start
4 everywhere from the concept phase up, so in the
5 whole manpower or manprint program, we are involved
6 with that, all the way through. Actually through
7 the cradle to grave.

8 Thank you very much. I appreciate this
9 opportunity.

10 COMMANDER RUDOLPH: Good morning. I am
11 Garry Rudolph, an occupational medicine physician at
12 the Navy Environmental Health Center, Norfolk,
13 Virginia. It is a pleasure for me to be here this
14 morning.

15 I am going to give you an overview of the
16 Navy occupational medicine programs. I am going to
17 take a slightly different approach. I am not going
18 through the organizational structure so much. I
19 must mention, I am going to be a little remiss in
20 not speaking much about the rest of the occupational
21 health and safety team in the Navy, because probably
22 if they do their work, we are out of business, but
23 time doesn't really allow me to go into the all the
24 programs for those areas. But I do want to

1 recognize our industrial hygiene, hazardous
2 materials, safety specialists, and the rest of the
3 team really in this whole effort.

4 So I am going to hit on some old programs
5 and a few initiatives. Hopefully, leave a couple of
6 minutes for questions.

7 To give you an idea just about size and
8 scope of the Navy occupational medicine program, we
9 run 153 occupational health clinics, or thereabouts,
10 worldwide. We have in full-time employee basis,
11 about 150 physicians and physicians' assistants in
12 these clinics, and, again, about 150 occupational
13 health nurses.

14 Those numbers really under-estimate to
15 quite a degree the number of people actually
16 performing occupational health, especially when we
17 talk about our operational forces, the sailors, our
18 float forces, where really every medical department
19 aboard a ship is functioning like an occupational
20 health clinic. So these are our funded, shore-
21 based, occupational health facilities, and we take
22 care of approximately a million Navy and Marine
23 Corps, civilians and active duty, quite a complex
24 industrial environment.

1 We still operate, depending on where are at
2 in the BRAC process, many shipyards, naval aviation
3 depots, which are similar to the logistics command
4 here at Ogden, so it is a complex industrial
5 environment. Our float forces are often working in
6 complex industrial environments. Maybe you have
7 seen those in the past. We still have many tenders
8 which are floating factories out there doing some
9 complex things. So it is really and interesting mix
10 of industrial environments.

11 Let me talk about one old program, I am
12 sure you have heard mention of it at least in the
13 past. It is now 15 years old, the Navy asbestos
14 medical surveillance program. I'll briefly just
15 give you a little background. It began in 1979. It
16 is a centralized collection of data regarding
17 physicals for people exposed to asbestos. It
18 includes X-rays which get a standardized reading
19 called a B reading, or the International Labor
20 Organization's classification of pneumoconiosis. We
21 also do a brief medical history and physical exam
22 and pulmonary function testing. Those results are
23 coded and centrally collected.

24 An important feature of the program is it

1 only covers active employees. And I'll mention
2 something about that in a minute. But, and the bulk
3 of those are people with historical exposure. OSHA
4 only requires employers to screen individuals with
5 current exposure to asbestos. The Navy program,
6 from its initiation, included all employees who had
7 had prior exposure during federal service, with what
8 I mention is a very liberal screening procedure to
9 put people in. We basically put people in that even
10 had very low and moderate exposures.

11 We do right now about 25,000 X-rays a year.

12 There are actually more people than that, because
13 some don't get X-rays every year.

14 Up until 1990, the data was collected and
15 maintained at the -- well, it was collected by the
16 Navy Environmental Health Center but maintained at
17 the Naval Medical Information Management Center.
18 Since '90 to '91, we have been collecting all the
19 data at the Navy Environmental Health Center. We
20 had restructured the forms we used at the time, so
21 we have a real issue right now about how to get that
22 data together. We have had trouble in the past,
23 quite a bit of it, accessing the data at NMIMC, and
24 we have the additional burden now of trying to marry

1 up data to different sources.

2 Next slide.

3 Just a general idea about this program,
4 there has been some studies published in the
5 literature about our asbestos program, but overall,
6 there is a relatively low prevalence of
7 abnormalities. You consider the two main reasons
8 for that I have already mentioned, one is we are
9 only screening active employees. As you know,
10 asbestos-related diseases are of long latency, many
11 cases aren't going to show up for 20 or 30 years or
12 longer, so we may be missing some individuals with
13 asbestos as these are likely to be.

14 In addition, we tended to put a lot of
15 people in the program that did have very low
16 exposure, people we really don't expect are going to
17 pneumoconiosis. So we see a low prevalence of
18 abnormalities. We have been trying to focus more on
19 the subsets of that population that are more at
20 risk, looking at some case, and I use that very
21 loosely, definitions by X-ray changes and pulmonary
22 function tests, clinical criteria. Looking at the
23 issue of latency because, like I said, it takes a
24 while for these things to show up.

1 It is very hard for us to make exposure
2 determinations. We only ask people for their
3 current employment, and this is useful for some
4 groups. But we have a large number of prior active
5 duty who are now civil service workers who had their
6 exposure while on active duty, maybe in the '50s or
7 '60s, and we are not necessarily capturing what
8 their true exposure history is in this very brief
9 screening form that we use.

10 This has been published well in the
11 literature and we have seen it certainly in our
12 databases, the variability you have in these X-ray
13 readings called B-readings is well known and it
14 continues to be seen. We are very interested in
15 looking at individuals. This is very difficult
16 clinical management.

17 We are doing a screening tool which is
18 designed for, hopefully, for epidemiologic purposes,
19 and we are asking people in clinics to clinically
20 manage these people with abnormalities, counsel
21 them, etcetera. Many of these people are abnormal
22 one year and normal the next, and you are trying to
23 communicate that appropriately. But we are very
24 interested in looking at how consistent, in an

1 individual who has abnormalities, how they persist
2 over time.

3 Next slide.

4 I am just going to briefly mention the
5 hearing conservation program. There's about 450,000
6 people in that program. Really, we are anxiously
7 awaiting what you heard earlier, this OHMIS
8 migration system and the Tri-Service HEARS
9 component, the Hearing Evaluation Automated Registry
10 System. We are doing very little with that data.
11 It is a very large data set and I think OHMIS holds
12 promise, or greater promise, DoD-wide, to look at
13 that data for hearing conservation.

14 Next slide.

15 We are making some recent efforts into heat
16 injury prevention. We are going to have a group, a
17 Navy, Marine Corps Heat Stress Working Group is
18 going to be getting together in a couple of weeks.
19 We are going to revise and consolidate and re-look
20 at many instructions we have. We have instructions
21 with the Marine Corps, with the Navy, with HUMED
22 (phon.) and many different sources often have some
23 technical disagreements among them, so we will be
24 doing some effort in standardizing the way we run

1 our heat stress programs, the way we report heat
2 injuries.

3 There is an extreme interest in looking at
4 PHEL curves. The PHEL curves are Physiologic Heat
5 Exposure Limits which were established for shipboard
6 use, were redeveloped based studies in men. Given
7 the large number of women now on all types of ships,
8 we are very interested in looking at how these
9 apply, what kind of research we may need to do. So
10 this will be an issue brought up by the working
11 group.

12 Next slide.

13 A relatively recent initiative, they met
14 for the first time in September '94, is the
15 Reproductive Hazards Review Board. It is a board
16 consisting of not only Navy but many from academia,
17 and we have an OSHA representative on that board.
18 They have several objectives for the group. One is
19 to help us look at our technical manual,
20 "Reproductive Hazards in the Work place," make
21 appropriate updates as necessary.

22 We put out an annual list of known
23 reproductive hazards. This group will be involved,
24 will be providing input to that process, and,

1 hopefully, identify research needs within this area.

2 Next slide.

3 The Navy, you heard mention of NOHIMS
4 before. NOHIMS really is only applicable, NOHIMS
5 was the Navy Occupational Health Information
6 Management System, it is only being used in a couple
7 of locations left over from its early days.

8 We do not have a system like Phoenix in use
9 at any of our, or the majority of clinics. One
10 thing we have made an effort at though is to
11 standardize our approach to doing medical
12 surveillance.

13 I will briefly give you a little
14 background. The Navy, I think for several years now
15 has made good efforts at developing a true hazard
16 based medical surveillance program. All Navy work
17 sites, all Navy work sites get a baseline industrial
18 hygiene survey. And, depending on the complexity
19 and the hazards, a periodic survey, usually
20 somewhere from one to three years.

21 Individuals selected for medical
22 surveillance are based on results of industrial
23 hygiene assessment. They are put in the program by
24 stressor. Stressors are identified in this document

1 I have up on the screen, called the Medical
2 Surveillance Procedures Manual, which was developed
3 by a committee of Navy representatives to
4 standardize the examination protocols we use in the
5 clinics.

6 That documents is in revision now, we hope
7 to have one out later this year. It basically
8 covers the majority, if not all of the hazards that
9 we do examinations for. It also includes standard
10 protocols for certification exams for fire fighters,
11 motor vehicle operators, etcetera.

12 We also have a computer program called PC
13 Matrix which generates standard form 600 overprints
14 of the examination forms, which include all these
15 elements, so the clinics have the opportunity at
16 least to have a standardized exam form. It does not
17 include at this time medical scheduling modules
18 where you can help coordinate scheduling of workers
19 for exams or data collection model. It is certainly
20 something we hope, but with OHMIS as a new migration
21 system, we need to get into.

22 Next slide.

23 A couple, I just want to mention a couple
24 of other large medical surveillance programs. These

1 are not centrally managed and data is not collected
2 centrally, but we have made great efforts in these
3 two areas. For cadmium, in the past 18 months we
4 have had, since OSHA essentially put out a new
5 standard for cadmium that included a lot of medical
6 monitoring requirements, we have made a lot of
7 effort into cadmium. Had a lot of concern about
8 individuals doing hot work, brazing and welding
9 operations, shipboard and in shipyards and other
10 places.

11 As you probably heard yesterday in our
12 tour, there are other areas where cadmium is used in
13 paints, so issues with painting and paint removal.
14 Also, some cadmium plated metals that you work on.
15 So we really weren't sure where we were at. OSHA
16 dropped exposure limit for cadmium dramatically with
17 this standard. We had not been doing medical
18 surveillance for cadmium prior to that, or if we
19 were, it was very limited.

20 But at least anecdotally I can tell you,
21 and based on some personal experience, we were quite
22 encouraged that there does not appear to be much of
23 a hazard for the workers in these areas. We have
24 done biological monitoring on many hundreds of

1 workers. Unfortunately, I don't have that data
2 centrally managed, but almost across the board,
3 uniformly, we are not seeing any elevations in the
4 biological monitoring parameters. In workers, where
5 the exposure really is to a metal that has a long
6 lifetime in the body, so it is not something that is
7 going to be cleared very quickly.

8 Lead has been a point of emphasis for a
9 long time in the Navy. In the last five years or
10 so, we have even put a stronger emphasis on some of
11 the paint removal aboard ships and in other places.

12 We have done biological monitoring on thousands of
13 Navy workers. And, again, I think we have a very
14 strong program. Our workers generally show, almost
15 90 percent or more of the cases, normal blood leads,
16 the individuals doing these paint removal
17 operations. So we continue, it is another large
18 program that we continue to run.

19 The next slide.

20 I just want to briefly mention something we
21 do at the Navy Environmental Health Center, which is
22 a medical review officer function, much like you see
23 mandated in the civilian sector for certain
24 employees required by the Department of

1 Transportation and other agencies to have drug
2 testing, it requires medical review. We have three
3 medical review, certified medical review officers.

4 For the Navy, at least we are doing review
5 of opiate positive urinalyses. That program was
6 initially created because of the concern of false
7 positives related to poppy seed ingestion, so all of
8 you out there eating the poppy seed muffins this
9 morning may have indeed been found positive on a DoD
10 drug test in the past. However, the DoD about a
11 year ago had raised the cut-off levels for morphine
12 which is the drug that shows up related to poppy
13 seeds, raised the cut-off levels. So we are not
14 seeing positive urinalyses anymore related to poppy
15 seed ingestion.

16 It really brings into question our central
17 role for medical review since most of the medical
18 review is actually done locally at clinics by the
19 physicians there.

20 Next slide.

21 I did mention our team. This is the one
22 slide I wanted to talk about, industrial hygiene. I
23 think a database that has great promise. It's a
24 new, relatively new database where we are centrally

1 managing results of all the industrial, air sampling
2 done by our industrial hygienists in the field.
3 Although this database does not standardize the
4 sample collection, there is a parallel program with
5 our industrial hygiene community to do that. All
6 air sampling done should be performed at Navy
7 industrial hygiene laboratories and the results from
8 all those laboratories are consolidated at the Navy
9 Environmental Health Center.

10 At this time we have the ability to
11 retrieve data by various operation codes and
12 stressors. Again, it is in the infancy as far as
13 making standardized reports or studies on, but it
14 holds great promise.

15 And, lastly, I wanted to mention a little
16 bit about our military occupational medicine
17 specialists. We have about 30 right now. About 20
18 of those are actually doing either direct clinical
19 or consulting work in occupational medicine. We
20 have many that are in executive medicine positions
21 or in jobs like mine that are more headquarters
22 level.

23 But there are some initiatives. We have
24 recognized for quite a while, and if we would look

1 at our preventive medicine community, it is
2 certainly demonstrated quite well there that our
3 occupation medicine people have not been involved
4 really with operational readiness. Our billets were
5 created based on a civilian work force in shipyards
6 and aviation depots and really did very little
7 direct support of our fighting forces in the Marine
8 Corps and the Navy.

9 There is some movement to develop
10 operational contingency assignments. We have a
11 couple of billets now with the Atlantic fleet as a
12 consultant level position helping the general
13 medical officers aboard ship, helping the industrial
14 hygiene and safety people in their programs. There
15 is talk at least, and I think this may happen of
16 positions at fleet hospitals, which deploy overseas
17 for occupational medicine specialists.

18 So I think you are going to see more in
19 that way. I think it is really a survivability
20 issue for our specialty. In this era of downsizing,
21 we are really looking at supporting the group out
22 there on the ships and with the fleet Marine force.

23 There is a new program, it is a dual track
24 you may be interested in, for undersea, actually,

1 hyperbaric medicine in occupational medicine. It is
2 run through Duke University, it is just starting.
3 And although these people may primarily stay in the
4 undersea community, they are certainly going to be
5 part of the general occupational medicine community.

6 That program will lead to board eligibility in
7 occupational medicine but also training in
8 hyperbarics.

9 I also mentioned we do have occupational
10 medicine physicians who are working with the FMF in
11 preventive medicine roles. We have a physician who
12 went from a Navy shipyard in Philadelphia who is now
13 the preventive medicine officer for the Second
14 Marine Expeditionary Forces. Certainly, opportunity
15 for crossover. We have seen it over the years, and
16 I think you are going to see more of it, again, in
17 this context of operational support.

18 That's all I have for comments. I would be
19 happy to take some questions.

20 DR. FLETCHER: Fletcher. I was very
21 interested in your comments on the heat stress
22 evaluation, perhaps you might be extending this to
23 cold stress, hypothermia relative to the experience
24 that the Army has had. I think this could really go

1 into some clinical --

2 COLONEL FLEMING: I probably neglected to
3 say that because we have a technical manual, for
4 instance, that is based on both heat and cold
5 injury. It is a prevention manual. We certainly in
6 our documents have stressed it. To tell you the
7 truth, from a reporting standpoint, heat stress
8 injuries dwarf by a considerable amount cold
9 injuries received. Of course we have concern about
10 under-reporting. But you are absolutely right,
11 include that in there.

12 LIEUTENANT COMMANDER PARKINSON: One of the
13 points that you highlight, Garry, is, again, the
14 scope of our industrial operations in the military.

15 And I am always struck, we looked pretty hard in a
16 previous life at the cadmium standard notion and
17 what really was the data that OSHA went forth on on
18 cadmium as it relates to lung cancer and potential
19 contamination with arsenic and the databases they
20 were looking at.

21 And it seems as if now, with the change in
22 the Administration, and the need to look at the
23 downstream costs of regulations based on, as always,
24 incomplete science, that maybe at a level above DoD

1 there is something to be said for establishing
2 something like an occupational environmental health
3 Framingham cohort.

4 I mean we have nothing on a national level
5 that looks at, either longitudinally prospective or
6 retrospective, industrial hygiene data put together
7 with health data, put together with medical follow-
8 up. And through the medical follow-up agency of the
9 VA, it seems we have a tremendous history of
10 occupational, environmental, industrial hygiene
11 information that we could bring to bear for national
12 standards, where the data is really done on a cohort
13 of battery workers. It's crazy. I mean we have got
14 millions of workers in DoD who have been working
15 with these materials.

16 And I don't know if it is a place for the
17 board to think about or get involved, but this is a
18 national issue that, really, we could bring some
19 things to bear on within DoD, because the scope of
20 our exposures is phenomenal and much better than a
21 company that NIOSH looks at to make a standard.
22 Just using it.

23 COMMANDER RUDOLPH: Right, just phenomenal.

24 I agree.

1 Thank you very much.

2 ACTING CHAIRMAN ASCHER: Yes. Thank you.

3 Colonel Zelnick. I would hope we have some
4 more open discussion after all three presentations,
5 so there may be further general comments.

6 COLONEL ZELNICK: Good morning. My name is
7 Sandy Zelnick. I am the chief of the Occupational
8 Medicine Survey at Kelly Air Force Base. And I
9 would like to echo the comments of some of my
10 predecessors, that it is a pleasure to speak before
11 this morning, and I am going to give an overview of
12 occupational health in the Air Force.

13 Let me have the next slide. Oh, do I click
14 it?

15 This is our paradigm for occupational
16 surveillance in the Air Force. We basically have a
17 team concept, and you have heard a fair amount about
18 this already in other presentations. I would like
19 to say that at Kelly Air Force Base certainly, where
20 I have been for the past two and a half, three
21 years, this works. This works real well. I have a
22 very, very close relationship with my industrial
23 hygienist, by base B, as well as my public health
24 officer.

1 At the smaller bases where there is not an
2 occupational medicine physician, that role will be
3 played by the, by either the aerospace medicine
4 physician who might be assigned there, or the flight
5 surgeon. At the larger bases, the air logistics
6 centers like Hill Air Force Base, where we are
7 currently located, will have an occupational
8 medicine consultant.

9 And as you can imagine, most of our, most
10 of this entire efforts begins with surveillance of
11 the work place, an organized medical monitoring
12 program, focused epidemiological surveys, and
13 intervention where appropriate.

14 This is sort of a general overview slide of
15 the, what I call AFCORP, the Air Forces as a
16 corporation preventive health service, and the range
17 of issues which focus on preventive health. And
18 occupational health has, in this case, just a
19 relatively small portion of all these major issues,
20 but what I would like to mention is that all of
21 these preventive medicine activities here, from
22 about 2:00 o'clock to 6:00 o'clock, would apply to
23 the occupational arena, can be described as
24 occupational health.

1 I am trying to move this slide. There it
2 goes.

3 I am going to go ahead and discuss some of
4 the major initiatives that are done by some of the
5 other groups that help support the occupational
6 medicine effort, such as the environmental -- the
7 industrial hygienists, the bio-environmental
8 engineers. Some of these initiatives were given to
9 me over the phone when I called in to Washington and
10 some of the other MAJCOM's.

11 Specially at Air Force materiel command are
12 looking at the budgeting initiatives. They are
13 trying to determine what the cost is of complying
14 with the various OSHA regulations which we are
15 required to comply with. And that's, the major
16 focus for that is being done over at Wright
17 Patterson Air Force Base in Ohio.

18 The bio-environmental engineers are
19 probably the major focal point for development of
20 the AFOSH, the Air Force Occupational Safety and
21 Health Standards. These standards will be reviewed
22 by someone like myself as well.

23 Sorry, what did I do wrong? I was leaning
24 on this. Thanks. No, that's not what I want to do.

1 Okay. Okay, we are back in business.

2 And these are some of the newer AFOSH
3 standards which have been promulgated. We have a
4 new respiratory protection standard which was
5 recently completed last year.

6 And one of the major highlights of this
7 standard that I would like to bring to the attention
8 of the board is that we no longer require routine
9 check X-rays or even annual physical examinations in
10 order to determine the ability of a worker to wear
11 an industrial respirator.

12 We issue them a questionnaire which focuses
13 on major medical problems which they might have. I
14 don't have a copy of that, but we deliver this
15 questionnaire, and any positives receive a screening
16 interview by an occupational physician. And we have
17 saved a lot of lost time. We have kept a lot of our
18 workers at work doing this. We have had no problems
19 with it whatsoever and it has worked out very, very
20 well. We have been doing this probably now for
21 about two years.

22 Other AFOSH standards. As you know, OSHA
23 is considering ergonomic and indoor air quality
24 standards. We are trying to develop these things

1 already within the Air Force occupational medicine
2 community, as well as a comprehensive standard for
3 hospital employee health.

4 In terms of some of the other preventive
5 medicine issues which have been, which will have
6 impact on my workers are the Air Force tobacco
7 reduction program, initiatives to make a smoke free
8 work place in the Air Force. This initiative is now
9 a line IG special interest item. So when the line
10 IG goes out and inspects the bases, they are going
11 to be asking the line commanders about their
12 compliance with this initiative.

13 Substance abuse. This traditionally was a
14 personnel, a direct responsibility under our
15 personnel directorate and this is now being
16 transferred over from the personnel system over to
17 the mental health community, who will be taking
18 ownership of this program..

19 You have heard from other presenters about
20 comprehensive wellness centers. I won't belabor
21 that point. We are trying to get that off the
22 ground in all of our Air Force facilities.

23 I would like to focus the majority of my
24 talk on the occupational medicine initiatives,

1 things that occupational medicine physicians do,
2 because that is what I am obviously most familiar
3 with.

4 Let me first talk about personnel. We have
5 an occupational medicine sort of core, or core group
6 of approximately 12 board certified occupational
7 physicians in the Air Force. Starting in 1990, we
8 began Air Force sponsorship of training in
9 occupational medicine, which we hadn't done for many
10 years prior to that. We initially were training
11 four residents a year; we currently dropped that
12 down to approximately -- not to approximately, to
13 exactly two residents in training per year.

14 Our major needs are for the, our major
15 needs are to supply occupational medicine physicians
16 to these air logistic centers. Currently, as you
17 know, you are at Hill Air Force Base, this is one of
18 our air logistic centers. We have five in the Air
19 Force. I am at Kelly down in San Antonio. We have
20 others at Warner Robbins, McClellan -- which one am
21 I missing? And Tinker. Thank you.

22 We have other bases in the Air Force
23 materiel command which have major occupational
24 medicine needs as well. We would like to provide an

1 occupational medicine physician as a consultant to
2 all of the major commands, as well as to provide
3 occupational medicine expertise at the Armstrong
4 Laboratories, the Occupational Environmental Health
5 Directorate over at OPHSA, the Office of Preventive
6 Services Health Assistance -- the Office of
7 Preventive Services Health Assessment, as well as at
8 Air Force headquarters.

9 I wanted to show, I didn't we were actually
10 going to be having a tour of Hill, I wanted to go
11 ahead and show a few slides of what we do at Kelly,
12 rather than to show a whole bunch of wordy slides.
13 This is one of the T-38s that we service in the
14 aircraft directorate, and this shows one of our
15 workers doing electric work on the T-38.

16 I am very, very proud of some of these
17 initiatives that we are going to be talking about
18 now. One of them was, one of the major initiatives
19 that I have been involved in for the past two and a
20 half years has been the development of a practicum
21 year in occupational medicine for our residents who
22 are in aerospace medicine training through the
23 School of Aerospace Medicine.

24 Right now we have 14 residents in training

1 in aerospace medicine and they have, we are applying
2 for approval for, approval of this occupational
3 medicine practicum year and this will graduate
4 approximately, as I mentioned, 14 residents per
5 year, making our program the largest occupational
6 medicine training program in the country.

7 And the goal of this program, we noticed
8 that a lot of residents in aerospace medicine, when
9 they went out into the field, were not comfortable
10 with some of the traditional occupational medicine
11 issues that they would be faced with, and that led
12 to the formation of this third year occupational
13 medicine practicum year.

14 And what we teach them, they spend eight
15 weeks at Kelly, where I am intimately involved with
16 them, and we teach them a great deal about fitness
17 for duty issues. They do fitness for duty
18 evaluations. They receive not only didactics, but
19 they confront a number of issues related to the ADA.

20 They evaluate disability retirement applications.
21 They do the same thing for workers compensation
22 claims. They participate in and are the direct
23 managers of occupational medicine injuries and
24 illnesses, and they investigate a number of indoor

1 air quality problems.

2 Part of our practicum year also involves
3 experience with cooperating industries which we
4 already have relationships already set up with, and
5 I have listed them here. We have relations, we send
6 our third year residents in aerospace medicine off
7 to Exxon USA, Delta Airlines, American Airlines.
8 They have rotations as well at the San Antonio
9 Metropolitan Health District, the State Health
10 Department for Texas. The Kelly rotation, as I
11 mentioned, is an eight week program at Kelly. They
12 also have a two month rotation over at Wilford Hall
13 Medical Center, and they receive additional didactic
14 training at Armstrong Laboratories, also in San
15 Antonio.

16 I would like to discuss some of the
17 projects that our residents, third year residents in
18 aerospace medicine are completing for these major
19 industries, because I think it is important for you
20 guys to have some idea of the scope of what our
21 residents are doing.

22 They, one of our residents made formal
23 recommendations for air crew surveillance to plague
24 infested areas. This was done for American

1 Airlines. For American Airlines, as well as Delta
2 Airlines, this was a formal document which was made
3 which they are currently using. Our residents have
4 designed the cadmium surveillance programs for
5 American Airlines as well as Delta. Lead
6 surveillance for American Airlines. Surveillance
7 programs for our air crew radiation, dealing with
8 cosmic radiation exposure. This was an issue for
9 American Airlines, and our residents have worked on
10 that. As well as dealing with a variety of
11 consulting type work issues involving the Americans
12 With Disabilities Act for American Airlines.

13 Other initiatives are a two week program in
14 occupational medicine that is going to be done
15 through the School of Aerospace Medicine down in San
16 Antonio. This is specifically to train our flight
17 surgeons. I have just showed you a number of slides
18 where we were training our third year residents in
19 aerospace medicine.

20 Now we are going to actually go ahead and
21 train our flight surgeons as well, so that at the
22 smaller bases they have more than just a rudimentary
23 experience with occupational medicine and they are
24 able to handle basic fitness for duty issues, basic

1 issues of workers compensation and so forth. And
2 this is going to start next month, I will be
3 lecturing at that. I will be giving several
4 presentations at that course. We are going to have
5 30 flight surgeons in our initial class and our
6 goal, our goal for their training is similar to that
7 of the aerospace medicine, the third year aerospace
8 medicine residents, but less detail. And this, we
9 are going to start off with flight surgeons where
10 there are no residents in aerospace, non-RAM bases,
11 where they are going to be, where they are either
12 currently assigned or will be assigned to places
13 where there is not a resident in aerospace medicine,
14 so they will be off by themselves. We would like to
15 get them some training.

16 I am going to speak briefly about other
17 inter-agency opportunities for people who are
18 currently in our bio-environmental health corps, as
19 well as our public health specialists. We have an
20 education with industries program where we send,
21 where we have, we currently have sent one resident
22 over to NIOSH. And these were some of the issues
23 that this resident, or fellow actually, is working
24 on.

1 We sent one resident over to the CDC as an
2 EIS officer, and we have currently one resident
3 over, fellow over at EPA.

4 This is our corrosion control facility.
5 You saw the abrasive bead blasting facility here at
6 Hill. This slide doesn't really do this building
7 justice. This building is humongous, okay, and it
8 can accommodate a C-5, okay. And we do blasting in
9 this facility on the C-5. It is the only facility
10 of its kind in the Air Force. And I would recommend
11 that if ever you get a chance to visit at San
12 Antonio, we would be more than happy to give a tour
13 for any member of the board to show some of these
14 facilities, because Kelly Air Force Base is truly
15 immense. Some of the things that are done are there
16 are just incredible. And when you see a C-5 going
17 into this facility to do the same process that you
18 saw, it is just incredible, the whole.

19 This is in our engine directorate LP. You
20 saw the landing gear chemical strip lines. This is
21 a chemical strip line for aircraft engine parts and
22 this is a part of an F-100 engine, and it is being
23 currently lowered into a dip tank and we also have a
24 computerized chemical cleaning operation similar to

1 what you saw for the landing gear assembly
2 yesterday.

3 I am going to mention a few words about
4 occupational diseases. As you know, they receive
5 various codes by OSHA. Most of our, what we
6 experience are disorders due to repetitive trauma,
7 or code 26 limit -- or rather leads the way in terms
8 of what we experience as occupational physicians in
9 the Air Force, in terms of the problems we have.

10 A few words about repetitive trauma
11 illness. As you know, in the mid-'80s there were
12 approximately 30,000 cases of carpal tunnel syndrome
13 reported. In 1992 that number jumped to, as you can
14 read here, 281,000. And this, for the Air Force,
15 calculates to about 60 percent of all of our
16 occupational illnesses. And this shows carpal
17 tunnel syndrome as a graphic presentation. These
18 are data collected by the Bureau of Labor Statistics
19 and, as showed in the earlier slide, the numbers
20 were about 30,000 here in the '80s, and it has
21 jumped now to 280,000, now 300,000. It is really
22 something of an epidemic.

23 We have an occupational illness database
24 that is located at Armstrong Laboratories in San

1 Antonio and we currently have approximately 4,000
2 occupational illnesses in that database, and 63
3 percent of them are from Air Force materiel command
4 bases like Kelly and Tinker and here and so forth.

5 In fiscal year '93 these repetitive trauma
6 injuries constituted the largest number of our
7 cases. The majorities were at the larger AFMC bases
8 like where you are currently located and, as I
9 mentioned, the majority were OSHA code 26,
10 repetitive trauma.

11 In fiscal year '94, the reporting for
12 repetitive trauma, the larger Air Force materiel
13 command bases, the reporting has been somewhat down,
14 but it has been increased in some of the smaller
15 bases for repetitive trauma. The net reporting is
16 down from 1993. We can talk about some of the
17 issues why that might be.

18 This also shows here for OSHA code 26 that
19 it is 47 percent of the occupational illnesses
20 reporting for the Air Force but about 60 percent for
21 the Air Force materiel command.

22 And this is one of my last slides. As you
23 notice, I didn't show any data on occupational
24 injuries. Similar to our illnesses, our ability to

1 capture a lot of this data is not very good, and
2 that is what I am trying to show here. This is for
3 years 1990 and '91 at Kelly, Lackland and Randolph,
4 which are bases in San Antonio. Our illnesses that
5 are registering, compared to the numbers for which
6 compensation claims have been received, constitute,
7 we are only capturing a small percentage of claims
8 in our database compared to actually claims for
9 workers compensation which are received, and that is
10 true for 1990 and 1991 at all these bases. That
11 might not be representative for the entire Air
12 Force, and we can talk about why this is the case.
13 But the bottom line, what I am trying to present, is
14 that we are not capturing our data terribly well for
15 occupational illnesses or injuries.

16 This shows a worker working in final
17 assembly on the F-100 engine in the propulsion
18 directorate. And this is a slide of the C-5. It is
19 incredible to see these things take off from the
20 ground and see them fixed at Kelly. They are like
21 flying monstrosities or flying elephants, that's
22 what they remind me. It is a pleasure to work
23 there. I have really enjoyed my job the past three
24 years.

1 And that is probably my last slide, and I
2 will take any questions you may have.

3 DR. FLETCHER: Dr. Fletcher. You mentioned
4 ergonomics. Would you expand briefly on that?

5 LIEUTENANT COLONEL ZELNICK: Well,
6 ergonomic considerations refer to a number of not
7 only repetitive trauma circumstances, but with
8 people working in abnormal body positions, non-
9 neutral body positions, people exposed to vibration,
10 people exposed to excessive forces in their work.
11 These are all ergonomic considerations. And there's
12 currently draft standards, as I understand, for
13 ergonomics.

14 One of our bases recently was cited for not
15 having a comprehensive ergonomic program, I believe
16 under the general duty clause of OSHA. We were not
17 actually fined but we were cited at one of the
18 bases. And this led to us considering that we
19 should develop an AFOSH standard for ergonomics, and
20 that is currently what we are doing. That is
21 currently in draft.

22 DR. FLETCHER: I certainly agree with that.

23 I think this is something that Mike Parkinson has
24 done. With exercise testing people, you really

1 don't have their, applicable to the work place, what
2 they are actually doing. I think this will give you
3 a great deal of information if there is some way you
4 can really evaluate their working capacity at a
5 certain job, or as you describe.

6 LIEUTENANT COLONEL ZELNICK: With regard to
7 ergonomics, I myself have thought of a way to study
8 repetitive trauma injury in data processors, but I
9 haven't yet a found, I need the proper number of
10 people in order to do the study and I don't have the
11 number at Kelly. But I am going to find the proper
12 place somewhere, if not in the Air Force, in one of
13 the other sister services, where I can get this
14 study off the ground.

15 DR. FLETCHER: Good.

16 ACTING CHAIRMAN ASCHER: Did we hear
17 yesterday that one of the inspection or quality
18 control programs here has voice recognition for data
19 entry, or did I misunderstand that?

20 LIEUTENANT COLONEL ZELNICK: Not that I
21 know of.

22 ACTING CHAIRMAN ASCHER: Is that not the
23 case? That seems like a rather interesting
24 approach. Was that true? That seems like a rather

1 interesting approach to the issue of sitting there
2 punching keyboards. You can talk, you might get a
3 sore throat or get hoarse but, you know, it is a
4 different injury.

5 LIEUTENANT COLONEL ZELNICK: This reminds
6 me of an investigation we did for repetitive trauma
7 injury at the AF News Agency, the Air Force News
8 Agency. A number of the employees there were coming
9 down with overuse type problems, Dequervain, rule
10 out carpal tunnel syndrome. And they were sitting
11 there, lines of them, wearing splints. And the
12 commander was very concerned about this, he thought
13 there might be an epidemic in his work place of
14 repetitive trauma problems, and he asked for us to
15 come out and take a look at the work site, which I
16 did with an ergonomist.

17 And the problems are daunting because many
18 of the devices which have been shown, many of the
19 devices which are currently used to quote "prevent"
20 repetitive trauma injury really haven't been
21 subjected to organized, thorough investigation. And
22 to spend money on some of these things is a very
23 difficult thing for me to recommend, things that
24 haven't been tried and true, when a work place may

1 have 500 or a 1,000 workers to recommend, for
2 example, track ball mice, or a specific type of a
3 keyboard, things that haven't been proven to work.
4 It is a very difficult issue and it is an issue that
5 needs a great deal more research.

6 ACTING CHAIRMAN ASCHER: Any more general
7 comments or questions?

8 (No response.)

9 ACTING CHAIRMAN ASCHER: I would like to
10 thank all three services for this comprehensive
11 overview and, particularly, the last one in
12 reference to your training program. I thought that
13 was an excellent program. I wish you good luck in
14 keeping it going, and we might be able to say
15 something if you became at risk in some way.
16 Hopefully.

17 Let's do our break, and then we will be
18 back for Dr. Broome.

19 (Whereupon, at 10:15 a.m. a brief recess
20 was taken.)

21 ACTING CHAIRMAN ASCHER: As we start to
22 trickle off, anybody that has to leave before we
23 complete the discussion of the hepatitis vaccine
24 protocol, there is a draft sitting on top of my

1 computer. There is a limited number, but anyone
2 could take it. It will look somewhat like the final
3 and it is, I think, close enough for, we want to
4 circulate it to everyone on the board, but if you
5 have to leave the room -- go and circulate it now,
6 that's fine.

7 If you have to leave the room, that's we
8 think respectable enough to take home and show your
9 friends, if you have to leave. Your Surgeons
10 General, they are your friends.

11 And now we follow-up with a recent
12 tradition which we think is really useful, that
13 board members, in this case this year two, present
14 things of their interest to the group. And we lead
15 off with Dr. Broome talking about two hot areas from
16 the perspective of CDC.

17 DR. BROOME: Thanks, Dr. Ascher. I
18 appreciate the opportunity to present in these
19 areas.

20 What I would propose to do is give a pretty
21 brief overview, and particularly with hantavirus,
22 many of you may be familiar with the material, but I
23 thought it would be important sort of for everybody
24 to have at least the background information, and

1 then I would really like to spend most of the time
2 taking questions, which I will answer to the best of
3 my ability.

4 Starting with hantavirus, many of you are
5 well aware that in May of 1993 there was an
6 unexplained cluster of severe, acute, respiratory
7 distress syndrome cases in previously health adults,
8 primarily Native Americans, and this all occurred in
9 the Four Corners area in the Southwest.

10 An investigation was undertaken by the
11 Indian Health Service, the involved tribes, and the
12 four states in the Four Corners area, and CDC was
13 invited to assist in the investigation.

14 Samples were obtained, and had been
15 obtained from a number of the cases which were sent
16 to CDC on June 1st. And serologic testing indicated
17 a connection to hantaviruses, which I think was
18 really a surprise to everybody considering the
19 clinical picture and what we knew about
20 hantaviruses.

21 But in fact further testing using PCR and
22 using immunohistochemistry confirmed that
23 hantaviruses were in fact involved as the causative
24 agents in this outbreak, and also showed that we

1 were dealing, based on the sequence data from PCR,
2 with a new hantavirus, which really looked to be a
3 separate species from the Seoul and Hantan viruses
4 that had been extensively worked with previously.

5 I think it is important to note that the
6 sequencing identification was completely dependent
7 on the important work that had been done previously
8 by the military and particularly the sequencing work
9 of Joel Dalrymple and Connie Schmaljahn were really
10 crucial to being able to have this rapid
11 identification of the new hantavirus.

12 Now, further studies have been, of course,
13 focused on the rodent population as the most likely
14 vector based on our historical knowledge of the
15 epidemiology of hantaviruses, and, in fact, 30
16 percent of rodents trapped in the area had
17 hantavirus antibodies and so the studies by PCR
18 showed that in fact they had the same virus as the
19 patient isolates.

20 Now, once we had the diagnostic capability
21 to identify hantavirus pulmonary syndrome, it was
22 possible to look for cases in other areas. And, in
23 fact, by July the first case had been recognized
24 outside the range of the deer mouse

1 peromyscusmaniculatus, which was the presumed
2 primary vector in the Four Corners area. And 47
3 hantavirus pulmonary syndrome patients have been
4 identified in 1993.

5 We went ahead to provide recombinant
6 antigen for ELISA testing and get additional states
7 trained for the diagnosis. And as you can see on
8 the next slide, there has identification of cases on
9 an ongoing basis. This just looks at both the
10 survivors in the yellow and the fatal cases in the
11 blue identified throughout 1993 and 1994.

12 There has also been the potential for
13 identifying cases retrospectively, so this slide
14 does not show the 18 additional cases with onset
15 before 1992 that have been identified.

16 Now, where are these cases coming from? As
17 you can see, we have had cases right up through
18 February of '95 that have been identified. Now, the
19 geographic location of the cases is shown in this
20 slide, and the vast majority of cases have in fact
21 come from the Four Corners area and there have been
22 a substantial number from California, which Dr.
23 Ascher can probably tell us more about.

24 But I would call your attention to several

1 cases that have occurred outside of the known range
2 of the deer mouse, including Rhode Island, Florida
3 and Louisiana, raising the issue of what in fact is
4 the vector in these particular cases, and there
5 wasn't any known clear-cut exposure in areas of the
6 known vector range.

7 The work is proceeding in terms of looking
8 at the exposures of the patients and possible
9 contact with rodents in those areas.

10 Now, the cases that have been identified to
11 date have been about evenly distributed by sex, 55
12 percent of male. Of interest, the age range is from
13 11 to 69 years. There has only been one case
14 identified in a child. Sixty-four percent of cases
15 have been white, 34 percent American Indian, 2
16 percent Black, 9 percent Hispanic ethnicity. Case
17 fatality rate overall has been 54 percent. The case
18 fatality rate in 1994 is closer to 40 percent,
19 however, clearly, still, a very severe disease and
20 there is no major drop in that. Although there was
21 a major search for milder cases of illness in the
22 Four Corners area during the outbreak
23 investigations, we really did not identify many
24 cases of milder asymptomatic infection. So our

1 understanding to date is that the human illness is
2 really quite severe in most cases.

3 Now, as with the traditional hantaviruses,
4 this may well be a problem for the military, and I
5 just wanted to let you know about a retrospective
6 investigation of a group of National Guard folks who
7 were out on maneuvers at Camp Williams here in Utah.

8 There were two cases with really typical clinical
9 presentation for hantavirus pulmonary syndrome. And
10 one of the cases in fact was fatal and died in July
11 1987. A case was diagnosed this past year by
12 immunohistochemistry and the other case survived
13 and was diagnosed by serology.

14 The guard had been working on some road
15 clearing activities and there is some further effort
16 to investigate exactly what happened with that
17 outbreak.

18 Now, there is a lot of unanswered questions
19 with regard to hantavirus and a number of
20 investigators around the country are trying to
21 clarify, first of all, how many hantaviruses are
22 involved with the clinical illness and what is the
23 geographic distribution, how does that correspond
24 with the distribution in rodent and other animal

1 populations?

2 Of note, by serologic testing, we have
3 looked at over 26,000 small mammals. There is about
4 5 percent positivity overall in the rodents we have
5 looked at, 3 percent in carnivores, which are
6 domestic cats basically, and a scattering in other
7 areas. But I think not surprisingly to people who
8 understand hantavirus epidemiology, there is likely
9 to be substantial rodent positivity.

10 The serologic test does not distinguish
11 between different species, so further work will be
12 necessary to clarify what the ecology is in the
13 different species and geographic areas. There is
14 still obvious issues in trying to improve our
15 ability to culture hantaviruses. The high
16 proportion of infected rodents and the relatively
17 small number of clinical cases requires some further
18 explanation in terms of when are humans at increased
19 risk for transmission of disease and how should we
20 approach the problem.

21 What does control rodent population
22 fluctuations and infection, and questions of
23 pathogenesis and the explanation for the limited
24 number of pediatric cases?

1 And that was what I was going to do as an
2 overview for the hantavirus.

3 Let me just say a few words about BCG and
4 then just take questions on either in the interests
5 of time. I actually, I didn't pick these topics, by
6 the way. Mike Peterson asked for updates on these
7 topics. So I am not, I have tried to sort of give a
8 general overview, but there may be some more
9 specific areas of interest.

10 BCG has been a relatively hot topic in the
11 last two years. As you know, the Advisory Committee
12 on Immunization Practices at CDC makes
13 recommendations for vaccine uses for the civilian
14 population, and in a joint statement with the
15 Advisory Committee for Elimination of Tuberculosis,
16 they had issued in 1988 a statement on utilization
17 of BCG for the United States which had very
18 restricted indications for the use of the vaccine.

19 However, in the last few years, you are all
20 very familiar with the fact that we have had a
21 number of outbreaks of multi-drug-resistant
22 tuberculosis, resistant to isoniazid and rifampin in
23 hospitals and prison settings, particularly in New
24 York and Miami. The outbreaks have involved

1 patients, health care workers, correctional facility
2 employees and inmates. And, as you may or may not
3 be aware, the case fatality rates have very high, in
4 the order of 60 to 80 percent.

5 Now, most of the patients who have died
6 have been known to be HIV-positive, but not all.
7 And, clearly, our ability to control multi-drug-
8 resistant tuberculosis has proved a real challenge
9 to the health care system.

10 Because the usual methods for control of
11 tuberculosis may or may not be as satisfactory for
12 multi-drug-resistant TB, specifically the use of
13 chemoprophalaxis of infected persons, the question
14 reemerged as to whether BCG could have a role in
15 controlling outbreaks in the setting of multi-drug-
16 resistance.

17 And we commissioned, we had a contract with
18 Grahame Colditz and his colleagues at the Harvard
19 School of Public Health to do another meta-analysis
20 of the clinical trials and the observational studies
21 that have been done to look at BCG efficacy.

22 They reviewed the published and unpublished
23 literature with collaboration of WHO and a number of
24 investigators to assess quality of studies, and

1 ultimately selected 14 clinical trials and 12 case
2 control studies of BCG efficacy. Using a random
3 effects regression model to statistically analyze
4 the data, they estimated the overall protective
5 effect of BCG vaccine against tuberculosis to be 51
6 percent, with a lower 95 percent CI of 30 percent in
7 the clinical trials and 49 percent in the case
8 control studies.

9 The result, the summary results of the
10 meta-analysis were published in JAMA. Rodriguez et
11 al. had also done a meta-analysis around the same
12 time with similar findings. The efficacy does
13 appear to be substantially greater in children and
14 against meningeal and miliary disease probably being
15 on the order of 85 percent efficacy.

16 The data are very sparse for protection in
17 persons who were vaccinated not in infancy, but at
18 either adolescence or adult age, so that there is
19 definitely a paucity of studies which address that
20 particular question, which is really the one of most
21 relevance to the health care worker question.

22 So, in response to these recent data and
23 recent concerns, the ACIP, together with the
24 Advisory Committee on Elimination of Tuberculosis,

1 and also in consultation with the Hospital Infection
2 Control Practices Advisory Committee, are re-issuing
3 a BCG statement which should be out fairly soon. It
4 emphasizes strongly that the use of BCG should not
5 be the primary strategy for controlling TB in the
6 United States. They should continue to rely on
7 early detection and treatment of patients with
8 active, communicable TB, the preventive therapy of
9 infected individuals, and prevention of nosocomial
10 transmission through the range of methods that are
11 well accepted and shown to prevent nosocomial
12 transmission.

13 However, they do raise the possibility that
14 BCG vaccination may contribute to control of TB in
15 limited circumstances. Specifically, there is a
16 recommendation to use it for infants and children
17 with negative tuberculin tests who have intimate and
18 prolonged exposure to patients with persistently
19 infectious pulmonary TB who cannot be removed from
20 the source of exposure or placed on long-term
21 preventive therapy, or infants and children
22 continuously exposed to TB patients with multi-drug-
23 resistant vacilli, including the resistance to
24 isoniazid and rifampin who cannot be removed from

1 the source of exposure.

2 Secondly, individual health care workers,
3 in settings where a high proportion of MTB isolates
4 are resistant to isoniazid and rifampin, and there
5 is strong likelihood of transmission and infection
6 with such drug-resistant organisms, and where
7 comprehensive infection control precautions have not
8 been successful, may be considered for the use of
9 BCG.

10 BCG vaccination is not recommended for
11 health care workers in low risk settings, or for
12 HIV-infected children or adults in the United
13 States.

14 So this, obviously, is intended to be a
15 cautious statement that does not encourage
16 widespread of BCG, but I think does offer it as a
17 consideration in selective very high risk settings
18 for MDR TB transmission.

19 So I will stop there and I will be happy to
20 answer any questions.

21 DR. GWALTNEY: What is the information on
22 hantavirus in terms of how long it has been around
23 and is it increasing and incidence and that kind of
24 thing?

1 DR. BROOME: Well, we obviously are
2 constrained by the quality of the surveillance. As
3 I have indicated, we have looked retrospectively,
4 using the diagnostic tools, and the earliest case I
5 am aware of is '55, but there may be earlier ones.
6 It is mostly a matter of people remembering a
7 particular case that clinically looked like it and
8 for which tissue are still available and, obviously,
9 this outbreak in '87 was detected retrospectively.

10 In terms of secular trends, I showed the
11 epi-curve to sort of give a sense that clearly there
12 was a cluster of cases around the Four Corners
13 epidemic. There were fewer cases diagnosed in '94,
14 but there have continued to be cases up through the
15 past month of, if you will, sporadic hantavirus
16 infection. And I think we are trying to look at
17 various studies that would give you more systematic
18 ability to estimate secular trends. But a lot of
19 that won't be clear until diagnostics are available
20 and people think of the diagnosis and evaluate
21 whether or not hantavirus may be causing an episode
22 of ARDS.

23 ACTING CHAIRMAN ASCHER: Thanks for the
24 invitation to say a few things. Maybe of couple of

1 our recent anecdotes would fill in a couple of these
2 points. A fascinating history of our four most
3 recent cases, not in time, but in terms of our
4 diagnosis.

5 One individual worked in the Lee Vining
6 area, which is the northern end of the Eastern
7 Sierra, which is sort of the range of this disease,
8 the northern end of this disease. He worked in,
9 lived in one location and worked in another, both
10 for Southern California Edison and had rodents in
11 both sites, his home and his work site. By
12 molecular epidemiology, the rodent from his home had
13 exactly the same virus as he did, and the rodent at
14 his other work site did not. So we were able to
15 actually show what rodent gave him the thing. And
16 that is about the only role for testing of rodents
17 we can figure out at this point in time, because
18 they are everywhere and they are all positive.

19 Another case in an isolated setting, a
20 place called Deep Springs College. Many of you may
21 know about it, it is a very famous school, a lot of
22 well known people went there. It is a small
23 college, it is a ranch, and everybody who goes there
24 transfers to Harvard or Yale. It is an interesting

1 program. They have had about 2,000 people through
2 there in the last 20 years and everyone knows of one
3 person in that period of time that has died of a
4 look-alike illness and she was positive from 1984,
5 the ranch manager's wife. And so that is sort of
6 the estimated level of risk. Extraordinarily low.

7 Back to the occupational medicine side, the
8 issue of the very first day here, and the
9 presentations about when you change someone's risk
10 group from an exposure situation. L.A. Power and
11 Water, after the earthquake, had a man working on
12 the aqueduct. At the southern end of this range, he
13 hurt himself and was transferred to cleaning out
14 rodent-infested buildings.

15 Now, they had a protection program in
16 place. They had workers who were doing it
17 completely covered, but he was transferred to this
18 program with no protection and died. This one is
19 not yet in the courts.

20 There is, as far as I know, no military
21 evidence of infection yet. There are in California
22 about six cases that if you looked at clinically,
23 you would say this has to be this syndrome,
24 absolutely classical story. One was a Naval aviator

1 from the middle of the state. That one is in court.

2 I think this is the first court case about the
3 issue of malpractice, when someone hits the ER, one
4 day has a headache and a little fever, comes back
5 the next day, collapses in front of you and lives
6 about four hours. The family gets upset. It looks
7 like the first test case of this issue of practice
8 is going to occur in the Navy. Interesting.

9 That is basically the only comments I had.

10 It is a fun story and it is all anecdotal but it is
11 beginning to assemble itself into a reasonable
12 picture.

13 COLONEL O'DONNELL: This is an easy
14 question. Does the virus kill the mice?

15 DR. BROOME: My understanding is generally
16 not.

17 ACTING CHAIRMAN ASCHER: J.B. Childs would
18 say that the infected mice are bigger and more
19 vigorous. It is either the chicken or the egg. It
20 appears when they bloom, there is more infection.
21 But the fatter the mouse, the higher the sero-
22 prevalence I believe.

23 Yeah. Go ahead. Sorry.

24 DR. POLAND: In the very early spring of

1 '93 I was at the European Congress of Infectious
2 Disease and we heard several addresses from various
3 infectious disease experts throughout Europe on this
4 weird disease none of us had ever heard of before,
5 hantavirus. So there had in fact been a number of
6 recent outbreaks throughout Europe, and I think one
7 was even in Finland. I am not sure. I take a tiny
8 bit of pride in that, because at the next ACIP
9 meeting I happened to eat lunch with Louise Chapman
10 Larry Schoenberger and mentioned the possibility of
11 these weird cases, could they be hantavirus? I
12 don't know that's what tipped it. I am sure it is
13 not.

14 Have they done sero-prevalence studies down
15 in the Four Corners area? You said they looked for
16 cases that might have been mild. I didn't know if
17 that was among people who had presented to the ER or
18 something. But have they actually done sero-
19 prevalence studies?

20 DR. BROOME: The overall sero-prevalence
21 has been about .2 percent.

22 DR. POLAND: Really low.

23 DR. BROOME: So it is pretty low.

24 ACTING CHAIRMAN BROOME: Hundreds of

1 forestry workers, hundreds of respiratory disease,
2 in a parent illness at the time.

3 DR. POLAND: Just one other question for
4 you, Claire. Is there any reason to suspect that
5 BCG efficacy would be different for MDR TB? It has
6 never been tested.

7 DR. BROOME: Well, since we don't really
8 know what the protective antigen is, there isn't
9 really any basis for answering that. I think, given
10 that your alternative prevention is antibiotics, I
11 think I would think that, you know, BCG, it is at
12 least a working presumption that it would have a
13 similar level of efficacy, whatever that is, for the
14 MDR strains.

15 ACTING CHAIRMAN ASCHER: Back to Dr.
16 Gwaltney's question for a second. At the New Mexico
17 -- Summary meeting, somebody asked a question of the
18 Navajo epidemiology people, what is the historical
19 knowledge of this disease? And they said absolutely
20 clearly that the influenza years worldwide were a
21 hantavirus year in the desert southwest, and there
22 was always this feeling that that Indian population
23 had more severe flu, and there was some genetic
24 susceptibility.

1 It turned out it was a bloom for rodents
2 and they had probably a hantavirus year. And the
3 guy said, but even more convincingly, the 1935 year
4 was a big rodent bloom and they had absolutely this
5 syndrome, very well known. And they figured it out.

6 They have a lot of little rules in a culture. If a
7 mouse touches your clothing, your burn it.

8 VOICE: The mouse or the clothing?

9 ACTING CHAIRMAN ASCHER: Yeah, right. The
10 clothing. If someone dies in a house, you don't re-
11 inhabit it. I mean it is interesting, and their
12 whole religious system says that mouse and man are
13 two major players and they should not overlap. And
14 they are probably right.

15 Yes.

16 CAPTAIN TRUMP: You had alluded to
17 occupational exposures to rodents. Based on the
18 hantavirus information to date, any discussion about
19 any unique recommendations for workers? The
20 particular question we have had asked is whether
21 there is sero-prevalence studies or, you know, sero-
22 surveillance would be of benefit in the work place?

23 DR. BROOME: Well, I think, you know, in
24 general, the recommendations that have been made

1 have been to try to minimize the contact between
2 rodents and people, whether that be occupational or
3 whether it be residential or whatever.

4 The issue of tracking by sero-prevalence is
5 problematic because of the low levels of human sero-
6 prevalence. So at this point, you know, we haven't
7 made any recommendations for that kind of
8 monitoring.

9 ACTING CHAIRMAN ASCHER: As Monty Python
10 used to say, "And now for something completely
11 different." We are going to go ahead with the
12 hepatitis discussion if it is all right, Barbara.
13 We are on time I think at this point.

14 I am going to crank up the computer on the
15 overhead display and ask Dr. Wolfe to review what we
16 have written so far. And you can look on the screen
17 and you can make any comments, and we can change it
18 in real time. I think.

19 VOICE: Isn't that fun.

20 DR. POLAND: Don't let it touch your
21 clothing.

22 DR. WOLFE: These preliminary
23 recommendations were drawn up late last night. We
24 had an earlier meeting with some of the people in

1 the disease control group, and then we retired to
2 Dr. Ascher's very plush accommodations, I must say.
3 Posh, as Colonel Leitch would say. And drew these
4 up for your deliberations.

5 This was based on the questions posed by
6 Dr. Joseph that you saw yesterday in your packet,
7 which they want to pull out. In response to your
8 request for recommendations regarding the use of the
9 newly licensed hepatitis-A vaccine on military
10 personnel, the board reviewed data on clinical
11 trials at its recent meeting and provides the
12 following conclusions.

13 Now, we started out by giving some of the
14 background before we got into recommendations.
15 Hepatitis-A vaccine is safe and efficacious and
16 offers certain distinct advantages over immune
17 globulin for prevention of hepatitis-A. Subending,
18 recently experienced shortages of IG can can be
19 expected to continue for the foreseeable future, and
20 the vaccine produces longer lasting active immunity.

21 I imagine there's some other things one can
22 mention, but we felt that these were really the
23 highlights of what the advantages were of vaccine of
24 immune globulin without having to go into any great

1 detail.

2 The cost of the vaccine is higher than IG
3 but vaccine may be more cost effective. Where are
4 we? The cost of vaccine is higher than IG but
5 vaccine may be more cost effective depending on risk
6 and logical factors. And that gets to some of the
7 points that we were talking about yesterday, being
8 able to have people pre-immunized before they go on
9 an immediate maneuver somewhere or immediate travel
10 overseas was being one of the major advantages of
11 vaccine, and, of course, not having to repeat it
12 frequently is the other advantage, plus the
13 expected, the lack of availability of sufficient
14 immune globulin. And, in fact, the cost of immune
15 globulin may well go up because of the PRC test --
16 PCR testing that they have to do.

17 Concurrent use of the vaccine with other
18 vaccines used in military personnel has no
19 recognized problems. That was well defined
20 yesterday. And, indeed, a combination hepatitis-A
21 and B vaccine will be cost effective and desirable,
22 and that is a goal that we would hope to be able to
23 integrate hepatitis-A and B vaccines together.

24 In outbreak situations, IG is the treatment

1 of choice. That is strong emphasized by the ACIP
2 recommendations. If, and they also state, if
3 providing long-term protection is desirable, vaccine
4 may be given simultaneously. But it is pretty much
5 redundant at a time of an outbreak to give both
6 immune globulin, which is going to give you your
7 immediate protection, and to give vaccine, which is
8 not going to give you immediate protection, but
9 perhaps in some situations if long-term protection
10 is considered desirable, it can be given.

11 Then we get into our recommendations.
12 Based on these findings, use of hepatitis-A vaccine
13 in military personnel is recommended. Special
14 priority can be given to use in the following groups
15 in descending order: deployed forces and dependents
16 currently assigned to geographic areas with known
17 risks; deployable forces active in reserve following
18 alert -- what is that? -- levels ranking; family
19 members assigned abroad to high risk areas,
20 following travel recommendations of the
21 manufacturer. They mention most -- well, all of the
22 developing world yesterday was mentioned. One could
23 get very specific if you had to, in terms of whether
24 they need it for certain areas of the developing

1 world like major cities.

2 Food handlers and day care workers. This
3 is somewhat controversial, as we discussed
4 yesterday, and we felt that the military should have
5 the option of protecting their food handlers.
6 Certainly, the military, direct military food
7 handlers, civil service people who probably could be
8 accommodated in this group, leaving out the
9 McDonald's and Taco Bell who really aren't employed
10 by the government, unless they could also, if it was
11 felt that it was necessary to integrate them into
12 the program.

13 IG should be given with -- this is out. I
14 must say this surprised me when I got in this
15 morning. When this was put to bed and I went to bed
16 last night, that statement was not in there. And we
17 felt that it is a little too specific at this point
18 to recommend IG for certain very specific
19 situations. Plus the fact that if we are trying to
20 get away from IG, it is a mistake at this point I
21 think to make any emphasis on including it with the
22 vaccine, but the option there if it seems to
23 indicate it to use IG at the first time when vaccine
24 is given.

1 Certainly, in my practice, is somebody is
2 going to come in tomorrow when I have the vaccine,
3 and is going to be going to deepest, darkest Africa
4 for three weeks, and he is not going to be protected
5 from the vaccine two weeks, I am going to suggest to
6 him that he also take globulin, assuming that we
7 have globulin available.

8 Use of the vaccine in dependents, including
9 children, should follow ACIP recommendations which
10 will be issued in the near future. This is a bit of
11 a punt because they really don't have definitive
12 recommendations for children. It is a big question
13 that I think has to be addressed and which I think
14 further thought will have to be given to. The same
15 thing about whether children in school should get
16 it. The question was asked should young adults get
17 it, and I think these need further attention.

18 This is another controversial area, the
19 screening, and it certainly may generate some
20 discussion. We felt we wanted to say something
21 about screening. If it can be cost effective, if an
22 inexpensive test can be done, and certainly if it
23 can be integrated into the HIV screening, the
24 additional cost should not be very much, and if you

1 can eliminate 30 percent of the population that is
2 going to get the vaccine above age 30, for instance,
3 at an inexpensive cost of testing, at least in that
4 age group it would be cost effective. It is
5 probably not terribly cost effective to pre-screen
6 recruits at age 18 who maybe 8-10 percent at the
7 most are going to be positive.

8 So screening to detect pre-existing
9 immunity could be cost effective if combined with
10 annual HIV screening of deployable personnel at the
11 start of the program.

12 ACTING CHAIRMAN ASCHER: The option was
13 suggested to that to that phrase.

14 DR. WOLFE: Studies to determine the value
15 of screening of new unit members and recruits on an
16 ongoing basis -- is not recommended?

17 VOICES: Is recommended.

18 DR. WOLFE: Is recommended. Okay.

19 ACTING CHAIRMAN ASCHER: It can go either
20 way. We need a consensus on that one.

21 DR. WOLFE: Okay. So that is something to
22 be discussed.

23 We felt that we should mention that Mark
24 will be having another vaccine. If they can show

1 that a single dose of vaccine is equivalent to the
2 two, the basic series, the single dose plus a
3 booster of the Smith-Klein, I think we would want to
4 reevaluate the recommendations and conceivably want
5 to use a different vaccine.

6 So that is the statement as it is and we
7 throw it open now to discussion. Dennis.

8 DR. PERROTTA: Actually, just two brief
9 editorial comments. It seemed like one of the major
10 limitations that we faced, and your committee faced,
11 was the limited data, especially for cost
12 effectiveness. So in the first sentence, I would
13 recommend "The board reviewed available data." That
14 may be redundant.

15 DR. WOLFE: Okay. Yeah.

16 DR. PERROTTA: And a question for the
17 physicians in the group to determine. On the
18 section that says, "In outbreak situations, IG is
19 the treatment of choice." Is IG truly treatment or
20 is it prophalactic measure? Or is that really an
21 important point?

22 DR. WOLFE: I can look and see how the ACIP
23 phrases that. There was another ACIP -- did you
24 have it?

1 Well, I'll check that.

2 DR. PERROTTA: It is just that IG is not
3 used to treat hepatitis-A outbreaks.

4 DR. WOLFE: Right.

5 ACTING CHAIRMAN ASCHER: Preventive
6 measure.

7 DR. WOLFE: Preventive measure. Okay.

8 DR. PERROTTA: Absolutely.

9 DR. WOLFE: Okay. Fine. Fine.

10 DR. PERROTTA: Thank you.

11 DR. WOLFE: Okay. Greg.

12 DR. POLAND: These are small editorial
13 comments. Under the very first part, where you talk
14 about the advantages of hepatitis-A, I would just
15 make those bullets. But because the known direct
16 cost and acquisition cost are expected to
17 substantially increase, I would put that in there.

18 VOICE: Of IG?

19 DR. POLAND: Yeah, of IG. So put as maybe
20 your second bullet, the cost, acquisition costs of
21 IG are expected to substantially increase.

22 DR. WOLFE: Okay. Put it in after that.
23 Okay.

24 DR. POLAND: Then on the next bullet --

1 DR. WOLFE: Expected acquisition --

2 DR. POLAND: Are expected to substantially
3 increase.

4 DR. WOLFE: We don't know if it going to
5 really be substantial. Anybody want to comment on
6 that?

7 DR. POLAND: Just say expected to increase.

8 DR. WOLFE: To increase, yeah.

9 DR. POLAND: Then the next bullet, I guess
10 I would like to get across the point that IG doesn't
11 produce any active immunity, it is all passive. But
12 maybe saying something like a vaccine produces long
13 lasting, and I don't know if we want to put
14 something in there like some time frame or possibly
15 lifelong or maybe just leave it as long lasting.

16 DR. WOLFE: I don't think we can say more
17 much than three or four years at this point.

18 DR. POLAND: Okay. Long lasting.

19 DR. WOLFE: That's why we said, I put the
20 term in "longer" rather than "long." "Long"
21 suggests that we know for sure that it is going to
22 be four years or more. At this point we only know
23 it is four years. It is longer than IG.

24 DR. POLAND: Okay.

1 DR. WOLFE: That's why that term was used.

2 DR. POLAND: Okay.

3 ACTING CHAIRMAN ASCHER: That also, you
4 like that one?

5 MR. POLAND: That's fine. And then the
6 next sentence, where it says "the cost of vaccine,"
7 you might say "the cost of vaccine is currently
8 higher." It may not be the case.

9 DR. WOLFE: Oh, I can't see that immune
10 globulin is going to approximate \$33 a dose at any
11 time. I mean this can't go up that much.

12 ACTING CHAIRMAN ASCHER: We also have a
13 written contract here on price. It is binding.

14 DR. POLAND: So maybe we know that.

15 ACTING CHAIRMAN ASCHER: \$32.59 -- or
16 \$82.59, I am not sure.

17 DR. WOLFE: \$32.59.

18 ACTING CHAIRMAN ASCHER: \$32.59.

19 VOICE: Is that series or dose?

20 DR. WOLFE: That is single dose.

21 DR. POLAND: And then one last small thing
22 under the concurrent use paragraph. Where it says -
23 - we passed it. Concurrent use of the vaccine with
24 other vaccines.

1 DR. WOLFE: Yeah, right.

2 DR. POLAND: It would be, maybe say "has no
3 recognized adverse effects." There are in fact a
4 host of logistical problems with making the vaccine.

5 DR. WOLFE: Okay. Well, by adverse effects
6 means side effects. We are also talking about it
7 doesn't interfere --

8 DR. POLAND: With immunity.

9 DR. WOLFE: With the immunity. So adverse
10 may be a little too specific there for what we are
11 trying to say.

12 DR. BROOME: But, also, I mean with the
13 possible exception of hepatitis-B, I certainly
14 haven't seen data that would be anywhere close to
15 sufficient to say whether or not there was
16 interference with many of the vaccines they would be
17 getting at the same time.

18 VOICE: It hasn't been studied.

19 DR. BROOME: Yeah.

20 DR. WOLFE: Well, there were limited
21 studies done, but we don't know much more, I mean
22 you guys are giving six or eight or ten vaccines at
23 a time without being too concerned about blockage of
24 immunity, and that has been going on as long as

1 there have been vaccines that the Army has been
2 using.

3 DR. POLAND: That's why I like the word
4 "recognized." I mean --

5 DR. WOLFE: Okay. Anybody, everybody happy
6 with the word "adverse" or is there some other word
7 we can use?

8 COLONEL TOMLINSON: I think that some
9 statement could be made concerning interference with
10 other vaccines, I think that's what --

11 DR. WOLFE: Adverse effects, or
12 interference -- shall we say "or interference"?

13 ACTING CHAIRMAN ASCHER: I like that.

14 LIEUTENANT COLONEL FALKENHEIMER: I would
15 suggest that you might also add "based on very
16 limited data" or something to that effect.

17 DR. WOLFE: Interference with immunity. I
18 mean "interference" by itself doesn't mean much.

19 DR. POLAND: Yes.

20 DR. WOLFE: "Interference with" or
21 "developing immunity." "Development of immunity"?
22 Interference with immune response is good.

23 DR. BROOME: I think that has to have
24 "based on very limited data" included.

1 DR. POLAND: That's a good, honest way to
2 put it.

3 DR. WOLFE: Based on the limited available
4 data?

5 But, I mean, Claire, historically, I mean
6 what we know about all other vaccine combinations,
7 whether they have been well studied or not, the
8 policy and the --

9 DR. BROOME: No, I understand that. I just
10 think that if we are going on record with a
11 recommendation, I would like to be clear about what
12 data we have seen and what we haven't.

13 ACTING CHAIRMAN ASCHER: Appears to have --
14 I mean, based on the limited available data. We are
15 just making an observation.

16 DR. WOLFE: Okay. Yeah, I like that.

17 Yes.

18 DR. GWALTNEY: The clause that went out, I
19 think is something that may come up, and I feel like
20 we should give some guidance. And that is also
21 related to another issue. Up at the beginning we
22 say "safe and efficacious." I wonder if we want to
23 put in there that it, I mean it really is highly
24 efficacious by vaccine standards. Do we want to put

1 in there that is, well, better than 95 percent
2 protection after two does, and around 75 percent
3 protection rate after two weeks to 15 days?

4 DR. WOLFE: Well, it is about 85 percent,
5 85 to 88 after two weeks.

6 DR. GWALTNEY: Because that is relevant to
7 the question of deployment, so that, I mean that
8 phrase you took out, you could say, "IG could be
9 given with vaccine at the time of deployment if
10 inadequate time is available to develop active
11 immunity." Well, one dose of vaccine appears to
12 confer immunity to most vaccinees within two weeks.

13 I do think that that may come up. And
14 without some guidance, people will not be able to
15 make informed judgments.

16 COLONEL TOMLINSON: I think that would be
17 excellent and extremely valuable to have that.

18 DR. WOLFE: ACIP does I believe include
19 that caveat, that you might want to give immune
20 globulin at the first.

21 DR. GWALTNEY: I was going to say, Mike,
22 say "could be given" instead of "should be given."

23 ACTING CHAIRMAN ASCHER: I like that.

24 DR. WOLFE: Bill, do you want to comment on

1 that?

2 COLONEL BANCROFT: I think that one of the
3 most important advantages of the vaccine is
4 overlooked here at the beginning, and that is the
5 convenience of scheduling the use of vaccine and not
6 having to give it just before deployment. And I
7 don't think that there is any advantage to putting
8 in any recommendation on the use of vaccine and IG
9 simultaneously for two reasons. It will be terribly
10 confusing at the time of deployment. And, secondly,
11 we know from studies done in Israel that IG given at
12 the same time of vaccine lowers the immune response
13 to the vaccine. And so I think we need to highlight
14 the fact that this vaccine will allow convenient
15 scheduling before deployments and avoid this last
16 minute urgency.

17 DR. GWALTNEY: Well, Bill, do you think you
18 should put in there then that it does confer
19 immunity within two weeks to a substantial portion?

20 I mean someone that doesn't know about the vaccine,
21 doesn't know that from reading this document.

22 COLONEL BANCROFT: I think that a comment
23 to that effect would be constructive.

24 DR. WOLFE: Right. Let's get this

1 statement in before we take another question.

2 ACTING CHAIRMAN ASCHER: Which?

3 DR. WOLFE: This, another bullet that --
4 how would we phrase that, the convenience of
5 administration or can be preplanned or what?

6 COLONEL BANCROFT: The schedule for
7 administration can be -- can be --

8 VOICE: Is not tied to time of deployment.

9 COLONEL BANCROFT: Is not tied to the time
10 of deployment. That's good.

11 LIEUTENANT COLONEL PARKINSON: And will
12 significantly enhance readiness.

13 ACTING CHAIRMAN ASCHER: That's true.

14 LIEUTENANT COLONEL PARKINSON: That's
15 right.

16 VOICE: That's right. People who are
17 sitting immunized, they are ready.

18 LIEUTENANT COLONEL PARKINSON: They are
19 ready to go.

20 DR. WOLFE: Now, at this point we can maybe
21 put in a caveat that it must be emphasized that
22 protection can not be expected for two weeks after
23 administration of the vaccine.

24 ACTING CHAIRMAN ASCHER: That's what you

1 want to add at the end of this one, Jack? A two
2 week comment here?

3 DR. POLAND: I think we had better be
4 careful.

5 DR. WOLFE: I think we should put it up
6 there where, under those bullets right here. No,
7 further up. Where we just put in a statement.
8 Somewhere there.

9 DR. POLAND: Marty, I think we ought to be
10 careful with saying two weeks. That may be true in
11 some fraction, but the data presented that make us
12 have that 80 percent number in mind are data that
13 are a manufacturer's assay. They haven't been
14 correlated with neutralizer titer. And, in fact, we
15 know of cases that have occurred as long as 21 days
16 after receipt of the vaccine. So, I think we ought
17 to --

18 DR. WOLFE: Well, even at four weeks, you
19 have got only 99 percent only. I mean that is very
20 good, but you have still got one out of hundred
21 people who are not going to be protected.

22 DR. POLAND: Right. I am speaking
23 particularly about making it sound like, well, if
24 you give you the vaccine, you are home free after

1 two weeks.

2 DR. WOLFE: Well, do we want to put
3 anything in as a caveat that one can not expect
4 immediate protection, something to that effect?

5 ACTING CHAIRMAN ASCHER: Can we say
6 adequate time, parentheses, (two to four weeks)?

7 DR. GWALTNEY: I can see the situation
8 developing when there are going to be people
9 deployed who have not been vaccinated, and I think
10 without something like that in there, there is a
11 much better chance they will end up getting immune
12 globulin than getting vaccine, which seems to me,
13 from the data we have at this point, the two week
14 protection rates are pretty good.

15 DR. WOLFE: Well, 85 percent. I wouldn't
16 consider that too good for thousands of men going at
17 one time into --

18 DR. POLAND: No, no, no, no. That 80
19 percent figure is not an efficacy rate. That is --

20 DR. WOLFE: Sero-positive.

21 DR. POLAND: -- an immuno-genicity rate
22 based on an assay that we don't have anything to
23 compare to.

24 ACTING CHAIRMAN ASCHER: Right.

1 DR. WOLFE: Do you have a suggested
2 statement that we could make?

3 ACTING CHAIRMAN ASCHER: Put two to three
4 weeks.

5 DR. POLAND: I think we have given them an
6 adequate frame work there.

7 DR. GWALTNEY: Well, what would you say
8 about the question of deployment of individuals who
9 have not been immunized? We have not said anything
10 about that.

11 DR. WOLFE: Well, that would be, that is
12 coming here. If we put that statement back in.

13 CAPTAIN TRUMP: I am not sure how much you
14 should worry about this. I mean with our
15 deployments now, with straight MRE's for the first
16 several weeks of deployment, with taking bottled
17 water in country, I mean the immediate period is
18 probably one of the lower risk periods.

19 VOICE: That's what I thought.

20 CAPTAIN TRUMP: They go in very well
21 controlled. I think it is the longer term as, you
22 know, the operation spreads out, that you are going
23 to have to start worrying about protection, and I
24 think the vaccine is going to do that.

1 DR. WOLFE: And if we take the statement
2 out, it will be less confusing I think.

3 ACTING CHAIRMAN ASCHER: Bill has got to be
4 the one who makes it operational at some level, and
5 if he doesn't like it, I don't like to have it in
6 there.

7 DR. WOLFE: Anybody opposed to taking this
8 out? Take it out.

9 ACTING CHAIRMAN ASCHER: The last sentence
10 we didn't get to -- yes, we did, I am sorry. Okay.

11 DR. WOLFE: Mike.

12 ACTING CHAIRMAN ASCHER: Do you want to
13 debate which way you want to go with this way? Do
14 you want to know about it or whether you want to
15 recommend it?

16 LIEUTENANT COLONEL PARKINSON: I would vote
17 to keep it there to recommend studies. I think we
18 need to look that. The cost effectiveness is very
19 dependent on your rate.

20 But two points. One of the areas that is
21 very valuable to us from AFEB is the AFEB's read of
22 existing data when the ACIP does not go as far as
23 perhaps the military might need for helpful
24 guidance. And that's why I would like to put in the

1 first section, where we talk about the efficacy,
2 some statement about the current evidence suggests
3 that the vaccine is effective for at least four
4 years. Because we get questions all the time from
5 the field about booster doses.

6 And then, similarly, in the final sentence
7 you could say that ongoing review of efficacy will
8 be part of the process of looking at new vaccines.
9 But some periodicity or statement about periodicity
10 would be effective up front.

11 The other point is in this paragraph on --
12 DR. WOLFE: Excuse me, Mike. Let's address
13 this one point. Vaccine produces longer lasting and
14 active immunity.

15 LIEUTENANT COLONEL PARKINSON: Right.

16 DR. WOLFE: Does that satisfy you, up to
17 four years?

18 LIEUTENANT COLONEL PARKINSON: That I think
19 is good.

20 DR. BROOME: I think it should be at least
21 four years.

22 LIEUTENANT COLONEL PARKINSON: At least up
23 to four years, right.

24 DR. WOLFE: Okay. At least four years.

1 LIEUTENANT COLONEL PARKINSON: And as we
2 see more data, we can amend that. Right.

3 Then, Dr. Ascher, in the last paragraph --
4 second to last paragraph, when you talk about
5 linking screening with HIV, just a small edit. That
6 is you might just drop the word "annual." All the
7 services have different periodicity for their HIV
8 screening programs.

9 COLONEL BANCROFT: I would like to make a
10 suggestion on this too. I would suggest we change
11 the wording there to screening to detect pre-
12 existing immunity may be cost effective in units
13 with high antibody prevalence, and not try to tie it
14 to any existing screening program. I think that
15 should be left up to the services to decide how they
16 might do that and which units might be screened.

17 The reason being that there may, the reason
18 for screening is to detect those groups of people
19 who have prevalence of hepatitis-A antibody.

20 DR. WOLFE: Maybe that should be put in.
21 High prevalence doesn't --

22 LIEUTENANT COLONEL PARKINSON: Right, high
23 prevalence.

24 DR. WOLFE: High prevalence of antibody to

1 hepatitis-A.

2 COLONEL BANCROFT: And that links it to age
3 and length of service.

4 LIEUTENANT COLONEL PARKINSON: Right.

5 COLONEL BANCROFT: And we don't want to
6 confuse hepatitis-A with HIV in the minds of anyone.

7 LIEUTENANT COLONEL PARKINSON: Right.

8 Agree, agree.

9 ACTING CHAIRMAN ASCHER: Some people know
10 the thought of how you might accomplish that but
11 that is not our business. Each service will have
12 their own way.

13 COLONEL BANCROFT: Right.

14 LIEUTENANT COLONEL PARKINSON: Likewise,
15 the other sentence that you might review, while
16 interesting, I don't think it speaks directly to a
17 health affairs recommendation, and that is the one
18 about ideally it could be combined with A and B
19 vaccine. It is true, but I am not sure that it
20 speaks to what this is really supposed to be
21 speaking to.

22 DR. WOLFE: Well, I think, our intent here
23 I think was to make the vaccine appear even more
24 strong relative to IG and that in the future it

1 should be possible to integrate the two, both of
2 which are considered important by the military. We
3 just thought that strengthened the case for the
4 vaccine somewhat.

5 ACTING CHAIRMAN ASCHER: It's a little
6 editorial but it is something that you want to be --

7 COLONEL BANCROFT: It may be a little
8 presumptuous to say it would be cost effective. It
9 may be cost effective. And it may be desirable. We
10 certainly are going to investigate such a product.

11 DR. WOLFE: The product would be a combined
12 vaccine, like a meningitis A and C, rather than two
13 separate vaccines given at the same time, is that
14 correct? I mean this is the goal?

15 COLONEL BANCROFT: That is the goal.

16 DR. WOLFE: And that's what we are talking
17 about here, is a combined vaccine with one needle.

18 Yes.

19 ACTING CHAIRMAN ASCHER: We leave that in?

20 COLONEL BANCROFT: Yes.

21 LIEUTENANT COLONEL ZELNICK: I don't know
22 if this the forum for this, but I have a number of
23 employees that I send worldwide doing DoD government
24 business, to the third world, handling government

1 contracts, and would be exposed to many of the same
2 sorts of environments as listed here. And I wonder,
3 I see here, you know, wordage about deployed forces
4 and dependents. Should there be some sort of
5 statement about DoD employees on government
6 business?

7 DR. WOLFE: That's the group I mentioned,
8 Mike, last night, TDY type people, I very
9 specifically mentioned that, should we include TDY
10 type people, that is what he is talking about.

11 ACTING CHAIRMAN ASCHER: Right.

12 DR. WOLFE: Civilians.

13 ACTING CHAIRMAN ASCHER: That got lost in
14 the IG discussion, but the phrase was IG can be
15 considered an alternative short-term, one-time
16 travelers.

17 LIEUTENANT COLONEL ZELNICK: What about the
18 people who routinely go on government --

19 DR. WOLFE: Well, we can add that group. I
20 mean that's basically what I see in my practice, and
21 that is basically what the State Department has a
22 lot of, is TDY people.

23 LIEUTENANT COLONEL ZELNICK: That is what I
24 am trying to get at.

1 COLONEL BANCROFT: Make it as broad a
2 statement as possible.

3 ACTING CHAIRMAN ASCHER: Routinely, more
4 than once?

5 DR. WOLFE: Yeah. I mean do you know how
6 many of those people would go on a once in a
7 lifetime trip as opposed to those who would go on
8 multiple trips? Is the great majority going on
9 multiple trips? So that in that case, we don't even
10 have to bring in IG for that group.

11 LIEUTENANT COLONEL ZELNICK: Right. We
12 have identified -- people who going --

13 THE REPORTER: Could you come back to the
14 mike, sir? Come back to the mike.

15 LIEUTENANT COLONEL ZELNICK: At Kelly we
16 have people who routinely go on these sorts of
17 trips. It is a bit problematic in that they usually
18 show up the day before they are ready to roll, if we
19 catch them, and we are working on that. But we do
20 have people who are identified as routine travelers,
21 I'll put it that way.

22 DR. WOLFE: Yeah, I recognize that. I
23 think we should include that.

24 ACTING CHAIRMAN ASCHER: You like that.

1 DR. WOLFE: No, I don't think that is the
2 point. The point is to include further up, when we
3 are talking about dependents living overseas, to pop
4 this group in, TDY travelers, frequent TDY travelers
5 I think is the point.

6 ACTING CHAIRMAN ASCHER: You can make it a
7 group.

8 DR. WOLFE: Probably after this, right in
9 here.

10 ACTING CHAIRMAN ASCHER: Right.

11 COLONEL TOMLINSON: How about family
12 members or DoD beneficiary?

13 LIEUTENANT COLONEL ZELNICK: Well, if we
14 can incorporate them here with family members, it
15 would save --

16 LIEUTENANT COLONEL PARKINSON: Yeah, put it
17 in there. Family members and DoD civilians assigned
18 abroad.

19 DR. WOLFE: You want to put it up here,
20 Mike? Family members and DoD dependents -- I mean --
21 -

22 DR. GWALTNEY: Civilians.

23 LIEUTENANT COLONEL PARKINSON: Assigned
24 abroad or with frequent travel to high risk areas.

1 Assigned abroad or with frequent travel to.

2 ACTING CHAIRMAN ASCHER: Together?

3 LIEUTENANT COLONEL PARKINSON: Recurrent
4 travel.

5 ACTING CHAIRMAN ASCHER: Yeah, whatever.
6 That covers its.

7 CAPTAIN TRUMP: While we are on that one, I
8 would like to bring up the question about following
9 the recommendations of the manufacturer as the
10 requirement there. I mean we have a population that
11 we have had assigned overseas and traveling overseas
12 for a long period of time. I am not sure we want
13 to, you know, be tied into what is in the package
14 insert for -- whether they are going to Korea,
15 whether they should get the vaccine.

16 DR. WOLFE: Well, originally that is very
17 inclusive. I mean it even mentions as specific as
18 certain Caribbean Islands.

19 CAPTAIN TRUMP: The way I am looking at it
20 is whether, with our military population and
21 families, we can be exclusive, where there is no
22 indication, based on the experience of our people
23 living in those areas, that even though the country
24 may be considered high risk, that the environment

1 they are in, the bases they are living on actually
2 pout them at a low risk, and there is no indication
3 for immune globulin or vaccine.

4 DR. WOLFE: I would have to argue that
5 point from my personal experience and that is you
6 have got somebody on a military base in Germany who
7 takes a trip to Southern Europe or North Africa.
8 You have got people living on a military base where
9 everything is controlled, and they go out into the
10 community to eat. It is just analogous to malaria.

11 The Air Force years ago had malaria cases in
12 Turkey. There is no problem on the base where they
13 controlled it very well, but when people went off
14 the base, they weren't taking prophylaxis, that's
15 how they got exposed to malaria.

16 So I never feel secure that somebody living
17 on a base is free of --

18 CAPTAIN TRUMP: Well, we have people living
19 in Sicily, in Naples, Italy, you know, for three
20 year tours.

21 DR. WOLFE: I would give gamma globulin, I
22 would give it in those places. They are eating
23 shellfish out of the Mediterranean.

24 CAPTAIN TRUMP: But we don't. We don't,

1 and we don't see hepatitis-A.

2 DR. WOLFE: We do.

3 DR. POLAND: A tiny thing up in the first
4 bullet there. Assigned to geographic areas with
5 known high risk, to make it compatible with the
6 others. Everybody goes to an area that is of known
7 risk. It is the high risk that we are worried
8 about.

9 DR. WOLFE: That is a hard thing to
10 quantitate. What is high risk and what is risk in a
11 particular country?

12 DR. POLAND: Well, the bullets following
13 that speak to high risk areas.

14 DR. WOLFE: Known high risk.

15 DR. POLAND: See, you have in third bullet,
16 high risk areas.

17 DR. WOLFE: Okay. So if we put geographic
18 areas with known high risk.

19 DR. POLAND: Okay.

20 DR. WOLFE: I am sorry. I didn't want to
21 gloss over that last point. Is there something
22 further you want to change?

23 ACTING CHAIRMAN ASCHER: Can we dump this,
24 can we dump this guy? Following the manufacture, it

1 is pretty clear that is --

2 COLONEL BANCROFT: Yes.

3 DR. WOLFE: Well, you can say CDC.

4 CAPTAIN TRUMP: Well, we have our own
5 organization and I am not sure we need to be, you
6 know, tied in to making recommendations when we have
7 years of experience in those areas with knowing what
8 the disease risk is for our populations.

9 LIEUTENANT COLONEL PARKINSON: I think it
10 is better, particularly because ACIP is not out yet.

11 ACTING CHAIRMAN ASCHER: So is it
12 consistent now, geographic areas, high risk?

13 We didn't get any objection on the food
14 handlers?

15 LIEUTENANT COLONEL PARKINSON: I would let
16 Ben Diniega make a comment here.

17 COLONEL DINIEGA: I have a comment, on the
18 first bullet, for the -- for use. We have, our
19 military forces are assigned to overseas areas, or
20 they get deployed, but their home base, like at Fort
21 Bragg, they get deployed and they come back. So I
22 would recommend that first bullet be changed to
23 reflect that, and say military personnel, military
24 forces deployed or assigned to geographic areas with

1 known high risk. And drop the dependents, because
2 you are covering that in the third bullet.

3 LIEUTENANT COLONEL PARKINSON: Just say in
4 the second bullet, the deployed and deployable
5 forces.

6 DR. WOLFE: That's what we had initially,
7 didn't we, deployed and deployable forces?

8 COLONEL DINIEGA: A deployed force on a
9 technical basis is home based ACONUS, when they go
10 and they come back. And then we have people in
11 Korea who are assigned there for a period of two
12 years.

13 LIEUTENANT COLONEL PARKINSON: Oh, I see.

14 COLONEL DINIEGA: So if we say military
15 forces assigned --

16 LIEUTENANT COLONEL PARKINSON: And
17 deployed.

18 COLONEL DINIEGA: -- or deployed to
19 geographic areas with known high risk.

20 ACTING CHAIRMAN ASCHER: I got it. That's
21 good.

22 DR. POLAND: So you could take out
23 "currently" too then.

24 COLONEL DINIEGA: Right, you can take out

1 "current."

2 And in the second bullet, the only problem
3 I have with that is the alert level for reserves is
4 done on a different methodology than alert levels
5 for active duty. I mean the number one alert force
6 in the reserve may not go until all the active duty,
7 or most of the active duty is deployed. So there's
8 different alert levels for the active duty and the
9 reserve forces.

10 So, you know, what I am saying, the number
11 one alert force on active duty is not the same as
12 the number one alert force in the reserves.

13 DR. WOLFE: (Inaudible) first active
14 reserve.

15 ACTING CHAIRMAN ASCHER: I don't think so.
16 Reservists, a lot of the guys get on the first
17 boat.

18 LIEUTENANT COLONEL PARKINSON: Yeah, I
19 think that's, in this total force concept, that's
20 hard to say, that phrase.

21 COLONEL BANCROFT: I would leave that up to
22 the Services.

23 ACTING CHAIRMAN ASCHER: Right. It's a
24 true point.

1 COLONEL BANCROFT: That says it, doesn't
2 it, following ranking, whether they are reserve or
3 active.

4 COLONEL O'DONNELL: Why don't you just take
5 out active and reserve.

6 COLONEL BANCROFT: Well, they shouldn't
7 overlook the reserve.

8 DR. WOLFE: Yes.

9 LIEUTENANT COLONEL PARKINSON: What is the
10 ACIP going to say, we talked about food handlers,
11 but what is the ACIP going to say on day care
12 workers?

13 DR. WOLFE: I would have to look at it
14 because, as I recall, it was a controversial --

15 LIEUTENANT COLONEL PARKINSON: We get a lot
16 of questions on this issue.

17 DR. BROOME: I think it is outbreak zones.

18 COLONEL BANCROFT: Yeah, they don't say
19 that they are in increased occupational risk.

20 LIEUTENANT COLONEL PARKINSON: Okay. Then
21 I would say that we basically strike that, because
22 that will be, that immediately will get all sorts of
23 red flags all over DoD that every home day care
24 provider, of which we have thousands, and others,

1 and many of whom are already immune by the way,
2 because of them are foreign, at least in the Air
3 Force, are foreign born spouses of active duty
4 members who have a high prevalence of immunity
5 anyway.

6 And the food handler issue, you might want
7 to put in the food handler as it relates to deployed
8 forces, to narrow that a little bit more.

9 ACTING CHAIRMAN ASCHER: That is covered as
10 deployed forces.

11 LIEUTENANT COLONEL PARKINSON: Well, it is
12 not clear in that bullet that that is a subset of
13 deployed forces.

14 DR. WOLFE: What, the food handlers? I
15 think, Bill brought up the point that he believes
16 that a lot of the hepatitis occurs in between
17 deployments in this country and that food handlers
18 would be, at least theoretically, one of the high
19 risk situations for outbreaks here or at any
20 military base.

21 LIEUTENANT COLONEL PARKINSON: Would this
22 be, would this apply --

23 DR. WOLFE: That was the reason to put that
24 in.

1 LIEUTENANT COLONEL PARKINSON: I guess my
2 concern is, the questions that we are going to get
3 is, okay, that means that the Burger King at
4 Bethesda Naval Base and those employees on that
5 base, should they be immunized? I mean that
6 rationale --

7 DR. WOLFE: Well, that's a tough question,
8 we talked about that.

9 CAPTAIN TRUMP: I would hesitate to put
10 that in there without doing a cost effectiveness
11 analysis like we did with the bigger question.

12 DR. WOLFE: Well, isn't that up to you guys
13 to decide which food handlers you give it to. We
14 are just telling you that food handlers should get
15 it.

16 LIEUTENANT COLONEL PARKINSON: Well, the
17 problem is once this is codified as a piece of paper
18 that starts circulating, food handlers without
19 qualification or day care workers without
20 qualification, or justification in that bullet as to
21 why in the military and not elsewhere, it raises
22 more questions than we have the data to answer.

23 COLONEL BANCROFT: Couldn't we just strike
24 it? In a way, if you went to total immunization of

1 the force, then you are protecting the diners.

2 LIEUTENANT COLONEL PARKINSON: Right. And
3 ironically, the food handlers that we ran into
4 problems with in most of deployments, we don't have
5 control over because they are foreign born workers.

6 I mean the outbreaks we had in the Gulf were not
7 active duty.

8 ACTING CHAIRMAN ASCHER: We are getting --
9 we are going to stop and finish this meeting in
10 executive session.

11 DR. GWALTNEY: Why don't we take that one
12 thing out though? I mean I can see that is creating
13 major problems in terms of --

14 LIEUTENANT COLONEL JONES: Could you simply
15 state that that is a consideration that deserves
16 further consideration? It would have to be put in
17 consideration.

18 LIEUTENANT COLONEL PARKINSON: I would
19 await entirely ACIP guidance and interpretation of
20 that.

21 DR. WOLFE: Well, if you want to put down
22 here, use of the vaccine in dependents, including
23 children, and food handlers and day care workers
24 should follow the ACIP recommendations.

1 LIEUTENANT COLONEL PARKINSON: I think that
2 would be acceptable.

3 DR. FLETCHER: Maybe I missed this. What
4 about health care workers? Did we decide just to
5 eliminate them?

6 COLONEL BANCROFT: Health care workers are
7 also not considered high priority risk for
8 hepatitis-A.

9 LIEUTENANT COLONEL PARKINSON: They are not
10 even referenced in the ACIP either.

11 COLONEL BANCROFT: One other comment you
12 might make as a last bullet here would be as a
13 recommendation the total force. It would be the
14 lowest priority perhaps, but I think it would --
15 made a statement endorsing the eventual total force
16 immunization.

17 ACTING CHAIRMAN ASCHER: It's last
18 priority, we may not get to it this year. But at
19 least it authorizes the concept.

20 COLONEL BANCROFT: Yes.

21 ACTING CHAIRMAN ASCHER: All of the forces?

22 COLONEL BANCROFT: Yeah, whatever.

23 ACTING CHAIRMAN ASCHER: Okay. We have got
24 to go on to Dr. Hansen. We will have a chance to go

1 over this a little bit more in the next few
2 meetings.

3 Thank you very much.

4 DR. HANSEN: I am pleased to bring to you a
5 report from the Injury Work Group that has met now
6 twice. First, I would like to acknowledge the
7 tremendous efforts of Lieutenant Colonel Bruce Jones
8 who has spearheaded this effort for the board for a
9 number of years, not just recently, but certainly
10 has brought our efforts to fruition.

11 We met in the Maryland area and then again
12 for a full day this week. And this week included a
13 number of outside experts in the area of injury
14 prevention. And I think we made some tremendous
15 progress on behalf of the board. I would like to
16 kind of give you a picture of where we are today,
17 because you are going to be receiving faxes, mail,
18 messages, that will require board response.

19 First of all, we made a decision to proceed
20 to making a formal report from the board to the
21 Department of Defense, Assistant Secretary for
22 Health. And the reason we decided to go forward is,
23 although we are all uncomfortable with the
24 completeness of the data that we have, we felt there

1 is so much evidence that injury is a major problem,
2 particularly in training, but at all levels of the
3 military, that it deserves to be increased in its
4 intensity of scrutiny by the higher levels of the
5 military administration.

6 So we have tentatively entitled the
7 proposed report "Injuries in the Military:
8 Surveillance, Research and Prevention." And have
9 concluded that it will be based simply on the data
10 that we currently have available, though it will go
11 on to point out some of the areas of database
12 improvements needed or data analyses needed.

13 We thought of a number of different ways of
14 organizing the report, but the conclusion of the
15 group was to organize around the various databases
16 that are available that provide evidence on injury.

17 To look at each database from the standpoint of the
18 information it conveys on injury. And the databases
19 that will be reviewed are the casualty office deaths
20 database; the safety center unintentional injury
21 fatalities database; the hospital medical records
22 system, which I mentioned earlier has primarily been
23 used in the past for administrative decision making;
24 the disability agency physical evaluation board

1 reports; outpatient records, although there is no
2 systematic set of outpatient records. This will
3 include principally research studies, medical
4 research reports that have been developed over the
5 last few years, and those reports are generally very
6 targeted, very specific, but will be useful for this
7 report.

8 And finally, deployment surveillance
9 systems which are principally useful for producing
10 denominator information where that is otherwise
11 missing.

12 The questions that will be addressed to
13 each subgroup, and around each of those five
14 databases we have subgroup created of two to four
15 people, each of those databases will be queried or
16 information stated concerning the following
17 questions.

18 The first is how big is the problem of
19 injuries relative to, for example, other causes of
20 morbidity or mortality, broken down for each of the
21 services? And when you say how big is the problem,
22 one death is obviously a big problem. Are three
23 sprains equal to one death? Well, that's, when we
24 got into talking about how you measure the magnitude

1 of a problem, we decided that at this stage we ought
2 to be reporting it with an eye toward the cost and
3 the potential for prevention.

4 So the problem's size will be assessed in
5 terms of its incidence, the days of limited or non-
6 duty time, any disability or compensation which
7 resulted from the injury, or results from the
8 injury, and other markers of impact on readiness and
9 on resources.

10 Now, in this case, in each case the issue
11 came up, what should the comparison group be?
12 Should it be 18 to 23 year old males who run a
13 minimum of five miles day, compared to our training
14 group? And in each case, it looks like different
15 comparison groups will be needed, and most of those
16 are not available to us at this time. So the report
17 will not be at the level of a final research report,
18 but will rather comment on the status as we
19 currently know it. And in the case of comparison
20 groups, point to needs for comparable information
21 elsewhere.

22 The second set of questions are what are
23 the most important types of injuries and which of
24 those injuries has the greatest impact on readiness

1 or on manpower? Some of the categories being
2 reviewed include fractures, stress fractures,
3 sprains, dislocations, head injuries, back injuries
4 and others, and each of those will be looked at in
5 turn, in terms of the incidence of the particular
6 injury, the days of limited duty, again, the
7 disability, and compensation and other aspects of
8 readiness.

9 Thirdly, what are the most important causes
10 of injuries? And then the question comes to how you
11 judge importance. The injuries that we reviewed
12 fell into a number of categories, vigorous physical
13 training and operational activities being among the
14 areas where significant preventive efforts could be
15 directed.

16 Sports and athletics, which proves to be
17 the source of many injuries in the military. Motor
18 vehicle accidents. And it was reinforced that the
19 seat belt efforts have made a difference, but that
20 nationally, as well as in the military, this is an
21 area that is declining in its severity but is still
22 a concern. Falls and jumps.

23 Fourthly, what works to prevent injuries
24 that are identified in this database? Now, it is

1 clear that very little has actually been done in the
2 way of direct prevention studies, but it is the
3 intention of the drafters of this report to include
4 those systematic studies or experiments that have
5 been done, where some kind of preventive measure was
6 initiated.

7 One of the examples provided to us was the
8 development of the parachute jumper's boot brace.
9 And there are others where at least the impact of
10 prevention, or potential prevention, can be pointed
11 to through these prototype studies.

12 Fifth, what are the strengths of the
13 databases and what are their weaknesses? In the
14 process of visiting these data, it is impossible not
15 to ask questions and discover that the question
16 can't be answered with the current state of the
17 database. And so it will be part of our writing to
18 try to identify where the answer to a question is
19 either difficult or impossible to obtain, and where
20 it would be important to work further to improve it.

21 It certainly will be a guess on the part of
22 the board as to what portion of injuries can be
23 prevented, at what cost for the prevention effort,
24 and at what savings due to the prevention, but at

1 this stage, such estimates can not be done in
2 concrete and will have to be done with just best
3 guesses and best estimates.

4 Finally, recommendations will be made
5 concerning the uses of various databases for
6 surveillance purposes. Some of them were not
7 created for that purpose but can possibly be refined
8 or bent towards such a purpose.

9 We will try to put forth at least some
10 beginning suggestions for prevention strategies and
11 programs, although we view that as a longer term
12 effort.

13 We will raise some questions about focuses
14 for future research in the area of injury
15 prevention. A number of areas that will be
16 considered, though not necessarily included in this
17 report, are comparisons between combat and non-
18 combat injuries, some of these data coming from the
19 data developed during Desert Storm. Comparisons of
20 acute injuries versus chronic stress injuries.

21 Those that include on -- that occur on or off duty.

22 Those which require hospitalization versus those
23 which are handled on an outpatient basis. And it is
24 certainly clear that the vast majority of injuries

1 are not hospitalized and still result in a
2 tremendous loss to the military.

3 Sex differences in injury rates will be
4 cited and some tables included, particularly where
5 those differences appear to require redress.

6 There will be also a focus on the issue of
7 training injuries versus operations injuries, and
8 this came directly out of some of the concerns about
9 the intensity of the training period and the fact
10 that so many injuries do seem to occur during that.

11 Causes are going to be the most difficult
12 thing to get at. One of our experts pointed out
13 that there are the intrinsic causes related to the
14 individual himself, perhaps his or her genetic
15 status or what he brings as he arrives in the
16 military. And extrinsic causes, which might be the
17 boots or it might be the terrain on which running
18 takes place or whatever. So much of the causal
19 information will not be present at this stage in the
20 report.

21 There will be some review of the potential
22 for prevention, but that too really relates to
23 causal inferences.

24 And sometimes there will be issues of

1 coding. And I mentioned earlier the issue of
2 alcoholism or simply alcohol involvement in
3 injuries, and the problem of being sure that the
4 injury is coded in a way that cause can ultimately
5 be discerned. As the database currently exists,
6 most of these databases, cause will be difficult to
7 get from the present records.

8 We have five subgroups and we have set for
9 ourselves perhaps the shortest time course, other
10 than your little computing, editing here today, of
11 any group. We expect in one month for each of the
12 subgroups to submit five to ten pages of text and
13 five to ten figures or tables relating to the
14 analysis of their particular database.

15 The following month, those pieces will be
16 edited, amplified and altered such as to make a
17 draft document. And we hope to have to the board,
18 the AFEB board, a first full draft document around
19 the end of April. The intensity time line is
20 related to budgeting decisions that will be coming
21 up and the importance of bringing injury and injury
22 prevention up to the higher level of attention in
23 the Assistant Secretary for Health DoD's office.

24 We hope within a month after we submit the

1 draft to you that we will have a final version. So
2 when you receive it, however, by fax or FedEx, I
3 urge you not to put it on your back burner, but to
4 give it that half-hour or hour of attention and get
5 it back to us so that we can produce at least a
6 reasonable document by the end of May.

7 Are there any questions? Yes.

8 DR. BROOME: Are you planning to include
9 injuries related to violence?

10 DR. HANSEN: Violence has certainly been
11 mentioned and is part of the databases that will be
12 reviewed, particularly in the casualty and death
13 database. My recollection, though we did not see it
14 these two meetings, but saw it rather in a previous
15 presentation to the board, is that the military
16 incidence of violence is not in fact excessive
17 compared to the public, or non-military, and, if
18 anything, is surprisingly low relative to the
19 availability of guns and all. So it probably will
20 not take a high level of priority, though it will
21 certainly be mentioned in the context.

22 I think the military's goal is to focus on
23 those aspects that are military-specific or that the
24 military environment can intervene in, or that the

1 military environment has caused.

2 Yes.

3 DR. FLETCHER: What about self-inflicted or
4 suicide, is that implied here?

5 DR. HANSEN: Suicide is broken out as well
6 in the casualty data.

7 DR. PERROTTA: As a member of the group
8 that is going to be looking at the casualty and
9 death data, we will look at the available
10 information for homicide and suicide, the two
11 violence categories, so we are going to be
12 interested in that. And it might be, indeed, that
13 that is a worthwhile point to make, what Barbara was
14 saying, that the rates compared to the nation are
15 low. I mean that may be the finding that we would
16 emphasize.

17 LIEUTENANT COLONEL JONES: Also, I think it
18 is worth noting that Dr. Ken Powell from the
19 Violence Division of the National Center for Injury
20 Prevention is on the committee, so I am sure it will
21 get some attention.

22 DR. HANSEN: Yes.

23 COLONEL DINIEGA: That was a good question.
24 I think, were you alluding to family environments

1 more than to deaths from homicides?

2 DR. BROOME: Well, the category of violent
3 injury really includes homicide, suicide, domestic,
4 you know.

5 COLONEL DINIEGA: That is probably a
6 database that was not considered in the
7 deliberations on Wednesday. And in the Army at
8 least, the database is available through the family
9 advocacy personnel, and I can get together with
10 Bruce to give him a name, if the work group wants to
11 include that data.

12 DR. HANSEN: Okay.

13 ACTING CHAIRMAN HANSEN: Unfortunately, Dr.
14 Gwaltney left but he, as you know, made some
15 comments that he thought the board should say
16 something about the adenovirus vaccine. And in one
17 of the breaks, we wrote a very short paragraph which
18 we will run by Dr. Kuller and others. I just want
19 to show it to you to see if there are any real
20 problems with it at this point. And Jack is going
21 to work on it further, but he had to leave.

22 LIEUTENANT COLONEL JONES: Before we go on,
23 Dr. Ascher, I think there is one other important
24 announcement regarding the injury work group that

1 Dr. Hansen would like to make.

2 ACTING CHAIRMAN ASCHER: Sorry.

3 LIEUTENANT COLONEL JONES: It is just an
4 oversight. Sorry.

5 DR. HANSEN: Bruce very carefully gave me
6 this piece of paper that was behind my other papers,
7 so I apologize. We have expanded the military
8 liaisons to the injury work group and they will
9 include Captain Brodine and Lieutenant Commander
10 Shaffer from the Navy, Lieutenant Commander Zelnick
11 and Major Grayson from the Air Force, and of course
12 we have Lieutenant Colonel Jones and another person
13 from the Army. And we all viewed it as extremely
14 important for the major military branches to be part
15 and parcel of the development of this report.

16 ACTING CHAIRMAN ASCHER: And for the
17 information of the rest of the group, it is I think
18 the consensus of the day here is that we don't
19 really have an executive session to discuss anything
20 particularly controversial in the absence of
21 everyone in the room. So we will just go right from
22 this little discussion into the last of the business
23 items and then we will close when we close.

24 We will open the floor for comments, of

1 course, of anything. And if there is a
2 recommendation to close the room to have a
3 discussion, that is also fine.

4 DR. WOLFE: Are we going to hand out a
5 revision of this hepatitis-A document?

6 ACTING CHAIRMAN ASCHER: If we could
7 arrange that, that's a very good suggestion.

8 Would you be able to print that in the next
9 few minutes if we mill around smartly?

10 SERGEANT HARRIS: Yes, sir.

11 COLONEL TOMLINSON: I would like to comment
12 on that because, at some point, maybe before it is
13 published. I think if this is the appropriate time,
14 on the hepatitis-A recommendation.

15 ACTING CHAIRMAN ASCHER: Do you want to see
16 it again?

17 COLONEL TOMLINSON: No. I can state it I
18 think.

19 DR. WOLFE: This is not final.

20 COLONEL TOMLINSON: That's okay.

21 DR. WOLFE: This handout, I think this has
22 got to be run by Dr. Kuller and --

23 ACTING CHAIRMAN ASCHER: Everybody.

24 DR. WOLFE: -- sent to you or the acting

1 head of the --

2 ACTING CHAIRMAN ASCHER: It will go through
3 your office.

4 COLONEL TOMLINSON: All right. But I would
5 like for the other services to hear this, and that
6 was that I agree with Colonel Bancroft, that the
7 great value of this vaccine is that it can be given
8 at a more leisurely time. However, I see a great
9 value of this vaccine in that it can be given very
10 shortly before deployment, and I think that's where
11 we are going to save a lot of money, where we will
12 save millions of dollars if we can vaccinate a fewer
13 number of people prior to their deployment.

14 It is not that we want to deprive other
15 individuals of getting the vaccine, but if we have
16 limited resources and limited amounts of money, if
17 we can vaccinate people two weeks before deployment,
18 that will make I think a big difference in the
19 amount of vaccine that we have to purchase
20 immediately.

21 I certainly believe in universal
22 vaccination against hepatitis-A and B, and I think
23 we will come to that. But until we get to that
24 point, I think that we will have to select the

1 groups that will be getting the vaccine. And we may
2 be vaccinating thousands of people who never leave
3 the country unless that is, you know, before they
4 get out of service. And I think we can use that
5 vaccine in trying to focus on individuals closer to
6 deployment, like two weeks, if we could do that, or
7 three weeks. Even shorter to deployment. Because,
8 as was mentioned, that first two to three weeks, a
9 soldier may be traveling, they may be on MRE's, they
10 may be at very low risk of contracting it, and by
11 the time they are exposed, they will have it.

12 But I don't think that is spelled out in --

13 DR. WOLFE: Well, I think the bullets that
14 we had put the first priority on the --

15 ACTING CHAIRMAN ASCHER: Deployed and
16 deployable.

17 DR. WOLFE: Deployed forces. Was first.
18 And that's up to you to decide whether you want to
19 give it in advance, on a regularly scheduled basis,
20 or you want to wait until you know these guys are
21 going to be deployed. And if you really want to
22 save money, that's where, that's the emphasis you
23 are going to put on is two or three weeks ideally
24 before a specific group is going to be deployed, if

1 you have got a minimum amount of money to spend on
2 vaccine.

3 ACTING CHAIRMAN ASCHER: The flavor of
4 this, taking the lead of Dr. Bancroft, was to make
5 this an empowering recommendation that gave you the
6 broad authority to do it all, but what you do is up
7 to your resources issues and your logistics. We
8 would not criticize you for only having done one-
9 tenth of the deployable forces with another strategy
10 to do the other ones with two weeks notice. That
11 would be still within the spirit of this. No one
12 would object to that. And that is for you to work
13 out.

14 Whether we want to say that, to give you
15 that flexibility, I don't think so. We want to
16 empower you to do your job.

17 COLONEL TOMLINSON: I foresee a great deal
18 of pressure coming from units that are deployable,
19 or say they are deployable, if they think the
20 medical department is going to provide the millions
21 of dollars that it takes to provide the vaccine.
22 While it is they themselves who can make the best
23 decision. They know what their time sequence is,
24 how much time they will have to get vaccine, that if

1 they can wait until later, a lot of money can be
2 saved.

3 ACTING CHAIRMAN ASCHER: That's true.

4 COLONEL TOMLINSON: And if that can be --
5 well, if that's going to be left up to the
6 individual services, that part of it, Colonel
7 O'Donnell, I think --

8 ACTING CHAIRMAN ASCHER: We just didn't
9 want to say something from your perspective that
10 would restrict the other services.

11 COLONEL TOMLINSON: That's right.

12 COLONEL O'DONNELL: What was left unsaid in
13 that draft, which I think everybody agrees, is that
14 you could have priority groups which really command
15 priority. You didn't say anything about people who
16 never CONUS. It is implicit they are about as low
17 as you can go on priority.

18 ACTING CHAIRMAN ASCHER: It's the last one.

19 COLONEL O'DONNELL: We may never get to
20 them.

21 ACTING CHAIRMAN ASCHER: Of all of the
22 forces. Yeah. And if you never get to it, that is
23 your decision. We are not going to criticize you
24 for not doing it, but if you want to, we say fine.

1 COLONEL O'DONNELL: Was there anything in
2 there, I can't recall, or was that taken out, at the
3 two to three period where there seems to be
4 immunity, is that in there?

5 ACTING CHAIRMAN ASCHER: Yes, it is. Let's
6 take a quick look at the adeno and then we will go
7 onto our sort of business items. Again, this is
8 following on what Jack said about the critical
9 importance of this.

10 It is also sort of a point of order, in the
11 past the board has been in a funny position of being
12 told that our role is to respond to questions, but
13 yet having things come up at this meeting that we
14 felt were worth of saying something and, according
15 to Colonel Tomlinson, this is an appropriate mode of
16 operation at this point and we are going to try it.

17 So this is a letter from Dr. Kuller to Dr.
18 Joseph that just references this series of comments,
19 which is that:

20 "At the recent meeting, the AFEB was
21 briefed on issues regarding the adenovirus vaccine
22 program.

23 "Although a short-term critical supply
24 problem appears to have been resolved, the board has

1 concerns about the long-term success of this
2 program. To assist you in prioritizing this
3 program, we discussed these issues and provide the
4 following general comments," and they are all there,
5 that's all we said.

6 "The risk and impact of adenovirus
7 infections to military operations are considered of
8 highest significance at present and in the
9 foreseeable future. Ensuring continuing and timely
10 availability of the current vaccine should be given
11 the highest priority in facilitating acquisition.

12 "Alternative scenarios for use of vaccines
13 such as outbreak control should be considered and
14 researched to determine the relative efficacy if
15 such programs should be conducted. Long-term
16 arrangements to assure a stable and reliable source
17 of vaccine should be pursued vigorously."

18 If that says too much or too little, we
19 will be happy to change it, but that is the start
20 that Jack recommended. Anybody have -- yes, Marty.

21 DR. WOLFE: A concern that was raised,
22 which I think is a real one, is this inability to
23 get serological diagnosis. And perhaps we should
24 emphasize that point, because if Pat Kelly has got

1 to run around recruiting the university or somebody
2 to do it, it should be recognized that some money
3 might have to be put towards this.

4 DR. BROOME: To me, the more concerning
5 part of the discussion was that we, it did not
6 appear that the data were available to have a
7 particularly rational approach to the problem, i.e.,
8 we didn't see the epi-curves of the past year in
9 comparison to previous years. We didn't have the
10 kind of microbiologic and etiologic information
11 you would like to have, the kind of information to
12 say whether or not outbreak control was even a
13 credible scenario. And, you know, some of that may
14 need prospective research, but some of that is not
15 so hard to pull together in a systematic way.

16 So I guess in terms of the recommendation,
17 I am not sure I would want to limit it to access to
18 diagnosis. I mean if you don't have it as part of
19 an epidemiologic evaluation of the merits of the
20 current vaccine and the need for either changes in
21 formulation or alternate strategies, you can't
22 really make intelligent decisions.

23 COLONEL O'DONNELL: Does the third bullet
24 cover your concerns?

1 DR. BROOME: I am talking really more
2 broadly.

3 LIEUTENANT COLONEL PARKINSON:
4 Epidemiological surveillance.

5 DR. BROOME: Having good epidemiologic data
6 that has been analyzed about what is the current
7 situation with adenovirus in the presence or absence
8 of that scene, and what do we know from the
9 epidemiologic data about the potential for an
10 outbreak control approach.

11 DR. HANSEN: It seems the experiment just
12 took place this past year and that we were not --

13 DR. BROOME: Well, and we didn't even see
14 the data.

15 DR. HANSEN: Yeah, exactly, that perhaps no
16 one has even really looked at what the implications
17 of the past year were.

18 DR. BROOME: Yeah.

19 DR. LUEPKER: The question is did the
20 experiment occur? Were you not given the --

21 DR. BROOME: That's right.

22 COLONEL O'DONNELL: That's correct.

23 DR. HANSEN: For one year.

24 VOICE: We don't have data, we don't have -

1 -

2 COLONEL BANCROFT: We know the rates are
3 still low.

4 DR. BROOME: And that may be okay for one
5 year. I mean, I don't know enough about the adeno.

6 DR. LUEPKER: The thing that worries me
7 about what you are saying, Claire, you seem to be
8 saying that we don't know anything about this, we
9 need to research it again, that history is
10 irrelevant.

11 DR. BROOME: No. No, I am not saying that,
12 and I certainly don't know enough about the
13 extensive database on adeno in the military to have
14 any conclusions. I guess I am just saying that when
15 you are faced with this kind of situation, where you
16 may have limited supplies, to me, the logical thing
17 to do is look at what happened to the epidemiology
18 last year. Get your diagnoses in place so that you
19 know what serotypes are in issue. Are they vaccine
20 or other? Figure out from what you know from your
21 extensive database, whether outbreak control is
22 credible. You know, know the shelf life of the
23 vaccine. And use the databased approach to decision
24 making.

1 ACTING CHAIRMAN ASCHER: If you remember,
2 in the San Diego Navy situation, they had walked
3 this tightrope as well where it was clear that if
4 you did proper epidemiology, you can make
5 recommendations to acquire treatment modalities and
6 the epidemiologic people supporting research said,
7 no, that is routine, and the people that were asked
8 to provide the drugs said, no, you have to prove
9 that it is necessary, and so they got caught in the
10 middle. And our recommendation basically empowered
11 them to go back to people and say you have got to do
12 both and wave this document and say, the AFEB said
13 it fits together.

14 And so what I added, starting with your
15 lead, I added epidemiologic surveillance activities,
16 including the development of diagnostic capability
17 should be conducted. Because that is the real
18 point. The diagnosis is only part of it. And it
19 fits together. I think that is in the same flavor
20 as our San Diego.

21 Anybody else have a comment?

22 DR. DINIEGA: I have a comment. We
23 discussed this among the Army representatives during
24 the breaks and one of the things we are thinking

1 about doing from the Army perspective is to later
2 come back to the board to, with a question, a formal
3 question that says, should we alter the current
4 policy for the use of adenovirus vaccine in the
5 Army? Which would have necessitated us to obtain
6 more data, and we listed some of them out which, you
7 know, including some of the things you mentioned.
8 So the board would be able to make a decision and
9 recommendation based on objective and current data.

10 ACTING CHAIRMAN ASCHER: Yeah, this is
11 actually welcoming that question. We are saying,
12 get the data, come back and --

13 DR. WOLFE: Well, that's okay for
14 retrospective data, but if you are going to try to
15 get any new data and you can't do the testing, how
16 are you going to get the data? I mean that's why
17 the testing is essential.

18 DR. DINIEGA: Right. I agree, and I think
19 that is needed in there.

20 COLONEL BANCROFT: I would suggest that the
21 last, in that last sentence, change the word
22 "conducted" to "strengthen".

23 ACTING CHAIRMAN ASCHER: So not the
24 development, just including diagnostic capabilities

1 should be strengthened. Okay.

2 COLONEL DINIEGA: That is probably more
3 appropriate because we have the viral isolation
4 capabilities. We have a cursory surveillance system
5 in place.

6 ACTING CHAIRMAN ASCHER: Right. I like
7 that. So you will see this in draft as it goes to
8 the board, board office and other people.

9 Do you -- with this, Claire?

10 DR. BROOME: Yes.

11 ACTING CHAIRMAN ASCHER: Thank you again.

12 Let's go on to some of the business items.

13 There is not a lot to talk about. There is
14 actually some relatively good news.

15 We have some plans for the next meeting.
16 It is the Navy's turn. Usually, we say anything,
17 you have to have left the room, you know. Do you
18 want to tentatively say anything? It was suggested
19 the Great Lakes might be an appropriate site based
20 on your changes there and recent problems.

21 CAPTAIN TRUMP: It makes sense, also I mean
22 I think that a lot of the issues have been discussed
23 at this one. You know, a focus on all the
24 immunization issues and recruit medicine issues,

1 some of which are inter-related. That would be a
2 good setting to do that.

3 ACTING CHAIRMAN ASCHER: And where is Great
4 Lakes? Barbara would like to know.

5 CAPTAIN TRUMP: Oh, just north of Chicago.

6 DR. HANSEN: I do know where the Great
7 Lakes area.

8 CAPTAIN TRUMP: It is North Chicago,
9 Illinois.

10 ACTING CHAIRMAN ASCHER: Excellent. Well,
11 see if you can find out, and that will go through
12 the office.

13 October 3rd -- this is July 6 to 7,
14 tentatively, the dates. October 3rd to 4 had been,
15 3 and 4 had been the next dates. Jean and maybe
16 Pitt as well had suggested there might be a delay in
17 that because of the fiscal year problems and stuff,
18 so look for a later in the month transfer of the
19 October, perhaps. October 3rd and 4th is soft.

20 DR. FLETCHER: It will still be on a
21 Thursday and a Friday?

22 ACTING CHAIRMAN ASCHER: I think that is
23 the format, yes.

24 DR. HANSEN: That decision should be made

1 right away though.

2 DR. FLETCHER: A lot of things in October.

3 ACTING CHAIRMAN ASCHER: Yeah, we need to
4 know that.

5 DR. HANSEN: Because the fall schedule, we
6 made a pact with ourselves that we would set these
7 way in advance. So if there is a just fiscal issue,
8 change it right now, or next week.

9 COLONEL TOMLINSON: I was unaware of the
10 problem, it must have come up.

11 DR. HANSEN: The fiscal year must start
12 October 1.

13 COLONEL O'DONNELL: Right. But sometimes
14 Congress has a --

15 ACTING CHAIRMAN ASCHER: A freeze.

16 COLONEL O'DONNELL: -- budget.

17 ACTING CHAIRMAN ASCHER: And you have
18 certain restrictions, you can't spend things.

19 DR. BROOME: You can't like travel people.

20 ACTING CHAIRMAN ASCHER: Right. Other than
21 that, everything is great. Nobody can come.

22 There was another document circulated which
23 was the JAMA article on the informed consent issue
24 around vaccines, and Dr. Kuller had brought that and

1 was interested in discussing it. We did have some
2 informal discussions, Dr. Gwaltney was involved in
3 that. And what Dr. Kuller is going to do is write a
4 letter for interested board members to sign as
5 private citizens, to Senator Rockefeller's office,
6 indicating our concern about the representation of
7 this matter as it appeared in this document. And
8 also Dr. Kuller, and I believe Dr. Gwaltney's
9 interest and willingness to testify before that
10 committee, to attempt to clarify some of the issues,
11 and other people that might be interested.

12 And Lou was also going to go further to see
13 if Jim Allen would help to somehow have JAMA set the
14 record straight. Because this came out rather
15 badly. If you looked at it carefully, it was not a
16 very kind thing said about that program. So we are
17 working on that behind the scenes. That will not go
18 through you. You can deny any knowledge of any of
19 this. Strike it from the record.

20 The next thing we would like to go over is
21 the items for the next meeting, and we have had very
22 successful experience today by having two board
23 members present. Thank you very much. And anyone
24 that is left will probably be nominated. But we

1 would maybe like to know if anyone here would like
2 to volunteer to say something at the next meeting.
3 If you volunteer, you get to talk about whatever you
4 like.

5 (Laughter.)

6 ACTING CHAIRMAN ASCHER: If you leave and
7 get reassigned by somebody, then you will get given
8 BCG vaccine.

9 DR. FLETCHER: I got a topic on, very
10 little health and hazard, -- he talked about this
11 before, but this really hasn't surfaced lately. We
12 have, just looking at some of the workers around
13 this base, the occupational diseases I think,
14 sedentary life style in the military, as in civilian
15 life, is a major issue. These issues I think we
16 should bring up occasionally. I think something, it
17 would take an agenda item next time, Mike.

18 ACTING CHAIRMAN ASCHER: Do you have a
19 speaker? Would you like to do it?

20 DR. FLETCHER: Mike Parkinson and I could
21 do something together probably.

22 ACTING CHAIRMAN ASCHER: No, we would like
23 to have you speak if you would, in this regard.

24 DR. FLETCHER: Yeah.

1 ACTING CHAIRMAN ASCHER: Anybody else
2 volunteer? Have a topic that is hot?

3 COLONEL O'DONNELL: Well, there was a
4 request that the --

5 ACTING CHAIRMAN ASCHER: What is that?

6 COLONEL O'DONNELL: There was a request
7 from Dr. Stevens about the LUPEC (phon.) program in
8 the military.

9 ACTING CHAIRMAN ASCHER: Yeah, I know,
10 that's a topic, that's the next item agenda about
11 suggested topics where we have to find outside
12 speaks.

13 But, Barbara, as you own work, obesity?

14 DR. HANSEN: Obesity.

15 DR. FLETCHER: We had talked about having,
16 like physical activity and obesity is sort of
17 together.

18 DR. HANSEN: Tied together as one thing,
19 kind of the current status of middle aged military.

20 DR. FLETCHER: Side by side.

21 ACTING CHAIRMAN ASCHER: Why don't you do
22 that, a joint presentation?

23 DR. FLETCHER: Okay.

24 ACTING CHAIRMAN ASCHER: Right. Cladd

1 Stevens had suggested that we ask the HIV people to
2 describe the Lookback program. That will have to
3 come out of your office I believe.

4 The issue was a little broader than the
5 conventional Lookback, because in military testing,
6 we find sero-incidence, and the question is how is
7 that managed? Is the program to then look for blood
8 donation, etc., etc.? How does that work? And just
9 somebody to maybe be around.

10 HIV people come to every other meeting, and
11 maybe just ask them, if they are coming, to cover
12 that one.

13 COLONEL TOMLINSON: I think blood factors
14 as well as HIV.

15 ACTING CHAIRMAN ASCHER: Okay. Let's see.

16 Greg Poland suggested that emerging pathogens in
17 the disease control area are always interesting and
18 he suggested babesia, which has apparently some
19 military connection. I wasn't completely familiar
20 with that, but I guess the newly described babesia
21 has a number of military effected.

22 And I don't remember who the speaker was,
23 but it was somebody from the Minnesota area that
24 would be an easy travel to Chicago.

1 Now, opening the floor to any other items
2 that the board or anybody in the audience would like
3 to have explored as topics.

4 DR. HANSEN: There will be follow-up from
5 the Injury Work Group.

6 ACTING CHAIRMAN ASCHER: Right.

7 DR. HANSEN: It should be on the agenda.

8 ACTING CHAIRMAN ASCHER: Definitely the --
9 and you will circulated that long before that? This
10 will be a wrap-up?

11 DR. HANSEN: It will be on the next step.
12 No, no, not the wrap-up. This is just the
13 beginning.

14 ACTING CHAIRMAN ASCHER: Right. I mean a
15 summary at that stage.

16 Marty.

17 DR. WOLFE: Last week a new typhoid vaccine
18 was licensed, typhin, which is an injectable
19 vaccine, but only two year duration of protection.
20 And it might be worthwhile to at least say something
21 about this vaccine, if the military has any interest
22 in using it. Maybe they don't, maybe they want to
23 stick with the oral vaccine or the old --

24 ACTING CHAIRMAN ASCHER: Within the spirit

1 of the meeting, when products get licensed, people
2 have been invited from the manufacturer. Would it
3 be inappropriate to ask them to come and talk about
4 a newly licensed product? Is that too
5 controversial, Bill?

6 DR. WOLFE: Do you folks have an interest
7 in this vaccine? Do you plan to use it?

8 COLONEL BANCROFT: We may have some people
9 who have done some testing. I would have to ask
10 around.

11 DR. WOLFE: I think if you are interested
12 in using it, I think this might be an appropriate
13 time to discuss it.

14 COLONEL TOMLINSON: We plan to use it, it
15 will be on the -- available, and we are going to use
16 it and the oral. We will have those two available
17 for different scenarios.

18 DR. WOLFE: Yeah. Yeah. So it might be
19 worthwhile if you want to invite the two companies,
20 the oral company, BERNA (phon.) and the other one is
21 the Malleau (phon.) I think, Castro-Malleau.

22 ACTING CHAIRMAN ASCHER: Okay. So those
23 are suggested topics.

24 Anything else? New business, old business?

1 Comments?

2 DR. FLETCHER: Do we have a tentative date
3 for that meeting? I am like Barbara, this October
4 is very tight, the October.

5 ACTING CHAIRMAN ASCHER: Oh, Jean, were you
6 the one who raised the issue of October? Would you
7 clarify that, please?

8 MS. WARD: Well, the fiscal year begins at
9 the end of September.

10 THE REPORTER: Would you come to the mike,
11 please?

12 MS. WARD: And it would be better if we
13 could pick a date later in October, other than
14 October 3-4, or whatever we had scheduled. If it
15 fits in with everyone's schedule.

16 DR. HANSEN: Well, I suggest you
17 immediately fax us a calendar and get it back and
18 find out who can come when, because we really need
19 that October one set. October is one of the most
20 busy months on most of our calendars.

21 MS. WARD: Okay.

22 DR. HANSEN: So if we are going to change
23 the date -- the current date is okay, but if you are
24 going to change it, we are going to need to do it

1 right away.

2 MS. WARD: Okay.

3 DR. FLETCHER: Later in the month is bad.

4 DR. HANSEN: Yeah.

5 ACTING CHAIRMAN ASCHER: Your point is well
6 taken. I completely agree.

7 COLONEL TOMLINSON: I might bring up, this
8 recommendation does drop out the two to three period
9 in which we might expect immunity from the vaccine,
10 and I don't know how strongly the board feels that
11 it can make such a statement.

12 COLONEL BANCROFT: We will just add it to
13 the first bullet, the second paragraph.

14 DR. BROOME: I did have an agenda item
15 before we --

16 ACTING CHAIRMAN ASCHER: Yes, please. Just
17 a second.

18 I thought we had that there. Did it fall
19 out of one of the edits?

20 DR. WOLFE: I thought it was on the last
21 one.

22 ACTING CHAIRMAN ASCHER: Where did it go?
23 It was in that whole thing we took out, and in and
24 out, and in and out. It was the IG one that had

1 there about, the whole IG clause. We will think
2 about --

3 DR. WOLFE: Let's find a place to put it in
4 right now.

5 ACTING CHAIRMAN ASCHER: Yeah. So it has
6 to be found.

7 DR. WOLFE: What wording would you like,
8 Pitt?

9 COLONEL TOMLINSON: How you had, you and
10 Dr. Gwaltney had stated it I thought was good. I am
11 not sure exactly how that was.

12 ACTING CHAIRMAN ASCHER: It was stated but
13 it was then taken out. Maybe --

14 COLONEL TOMLINSON: A statement that
15 immunity to the vaccine could be expected within two
16 to three weeks after it was --

17 LIEUTENANT COLONEL PARKINSON: What if we
18 made it a fifth bullet under the first paragraph,
19 because it really is a scientific finding? You
20 know, the fifth bullet is, you know --

21 ACTING CHAIRMAN ASCHER: I got it.
22 "Vaccine produces rapid," parenthesis "(two to three
23 weeks) and longer lasting and active immunity (at
24 least four years)." Make it a symmetrical two

1 clauses.

2 LIEUTENANT COLONEL PARKINSON: Right.
3 Something like that.

4 ACTING CHAIRMAN ASCHER: "Rapid (two to
5 three weeks) and longer lasting and active immunity
6 (at least four years)."

7 COLONEL TOMLINSON: Sounds good.

8 LIEUTENANT COLONEL PARKINSON: Well, did
9 you want to say two to three weeks after a first
10 dose? Because you are really not -- because,
11 really, you are not talking about --

12 DR. WOLFE: "Full protection can not be
13 expected before two weeks."?

14 LIEUTENANT COLONEL PARKINSON: Right.

15 DR. WOLFE: That is not even full
16 protection, that's only 85 percent.

17 LIEUTENANT COLONEL PARKINSON: That is not
18 even true. That is not true.

19 ACTING CHAIRMAN ASCHER: "Produces rapid
20 (two to three weeks after a first dose)," end
21 parenthesis, "and longer lasting and active
22 immunity," in parentheses, "(up to four years)."

23 All right, we'll see how that sounds. But
24 I think it is important --

1 DR. WOLFE: Can I put "Vaccine produces
2 longer lasting," parentheses -- no, that is not it.
3 Produces rapid.

4 ACTING CHAIRMAN ASCHER: Rapid (two to
5 three weeks after the first dose) and longer
6 lasting.

7 LIEUTENANT COLONEL PARKINSON: In 80
8 percent of individuals, don't you want to say too?

9 ACTING CHAIRMAN ASCHER: No, it's immune
10 response in 80 percent, we don't know about the --

11 LIEUTENANT COLONEL PARKINSON: Yeah, but
12 that implies that after a single dose, they are
13 fully protected after two to three weeks.

14 ACTING CHAIRMAN ASCHER: The data suggests
15 three weeks is about it. That was --

16 DR. WOLFE: That one case, it developed
17 after about two weeks.

18 LIEUTENANT COLONEL PARKINSON: Okay.

19 ACTING CHAIRMAN ASCHER: Dr. Broome has
20 another item, please.

21 DR. WOLFE: Eighty-five percent in two
22 weeks.

23 ACTING CHAIRMAN ASCHER: We will play with
24 it a little bit. The committee will see it again I

1 would think.

2 DR. BROOME: In light of the emerging
3 infections area, and some discussions we had last
4 night about CISET and inter-departmental
5 considerations about international surveillance for
6 emerging infections, it might be worth having a
7 presentation on what current plans for the
8 international field stations to participate in
9 emerging infection surveillance and how that might
10 work together with other departments or multi-
11 national agencies.

12 ACTING CHAIRMAN ASCHER: Do you have a
13 speaker?

14 Bill, do you have any thoughts on that one?

15 To try to get the international stations to speak
16 to their involvement in emerging pathogen issues.

17 COLONEL BANCROFT: We can have a
18 presentation on the overseas labs you are referring
19 to.

20 THE REPORTER: Can you speak up, please?

21 ACTING CHAIRMAN ASCHER: Yeah. Well,
22 right. The concept of what is the military doing
23 with their resources in the context of the emerging
24 pathogens initiative.

1 DR. BROOME: And I am not even sure, I know
2 DoD has a representative to this, it is a federal
3 coordinating committee.

4 ACTING CHAIRMAN ASCHER: Right.

5 DR. BROOME: I am just not sure who it is.
6 I can find that out.

7 ACTING CHAIRMAN ASCHER: If not, there
8 probably should be one.

9 DR. BROOME: No, I am sure there is. It is
10 just a question of who.

11 DR. WOLFE: There is a meeting this week.
12 There is a meeting the 28th I think it is, at the
13 State Department. I haven't been to previous
14 meetings.

15 ACTING CHAIRMAN ASCHER: If you have a
16 speaker that comes out, that stands out at that
17 group that would be a good candidate?

18 DR. WOLFE: I am planning to go to that
19 meeting, so --

20 ACTING CHAIRMAN ASCHER: Okay. Pick
21 somebody and invite them. Okay.

22 Yeah.

23 DR. FLETCHER: A brief follow-up, if Frank
24 would, on the hypothermia cases, the deaths.

1 ACTING CHAIRMAN ASCHER: The standards,
2 corrective actions.

3 DR. FLETCHER: Yeah, what since that.
4 Would be great.

5 LIEUTENANT COLONEL PARKINSON: A couple of
6 things that should be on the horizon, either for
7 formal questions, probably formal questions, I
8 think, one of the things I will just put a plug in
9 for, I think ongoing, continued communication and
10 feedback to Health Affairs is very important.

11 Either formal, informal, I think the
12 positions that you are taking kind of, this is just
13 editorial, on your own, of saying when we see
14 misrepresentation of a position or data as it
15 reflects the DoD, and if the board sees that and
16 wants to coordinate with Health Affairs staff and
17 the SG's offices to right that, I think that is a
18 very positive thing for the board to do, I mean to
19 just say that.

20 But I think some areas are going to come
21 up. The varicella vaccine is going to have a
22 question of the board I imagine, particularly as it
23 relates to I am sure of the Navy and the recurring
24 outbreaks at Great Lakes. It might even be

1 appropriate at the Great Lakes meeting to talk about
2 that because varicella is big problem with them.

3 Secondly, is the other issue that we could
4 use some clarification on I think, is the
5 periodicity of meningococcal boosters. I mean we
6 have differing services, the data is relatively
7 incomplete, as best I can tell. These are areas
8 where the science is not totally clear and you can't
9 go to ACIP, where, you know, it would help us.

10 DR. BROOME: Well, there's, you know that
11 study that the Air Force has been doing with CDC.

12 LIEUTENANT COLONEL PARKINSON: Right. It
13 shows very -- right.

14 DR. BROOME: It is really the best data.

15 LIEUTENANT COLONEL PARKINSON: The best
16 study that has been done. That probably should be,
17 you know, but we need to work these up, put it in
18 the form of questions, if nothing else, to show a
19 productivity aspect of the AFEB and service to the
20 services.

21 DR. BROOME: That actually came out of the
22 meeting I attended five years ago, sort of getting
23 people together to answer useful questions.

24 LIEUTENANT COLONEL PARKINSON: One of the

1 functions of the executive secretary, now that we
2 are the middle of looking at Executive Secretary and
3 a lot of talk going on about how it works, I think
4 the Executive Secretary has to be extremely
5 proactive about generating questions and
6 coordinating with the Services, having radar up in
7 the news and the media, and with Health Affairs as
8 to issues, because there are questions out there all
9 the time, they just don't get raised.

10 But, quite frankly, just as you all in the
11 press business, you know, one phone call and my day
12 is shot, and we don't get around to it. So I think
13 the Executive Secretary is a very important role in
14 helping the Services articulate, formulate, bring
15 to, and get the responses back in a timely fashion.
16 We have got to do it.

17 ACTING CHAIRMAN ASCHER: It reminds me of
18 the Johnny Carson skit with the question man, where
19 the Secretary has to have that envelope. They have
20 to really know at the time of the meeting, in
21 advance, what the question is going to be. Because
22 that is one of the issues. administratively, you get
23 judged on your response to questions in the formal
24 process, and we have got to have one next time, or

1 more. You have got to really see far ahead what is
2 going on.

3 Good.

4 DR. FLETCHER: Pitt, will you be doing this
5 indefinitely, or this will be a --

6 COLONEL TOMLINSON: My formal term ends at
7 1:00 today.

8 (Laughter.)

9 COLONEL TOMLINSON: I will help Jean get
10 things out, but I am also very hopeful that Health
11 Affairs will get the request out to the Surgeon
12 Generals to get the nominations, because I agree, I
13 think we need someone in the job. And I think that
14 these are two excellent things that are coming out
15 of the AFEB, three, with the injury.

16 So I think, in looking at products, I think
17 that the group really produced something this time.

18 So I don't know what can be done, or what will be
19 done to expedite the appointment of a new Executive
20 Secretary.

21 ACTING CHAIRMAN ASCHER: You can say I
22 think by acclamation the board is concerned and
23 supports that.

24 DR. BROOME: Yes.

1 ACTING CHAIRMAN ASCHER: Without even
2 asking. That is a question you don't have to ask.

3 Any other items? Jean, do you have
4 anything to say?

5 MS. WARD: I don't think so. You have done
6 all the work.

7 ACTING CHAIRMAN ASCHER: How about we thank
8 our hostess, is that appropriate? I don't know if
9 can do that. Is that sexist?

10 Would you say anything more, Sharon, do you
11 have any comments?

12 LIEUTENANT COLONEL FALKENHEIMER: I would
13 just like to thank you for coming to Hill. I have
14 missed being at the board since I moved here, and
15 certainly had a method in my madness in having you
16 here. So I really enjoyed the chance to attend the
17 meeting as well and hope you had a good time.

18 If you did notice anything that needs
19 fixing, please let us know and we can pass that on
20 as well.

21 ACTING CHAIRMAN ASCHER: Well done all
22 around, the team. Very nicely arranged.

23 Going once. Bang.

24 (Whereupon, at 12:30 p.m., the meeting was

1 concluded.)

2

3