

BEFORE THE
UNITED STATES DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

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PUBLIC MEETING: :
: :
GREAT LAKES NAVAL TRAINING :
CENTER, ILLINOIS :
: :
- - - - -X

Thursday, July 6, 1995
Great Lakes, Illinois

The above-entitled matter came on for meeting pursuant to Notice before LEWIS H. KULLER, President, Armed Forces Epidemiological Board, at Building 140, Great Lakes Naval Training Center, Illinois, in the Banquet Room, on Thursday, July 6, 1995, at 8:00 a.m.

APPEARANCES:

- LEWIS H. KULLER, President, AFEB
- Dr. David Arday
- Dr. John. B. Bagby
- Dr. G. Vaden Blackwood
- Dr. Rosent Brawley
- Dr. C. Broome
- Dr. Joseph P. Bryan
- Dr. James Chin

Ron Conley
Florence Cook
Dr. Benedici M. Dinega
Dr. James L. Fleming
Dr. Gary Guckstetter
Dr. Bruce H. Jones
Dr. Stephen Joseph
Dr. Kenton Kaufman
Dr. William Klenke
Dr. Sven Knudsen
Dr. Amy Luckey
Dr. Sharon L. Ludwig
Lieutenant J. J. McLaughlin
Dr. Seileen Mullen
Dr. Francis L. O'Donnell
Dr. Jennifer B. Ota
Dr. Michael D. Parkinson
Dr. D. M. Perotta
Dr. Mary Peters
Dr. Steve Plunkett
Dr. G. Poland
Dr. Gil Potter
Ruth A. Kiraly, RN
Dr. Jim Roudebush

Dr. Margaret A. K. Ryan

Dr. Cladd E. Stevens

Dr. Ernest T. Takafuji

Janette Tavs

Admiral P.A. Tracey

Dr. David Trump

Dr. Jo White

Dr. Sanford Zelnick

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

2 DR. KULLER: We can started. I am
3 Dr. Kuller. I am the current President of the Armed
4 Forces Epi Board. I would like to welcome you all
5 to this meeting. We appreciate the hospitality of
6 the Great Lakes Naval Training Center for inviting
7 us here and having us for the next couple of days.

8 I'm going to turn the meeting over briefly
9 to Colonel O'Donnell, who will make some other
10 introductions and some statements about what we're
11 up to.

12 COLONEL O'DONNELL: There are just a couple
13 of administrative announcements I would like to
14 make. First of all, to get down to basics, I
15 believe the bathrooms -- I'll use the word -- is not
16 service specific or -- at least the men's room, I
17 know is down the hall. I don't actually know about
18 the ladies room.

19 MS. WARD: It's right outside the door.

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1 COLONEL O'DONNELL: Okay. It's right
2 outside the door. The second thing is there are
3 -- the coffee service is right over there on the
4 right. For those who would care to partake, speak
5 to Ms. Jean Ward, who is the administrative
6 assistant for the AFEB. She is standing right over
7 there. Because coffee is not free. Everything
8 comes with a price and the coffee is included.

9 If there are any other questions you might
10 have about the AFEB administrative process and I
11 cannot help, Ms. Ward may be -- she is a permanent
12 employee of the AFEB. She may be the one who can
13 best answer your questions.

14 The only other thing I would like to
15 mention is to remind everyone this is a public
16 meeting. This is not a closed meeting. So there
17 are representatives of the public. The media may be
18 present. And to just bear that in mind in making
19 any comments you might have.

1 I would also like to acknowledge the
2 assistance of the folks here at Great Lakes who very
3 graciously hosted, in particular, Ensign Boyce, who
4 has sort of been the primary action officer who has
5 done an awful lot to lay the groundwork for this
6 meeting.

7 Commander Mewshaw, I know, has been behind
8 the scenes of making sure that Ensign did his thing.

9 Then, lastly -- and some other folks who I
10 probably don't even know about here at Great Lakes
11 who have done an excellent job in setting this all
12 up.

13 Those are all of the administrative
14 announcements I have. I'll probably think of some
15 later today. But if one has a question, please feel
16 free to ask me or Ms. Ward about the process today.

17 I think you all have an agenda. We have on tap a
18 tour of the training command. And I think that will
19 be the highlight of this morning. And as the agenda

1 indicates, Dr. Joseph of the ASSIGNED will be here
2 later this morning.

3 That's all I've got.

4 DR. KULLER: Lieutenant Colonel Mewshaw.

5 LT. COLONEL MEWSHAW: Mewshaw, yes.

6 DR. KULLER: I did pretty good. Okay.

7 LT. COLONEL MEWSHAW: Just admin
8 announcements, too. The female head or latrine is
9 immediately out the door to the left. And the males
10 is just down to the right. The emergency exits are
11 in the rear, as you can see. So if we need to, we
12 can exit out to beautiful Lake Michigan.

13 You also have access to phones out in the
14 hallway, or there is pay phones in the building
15 also, upstairs and down. And we also have available
16 faxes or any copies that anybody needs. We can
17 facilitate that. Just contact myself or Ensign
18 Boyce or anyone on the staff. Most of us are
19 wearing a type of name tag, so you recognize us.

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1 If there is anything we can do for you
2 while you're here, please let us know. It's our
3 pleasure to welcome you all aboard the Naval
4 Training Center.

5 I guess we can move on to Admiral Tracy.
6 Admiral Tracy is Commander Naval Training Center.
7 He just took over the change of command at the end
8 of last month.

9 ADMIRAL TRACY: Welcome. You are my first
10 official guests as Admiral at NTC. And I am really
11 delighted that you chose to come here to NTC. If
12 you are like me and have not been here before, I
13 think you'll find some surprises. We are bigger
14 than I thought we were geographically.

15 The scope of responsibility is really a
16 little bit awesome. We do everything from training
17 every sailor who will join the United States Navy
18 comes to boot camp here. We are the single site of
19 boot camp. And we train literally thousands of

1 those who will go on to surface warfare assignments
2 in the Navy. We're the primary surface warfare ace
3 school on site for the Navy.

4 But in addition to that, we ship uniforms
5 all over the country to ROTC and JROTC units
6 throughout the country. We are the household goods
7 shipment people for a five-state area. I'm the
8 disaster preparedness coordinator for that same
9 area. This is a tornado and earthquake area, so
10 it's been an exciting challenge. I think you'll
11 find it an interesting combination of
12 responsibilities.

13 It's particularly good that you're going to
14 have a chance to go tour the RTC. You'll find it an
15 old facility, but one that has been able to update
16 itself pretty continuously to keep pace with the
17 changing Navy needs.

18 The kids we get here are absolutely superb.
19 This is the finest -- difficult, but finest

1 recruiting market that we've worked, I think, in my
2 time in the Navy. And you'll find them truly
3 outstanding kids. I don't remember being that
4 young, but maybe we all were once. I think you'll
5 see that that's a pretty awesome operation.

6 We are entering our peak training period
7 for the year, so you'll see a pretty busy schedule
8 over there.

9 This is the place where sailors can learn
10 health promotion and accident injury prevention. So
11 I think it's particularly good that you come here to
12 host your meeting. And I hope that our folks can
13 take away from it. There are some good lessons that
14 we can use in our training requirement.

15 If there is anything that we can do to make
16 your meeting more productive or your stay more
17 pleasant, please don't hesitate to ask. We're
18 delighted to have you. As I said, I think you'll
19 find this kind of an interesting location. It's

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1 old, but it's transforming itself into a real center
2 for excellence and a real center for invention and
3 reinvention in the Federal Government. I think
4 you'll find that interesting.

5 Welcome aboard.

6 DR. KULLER: Thank you.

7 ADMIRAL TRACY: Enjoy the rest of the
8 meeting.

9 DR. KULLER: Thank you. Commander Albers
10 is going to give us a pre-brief on the visit to the
11 recruit training command.

12 (Pause.)

13 DR. KULLER: Is he not here? We're a
14 little ahead of time. He's not late. We're early,
15 so it's all right.

16 LT. COLONEL MEWSHAW: We're set to go with
17 the next section here. We'll proceed with the brief
18 on RTC.

19 COMMANDER ALBERS: Good morning, Dr. Broome

1 and the rest of the Board. I was asked to address
2 the Armed Forces Epidemiological Board -- did I say
3 that right? I'm very proud of myself. I learned
4 how to pronounce that word.

5 I really wonder what you would be
6 interested in hearing. What I decided to do is give
7 you a little bit of recent history of recruit
8 training command. And then I'm going to show -- I
9 have a 16-minute video tape. You're scheduled to
10 visit RTC, but we've only got a couple of hours.
11 And with 140 acres, 43 buildings and right around
12 8500 people on board the base today, you're not
13 going to see very much of it. So this video will
14 show you a lot in a short amount of time.

15 Navy recruit training has really undergone
16 some wrenching changes within the past year,
17 comprehensive changes. A year ago, there were three
18 Navy boot camps -- San Diego, Orlando and Great
19 Lakes. Females were trained only at Orlando.

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1 And the curriculum at that point in time
2 was what I could best categorize as a shot-gun
3 approach. Every time some senior flag officer or a
4 government official would tour one of the boot
5 camps, they'd say something like, gee, you know, I
6 think boot camp ought to teach such and such topic.
7 And sure enough, that would get added to the
8 curriculum at all three boot camps.

9 So, you see, after several years of that,
10 boot camp just became a long list of topics that
11 bore very little relation to one another and really
12 had no common focus. Boot camp was primarily
13 classroom instruction. The young people would spend
14 eight hours a day, five days a week sitting in a
15 classroom, listening to someone standing behind a
16 podium with one of these variable machines showing
17 slides up on a screen.

18 Well, today's young people -- what the
19 media likes to call Generation X, but I call the MTV

1 generation, the MTV generation doesn't respond to
2 that very well. As a matter of fact, their first
3 response when faced with that kind of presentation
4 is to have their face hit the desk, because they
5 just -- we lose them right away. They like to touch
6 things. You know, they like to play with things.
7 They were raised on video games. They were raised
8 on music videos and cable television, and they don't
9 respond to this kind of instruction.

10 That was the situation a year to two -- a
11 couple of years ago.

12 Two major forces really revolutionized boot
13 camp training in the Navy. The first was the base
14 realignment closure process, the BRAC decisions.
15 The BRAC commission decided to consolidate all Navy
16 boot camp training here at Great Lakes. So instead
17 of one of three boot camps, we became the only boot
18 camp, brought females here, female recruits here for
19 the first time since World War II.

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1 Females were trained at Great Lakes. You
2 know, WAVES were trained at Great Lakes during World
3 War II, but not since then.

4 And the second major change was that as a
5 result of those problems with the curriculum that I
6 was talking about, at chief of Naval operations
7 commissioned a blue ribbon panel composed of some
8 senior enlisted leaders throughout the Navy, a panel
9 of force master chiefs. And they got together and
10 did some serious thinking about what a sailor should
11 look like when they come out of boot camp.

12 The Air Force has a very clear statement of
13 what a new airman is. They call it the bluing of an
14 airman. If you open up the Air Force training
15 manual that they hand to every new recruit in the
16 Air Force, right on the first page, it lists the ten
17 or eleven things that constitute what an airman is.
18 The Navy didn't have anything that was similar.

19 So this blue ribbon panel really did a lot

1 to refocus the curriculum and throw out all of these
2 extraneous topics that have been added over the
3 years, that were going right over the head of the
4 kids anyway, because they don't respond to being
5 talked to. And a lot more hands on things to the
6 curriculum.

7 The instructional hours expanded from the
8 eight hours a day, five days a week, to 18 hours a
9 day, seven days a week, except for Sunday mornings.
10 We give them Sunday mornings off. But the rest of
11 the time, they're in scheduled events.

12 We have tripled the amount of physical
13 fitness training because we were having kids
14 graduate from boot camp that could not pass the
15 Navy's physical fitness test. Now, every recruit is
16 required to pass that physical fitness test if they
17 don't leave boot camp.

18 So we added significantly more hands-on
19 laboratory type things, a lot of which you'll see in

1 the video, so I won't go into great detail.

2 We instituted our new curriculum in January
3 1995. That's when the new curriculum really came on
4 line. We brought the first females here in -- last
5 July. So we've had them just about a year now.
6 You'll see a lot about this new curriculum in this
7 video tape I'm going to show you. So I won't dwell
8 on that.

9 The last thing I want to talk about before
10 I show you this tape is the environment at boot camp
11 and how that environment has some of the medical
12 ramifications, speaking as someone who is not a
13 medical person. My brother is a doctor, though, so
14 I'm not totally lost.

15 Boot camp. We take young people from all
16 over the continental United States, Alaska, Hawaii,
17 Puerto Rico, several foreign countries, and we mix
18 them all together -- so we get germs from all over
19 the country. And then we make them live in an open

1 bay barracks with common shower facilities. And we
2 keep them tightly together 24 hours a day. That
3 leads to some obvious problems.

4 A lot of the young people we get today are
5 pretty sedentary. You know, watching all of those
6 music videos and playing all of those video games,
7 you could do that comfortably seated on your sofa.
8 And to run down to McDonald's, you go hop in dad's
9 car and drive down the street.

10 Well, here at boot camp, we don't have
11 buses. The mode of transportation is the recruits
12 walk or more precisely they march or double time
13 everywhere they go. So to go to breakfast, lunch and
14 dinner, they have to march down to the dining
15 facility.

16 So you take somebody who is not used to a
17 lot of effort and all of a sudden now they have to
18 march five, ten, you know, twelve miles a day just
19 to get to class, just to get to eat, just to get to

1 go to their training events. And, of course, they
2 go in big groups. So we're very good at boot camp
3 of keeping track of groups of people.

4 Incidentally, we changed the names of the
5 recruit formations. We used to have company
6 commanders and we had companies. Well, you know,
7 the Navy is not organized like that. There is no
8 such thing as a company out in the active duty Navy.
9 So we decided to make our recruit environment more
10 like a ship. We named all of our barracks building
11 after ships. There is USS Joseph, Daniels, USS
12 Enterprise, et cetera.

13 We stenciled all of the bulk heads in there
14 with the same kind of stencils you see on a ship.
15 So they have frame numbers stenciled on the wall.

16 If you go into a compartment, it says
17 compartment C, tac lima, tac 1. If you've ever been
18 on a Navy ship, that means something to you. If you
19 haven't, you're kind of lost. And the idea is to

1 get the recruits to being on a ship. So when they
2 walk on board their first ship out in the fleet,
3 they're not totally lost.

4 Totally lost with what I was talking about.

5 Okay. We'll get into the video.

6 Anyway, they have to walk everywhere they
7 go. So they're not used to a lot of physical
8 activity. They're used to maybe getting a lot of
9 rest. We try to guarantee them six hours of sleep a
10 night, but in a strange, unfamiliar environment
11 where information is being fed at them at a rapid
12 pace, some of them may not go to sleep after the
13 lights are out.

14 And adding to that busy schedule, boot camp
15 is a very stressful time. These young people have
16 spent 17, 18, maybe as many as 24 or 25 years
17 learning how to be a civilian. In nine weeks, we're
18 trying to unlearn them how to be a civilian and
19 learn them how to be a military person. That

1 environment is stressful.

2 We deliberately put the recruits under
3 stress, because we're going to send them out to the
4 fleet, invest a lot of the Government's time and
5 money giving them sophisticated, advanced training
6 to operate some of the most technologically
7 sophisticated equipment in the world. We have to
8 know that they can perform under at least a minimal
9 amount of stress before we send them out to the
10 fleet.

11 So we have people who are crammed together
12 in open bay barracks, under stress, with a lot more
13 exercise than they're used to getting and a lot less
14 sleep. The branch clinic stays fairly busy at
15 recruit training command.

16 Subject to any questions right now, I'm
17 going to go ahead and show the video.

18 Yes, sir.

19 DR. ASCHER: What's your smoking policy?

1 COMMANDER ALBERS: Per Department of
2 Defense policy, there is no smoking in any buildings
3 at recruit training command. I would like to make
4 RTC a totally non-smoking base. Unfortunately, I
5 have some civilian contract issues, where some of my
6 civilian labor force has written into their contract
7 they're allowed to smoke. So we have designated
8 some outdoor smoking areas away from recruits for
9 our civilian employees. No military person is
10 allowed to smoke on RTC.

11 DR. POLAND: How many recruits come
12 through?

13 COMMANDER ALBERS: We train roughly 52,000
14 recruits a year. This is the first full year that
15 we've been the only boot camp, but last year I think
16 we saw 40,000. Anything else?

17 Why don't we get on to the video. Thank
18 you for your time and attention.

19 (Video displayed.)

1 COMMANDER ALBERS: Any questions raised by
2 the video? I would now like to introduce Lieutenant
3 Sheena Fountain, my public affairs officer, who will
4 be guiding you on your tour of RTC.

5 LIEUTENANT FOUNTAIN: Are we ready?

6 COLONEL O'DONNELL: We have three white
7 vans out there, 15-passenger vans. Hopefully that
8 will accommodate everybody. We are going to be
9 going to the recruit training center side. Just for
10 a little bit of information, the Naval Training
11 Center is kind of spread out. There is different
12 sections, as you can see. It's not like a lot of
13 garrisons or posts, where you drive in the main gate
14 and there everything is behind the barbed wire.
15 We're going to the RTC side. Just for your
16 information, there is what we call the service
17 school side, which is where we're at right now.
18 That's where the A school training takes place or
19 AIT which would be the Army or Air Force, I believe.

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1 But the recruits are pretty well contained behind
2 the barbed wire, so you're going to be safe and
3 that's where we're headed to right now.

4 So with no further adieu.

5 (Whereupon, the meeting congregation
6 embarked on RTC tour.)

7 (Meeting resumes at 12:00 p.m.)

8 DR. KULLER: Let's get started. Dr.
9 Fletcher.

10 DR. FLETCHER: Thank you, Dr. Kuller. This
11 part of the program deals in health and exercise in
12 war space. For your information, you may or may
13 know, we have a health maintenance subcommittee of
14 AFEB. I think Dr. Hansen is on that group. We're
15 working with this. We hope to have more activity in
16 the future.

17 I want to go over with you some things that
18 we produce at the work place meeting. Today I'll
19 show you some things in private industry. We're

1 looking 2.7, what is it, 2.9 million people in the
2 military active were in that.

3 I think we have a tremendous opportunity to
4 look at some areas of concern there in prevention of
5 disease. The disease process we deal with is
6 basically about coronary heart disease.

7 Can we have the lights down just a bit?

8 This is -- deals more in average, middle
9 aged people. The point in mentioning this to you is
10 prevention performance which we must address in
11 populations that we deal with in the Department of
12 Defense.

13 About 7 million Americans have one or more
14 type of cardiovascular disease now. High blood
15 pressure, about 63 million. Coronary heart disease,
16 heart attack, 6 million. Stroke, 3 million.
17 Rheumatic heart disease is still around. I think
18 we've mentioned briefly at these meetings about the
19 decrease in that.

1 Now, the leading causes of death -- this is
2 all, men and women, far surpass, cardiovascular
3 disease than any other types of disease or
4 morbidity. There is no doubt.

5 So this reflects again what prevention can
6 maybe do.

7 Looking more specifically at this, there is
8 a prevalence, you still see less at the age of 40.
9 There is still a high presence of this disease.
10 That expands from zero to 40. Many of these age
11 people are in the various branches of the military
12 or their dependents. So I think it's appropriate to
13 mention health promotion and prevention in this
14 context.

15 While we look at this, the ten leading
16 causes of death in the left column -- here again
17 heart disease, cancer running a close second, and
18 various other types of things and the lifestyle
19 factors that lead to half of it. This is from the

1 National Center for Health Statistics in 1990.

2 Looking at the factor -- lifestyle factors,
3 leading to half. Tobacco, 400,000. Diet, sedentary
4 lifestyle, 300,000. And on down. Ways we can
5 prevent. These are not diseases that happen to the
6 American public. These are the diseases that by and
7 large we bring on ourselves.

8 And as you can see, the 1 million here
9 versus the 2 million here, a lot of this disease can
10 be prevented. And I think this is the focus of the
11 brief few minutes I've had with you today.

12 Risk profiles and coronary heart disease,
13 you can't change your gender. Most people can't.
14 Family history you can't change. These other things
15 we can change. These are the major risk factors you
16 deal with in today's health prevention arena.

17 The American Heart Association is the basis
18 for much of this data, many of these slides. And
19 the major risk factors that are -- of course,

1 nothing new to all of you. High blood pressure.
2 Blood pressure and cholesterol. Cholesterol, blood
3 pressure and smoking, all put together, increasing
4 the risk in 50-year-old people.

5 Again, these things start before people
6 become 50 years of age, and thus the purpose of this
7 population, though younger. I think the people we
8 deal with in the military is of vast importance.

9 This is something out of the Wall Street
10 Journal. It's research and development. And its
11 latest study shows that butter may actually kill
12 more people than guns. So I think in our violent
13 society and things that deal with this is something
14 that current data on the value of a so-called drug
15 that was in USA Today about war and death and
16 keeping people alive.

17 So major, modifiable coronary risk factors
18 or risk factors for cardiovascular disease are
19 leading. And more recently, the one I'd like to

1 focus on today, physical inactivity has been
2 designated by the American Heart Association as a
3 major and modifiable coronary risk factor.

4 Physical inactivity is an independent risk.
5 There isn't much data to show it as a development
6 factor for coronary artery disease.

7 Exercise training, on the other hand,
8 favorably alters lipid metabolism, particularly
9 triglycerides and carbohydrates. And the increase
10 of HDLs or the good cholesterol, high lipoprotein
11 levels, is substantially associated with exercise
12 and changes in body weight. If one decreases weight
13 and stops smoking, the HDLs could go up.

14 Lipid abnormalities, we've mentioned, the
15 obesity, diabetes, are factors that can be altered
16 with proper physical activity.

17 And also independent -- but modest
18 independent of that in certain hypertensive
19 populations. Many people are on healthy programs

1 who are on mild, anti-hypertensive aids can come off
2 those aids with the proper exercise and weight
3 control.

4 Regular exercise in overweight particularly
5 and in men enhances the beneficial effect of
6 lipoprotein levels that result in low saturated fat
7 and cholesterol. This is a study from Stanford that
8 is just showing the major differences you see in men
9 versus women, where exercise, past diet or no diet,
10 sort of incrementally is beneficial in men. But
11 women really had to have the exercise with the diet
12 to make a difference in the LDL/ACL ratio in a more
13 positive, more health arena. So it's even more
14 important in women.

15 There are a number of studies -- I will
16 cite only one -- that show the preventative benefits
17 of exercise alone for prevention of these disease
18 problems. One I think is most important is Dr.
19 Steve Blaire's summary from the aerobic center in

1 Dallas, looking at about 10,000 men, health and
2 unhealthy, over a period of about five years.
3 Initial exercise test to determine how additional
4 fit they were, followed up by exercise tests five
5 years later.

6 And looking just at the work capacity on
7 the exercise test -- they used treadmill tests in
8 this particular test. Looking at the dark bar, the
9 middle bar and this bar, in all ages, these were the
10 people who were unfit initially and unfit in the
11 follow-up. No improvement after having the aerobic
12 center available to them.

13 These were people in the second bar who
14 were not conditioned initially, but the follow-up
15 exercise test showed more time and more condition.

16 These were the fit people initially and the
17 follow-up.

18 In looking at the all causes of death
19 raised particularly is cardiovascular disease. This

1 group was followed over many years, about 10,000
2 people shows to benefit just from being fit from
3 whatever type of exercise you do. So probably the
4 largest study of these clinical trials.

5 There are several others that I show, but
6 let me just go over the Paffenbarger study. This
7 one is probably the biggest and most current study
8 out of the JAMA about four or five months ago.

9 So into community groups and employers and
10 home, you're talking about most specifically with
11 the military and private industry, there is
12 increasing evidence that work site promotional
13 programs, with a comprehensive approach to employee
14 health, including prevention and cessation of
15 smoking, dietary intervention and exercise are not
16 only effective to modifying coronary risk factors,
17 but could also aid in the care of -- in health
18 costs.

19 Examples are hospital admissions and days

1 of rehabilitation. This is largely taken from the
2 exercise statement of the American Heart
3 Association. But other data has shown this quite
4 clearly.

5 We as the medical profession really have
6 the opportunity, but more so of a responsibility to
7 our patients, to our people, to the people we
8 socially interchange with, to promote regular
9 exercise with high blood pressure, abnormal lipid
10 and sedentary, cessation of smoking. Physical
11 activity. I don't ask any more, do you exercise. I
12 ask, what kind of exercise do you do. How much do
13 you do? This should be rather routine. People and
14 patients are beginning to accept that.

15 Those are the kinds of things that I think
16 -- I read Fortune Magazine occasionally. I'm not
17 really sure why. But my wife's interested in
18 businesses. And this magazine, about three months
19 ago, the Everett Koop National Award, which I've

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1 heard of, but it was very clearly brought out in
2 this article. Awarded companies with America's Best
3 Wellness Programs.

4 I guess we could look at components of the
5 military as companies or whatever. It's groups of
6 people.

7 The 12 recent winners below were chosen
8 because their plans offered a range of services and
9 generated the biggest savings. I want to show you
10 about six of these plans which are rather
11 significant.

12 Aetna boasts five state of the art health
13 clubs with 7600 enrollees. Nautilus machines pay
14 big dividends, they tell us. Exercisers cost \$280
15 less per year to insure than does a couch potato.

16 Mail order giant, L.L. Bean, a wonderful
17 operation up in Freeport, Maine, pays up to \$200 to
18 employees whose families quit smoking or take
19 prenatal classes. The result is annual premiums on

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1 \$2,000 per worker have -- the national average.

2 L.L. Bean.

3 Champion, 18,000 mill workers pay no
4 deductible on a host of preventative exams and
5 immunizations. The pay off is big savings for early
6 detection of cancer and diabetes, diabetes
7 particularly relating to heart disease.

8 Bonuses for healthy habits. Coors. Coors
9 Beer pays bonuses for healthy habits. I'm not sure
10 if they pay it off in beer, but according to this,
11 the employees can use the award, a maximum of \$500
12 per family to buy extra holidays or to pay for
13 financial planning.

14 Jogging for dollars. Quaker. Quaker
15 grants bonuses as much as \$500 per family who
16 exercise, stop smoking, wear seatbelts. The
17 employees can keep the money or invest it in added
18 benefits.

19 So a little enticement stimulation seems to

1 work.

2 Steelcase, this large company of furniture
3 makers, tested 4,000 workers. Everything from
4 seatbelts to cholesterol. By promoting a healthy
5 life, the furniture should save \$20 million over ten
6 years.

7 Shrinking waist lines, Tenneco, hungry
8 pipeline workers. Same type thing here.

9 Union Pacific, various types of generating
10 things. Some various companies, just for the sake
11 of time and moving on here. They have shown
12 substantial benefits.

13 The University of Michigan calculated with
14 some of these companies some of the potential
15 savings for health promotion. Just to itemize with
16 you.

17 Quitting smoking, \$1100 a year, the average
18 extra cost of a smoker. Savings.

19 Organized exercise, from couch potato to

1 fitness fan, saves \$260 a year. Now, they've
2 calculated this, but others have done this.

3 Lowered cholesterol, 240 to 190, we're
4 really shooting more near 180. But 190 is still
5 good in healthy people. Could pad the annual bill
6 for cardiac care by \$1200.

7 Losing weight, obese to normal, save \$177 a
8 year, or about three per pound lost.

9 This is some of our patients we still have
10 in Atlanta. Looking down over the rolls of fat, I
11 think we occasionally see those on military bases,
12 tours, but not as much, not as much.

13 The American Heart Association standards in
14 brief, we'll just go through some of the specific
15 recommendations. For health promotion, these are at
16 least -- at least 30 to 60 minutes three to four
17 times a week. The training effect resulting effect
18 the Navy has seen actually 40 to 50 percent of your
19 maximum capacity. That's minimum.

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1 According to the standards on secondary
2 prevention, we are insisting on six days a week of
3 exercise, five to six hours a week as being optimal.

4 And just another way to look at it in the
5 chart and to just say the thing again.

6 Occupational activity. People wondering,
7 you know, what can I do at my work. This is hard to
8 cover here. I'm familiar with the standards that
9 says continual climbing. I assume we meant there if
10 you work on an active job, run up and down some
11 hills with construction, or whatever. That's good
12 occupational activity.

13 Lifting 20,000 lifts on the airports, I
14 guess the guys who lift the baggage and so forth and
15 carrying loads out.

16 It's hard to designate occupation activity,
17 to be certain that is not as extreme as it used to
18 be 20 years ago with the progress of the now
19 industrial revolution.

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1 Leisure time activity. The data that many
2 have come up with for years, that 700 calories
3 weekly on three or more consecutive days or non-
4 consecutive days.

5 Tennis, whatever you please, sports of
6 various kinds. Hiking. The maximum 2000 calories
7 weekly for maximum benefit, walking up to 20 miles
8 weekly. This is kilo-calorie expenditure. It may
9 have something to do also with the lack of calorie
10 intake. It's a calorie roll-over, so to speak.

11 And a threshold -- keep in mind that
12 individuals, I think, in medical arenas, keep in
13 mind that this has to be tailored and
14 individualized. That there is a threshold of
15 intensity to achieve benefit, but this exact level
16 is not really a known from person to person. So I
17 think we need to talk to our patients or people.
18 They don't all need an exercise test. Some may need
19 an exercise test. But we need to determine this

1 sort of on an individual basis.

2 How these exercise patterns, mechanism
3 through which we can affect this tremendous problem
4 of cardiac artery disease, this starts in people who
5 -- groups coming into the Navy here. I think it's
6 important to keep all of this in mind at an early
7 time.

8 This factor, exercise increases HDL
9 cholesterol, decreases triglyceride markedly. And a
10 decrease in the body fat, weight ratio. Reduce
11 glucose intolerance, hyperinsulin nemia. This
12 insulin uptake is less resistant. There are many
13 improvements in glucose and insulin levels. Control
14 of blood pressure immediately. And it has a
15 favorable influence on hyper-coagulatability. Not
16 to make people bleed, but to anti-thrombus effect
17 appropriately with exercise is a positive factor.

18 This was last year and we're still behind
19 on this. This is what we're losing in

1 cardiovascular disease in this country, far above
2 any other type of disease problem, which again
3 begins with every life. But we're not born with
4 this problem. The things we do and don't modify
5 aggravate this problem.

6 And based on some data back in the late
7 80s, mortality estimates generally for physical
8 activity, we lose about \$5 billion a year.

9 So I think this will summarize here that we
10 have probably a Rudyard Kipling's, nations have
11 passed away and left no traces. It just reviews the
12 naked cause of it. One single reason of all causes,
13 they failed because their people were not fit.

14 More often I have -- the life's secret of
15 my abundant health is that whenever the impulse to
16 exercise comes over me, I simply lie down until it
17 passes away.

18 Interestingly in the follow-up on the 2,000
19 health people -- some of you might be familiar with

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1 this -- more people that were exercising or
2 exercising more, 30 percent ten years ago who were
3 not exercising are still not exercising. So we have
4 30 percent of the American population who is quite
5 sedentary.

6 The other 70 percent are doing more, which
7 we like to see. We've made some progress, but it's
8 not real good.

9 Thank you very much.

10 (Applause.)

11 DR. KULLER: Just a few minutes for
12 questions and issues. Mike.

13 DR. ASCHER: Is there any literature
14 information on what happens to younger people who
15 are given what the military is doing now, these
16 exercise and smoking cessation in terms of the
17 follow-on and the 20-year follow-up, whether people
18 continue these programs?

19 DR. FLETCHER: Compliance, I guess you're

1 referring to. Not really. Mike, do you have
2 anything other than -- I don't have a general
3 population. So that's a great concern. There are
4 certain populations that never smoke, either because
5 of cultural reasons or that type of follow-up. But,
6 really, I don't think that data is available.

7 DR. ASCHER: Well, there is good data
8 available on individuals who have been evaluated in
9 their 30s and then followed. And the experience has
10 been in both men and women, that the morbidity and
11 mortality is much, much higher in those that even
12 have moderately elevated risk factors. There is the
13 follow-up of the Johns Hopkins medical students as
14 they went through and physicians as a follow-up from
15 Mahari -- of the Mahari students, as a follow-up
16 that Jerry Stendler has done in Chicago, from his
17 Chicago occupational screening of the employees and
18 younger age groups.

19 There is a study that's going to come out

1 very shortly from Seattle, which has an entire
2 community of all of the women who have had heart
3 attacks under the age of 45.

4 And we've done a similar study in men,
5 several of them, in fact. And what you find is that
6 almost all of the men who have clinical events can
7 be identified by smoking, hyper -- slightly elevated
8 blood pressure, hypertension, high cholesterol, lack
9 of activity, et cetera. And that accounts for a
10 huge population. And as you know, one of the things
11 that we've discussed in the past here, which has
12 been of critical importance has been the issue of
13 heart attacks in the military basically and
14 especially sudden death, because in people who are
15 trained and who are not fit or who are smoking or
16 who have hyper-cholesterol anemia and then exercise
17 a lot, the exercise becomes a very significant risk
18 fact for sudden demise.

19 The obvious is that if you -- exercise is

1 very good in reducing your risks, but if you think
2 you're just going to exercise occasionally in the
3 presence of smoking or hyper-cholesterol anemia, we
4 already have atherosclerotic disease or at high risk
5 and then you go out and exercise. And this is a
6 major, major risk factor in relatively young people
7 -- both in terms of precipitating heart attacks as
8 opposed to exercising to essentially a healthy
9 state.

10 But I suspect that -- I don't know how many
11 events there are. But I suspect if you look in the
12 military -- Tom Mattingly did this God knows how
13 many years ago. I remember having to read this in
14 the 1950s or 60s, his studies at Walter Reed during
15 World -- literally after World War II, almost the
16 1950s or early 50s, on heart attacks in the military
17 and its relationship to vascular disease.

18 And then there are the studies of the
19 Korean War veterans -- Korean War, people who died

1 during the Korean War and people who died during the
2 Vietnam War similarly. And actually both of those
3 studies showed no change at all in the extent of
4 atherosclerosis, and it's very significant.

5 By the age of 40, a very significant
6 proportion of men have very significant
7 atherosclerotic disease, even though they don't know
8 it until they have an event. And the event is
9 often a demise. It's probably a major cause of
10 mortality from non-traumatic causes in the military.

11 It's probably sudden demise related to
12 these risk factors.

13 DR. FLETCHER: I was starting to say,
14 that's also true in the non-military population.
15 People go out, have the event, or make a decision
16 about exercise and it just won't do it.

17 DR. ASCHER: I think one of the things
18 that's important here is that with the development
19 of the fitness programs in the military would be to

1 develop a very good monitoring system for all of the
2 heart attacks and sudden deaths that do occur in the
3 military and then trace them back to the prior risk
4 factor levels, health promotion status and things of
5 this sort, so you could document fairly carefully
6 whether the programs are really -- where the
7 programs are working and not working and where the
8 sentinel events are occurring in relationship to
9 potential changes in the program.

10 When we looked at the heart attacks briefly
11 a couple of years ago, I guess it was, down at the
12 Pentagon and tried to look at the cases, it was
13 quite obvious that the sudden demises were occurring
14 among individuals who were smoking substantially
15 overweight, who were essentially out of shape and
16 then were basically being thrown into vigorous
17 exercise programs in short of a short burst to get
18 them back into shape. But the exercise became the
19 fatal event.

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1 DR. KULLER: Yes.

2 DR. HANSEN: Obviously your implications
3 have -- your comments have implications for the
4 injury prevention work group. We were talking a
5 great deal yesterday about fitness levels. And you
6 made a comment that probably they need to be
7 individualized in your final comment there.

8 Do you know of any data that have ever
9 developed a good system for individualizing and
10 fitness increments in such a way that a system could
11 be applied to large numbers of middle-aged people?

12 For example, one of the questions is: What
13 should the fitness level be? And how do you measure
14 it in, say, 40-year-olds? And what kind of, you
15 know, increment should you expect with some kind of
16 --

17 DR. FLETCHER: This data is available in
18 normal healthy people from -- in fact, in Swedish
19 studies, there are tables of what you're supposed to

1 be. Now, these are very general guidelines. It
2 doesn't take into account those that are overweight
3 necessarily or other problems. So the College of
4 Sports Medicine has these guidelines and there are
5 certain levels of age, certain oxygen consumptions.
6 If you continue to exercise, that will decrease
7 less with time.

8 Those are general guidelines. I'm not sure
9 of anything else.

10 LT. COL. PARKINSON: One of the things that
11 we have recently done in the Air Force is look at
12 our recruit training at Lacklin, which many of the
13 Board members visited a few years ago. And what we
14 do is we triage the recruits into the levels of
15 fitness based on their previous level of activity,
16 such that they train with people at their own
17 fitness level -- at least if we don't measure it
18 directly using our cycleodometry tests during
19 recruit training.

1 But we take the approach that if you had
2 been sedentary, that you're not regularly
3 exercising, that your introductory level of fitness
4 is less than that than somebody who is a high school
5 jogger and that therefore the intensity with which
6 you start off with is less. And we can provide
7 information to the Board as to how we do that, but
8 it's using a past history to set the starting point
9 for their level, working them up, making sure they
10 meet the Air Force standard by the end, but the Air
11 Force standard is about -- you know, at least in
12 terms of our DO2 max scores, about the 25th
13 percentile of the general U.S. population, which is
14 reasonable.

15 So we would make sure they get above that,
16 but how you get them is graded based on their level
17 of --

18 DR. FLETCHER: When we do a minimum of
19 exercise tests, it's always helpful if you can

1 justify that.

2 DR. ASCHER: And your injury data would
3 reflect that the program is also working out.

4 LT. COL. PARKINSON: Right. We're
5 analyzing that now.

6 CAPTAIN COLLINS: Is that a unique program
7 or it's a military general program? Is there a
8 system in the military to collect data regularly on
9 cardiovascular disease risk factors?

10 DR. ASCHER: Yes.

11 LT. COL. PARKINSON: Each one of the
12 services has their own way to collect HRA type of
13 information. But to be honest, I mean there's been
14 an ongoing work group to standardize the DOD HRA.
15 We ourselves -- you'll hear tomorrow we are -- the
16 Air Force will be fielding within three months the
17 Air Force version of the Hagle list factor survey
18 with certain things in it that are more
19 operationally relevant to the military population.

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1 But I would say right now if you had to ask
2 me what is the overall rate of the cholesterol level
3 in the Air Force, I don't have that information.
4 And part of that gets again to our ambulatory data
5 system. The data systems generally are not
6 standardized across the services to collect data
7 across the board.

8 DR. ASCHER: I don't know how broadly it's
9 being used, but I've taken it a couple of times as a
10 reservist. And it's interesting, they have all of
11 the data and then they give you feedback as if they
12 sort of know the answer. And if you sort of cook
13 it, put in a glass of wine a day and exercising
14 three days a week and you --

15 DR. FLETCHER: Red wine.

16 DR. ASCHER: Right. You come up with high
17 HGLs, so you get the right -- they say you increase
18 your exercise to six days and stop the wine. I'm
19 interested whether somebody could get into that data

1 and see if that's really the correct answer. It
2 could be a gold mine in terms of data analysis.

3 DR. BROOME: You did mention the recent
4 reports on folic acid and its affect on existing
5 levels. I think it's interesting of itself, but it
6 also might be interesting in terms of what the
7 military diet would look like.

8 DR. FLETCHER: We sort of mentioned it once
9 before. We purposely sort of avoided it, though.

10 COLONEL DINIEGA: The Army has been using a
11 health strength tool for a number of years. If the
12 Board would like to arrange for our health risk data
13 to be presented to the Board at the next Board
14 meeting.

15 DR. KULLER: Yes.

16 COLONEL DINIEGA: We could look at trends
17 over time in active duty in the Army. The other
18 thing is that at age 40, we're all required to
19 undergo cardiovascular screening. In that age

1 group, we do get another screening.

2 DR. KULLER: I think one of the things
3 that's important, as I mentioned before, is that at
4 least for the last four or five years, we've
5 discussed the issue of monitoring surveillance. I
6 think health risk appraisals are important, but I
7 think there is also an end point event here. And
8 that is a way of monitoring much like industry does,
9 what's the outcome in the sense of both heart
10 attacks and sudden deaths in the military which
11 should be a reasonably key thing to monitor.
12 They're not inconsequential from some previous data
13 we've looked at.

14 We talked several years ago again at the
15 Pentagon about the idea of being able to look at
16 this and then use that as a sentinel marker to
17 investigate the circumstances and the training and
18 also the health risks, the past health risks of
19 these individuals, so that you could have something

1 to use in generating a reasonable argument to
2 looking at these problems.

3 But I think it's an important question.

4 Interestingly enough, when we look to some
5 crude rates in the military at that time, it looked
6 like the rates of at least of sudden demise, which
7 is all we really could get. Weren't terribly
8 different than in the civilian population, which was
9 kind of worrisome and in these younger age groups at
10 least. But the numbers were fairly small.

11 It was a little bit worrisome, because
12 we've got the -- you know -- the potential
13 impression that some of these were occurring in
14 individuals who were still smoking. And I don't
15 know what the problems of smoking was. But still
16 smoking or basically were not in very, very good
17 shape. And then basically tried to get into shape
18 very quickly to pass their annual exams. And at
19 that point were getting into some big time trouble,

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1 which happens in civilian life, as well.

2 DR. ASCHER: My first comment on ergometry,
3 and I made the comment that it's better to have a
4 heart attack on a cycle than out in the field
5 somewhere.

6 DR. FLETCHER: At least somebody is
7 watching him.

8 DR. ASCHER: Yeah.

9 DR. KULLER: It's probably better not to
10 have them in the first place. Thank you very much.
11 We appreciate that.

12 I think we're very fortunate today to have
13 Dr. Joseph join us, the Assistant Secretary of
14 Defense for Health Affairs. He's had a major
15 interest in the activities of the Board and has
16 worked with the Board, especially in the last few
17 months on several very important issues. So I'm
18 very glad he's here and he's promised to talk to us
19 about some of the key issues.

1 Dr. Joseph.

2 DR. JOSEPH: Is there any media in the
3 room?

4 DR. KULLER: No.

5 DR. JOSEPH: I'm awfully glad to be with
6 you for two reasons. The first reason is it's way
7 over due. I think I was scheduled to make two of
8 your prior meetings, and one thing or another came
9 up, but here we are.

10 The second reason is that it isn't very
11 often that they let me out to do some good stuff
12 like this so we could talk about interesting issues,
13 ponder things. I mean, I had about 20 questions go
14 through my head. I was looking at Mike down the
15 table about things that came up, whether it had to
16 do with data systems or the virtues of our cycle
17 ergometry versus jogging. You know, so it's kind of
18 a pleasure. It's a day out of school for me, if you
19 would put it that way.

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1 A number of you are old colleagues and
2 friends, some of you for many years -- Mike and
3 Clyde and Jim Chin and Jim Allen, Russ Luckern who
4 is not here today. Others of you I hope to
5 establish an ongoing relationship as we go along.

6 I thought what I would do is talk about
7 three sets of things. I'll get them mixed up
8 because they don't really come neatly sequentially.

9
10 But I thought you might like to hear a
11 little bit about some of the issues. And, believe
12 me, there really are some issues going on in the
13 military health services systems in general. It's
14 sort of that outside umbrella into which your work
15 fits.

16 Then related to that, I wanted to talk a
17 little bit about the Board and about the functions
18 of the Board and some ideas I hope to challenge you
19 with in terms of things that I think are very

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1 important from our perspective where your help can
2 be key in the months ahead.

3 And then I will also talk about some
4 specific issues, topics that relate more or less
5 closely to your expertise and in some instances to
6 the work of the Board that I'd like to do in a kind
7 of thought provoking way.

8 I'm afraid I'm going to talk at some
9 length, in part because it's a day out of school and
10 I get a chance, which I don't always get, to talk
11 about things that are really professionally
12 interesting in a technical way. I'll watch your
13 eyes and if people start to glaze over, I'll sort of
14 quit.

15 We scheduled this at this time, so that it
16 would be before lunch and then we could continue
17 discussion back and forth as people wish during the
18 lunch period. And I'll be able to stay around for
19 most of the afternoon. I think what I'll do is duck

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1 out at 4:00 when you go into the bio-defense
2 briefings, although don't let me forget there are
3 some things I want to say in this unclassified
4 setting about that, that I hope you'll keep in mind
5 when you go into the classified meeting a little bit
6 -- a little bit later.

7 And please feel free to break in as I -- as
8 I talk my way through these sort of three major
9 issues.

10 I will not start out with the traditional,
11 thank for all that you do and this Bud is for you.
12 I think from what you contribute to this, you must
13 understand the importance of that, both on kind of
14 substantive specific tangible issues and in a larger
15 sense for the stimulation that -- Mike and I were
16 looking at each other when we were talking about
17 ways you might track cardiac events throughout the
18 military.

19 We're in the time of tremendous change and

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1 ferment in the military health services system.
2 Part of it relates to down-sizing, the new world
3 order, reductions. And part of it relates to just,
4 this is a time of ferment and change throughout
5 society.

6 There are two major -- two major sets of
7 things that we're intentionally involved in. And
8 both of them relate directly to the work that you
9 do.

10 One set, which probably relates most
11 directly is in the HMSS, try to focus more tangibly
12 on readiness issues. I gather it's been traditional
13 in the system that we always say. Readiness is our
14 first priority. That's the bottom line, et cetera.

15 But I think especially in the last years,
16 in recent years, with the pressures of the
17 reorganization of what we call the peace time health
18 care system in the military, we may not have paid as
19 much tangible, specific focused attention to

1 readiness issues.

2 And certainly with the downsizing, with
3 some of the new threats and the changes, some of
4 which you're going to talk about this afternoon and
5 some of which Ernie is going to mention this
6 afternoon -- the smallpox issue. You see, I can't
7 keep these things in order. With some of these
8 issues and other pressures on us, we are really
9 trying to focus on ways that we can work on the
10 readiness issues.

11 There has been produced after a couple of
12 years, effort, a medical readiness strategic plan,
13 Mrs. P is the acronym. If the Board has not seen
14 that, you should see it, because again it's a kind
15 of policy framework that relates very directly to
16 the tasks that are placed before you. And I sort of
17 see by your blank looks that you haven't seen that.
18 That's number one of the list for today.

19 Julie Mullen, who is my special assistant

1 is going to be here today and tomorrow. So if
2 things come up like this that we don't get clear
3 today, please feed those into her tomorrow.

4 When I say "we" throughout this -- this
5 gives me a chance to make a second point. Generally
6 when I say "we," I mean most specifically the three
7 surgeons general and myself. Because, almost number
8 one on my work list for the last year and a half has
9 been the effort to weld us -- the three surgeons
10 general and myself -- into an essence of corporate
11 culture and military bases.

12 We spend an enormous amount of time -- and
13 that's not easy, as all of you who have been through
14 that process in organizations know. We have made
15 tremendous progress. And part of that has been
16 committing ourselves to four two-day sessions away
17 over this -- I guess this calendar year, in which
18 we're working through a kind of longer range of
19 strategic plan for military medicine. Where is it

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1 we want to go? What are really the issues for the
2 smarter people who are going to come after us? And
3 how can we best position the system to help those
4 people move it along.

5 The other side of the two -- the two major
6 clumps of things is, of course -- revolution is not
7 too strong a word that's going on in our peace time
8 health care system. We run, as I suppose you know,
9 the largest medical care system in the country,
10 except for the VA. Eight and a half million people.
11 We still have a 130 hospitals left. A dozen or
12 more major medical centers. And we take care of
13 active duty, active duty dependents, retirees and
14 their dependents.

15 And over the course of the last three or
16 four years -- this is not something that began with
17 this Administration. This is not something that's
18 personal to me. Over the course of the last three
19 or four years, that system has undergone a radical

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1 change. We are moving that into a regionalized,
2 primary care oriented, capitation budgeted, managed
3 care system that operates very heavily in a tri-
4 service environment.

5 And the trick -- one of the tricks there
6 and there are a lot of tricks there. And I wish I
7 knew more of them. One of the tricks there is to
8 retain the necessary -- mind you -- absolutely
9 necessary unique identity and missions of the
10 individual services; while at the same time merging
11 the things in which there are economies of scale and
12 obvious benefit to be gained from a common effort.

13 Here is one we're talking about. The fact
14 that we can't, in a coordinate way, across all
15 services turn out data for whatever kind for health
16 promotion purposes is not -- it doesn't make a lot
17 of sense.

18 And in this movement to a managed care
19 system, we are probably in greater purdivation and

1 with more challenge than at any time since the CHMPS
2 system went in 30 years ago.

3 We're doing very well at that. And we're
4 doing very well in no small part because of the
5 commitment of the surgeons general to kind of help
6 it come on line. But it's an enormous struggle,
7 particularly at a time of down-sizing, pressures on
8 the system to reduce end strength, to reduce
9 dollars, to reduce hospitals and kind of have all of
10 those balls in the air at once.

11 As we get through that process, among other
12 things -- this is by no means the most important
13 item. But among other things, we probably have the
14 potential for a richer data field than anybody else
15 I can think of. And as we begin to get our -- that
16 Holy Grail of being able to track out out-patient
17 system, which everybody aspires to and few people
18 achieve, the kinds of issues you were talking about
19 during your presentation, as well as many more,

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1 really would be within our grasp.

2 And I think one of the things I would hope
3 that you would think about -- not so much for your
4 work this year or next year, but as the Board goes
5 into the future, is how you can -- how you can keep
6 pace. I don't mean keep up, but keep pace, and link
7 the function of this Board to the kind of data
8 systems that are building and the kind of
9 epidemiologic questions that it will possible to ask
10 and answer, if only we think about it.

11 And probably the same as you and your
12 individual organizations, we are not smart enough,
13 nor are we -- we are so immersed in our everyday
14 work within our system, just like you are in your
15 system there, that we probably won't see a lot of
16 the opportunities for doing good epidemiology,
17 leading to better health, et cetera, within the
18 system.

19 So I think one of the important things I'd

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1 like to kind of leave in the back of your head is as
2 our peace time health care system evolves into this
3 managed care entity on a regional basis -- tri-
4 service visibility, capitation budgeting -- because
5 you ought to be thinking about dollars, as well as
6 the other parts of epidemiology.

7 How should the Board relate to that? What
8 kinds of questions do you want us to be thinking
9 about? And can you stimulate us to engage as we go
10 into that? That's sort of the good news.

11 The not-so-good news is that it's a time of
12 enormous downward pressures. And the medical part
13 of the department is not immune any more than the
14 other parts of the department are immune to that.
15 In fact, something that I tell our people constantly
16 is it's just critical that we never give the line
17 either the impression or the actuality that those
18 medics are kind of off there by themselves, taking
19 care of themselves, doing their own thing, immune

1 from the burdens and the sacrifices that we're
2 making somewhere else.

3 Our support within the department,
4 essentially and in the last analysis, comes from the
5 line. In every major struggle that I've had in the
6 department around dollars or people or shape or
7 program, all of the major -- the ones that get to
8 the deputy secretary or the secretary, the people
9 who have always bailed us out are the senior line in
10 the military. And they have the credibility to do
11 that. And they also have the will to do that. They
12 want to do that.

13 In this time where they're suppressed, it's
14 harder to count on that support when the chips are
15 down, because they're hurting, too. And if we ever
16 give them the sense that they shouldn't give us
17 their support or that we're kind of a different
18 separate outfit from them, we really are lost.

19 So I think -- again, trying to relate this

1 back, although it may seem a few steps to you, to me
2 it's very directly related to the kinds of things
3 this Board thinks about. Ways that you look -- the
4 ways that you look at injury prevention for the line
5 and the military, for example, are terribly
6 important to us in maintaining credibility and
7 maintaining support when it comes to health dollars
8 and number of doctors and number of epidemiologists
9 and the rest.

10 We are going to go through a very difficult
11 year this year, because we have squeezed out through
12 the -- through the evolution of what's becoming a
13 managed care system, a fair amount of efficiency out
14 of the system so far. As in everybody's system,
15 there is still some fat left. We could always
16 survive with a few less of this or that. We've
17 squeezed out a few -- a good part of it. And I
18 think there is a clear perception on the part of the
19 department, that if there are big dollars to be

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1 saved in the MHSS, those big dollars will come not
2 from tinkered around the edges and making us getting
3 our utilization management a little sharper. You
4 know, those big dollars will come from a very
5 fundamental change in the system, like charging user
6 fees in the military treatment facility, which is
7 sort of anathema to people in my end of the
8 business.

9 Or, like changing the covenant that we've
10 had with retirees and yet can't get paid for because
11 of the inability to receive reimbursement from
12 Medicare or for our over-65s.

13 So we're going to be facing this year not
14 kind of questions about, can you do with -- you
15 know -- X-hundred docs fewer or one less med cent or
16 whatever. You're going to be faced with questions
17 sort of that go right to the way we're organized and
18 the way we provide services and get reimbursements.
19 I feel pretty confident about that.

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1 I guess to bottom line it for you, I would
2 say that we're going to bleed this year, but we're
3 going to win in terms of keeping the structure and
4 moving forward with the tri-care program. I do feel
5 very confident, but we will not come out of it
6 unscathed, nor without a great deal of work.

7 Now, the Board. One of the things I've
8 been trying to do -- and I think I'm doing it for a
9 very short range technical advantage reasons, but
10 also I think for a longer range, sort of
11 philosophical reasons, is to get more external
12 penetration of advice and assistance into our
13 system.

14 I guess most of us come from a tradition
15 where outside consultation is a good thing until
16 proven otherwise. And I think there are a number of
17 areas where we would benefit very much from
18 increased interaction, visibility, buffering, et
19 cetera. We have -- we have just set up for the

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1 first time -- we got a mandate from Congress to do
2 this, although we helped stimulate and shape that
3 mandate to a significant extent. We've set up an
4 overall external advisory committee for the military
5 health services system. And we have a group of 15,
6 16 -- I think it's 16 people drawn from all over the
7 sector. I mean, we have academics and people in the
8 managed care business, though none of our
9 contractors, ex-military, ex-military medical,
10 consumer, what you would do if you put together in
11 essence an overall advisory board.

12 And we've asked Admiral Tom Kilcline, who
13 is a retired Navy aviator and who currently is the
14 president of one of our constituent groups, the
15 Retired Officers Association to chair that group
16 -- we've just had our first meeting. And you could
17 see even from that first meeting, I mean it's a good
18 thing when you open the windows up. People get a
19 better sense of who you are, what you're doing. You

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1 get a better sense of ideas that can only come from
2 people who stand back a step or two.

3 That won't be an entirely smooth
4 interaction, but it will clearly be a very
5 beneficial one.

6 We also -- I just learned this week, have
7 gotten approval from the White House to reconstitute
8 the advisory board, the board of governors in
9 effect, though it's an advisory group, for the
10 university. Many of you probably have heard about
11 the backs and forth about the Yuches. It's -- I
12 think it's -- I guess I can speak pretty -- with
13 nobody from the media in the room, I can speak
14 pretty frankly about it. Those of us who believe
15 that's an absolutely irreplaceable and unique
16 resource, I think are beginning to feel pretty
17 confident that it will be around for a while.

18 It -- you know -- it's like all questions.
19 It's not black and white. In a time when we're

1 losing helicopter rescue squadrons and ship drivers,
2 you know, there is an issue about whether we should
3 be educating our own physicians. And those of us
4 who are from that side of the business can give you
5 all of the good arguments why that -- why the kind
6 of product that we get -- the kind of -- I don't
7 know. Have you ever met at Yuches. Do you know
8 those students? Have you seen those students and
9 met them?

10 Let me tell you. It's quite an experience.
11 Thirty percent of this year's freshmen medical
12 class are former line officers or enlisted or
13 products of the service academies. So these people
14 -- I mean, it's a different kind of product than you
15 otherwise get. It's not the only kind of product
16 you need, but it's an important kind of yeast in the
17 future of this system.

18 And I think -- I think probably we can be
19 pretty optimistic about that, largely because of

1 help that we've gotten all along the way from the
2 Congress.

3 But we -- I know what I -- another group
4 that we have been able to set up is the
5 reconstitution of that Board. And I think that will
6 help not only with the Yuches issue, but in linking
7 Yuches to other research and development questions
8 within the MHSS.

9 Similarly -- and this kind of brings me to
10 the main point I want to make about organizations.
11 I think it's important for us together to take a
12 hard look at what may be unexploited opportunities
13 for the AFEB. As I understand it -- and my
14 understanding may not be perfect, most of the issues
15 -- it may be far from perfect. But most of the
16 issues that the Board has dealt with, at least in
17 recent years, has been kind of focussed,
18 categorical, epi-specific -- specific epi, I guess
19 is a better word, kinds of issues.

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1 And that's important. That's very good. I
2 mean, the kinds of work that you've done -- let me
3 mention the smallpox thing again here. Or on the
4 hepatitis vaccine or on a host of other issues.
5 It's not only critical, but we really couldn't have
6 done it without you.

7 But I think in this kind of time that I'm
8 trying to describe for you, there are a range of
9 larger and longer questions. Whether you call them
10 policy issues or not, I think is immaterial. But
11 larger and longer questions. That it would be very,
12 very useful to have a kind of ongoing group of smart
13 people who know us and have thought about these
14 issues from an essence outside of our system to help
15 us with.

16 We're moving into a time that many people
17 are very reluctant to recognize is the age of a
18 different kind of weapons of mass destruction than
19 nuclear weapons.

1 And whether you are comfortable looking at
2 that fact or not, I think it's an innocent -- all
3 you have to do is look at the data and you can see
4 it coming in a sense. How fast, where, what kind.

5 It would be nice before we get there. And
6 while we're thinking about issues, such as Ernie is
7 going to talk about this afternoon, or the smallpox
8 issue that I'm going to talk about, or some of the
9 bio-defense issues that you'll talk about at 4:00.
10 It would be nice if we had some considered dialogue
11 on an ongoing basis around the contextual issues
12 involved in that. It's one thing to call you up
13 when we need a question about whether our troops
14 should be immunized -- an answer about this or that.

15

16 It's another thing to kind of have a
17 dialogue that's sort of percolated over time about
18 those issues. That's just one example. Bio-defense
19 is one example. Emerging infections and global

1 surveillance is another issue. The whole range of
2 health promotion and prevention.

3 So I would like to find a way -- and I
4 don't think there is a magic way to do it. I don't
5 have a -- here, we can walk out of this room this
6 afternoon and have it fixed. I'd like to find a way
7 where the Board begins to evolve it through a pretty
8 ongoing and heavy share of your work in that sort of
9 area as opposed to the more discreet area.

10 I had hoped that we would sort of begin
11 this event a year or so ago when Sue Bailey, Dr.
12 Bailey, who was until recently my deputy for
13 clinical services, I had hoped that she would sort
14 of keep an ongoing direct connection with the Board
15 and help us move in this direction. That for a
16 variety of reasons didn't work out.

17 I think we're better positioned now with a
18 revision of an AFEB chart, which though it doesn't
19 -- it doesn't really kind of overturn any big

1 stones, I think the position is better with health
2 affairs and the three services through the surgeons
3 and the new Armed Forces R&D Agency, in which we're
4 going to kind of englobe the separate research or
5 many of the separate research and epidemiologic
6 efforts of the individual services. I think we'll
7 be better prepared to do that.

8 So that's another -- that's sort of number
9 four that I would like to just throw out on the
10 table and get people thinking about it and talking
11 about it in this meeting and beyond, because there
12 are a -- we're back in the age of epidemiology.
13 Fifteen years ago, I think a lot of people
14 -- particularly those of us who thought that was
15 kind of behind us. Mass infectious disease and
16 thinking about large scale acute protection efforts.

17 But all you need to do is look around us,
18 particularly in the military context, and realize
19 we're back in that world again. And there are a lot

1 of fascinating issues out there. And we would like
2 your help to kind of find our way into them.

3 Let me kind of switch gears and talk then
4 for a few minutes anyway about some of the specific
5 programmatic issues. And, again, I hope you'll see
6 how these three what's happening in the MHSS, where
7 at least I would like to see the Board begin to move
8 in the next couple of years. And now some of these
9 specific issues can relate one to another.

10 And among many I could talk about, I wanted
11 to talk about three. One was the smallpox. And if
12 you don't mind, I'll do that now and we can use the
13 time later for something else.

14 A second is global surveillance and
15 emerging infections and a third is the Persian Gulf,
16 so-called Persian Gulf illness.

17 Your help to us, the subcommittee's help to
18 us, and the Board's help to us in the next couple of
19 months was really key on the smallpox issue. What

1 was going on at that point was that a difference of
2 opinion within the Federal Government, largely
3 between health and human services and the Department
4 of Defense, got all tied up with national and
5 international political issues and postures related
6 to the -- related to the proposed destruction of
7 remaining stocks of virus in the summer.

8 We felt very strongly in the Department
9 that, both for national security reasons, some of
10 which I guess you'll talk about this afternoon and
11 for reasons of important gaps in our scientific
12 knowledge, that it was premature to take an
13 irrevocable step. And there were many pressures,
14 some of them honest, professional disagreement -- I
15 don't know, Claire, where you were on that issue
16 -- but some of them honest, professional
17 disagreement; some of them sort of political,
18 perceptual, public visibility reasons.

19 There were a lot of pressures to just go

1 ahead and let's do this. And after all, we said in
2 1995 we're going to do it. It's '95. Let's do it.

3 We were able because of the kind of
4 substantive work that the joint group that was set
5 up by CDC and ourselves to really sit down and kind
6 of get past that level of rhetoric and talk about,
7 well, what is an important research agenda. I mean,
8 the questions that the NSC was asking me was, well,
9 you guys are saying they're important, unresolved
10 research issues. But that doesn't wash. What are
11 they?

12 So we were able, as some of you know better
13 than I, to actually sit down and work out with HHS a
14 prospectus and a way of achieving that prospectus
15 around a series of research questions that are very
16 important, at least in my view and that really ought
17 to be answered before we take an irrevocable step,
18 particularly in the context of the national security
19 concerns that we have.

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1 That's a kind of example of what I mean by
2 I think a heightened importance for the Board in the
3 type of world that we're living in and moving into.

4 We could not have done that purely,
5 internally in the Department. There would be no
6 way, even if we had the scientific expertise that we
7 could marshal to do it. There is no way that we
8 could have had the external credibility to be able
9 to do that.

10 So I rest my case. I rest my case on that.

11 We and HHS, Phil Lee and I sent a letter to
12 the National Security Council last week -- early
13 this week or last week -- which we said, here it is.

14 We promised you by the end of June a list of
15 research issues that we thought needed to be
16 addressed. And here's how they ought to be
17 addressed. Here it is. We're ready to talk about
18 it.

19 Now, take the next step. And we feel

1 confident that -- you know -- we will get the
2 latitude to address some of those research questions
3 in the sense of improved vaccine, anti-virals and
4 -- what's the third one, Jim? Diagnostics. Thank
5 you. And diagnostics. That we ought to at least
6 -- we ought to have more than just a pass act before
7 we go further down the road. I think that's going
8 to work out very well. And I really think it's
9 going to be in the public interest, because at the
10 end of this year or next year, we say, we can't get
11 any further with this. Okay. At least we know
12 that.

13 On the other hand, there are issues that
14 arise that we can get further on. I think you did
15 good work on that one. Very good.

16 Global surveillance. I've got -- I've got
17 kind of a mild obsession on that for about the last
18 year. And I'm not alone in it. And it's not an
19 original idea by any means. The first person I ever

1 heard talk about it was Josh Letterberg back seven
2 or eight years ago in New York. That we really as a
3 species need to get our act together and think about
4 global surveillance in a functional way and in a way
5 for what CDC has done and what WHO has done. We
6 have not -- we just have not approached the reality
7 of building a surveillance network for on into the
8 next century.

9 I will tell you. I wrote to Peter Goldmark
10 and John Evans at Rockefeller about four or five
11 months ago. And I said this. I said, this is a
12 crucial problem for the species and the next
13 generation. And no one -- nobody can do it. CDC
14 can't do it. WHO can't do it. DOD can't do it.
15 The PVOs can't do it. What we need to do is find
16 some way to pull together a network of people, each
17 of whom can do an important piece of this.

18 I was -- and I said to them, the historical
19 importance in health of the Rockefeller Foundation

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1 has been that you've often served as mid-wives for
2 this kind of effort. So I ask that this be a
3 catalyst. Not put some money into a program. Bring
4 together a group of people. I mean, we couldn't
5 convene such a group out of DOD. I don't think you
6 could.

7 And they were not -- they were not
8 confident of the utility of that. So that didn't
9 get done.

10 In the last few months, I think helped by a
11 boa, if I can put it that way, there's been -- you
12 know -- whatever works. And there has been
13 heightened interest across the Government and state
14 and HHS, CDC, ourselves, about -- about the global
15 surveillance issue. And we've begun to play much
16 more heavily in that.

17 About four or five months ago, Ernie? Four
18 or five months ago, we began in the Department
19 -- well, I asked the Army Medical R&D Command to

1 take a look at this question. We've got a priceless
2 set of assets in the DOD that nobody else has.
3 We've got these overseas laboratories. They are
4 jewels. They used to be a lot brighter jewels in
5 the sense than I think they are now. They aren't
6 very well connected to the academic health
7 establishment and research establishment in the U.S.
8 What can we do to kind of polish those
9 jewels up and really make them work? And what other
10 pieces can we do to begin to help make a global
11 surveillance system a reality? Obviously there are
12 parts of it we can't do. There are particular
13 interests that we have, because of our national
14 security responsibilities that are different from
15 what some other people can do in the system. But
16 without doubt, DOD has the wherewithal and has the
17 very strong self-interest to become a major player
18 in the global surveillance system, the creation of
19 gain.

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1 So we've been working on that for a couple
2 of months. It's always slower than you'd like it,
3 but it's beginning to go pretty well. One of the
4 big problems is resources in this time, but I don't
5 think that's the overall obstacle. That to me seems
6 to be an ideal issue that this Board could help us
7 with.

8 What ought such a system to look like. And
9 what ought to be DOD's part in such a system. And
10 how can DOD link to especially other institutions?
11 I tend to think about the academic biomedical
12 research establishment, but there are others in this
13 country.

14 How can we link to them training, research
15 and surveillance purposes?

16 That is a fabulous -- I mean, that's a
17 world class magnitude problem. And I think it is
18 also one where we would not be able to really either
19 have the expertise or the credibility to do it all

1 internally. And I think it's a perfect example of
2 an issue for this Board. It is not an issue for one
3 meetings or two meetings. It's a kind of ongoing
4 issue, but that's another one I would like to tee up
5 and leave with you as something that I think has
6 real importance over the longer haul.

7 Lastly, let me talk about the Persian Gulf.

8 Our people have done, I think, an extraordinary
9 thing on Persian Gulf illness. One of the people
10 heavily responsible for that is the fellow over
11 there in the blue suit, when he's not wearing a
12 different color blue suit, Gary Guckstetter.

13 We have gone in a little over 12 months
14 time from a clinical perspective at ground zero to a
15 position where in about two weeks we're going to
16 publish I think a fairly sophisticated clinical
17 study of over 10,000 patients. And that also hasn't
18 been easy. But I think we probably have the largest
19 -- I don't think it's been done before. It's kind

1 of a new disease phenomenon area to go with that
2 speed and that level of sophistication.

3 We did that for two reasons. One reason
4 was it was our responsibility to our people, as the
5 Persian Gulf illness thing began percolating the
6 last about a year and a half ago. It was clear we
7 had a lot of people out there who were hurting and
8 who were our patients. So the first -- the first
9 driver in that effort was to provide diagnosis and
10 treatment to our folks and to do that in such a way
11 that we learned a little bit about what was going on
12 in the process or we learned a lot about what's
13 going on in the process.

14 The second driver was that the Department
15 was getting hammered. And in the context of general
16 paranoia, suspicion of the Government, history of
17 Agent Orange, et cetera, et cetera, we were, if you
18 remember, back to the last -- a year ago, winter and
19 spring, just being hammered on the issue. There's a

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1 secret in the basement of the Pentagon. These guys
2 know what happened. They're not telling anybody.
3 They did it anyway.

4 I know some of the people on this Board
5 were not pleased that when we set up this effort, we
6 didn't turn to the AFEB for their advice. I did
7 that for a very deliberate reason. What we needed
8 at that time is we needed an outside buffer that was
9 clearly viewed as not something related to the DOD.

10 I think at that point, we -- I would be
11 happy to argue, had we turned to the AFEB, it
12 probably would have had about the same result as
13 when the Department turned to the Defense Science
14 Board to look at the Cambayo warfare issue. It just
15 was not -- it just didn't fly. I remember John
16 Dolce at those press conferences in reducing Josh
17 Letterberg and the Defense Science Board report, and
18 it just -- that dog would not hunt.

19 So we turned instead to the Institute of

1 Medicine and asked them to set up a small group that
2 would work with us and critique our efforts, et
3 cetera. We really got a great -- we got a terrific
4 group chaired by Jerry Burroughs at Yale. We got
5 all of the advantages of the IOM's involvement. And
6 we got the great disadvantage of the IOM's
7 involvement, which is they don't move very rapidly.

8 But on balance, I think it's been a very
9 positive thing. And I think as we go further, it
10 will turn out to be even more positive.

11 In any event, we're going to publish within
12 a couple of weeks a report on the first 10,000
13 patients. Actually we finished 13,000 patients, but
14 we've got 10,000 that we kind of scrubbed that are
15 going to report. And we will see that all of the
16 Board members individually get a copy of that when
17 it's printed out. And we would welcome your
18 comments individually and collectively as you wish.

19 If you want me to tell you what we found, I

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1 can tell you.

2 DR. KULLER: Did you have a definition?

3 DR. JOSEPH: No, we did not have a
4 definition. And it's a self-selected population.
5 And about four times in the first two pages we point
6 out the weakness. This is not a proper research
7 study. And this is not an epidemiologically valid
8 sample for purposes of either creating a definition
9 or being specific about -- about etiology.

10 But what it does do is give you the
11 enormous power of a carefully examined large group
12 of people that -- and that leads you very clearly in
13 some directions and away from some other directions.
14 Then other people can pick that up and do further
15 work with it. In fact, one of the things we're
16 going to do is we're going to make the database for
17 the comprehensive clinical evaluation, CCP, we're
18 going to make that database available to researchers
19 to do whatever things they want to do.

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1 No, and we still don't have a definition.
2 And I think the bottom line, Jim, is what we have is
3 a very clear spectrum of symptoms that mirror quite
4 closely the occurrence of symptoms in general out-
5 patient populations in the United States. And that
6 by the kind of murky glass you look through with
7 this sort of study show absolutely no relationship
8 to a single, unique or unusual cause of a
9 significant fraction of this inference in that
10 population. I'm sure we'll hear more from you when
11 you look at the data and I would very much
12 appreciate that.

13 But the effort that went into this by our
14 people was just fabulous. And I think -- I think in
15 the long run will be important and have some weight.
16 I think in the short run it won't make any
17 difference at all in terms of the media's perception
18 of green cheese from the moon causing mystery
19 illness.

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1 But I think as people sift through this and
2 the follow-on stuff that will come over the next
3 couple of years, it will make a difference. And I
4 think the other difference it will make -- I think
5 has made already, I think we've dispelled maybe 20
6 percent of the sort of conspiratorial theories that
7 the Department is hiding some ugly secret or doesn't
8 want to look at this issue.

9 I think I will finally stop at that point,
10 looking at those three issues as specifics related
11 to ways that I would hope the Board would begin to
12 see its importance, not only on focused
13 epidemiological tasks, but on broader, general
14 issues, particularly ones that have a long range
15 effect and then see that within the context of the
16 way the entire system is changing. And then stop
17 for discussion and challenges.

18 Those of you who know me from New York know
19 that I'm not embarrassed by any questions.

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1 DR. KULLER: A point that I'll make in a
2 moment. Go ahead.

3 DR. ALLEN: Let me go back to your closing
4 comments on the Gulf War study. I think one of the
5 concerns that the AFEB threw around in its
6 discussions at various points in time on that issue
7 was not only defining what was going on with this
8 group, but what was the system that allowed that to
9 happen.

10 And, you know, again with the thought of if
11 we're in the limited skirmishes of this type or even
12 a more broad scale war for whatever reason in the
13 future, at some unknown point on the globe, unless
14 we understand clearly what went wrong with the
15 system and health care system that enabled this to
16 fester the way it did, we may have learned a lot
17 about this clinical problem, but may not be able to
18 prevent it in the future.

19 I think -- I would hope that this study

1 would have allowed people looking at that in the
2 Department of Defense or others on the outside to
3 identify --

4 DR. JOSEPH: Didn't you guys get -- didn't
5 you get a brief in terms of the follow-on actions
6 and the changes in predeployment that said that
7 we're looking at it. Isn't that on your agenda
8 somewhere? Or am I mistaken?

9 DR. ASCHER: It's word of mouth. The
10 example I gave at one of the meetings was that
11 observers -- you know -- if you get deployed and go
12 home and are sick, there's a number to call. And
13 somebody asked the question, does that imply that
14 when the Gulf War veterans came home from the Gulf
15 and were sick, they didn't have a number to call.
16 And the guy wouldn't answer the question.

17 But there was corrective action of that
18 type within place. And we saw some of it.

19 DR. JOSEPH: I'm not clearly saying what

1 I'm trying to say. We've had a group at work under
2 the direction of Rick Erdman. And developing policy
3 changes pre, during and post deployment. Mike,
4 you're working on that group.

5 LT. COL. PARKINSON: The outline of the 12
6 points surveillance was presented in hand-out form
7 and discussed the problem.

8 DR. JOSEPH: That's an example to me of the
9 kind of area -- again, you know -- where the Board I
10 think could be of great help. I thought you had
11 that on your agenda ready.

12 DR. ALLEN: I missed part of the last
13 meeting and it's possible that's when it came up.

14 DR. ASCHER: The other thing of that, which
15 I think relates to earlier down-sizing, is that as
16 you talk about readiness, the aspect of there are
17 pre-morbid factors in larger scale of the military
18 when you start doing this. We have sort of
19 concluded that if you have in the down-sizing the

1 emphasis on readiness, if we really did work on
2 that, there would be much less of a problem of this
3 in the future. It was the unprepared nature of much
4 of the population for these kinds of activities that
5 it's clearly part of the pre-morbid situation.

6 DR. JOSEPH: Well, you know, that's a topic
7 for maybe a long discussion, because it depends what
8 you mean by pre-mortal factors. Some of the -- some
9 of the people who worked on the CCP have a strong
10 impression that the pre-morbid -- that if there are
11 pre-morbid factors, they are -- they include early
12 childhood behavioral experiences. And how you weave
13 that into a kind of hard tangible prevention when
14 people get to be in their 20s in the military is a
15 very complicated question.

16 If you're talking about, are there things
17 that we should do better, so that when John or Jane
18 Smith find themselves from one week to the other
19 sitting in the desert waiting for somebody to drop

1 biological weapons on them and then sit there for
2 six months waiting for it to happen or not happen,
3 with all of the buzz going back. I mean, there I
4 can see very clearly the kinds of things we ought to
5 think about better in terms of prevention and health
6 promotion.

7 But that's part of the dilemma. And what
8 do you really -- what do you consider the
9 environmental and pre-morbid factors that are
10 drivers in this. And I suspect there is a large
11 range in the very approximate ones, like watching
12 the scud missiles drop on CNN and sitting on the
13 desert to ones that have to do with one's basic
14 personality and early childhood experiences.

15 DR. KULLER: One of the things I think the
16 Board can do perhaps as consultants is use their
17 -- you might say broad experience of what's going on
18 in the outside as a -- global surveillance is
19 extremely interesting and we've been very interested

1 in it. But as I heard you talk, I was thinking
2 because we've been involved with NASA for the past
3 year or so -- not the Board but us individually in
4 trying to develop a global surveillance system, and
5 actually having worked with NASA in a variety of
6 efforts.

7 One of them has been to develop these
8 satellite stations which would be essentially all
9 over the world, which basically the NASA satellite
10 would be able to pick up much like CBC from the
11 States does right now, sort of a weekly surveillance
12 report of infectious diseases from every place in
13 the world literally, using the NASA satellites. And
14 then NASA would basically utilize this. They've
15 been working with PAHO to try to start this out in
16 South America.

17 I was trying with this and say, you know,
18 this is very interesting and given the talents on
19 the Board -- and I think it's a very important

1 issue. The potential for the Board perhaps to get
2 involved in this primarily because they have pseudo
3 pots around the entire community of people that are
4 interested in this particular problem. And it
5 seemed to me that this may be one area where the
6 Board could make a contribution.

7 We're working very, very actively with NASA
8 right now. We've had numerous meetings. We've had
9 people from NASA and people in the top field of
10 computer sciences and information sciences working
11 to look at ways in which this whole field could
12 develop.

13 There is now an international epidemiology
14 Internet system, which is basically trying to link
15 up epidemiologists, field epidemiologists, all over
16 the world and also to try and begin to produce on
17 the Internet actually documents that basically
18 people could pick up -- for example, the British
19 Medical Journal has now agreed with us to publish

1 the British Medical -- print the entire British
2 Medical Journal is now going to be on Internet and
3 available to anybody on the Internet system.

4 There is a move right now to do the same
5 thing with a whole bunch of other documents that
6 would be surveillance documents in communicable
7 diseases and prevention, and link this.

8 So the whole idea of global surveillance, I
9 think you're absolutely correct, is of an
10 extraordinarily important issue. But it's also
11 -- it seems to me again like we talked before, an
12 issues where you may have a whole bunch of people
13 trying to do little pieces, but maybe the Board
14 could serve as a focus for trying to get all of the
15 different pieces together and come up with something
16 that would link all of the resources, which are
17 available. There are people here who have contacts
18 obviously with WHO, with PAHO, with NASA, with the
19 state health departments obviously, with CBC.

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1 DR. JOSEPH: The problem like so many
2 problems, it's primarily a methodological process
3 problem. It seems to me -- again, I may be -- I may
4 be not correctly informed, but it seems to me we
5 have a very good method and process for asking you
6 help on specific issues.

7 When I needed to know in quick time whether
8 we should re-immunize our people going to Rowanda
9 with cholera vaccine, there were two places I
10 called. I called Allen and I asked the Board that
11 question. We've got a mechanism. It's time
12 honored. It works. We've got good answers. The
13 smallpox thing is another example.

14 I don't sense -- and some of you who either
15 may know more about the Board's history than I do or
16 to the extent I'm wrong, correct me. I don't sense
17 that we have a well thought out and smoothly oiled
18 path for approaching a longer term, continuous, kind
19 of multi-faceted issue of the kind that the global

1 surveillance network issue.

2 So I think that's what we ought to be
3 trying to work out.

4 DR. KULLER: I think in the past, though,
5 exactly what the Board did, the Board has task
6 forces on rheumatic fever, tuberculosis, which
7 lasted for years and published -- actually published
8 books. And there is a whole historical publication
9 of the Board which dealt with all of these issues,
10 which were major issues, which lasted more than a
11 few months -- but were the issue of rheumatic fever
12 and streptococcal and gramalarian afridus, which
13 literally started out here obviously and had to
14 control that; and the whole experience of the Board
15 for many years in developing the process which led
16 to the control of many of these diseases.

17 DR. JOSEPH: You see -- I mean -- let me
18 just prolong it for a second here. There are global
19 surveillance and medical bio-defense are clearly two

1 such issues. There are probably 20 more that we
2 could think of around this table. You can't think
3 have 20 subcommittees. The question is, how you do
4 it, how you structure it, and then how we build in a
5 relationship where it literally works over time and
6 not just in kind of discontinuous and self-limited
7 quanta, I think takes a little thought.

8 And I don't come with a proposal to do it,
9 but I come with a pretty clear sense that it's
10 something that would be very useful to do and I
11 assume it would be something that would be, you
12 know, interesting for the Board to be in.

13 DR. BROOME: I'd like to follow-up on that.
14 It's been my experience from the CDC advisory
15 committees and I would say this is a very good time
16 to think about it as you're searching for a new
17 executive secretary and continuing the charter of
18 the Board. To me, there is a couple of key elements
19 in here.

1 One is to define either from a you or the
2 Board might through a priority study, exercise from
3 the services, what are the key questions within the
4 specific charge. And then pick both specific and
5 general issues.

6 To me, the second key thing is sufficient
7 steps for -- and not having just an executive
8 secretary, but a real commitment of sufficient staff
9 support from the preventative medicine offices or
10 other individuals to really facilitate the committee
11 doing some substantial work. It involves several
12 full-time jobs. I think it's unrealistic to think
13 the Board could fairly -- one of the intra-
14 committees or subcommittees.

15 DR. HANSEN: I was going to intervene with
16 a comment since you brought that up. The injury
17 prevention effort had its roots in my history, which
18 is limited, about two or three years ago when we
19 heard a presentation on the injuries in training.

1 The training related injuries from all of the
2 services.

3 And it grew into a much bigger project that
4 has had excellent, although it's small numbers of
5 people, but excellent staff support and commitment.

6 It's clear that that group has been able to use the
7 existing staff, which is probably good as opposed to
8 having dedicated a team of staff sitting in an AFEB
9 office, for example.

10 But it's also clear --

11 DR. BROOME: You're adding a substantial
12 time commitment to your --

13 DR. HANSEN: Well, that's what I was going
14 to say. It's also clear that the people involved
15 from whatever piece of the surgeons general's office
16 need to have a commitment to the particular
17 subcommittee or issue. And in the case of the
18 injury prevention, we've come to what I would call a
19 stepping point. We have now completed, which you

1 will shortly see a report. Conclusions were drafted
2 yesterday after review with several different
3 meetings. And now the question is, this effort
4 clearly needs to be bigger.

5 The impact of the report will be to say
6 there is a major problem here. It needs study.
7 It's testing. It's research. It needs monitoring.
8 It needs surveillance in a higher level of
9 commitment for readiness purposes -- for readiness
10 purposes. And for cost saving purposes, two things.

11 And the question now is, what should the
12 AFEB role be. We have done that initial evaluation
13 of a problem. We've structured a report with
14 conclusions and recommendations.

15 But now I think you're going to have to
16 make a decision as to whether this is going to
17 become a minor illness committee, a TB committee,
18 something with the kind of ongoing continuity that
19 you're looking for to set forth a plan, a five to

1 ten year plan, for altering the injury rate of
2 various sorts. And, by the way, there is not a
3 single cause issue well known.

4 So I think this is an important time to be
5 looking at that long-range perspective of this Board
6 and how that expertise can be funneled toward the
7 future.

8 DR. JOSEPH: If I could -- just before you
9 -- if you were to have to say today what kind and
10 through what structure an ongoing role with the AFEB
11 in the monitoring and whatever of a tri-service
12 injury control program would be, how would you
13 define it?

14 DR. HANSEN: Regular commitment to every
15 three months minimum; continued looking at the data
16 and testing, looking at the research, instigating
17 research programs, helping -- encourage the research
18 programs. You have, by the way, some excellent ones
19 going on. But only two. And there should more and

1 more hypotheses. There should be testing.

2 DR. JOSEPH: And that implies -- it goes
3 back to the clearest thing about resources and staff
4 support. And we would have to do the work for which
5 you're --

6 DR. HANSEN: Right. Right. But I think
7 the other thing is the continuity. You mentioned
8 continuity. But with only meeting once a year
9 -- for example, the injury prevention group does not
10 believe it's going to meet again until next January
11 or February, if at all -- if at all. And it's at
12 that point where all of the expertise has now been
13 congealed.

14 There's a lot of outside people, by the
15 way. This has not been heavily board members. It's
16 been heavily outside people and a few board members.
17 And it's that group that has really developed the
18 understanding of the databases, of which there are
19 at least a dozen different databases. The

1 understanding of the problems.

2 And now that the understanding is there,
3 both of the databases and of the problems, what
4 next?

5 DR. JOSEPH: Very interesting prototype.

6 DR. BROOME: Can I can just finish up on
7 this? I mean, I think the point about staffing is
8 key is not that you have some people who are just
9 happy to do these things and use the preventative
10 medicine and other staff who are working on these
11 projects, that they have substantial time. But,
12 again, you do that with initial injury -- you -- but
13 maybe more importantly, it's not like AFEB is going
14 to be the PI or the supervisor. You ask the
15 questions. And then the data can be analyzed and
16 the research projects can be done. And that can
17 come back to the AFEB in six months and say, has
18 this question been satisfactorily addressed and
19 answered. And see what the impact of this

1 particular intervention --

2 This is a sort of a fairly tradition way
3 that the ACI people would -- that you look at the
4 data that you have to address a particular issue
5 question. If it's not there, CDC considers it their
6 responsibility to go out and do the study to get the
7 answers.

8 And I think that's not a bad model to
9 accommodate AFEB.

10 DR. ASCHER: That's fantastic, but you've
11 got to go back four years when Barbara and a few
12 others joined. We weren't really at the of the
13 Board and small -- told we could not respond, other
14 than to very specific questions. General discussion
15 was not allowed.

16 At this point in time, two things happened.
17 Walt could see that this wasn't very good. And he
18 added a large number of people to the Board to
19 increase its expertise. And we started answering

1 questions we wanted to ask.

2 And with Barbara as one person from this
3 activity, and volunteered a new approach to a
4 problem. We weren't asked. But from a meeting, it
5 was clearly something. And this is the model of how
6 I think once in the spiel, these things could get
7 generated.

8 Now the question is: How do you reconcile
9 those two? It's not a question, but yet we
10 volunteered. And then your point, how do you finish
11 the job? I don't know. This is a wonderful model
12 of how you initiate the process that you didn't ask.
13 But at the same time, it doesn't necessarily help
14 you if you've elected the problems and let the staff
15 resolve it.

16 DR. KULLER: But the Board generated -- the
17 problem was generated not by the Board, but by I
18 think some very excellent presentations to the Board
19 at the meeting, which said, we have a very serious

1 problem in the sense of training and that basically
2 we're losing a lot of people through training. And
3 it's clear that there are certain markers which are
4 fairly obvious, which discriminate those who are
5 doing well and doing poorly in the training. But
6 the training losses are very substantial and what
7 can we do about this, given the resources. And this
8 generated bringing a lot of expertise to develop the
9 document, look at the data and now some conclusions
10 about what should be done next.

11 But I think the follow-through, much like
12 it has been in the past and the history of the
13 Board, is the need -- I think as we're pointing out
14 here -- is also the need to be able to say, okay,
15 now that the problem has been generated, now that a
16 Board has made some recommendations, how do we
17 maintain the surveillance to find out whether there
18 are any results. I mean, does it make any change.
19 Can you really change the accident rates and improve

1 preparedness by changing certain things related?

2 One of the examples was obviously the idea
3 of separating people by prior experience, so that we
4 basically don't have people who happen to exercise
5 at all or who have very little fitness. Put them
6 into a very active fitness and in the first three
7 weeks, have a great number of them who are dropping
8 out because of injuries related to training or body
9 size as a major determinant. But a lot of factors
10 and having a very good Board.

11 I think in the area of a lot of the topics
12 you just raised, I think similar phenomenon, once a
13 problem is identified and the presentations have
14 been absolutely superb -- I've always -- as probably
15 people know here, I've always said that the
16 epidemiology that I hear and the reason I enjoy
17 coming to the Board is the best epidemiology you
18 hear is generally from the people at the preventive
19 medicine offices. They probably do the best job of

1 almost anybody in presenting the epidemiological
2 problems.

3 The question really is how do we maintain a
4 longitudinal follow-up with the issues that they
5 have presented.

6 In the past, there were -- there still are
7 to some degree, there are infectious diseases or
8 product diseases, which have a major impact on
9 preparedness of cost, because they generate a great
10 deal of health care, if they're not dealt with
11 effectively. And also very sensitive issues: these
12 are the issues related to, as we've discussed,
13 problems with pneumonia on some of the bases where
14 the issues occurred is pneumonia, where there only
15 may be a relatively small number of cases. But if
16 you have two or three recruits dying of pneumonia on
17 a base, it just doesn't go well with the press or
18 anybody else, as we all know, and as well as a very
19 unfortunate situation if it's preventable.

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1 And that's been one of the things the Board
2 has tried to do, and that is to work to try and
3 maximize prevention. I think the Board's biggest
4 role is probably in trying to maximize the
5 preventive efforts, whether it's prevention of
6 injuries, preventions of infectious diseases, which
7 -- whether it's meningococcal or pneumococcal
8 disease, or whether it's -- as you pointed out, or
9 whether it's the planning for potential biological
10 warfare issues that the Board can -- has a lot of
11 expertise that can deal with it in the long term.

12 The other point you raised and one again
13 which I've been involved for umpteen years both with
14 the Board and in my past years with the Board and is
15 still, I think, a very basic problem, and that's
16 surveillance. I think there is a tendency to
17 believe that we can generate computer programmers
18 and data people who can develop a surveillance
19 system in the -- on their own. And I think what

1 we've heard has been surveillance systems which may
2 not work, at least in our own experience.

3 I think it proves surveillance. And that
4 came up in discussion again a little while ago.
5 That there needs to be a major effort toward a much
6 improved surveillance system, which I think requires
7 an input of not only people who are experts in
8 computer sciences, but people who are also experts
9 in what the surveillance system is supposed to do
10 for them and how they're going to do it. And the
11 Board can perhaps make a major contribution there,
12 as well.

13 DR. ASCHER: The other thing we haven't
14 figured out is when we see presentations that are
15 not really worthy of the task force, there's not a
16 question. How do we feed back some of the feelings?
17 You're being here is the answer to some of that,
18 but -- like the telemedicine in Utah got a mixed
19 reaction from the presentation. Electronic

1 ambulance, vis-a-vis the role of surveillance. It's
2 very important.

3 LT. COL. PARKINSON: Just an observation.
4 The things different about the global surveillance
5 initiative, though, in contrast to the previous
6 Board efforts, to my understanding, is they have
7 been internally looking at DOD operations and not
8 really looking at the tougher issues of how you
9 engage WHO or CDC or ACTO or the private
10 practitioner in his office who sees a traveler.

11 And maybe the role where this is different
12 is DOD as an agency is saying, it's more important
13 to us -- maybe even in WHO, if only in the sense
14 that it's our people in uniform who are going to be
15 the first people over there. They're the sentinel
16 chicken, you know, by merely them being overseas.
17 And we want to take the lead on it, rather than just
18 be -- you know -- we want to be a cooperative
19 partner, but we stick our hand up, and we believe

1 it's easier for the AFEB to take the lead on this,
2 at least for the purposes of coordination.

3 Now, that's a totally different statement
4 that's been made looking at the roles of the
5 overseas labs, which likewise the Board did over a
6 two-year process with site visits and accompanying
7 report. It worked very well. So it's the external
8 nature of the global surveillance. I think it's
9 different. It involves a different set of skills
10 and methodology than perhaps we've done for injury
11 work groups or, you know, emerging infections or
12 things like that.

13 The only other thing is on the staff
14 support from the PM officer's standpoint, I think
15 all of us basically feel that AFEB has been under-
16 utilized, perhaps over the last three to four years,
17 rather than over-utilized. And some of that degree
18 of utilization is directly dependent on the amount
19 of staff time that we can devote through our busy

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1 schedules to get ready for the meetings and to put
2 together cogent arguments or rationales for why
3 issues should come before you.

4 And that's where I think at the front
5 office, the purpose of the staff or executive
6 secretary is not just to make sure the buses take
7 you around the base tours, but it's really a
8 methodological and conceptual framework. That
9 person has to be much more engaged content wise than
10 strictly scheduled in the meetings, particularly if
11 the directions that Dr. Joseph wants to happen are
12 going to happen.

13 DR. JOSEPH: Well, I think this requires
14 one other thing. I think that's well said. But I
15 think that that staff support has to be -- has to
16 really be an enzymatic linkage between the Board and
17 the Department. That the staff support can neither
18 be just staff to the Board -- if you understand. I
19 mean, I don't mean in that in a disparaging way.

1 Nor can it be our person kind of keeping a watch on
2 the Board.

3 It needs to be somebody who really serves
4 as an interface with stuff flowing in both
5 directions. Again, as somebody who has -- who
6 hasn't had a lot of contact with the Board, I'm not
7 sure we've had that in at least the recent past.

8 That's part of the answer to both Claire
9 and Barbara's comments.

10 DR. HANSEN: Yes, that's chemistry to some
11 degree.

12 DR. JOSEPH: Part of it's chemistry and
13 part of it is adequacy resources. I take Claire's
14 point --

15 DR. JOSEPH: It's also evolution. Four
16 years ago we didn't have these things to worry
17 about. There is a lot happening.

18 DR. PEROTTA: Well, we did. We just didn't
19 know it.

1 DR. HANSEN: The other thing you might want
2 to think about as you're looking long range at this
3 Board, if you look at its 50-year history, 95
4 percent of its efforts -- I think I'm estimating
5 right -- went to bio-defense in all of its
6 ramifications, vaccines, viruses, bacterial, et
7 cetera. And it was really only when Ted took a look
8 at that to deliver it about seven years ago, that he
9 started thinking about the broader epidemiologic
10 contributions to military health.

11 And that's when the Board as an
12 epidemiology board really began the initiative of
13 looking at prevention outside of the realm of
14 infectious disorders and biological warfare.

15 And I think as we stand today, if we were
16 to apportion the priorities of the military, my
17 personal view -- which is very biased -- is that
18 this Board is still highly constituted to address
19 the bio-defense side and not nearly well enough

1 constituted to address the injury prevention, the
2 cardiovascular surveillance, the diabetes, the
3 environment, the fitness, that half which I believe
4 is fully half of what should be the Board's agenda.

5 DR. JOSEPH: Well, that comes back to
6 Claire's thing about priorities.

7 DR. HANSEN: I think you ought to think
8 about that as you set the directions, or whether we
9 really ought to have two boards.

10 DR. JOSEPH: I mean, it would be
11 interesting to have -- I would love to be the fly on
12 the wall when the Board really debated that. Should
13 we happen to have --

14 DR. HANSEN: Or should you have two boards?
15 The expertise involvement is extremely advanced.

16 DR. BROOME: If I could just raise one
17 other issue? I'm not sure how frequently this has
18 occurred. But it seems to me the Board could also
19 be a focal point for enhancing collaborations

1 between military and epidemia and other government
2 agencies.

3 DR. ASCHER: It used to do that.

4 DR. JOSEPH: It used to do that.

5 DR. ASCHER: I looked at the faces around
6 the room when you said, is there an instrument for
7 health risk assessment. People were going
8 (indicating). You know. I mean, let's just have a
9 presentation on that. They should pull that
10 together. We could be the focus group. And then
11 bring in the academics as a part of it.

12 DR. BROOME: And the domestic part of it.

13 DR. ASCHER: But I don't think without
14 focus it's going to happen.

15 MR. ROUDEBUSH: If I could give you just a
16 different view as a user? I'm here --

17 DR. HANSEN: Speak up, please.

18 MR. ROUDEBUSH: Yes, Jim Roudebush, Central
19 Command. And I guess the point that I'd like to

1 make is to tag onto the casualty prevention aspect.

2 I've got 8,000 miles in terms of lines of
3 communication and a rapid deployment requirement
4 that suggests that whatever terms we set are not
5 likely to be replaced very rapidly in terms of once
6 they get into the theater.

7 Therefore, my task is to make sure that the
8 troops that are there are fit, that pre-deployment
9 fitness, that they're protected while they're there,
10 bio-defense, counter-measures, whatever. And that
11 after the deployment or after the activity, that
12 we've got some visibility into the health status of
13 those folks over time so that we get a cause and
14 effect. And we don't get the fallacy after this
15 because of this.

16 If we can identify a cause and effect, then
17 it makes my job much easier in terms of applying the
18 next such activity to prevent that.

19 So infectious disease, one slice of that,

1 is certainly part of it. But I think your point
2 about the entire spectrum of casualty prevention is
3 one that certainly has a lot of meaning to me. And
4 I'd like to bring that up just as a user's point.

5 I will also tell you that I've taken the
6 opportunity to raise issues, for example, through
7 the joint staff. Write a letter, saying, here are
8 my concerns about these particular illnesses,
9 vaccines, whatever to be filtered up to the Board
10 for deliberation or consideration if in fact after
11 they have that betting process they're deemed worthy
12 of consideration, and I think some of them are.

13 So I'm pushing from the bottom up in order
14 to get some things. And the fact that I think this
15 is important enough for me to come spend my time at
16 -- you know -- you have a lot of influence over what
17 I do. So, as a user, I'd just like to lend my voice
18 to that in terms of that casualty prevention.

19 COLONEL TAKAFUJI: I've had the opportunity

1 -- this is Colonel Takafuji. I've had the
2 opportunity to -- and pleasure to work with quite a
3 varied mix of board members through about 15 years
4 of experience. And I've had the opportunity to
5 present on various issues and to address everything
6 from environmental issues to infectious diseases,
7 injury issues and so forth.

8 And what we're dealing with in my opinion
9 is a moving train in terms of the continuity of
10 different problems that has to do with also the
11 different awareness that we're dealing with. And if
12 -- it seems as if we're sort of fumbling with issues
13 in terms of what we should be doing, be it re-
14 establishment of commissions or the like. It's
15 because we're dealing with a different time frame,
16 with different issues, different priorities. But
17 also with different technologies that are coming
18 into play.

19 There are some specific issues that clearly

1 the Board can be more helpful to the services with
2 than other issues. So the Board should not in my
3 opinion take on necessarily the charter of trying to
4 solve all of the services' problems, because I don't
5 think that can be done. But it needs to focus on
6 those issues that are particularly important and
7 challenging to the services that we deal with. Some
8 of them are going to be very specific, like
9 meningococcal vaccine issues or whatever.

10 But there are going to be some other issues
11 that are much more broader in scope, such as the
12 things that Dr. Joseph alluded to, like global
13 surveillance.

14 But even with global surveillance, in a
15 military setting, there are certain things that make
16 us different. There are certain things that we can
17 discuss in terms of surveillance of diseases or
18 primal factors that can not be shared with the
19 international outside community. Some of them have

1 to do with security concerns, classified
2 information, and the like.

3 Our laboratories out there in overseas
4 areas have to have a relationship with the host
5 countries. They just can't report disease incidence
6 to the general community internationally, because as
7 you well know, there is some sensitivity about
8 outbreaks in different countries. And we saw this
9 recently with plague in India and on and on it goes.
10 Cholera in Egypt and so forth.

11 Many incidence were -- they're clearly
12 international health problems, but we as a military,
13 laboratory or community, cannot necessarily address
14 openly. So the issue of surveillance has some very
15 unique features that are specific to the military
16 situation.

17 What I would recommend is that with the
18 issue, Dr. Joseph, of surveillance is -- you have
19 heard the briefing that we have put together in

1 terms of the global surveillance plan. I would
2 suggest at the next AFEB meeting we present that and
3 discuss that in terms of where we are and get their
4 input in terms of whether we are concerning all of
5 the different factors that are relative and so
6 forth, and get the Board's input in terms of how we
7 can improve that structure, that strategic approach
8 in terms of how we see the roles, and start there as
9 a working process.

10 And not be so concerned as to whether we
11 should set up commissions and the like, but just to
12 see how that thing evolves. Because I think what
13 we're going to find out is as we get into
14 surveillance -- there are going to be all kinds of
15 subsets, everything having to do with things that
16 are purely technical in terms of computer support,
17 satellite surveillance, GIS systems, whatever it may
18 be. They're things that are much broader in terms
19 of like what diseases do we survey for, what things

1 should we be concerned about militarily.

2 We focussed with the Gulf War on things
3 such as lesion-maniasis as being a potential problem
4 and we haven't solved that problem.

5 But if you look back at the other
6 experiences we have had with Somalia and malaria and
7 so forth -- and even with Haiti, there have been
8 some things that have happened with the Haitian
9 deployments that I'm sure the Board is not
10 necessarily brought up to speed on. Those kinds of
11 issues I think need to be brought forth in terms of
12 some regularity or presentations to the Board, with
13 the idea that they would be free to provide advice
14 to us as we deal with it at the service level, at
15 the joint level, at the level of DOD in terms of
16 things much more broad in scope.

17 So my feeling is, yes, there are some
18 concerns that we have about injury prevention and
19 the like. There are things that we clearly can do

1 better. There are clearly things we need to
2 address.

3 But I'm not too concerned about the
4 business about setting up ad hoc committees right
5 now. But I think it's -- the problem is back on the
6 services now. You've made your recommendations.
7 Now it's up to the services to be given a chance to
8 try and resolve it.

9 DR. HANSEN: Negative. Negative. Let me
10 speak to that, because that's a real big problem.
11 What we have done -- it took us almost a year to get
12 a good picture of the problem by studying the
13 databases. We have not identified an agenda for you
14 by any means. We are simply at the point of the
15 table where our perceptions of what's going on has
16 now become useful to you.

17 COLONEL TACHYPHAGIA. Well, we have not
18 seen the report. Okay. So we need to see the
19 report.

1 DR. HANSEN: Of course.

2 COLONEL TAKAFUJI: And then we as a
3 service, though, need to see how we can improve what
4 we have going on right now. I think -- I happen to
5 feel very strongly that injuries can be prevented
6 much better than we're doing them right now. We're
7 over-training in many situations. There is no
8 rationale for people to be running around with 60-
9 pound rucksacks to prove a point how macho they are,
10 for example, if they're resulting with back
11 injuries.

12 So the point is, there is a certain point
13 where it comes back to the services to now institute
14 some changes, some modifications. That then comes
15 back to the Board, saying, here's what we have done.
16 Are we doing the right thing? Give us some advice
17 and so forth.

18 DR. JOSEPH: That's what I'm getting at.
19 It's that link that's missing.

1 DR. HANSEN: But that's what I'm saying.
2 That it should be -- and I'm not arguing for me.
3 I'm an old board member. I'll be going off. But
4 that there be a continuity on this area of expertise
5 and interchange if it's going to be useful. If it's
6 going to simply be cut off and come back again in a
7 couple of years and see if it's improved, it won't
8 be effective.

9 COLONEL TAKAFUJI: Then it gets to the
10 point that we addressed earlier about the executive
11 secretary. I'll be very honest and tell you I'm
12 very dismayed that we don't have a position of the
13 executive secretary defined, because I disagree with
14 Mike Peterson from the standpoint that the job was
15 not that busy a job. In fact, it could have been
16 increased in its visibility and importance. It has
17 not been developed the right way. And part of the
18 things that you're raising about what are the
19 services doing to follow-up and so forth, could very

1 well be put on the back of these individuals to make
2 sure that there is a tracking mechanisms, so that
3 these issues are coming back to the Board for their
4 comment and recommendation.

5 The services don't necessarily have to
6 follow the recommendations of the AFEB. But in rare
7 situations have we not followed the advice of the
8 AFEB.

9 So I think it's a very valuable tool that
10 we as different services have. But it's a moving
11 train. The joint issue is raised about JCS.
12 They're clearly developing into a bigger animal, but
13 that's not even clear. When the military is
14 changing in its roles in terms of humanitarian
15 actions.

16 JCS doesn't deal with domestic issues. Yet
17 we're getting into issues having to do with domestic
18 terrorism and the like. So we are -- as a big
19 organization, the Department of Defense struggling

1 with what our roles and responsibilities should be,
2 and it comes in conflict that have to do with legal
3 issues like posi-comitatus and what we should and
4 should not be doing in the military.

5 It's a very complicated issue. What I
6 would like to see coming out of this meeting is a
7 commitment that there should be an executive
8 secretary that has some clear responsibilities to
9 support you on the Board administratively, but also
10 be directly interfacing with the services to get the
11 issues addressed.

12 DR. ASCHER: Well, and the other thing
13 -- to kind of get into the tangibles. It would be
14 very helpful to have a concrete statement from the
15 Board in what you would see as the ideal staff
16 support for the Board in the near future, because
17 we're right at that point now.

18 You know, in specifics. What professional
19 qualifications. What kinds of duties. How would

1 that work. The more you give us on that, the more
2 we can try to be responsible for.

3 DR. ASCHER: But I don't think -- I think
4 it was the way it was defined from the top, which is
5 as much the problem for a year ago NADR, that there
6 would be no vision before this kind of Board
7 meeting.

8 DR. JOSEPH: Well, and the other tangible
9 we could agree on together maybe is to work -- I
10 mean, I think this goes on much beyond the specific
11 charter. But for you to share with us and we will
12 share back with you some specific thoughts on what
13 kinds of processes around these, both short-term
14 discreet, long-term discreet, broader issues. How
15 we could work that together. What kind of
16 environment we could set up.

17 I think if we had those two things, there
18 would be a clearer understanding of what would make
19 most sense in an executive secretary. And then how

1 we'd like the process together. The might -- might
2 be a way. And then take some of the specifics that
3 you mentioned, Ernie, and try them out for the
4 continuation.

5 I think that's a very interesting paradigm.
6 If it's the right one, I don't know.

7 DR. KULLER: I think we're going to have to
8 stop for lunch, which is right down there. We have
9 one announcement. We can continue this dialogue, as
10 Dr. Joseph said at lunch. We can continue with the
11 dialogue at lunch. Certainly I think it's been
12 extremely worthwhile, with one minor change.

13 COLONEL O'DONNELL: One announcement. At
14 least my version of the agenda for this afternoon,
15 the second page at the top, it says at 14:00 is the
16 presentation on hypothermia. That's an old agenda.
17 The hypothermia presentation is tomorrow at 10:00
18 hours. Otherwise, the agenda as you --

19 DR. HANSEN: What is instead of that?

1 COLONEL O'DONNELL: The meningococcal
2 vaccine. Of course, we're running behind. So we
3 may catch up.

4 (Whereupon, at 12:40 p.m., the lunch recess
5 was taken.)

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2 A F T E R N O O N S E S S I O N

3 (Time Noted: 1:45 p.m.)

4 DR. KULLER: We're going to talk about
5 varicella vaccine now. Dr. Sharon -- Major Sharon
6 Ludwig, are you here?

7 DR. SHARON: Yes. I think we'll have a
8 little better continuity if we start with Dr. White.

9 DR. KULLER: Sure. Whatever you think.

10 DR. WHITE: Hello. I'm Joan White. Thanks
11 for inviting me here. I was involved in the
12 clinical development of the varicella vaccine during
13 my seven and a half years at MURK. So I'm going to
14 tell you about -- actually it's about 26 years at
15 MURK in the next 15 minutes.

16 We've got this condensed. Feel free to
17 interrupt me at any time for questions. Can you
18 hear me in the back? All right. So if I start
19 dwindling, just raise your hands.

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1 This slide, I started a few show and tell.
2 You can give a clinical talk through show and tell
3 slides.

4 This is an unfortunate adult, actually from
5 Haiti where the incident of varicella in children is
6 not as high. So a lot of adults are left
7 susceptible. I think you have some of this problem
8 in the military. People from Puerto Rico, there
9 have been several cases written by the Armed Forces.

10 The problem with adults is that they get
11 more severe disease. Here is a classic picture of a
12 -- viral, secondarily infected with bacteria. These
13 are the viral in about 15 percent of the adults.
14 And it can be fatal, especially in pregnant women.

15 This is what you see in your kids, a
16 typical varicella.

17 And this guy doesn't look too happy. But
18 unfortunately there are about 50 healthy individual
19 children that die every year of chicken pox that

1 have been previously health. So it's not always a
2 benign disease.

3 As I say, if we could pick these 50 or the
4 7,000 that are going to be hospitalized, those would
5 be the ones we need to vaccinate. But unfortunately
6 we don't know which ones are going to get that
7 disease.

8 So the vaccine was recently licensed St.
9 Patrick's Day this year. And it's been recommended
10 by both the AAP and the ACP, just voted and passed
11 their recommendations this past week for universal
12 childhood vaccination and also to certain
13 susceptible high risk adults.

14 So here's the virus. It's a DNA virus.
15 It's part of the herpes virus family. And it has a
16 lipid layer. It's ubiquitous in man. It's the only
17 known reservoir is man. However, if you know the
18 literature on varicella, there is a case in a
19 guerilla. And I know that -- that's been reported.

1 Martin Levin, who has been working on zoster
2 prevention is trying to work out an animal model in
3 primates.

4 It usually only affects humans.

5 This is the incidence of varicella by age.

6 Now, the military we're talking about a small
7 number of cases that occur in adults. But as I'll
8 show you in the next few slides, these are more
9 severe than you see in the children.

10 Most of the cases occur from five to nine
11 years of age in children and through school age.
12 About 50 percent of the cases are then -- about 1.5
13 percent or 2 percent of the cases occur in adults.

14 You also can see around 18 or 19, you have
15 a fairly high rate of 13 percent.

16 There are four million cases right now of
17 varicella in the U.S. that is about equal to the
18 birth cohort. It's not a reportable disease to the
19 CDC, so these are estimates. Medium number of

1 lesions in a classical case in children are 300 to
2 500 lesions, most of them are febrile.

3 Most common complications in children also
4 can happen in adults are bacterial superinfection.
5 And as you know, there have been some bad Group A
6 streps going around. There was a bad outbreak in
7 Seattle earlier this year where 11 cases of
8 necartizing facciitis complicating varicella
9 infection. There were actually five deaths in 1993
10 in children from Group A strep infections. So it's
11 not always benign.

12 Encephalitis is much more rare, but can
13 occur with long-term coli. Cerebellar ataxia
14 usually goes away. Actually it always goes away.
15 But it's pretty scary for the parent.

16 Pneumonia, less common in children. And
17 Rye Syndrome which we don't see much any more,
18 because people don't aspirin in children.

19 Fifty deaths per year, as I mentioned

1 before in children, and about 7,000
2 hospitalizations. That's the number from the CDC.

3 Now, adults, although they're only 2
4 percent of the reported cases, they actually count
5 for 50 percent of the mortality from the disease.
6 That's a bad disease in adults.

7 Eleven percent of encephalitis cases and 14
8 percent of the hospitalizations due to varicella.

9 It's teratogenic if you get it in the first
10 trimester. And I have -- the next slide tells a
11 little bit more about that. And the fatality rate
12 is much higher. It's about 25 times more likely to
13 die of chicken pox if you're an adult than when
14 you're a child.

15 This talks about in pregnancy, because I
16 know that in some situations you might end up here
17 in the Armed Services. It does complicate
18 pregnancies. If you get it in the first trimester,
19 there is a classical fetal syndrome. They get short

1 limbs, cortical atrophy, cornea retinitis.

2 It only affects 2 to 3 percent of those
3 affected in their first trimester. You can compare
4 that to rubella, which is much worse. About 20
5 percent of babies are infected if their mother is
6 infected in the first trimester. So not as high
7 risk, but if it's your baby, then it's 100 percent.

8 And it's also very dangerous to have it in
9 the young infant. If their mother is sera negative,
10 they can very severe varicella if they get it in the
11 perinatal period.

12 And this is just a slide that I guess this
13 morning set a nice scene. That was very nice to
14 talk about prevention versus treatment. Prevention
15 is always much more cost effective even though
16 nobody likes to pay for vaccines and nobody likes to
17 go in and get vaccines, especially adults because
18 their arm hurts when they walked out and they didn't
19 hurt when they went in.

1 But you can see here from this slide. And
2 there are many people in the room here that are
3 vaccinologists and probably were in on licensing
4 some of these vaccines.

5 You can see these are the number of cases
6 in the year, the maximum number of cases that were
7 reported. You can see the percent change. You can
8 see between 96 and 100 percent change in incidents
9 of disease with these effective vaccines, some not
10 so quite so effective. As you know, pertussis, we
11 still see several outbreaks and have to give several
12 doses. But even with that, you decrease the
13 incidence of disease dramatically.

14 Now we'll talk a little bit about the
15 clinical development program. And then Sharon will
16 talk about the cost effectiveness and how you plan
17 or present scenarios of how to plan to use it in
18 susceptible Armed Forces workers -- soldiers, I
19 guess. Isn't that what you call them?

1 Clinical development for 12 years, we've
2 vaccinated over 11,000 individuals, mostly children,
3 because most adults are not susceptible any more.
4 And over that 12 years, we've been able to survey
5 for safety and also, for instance, for zoster, and
6 also protection from the vaccine.

7 What we've done over the last 12 years is
8 optimize production. If there are any virologists
9 in the room, they'll know that varicella is a
10 difficult virus to grow in culture. And whenever
11 you scale up into these big manufacturing
12 facilities, it is difficult to preserve the
13 infectivity. And that's what's been difficult with
14 the varicella virus. It's very heat label.

15 So I'm showing you these three because this
16 is what is in the package circular and it will help
17 refer you to or help you understand the efficacy
18 rates that I'll talk about in a minute.

19 There are three big campaigns that we

1 tested in the clinical trials. I got involved in
2 1987 when this is the -- one of the first
3 manufacturing lots in the big facility. You can see
4 that the plaque forming units or the infectivity
5 titre went down as we scaled up.

6 We vaccinated most of the individuals with
7 these lots. However, the new lots that are on the
8 markets now, the ones that are for sale, have
9 between 3,000 and 9,000 PFUs. Most of them are
10 around 3,000. We've vaccinated 2500 with those.
11 And I'll show you results from those studies.

12 The efficacy study was done with the first
13 lots made in the laboratory setting. Those had
14 17,000 plaque forming units, which is obviously
15 higher than what we're selling now. So you have to
16 keep that in mind when we look at the data.

17 The average age of the children we've
18 vaccinated is four.

19 You can see that in this slide, what we

1 found is that we saw 93 percent reduction in the
2 current vaccine compared to historical controls. We
3 left it at the efficacy three different ways. One
4 is in varicella vaccines over time. And if you
5 looked in those lots that I showed that you had
6 between 3,000 and 9,000, we've got a 93 percent
7 reduction in varicella.

8 If you look at the individuals who got
9 vaccinated with the 1987 lots, which were less
10 effective, there was only 67 percent reduction of
11 disease. However, the people who got disease got
12 modified disease, usually less than 50 lesions.

13 We also looked at protection following
14 household exposure. And then finally a double
15 blind, randomized placebo. And these are a lot of
16 numbers, but I think it gets -- and I'll just point
17 out the ones that I think are important.

18 These are -- I picked this one out because
19 this is the 1982 campaign that we've had eight years

1 of follow-up on. And this is the low titer lot. I
2 picked that one out as the worst case scenario.

3 And this one said, break-through disease
4 over time has vaccination. That's a question that I
5 think is foremost in everybody's mind is, how long
6 is protection going to last after you give this
7 vaccine.

8 And the best I can tell you is from our own
9 clinical data.

10 You can see the break-through rates,
11 varying, where from less than 1 percent to up to 2.1
12 percent.

13 The interesting thing to note here is that
14 the medium number of lesions I told you in children,
15 usually 300 to 500 lesions. You can see that even
16 though they do develop disease, most of them have
17 very modified disease, even out to eight years post-
18 vaccination.

19 And you don't see the break-through rates

1 increasing.

2 The 87 lots had higher break-through rates.

3 There are probably a couple of reasons for that
4 one. They probably weren't as potent as the older
5 lots. And the other reason is the way we designed
6 our clinical trials. We had much more active
7 follow-up and we had the parents come in for any
8 symptoms of two or three spots. So we can see
9 break-through rates peaked out at about 3.6 percent,
10 but over the next couple of years did not increase.
11 Again, the medium number of lesions did not
12 increase over time.

13 And then finally the lots that we are using
14 now in the market place have a better stabilizer,
15 more PFUs, in the vaccine and we're very pleased
16 with the break-through rates. It's much lower.
17 That's what we were targeting for by increasing the
18 infectivity.

19 This is just a summary. You'll see this in

1 the package labeling. You can see that a single
2 dose in children -- that with the current lots, you
3 see a 93 percent reduction of disease when you
4 compare it to a historical type rated, 8.3 to 9.1
5 percent varicella per year in this age group.

6 We looked at also protection following
7 household exposure. Varicella is a very contagious
8 disease, as you might know, especially -- I actually
9 came up here five -- about four years ago, we were
10 thinking about doing a study in recruits with the
11 varicella vaccine. At that time, they were having a
12 lot of outbreaks with chicken pox that seemed to
13 -- we just came and talked about the vaccine and
14 then stopped. I don't know what happened.

15 I'll be happy to go talk to any other place
16 that's having outbreaks, plan a clinical study, and
17 then they'll stop. So that's the way life goes.

18 But anyway, it is very contagious. And
19 actually I found out the reason for that. I was

1 here in February. And they have these huge
2 barracks. And, you know, everybody was taking
3 showers. They weren't taking showers when we were
4 in there, but it was very humid and a great place to
5 transmit varicella.

6 So what we did is looked at individuals who
7 had been exposed in the household setting. This is
8 certainly the most extraordinary challenge for a
9 vaccine. We actually only had out of the 9,000 267
10 exposed in the household. That's because mothers
11 usually bring in the whole family and get them
12 vaccinated.

13 But the odd sibling will come along that
14 didn't get vaccinated and expose everybody. We had
15 53 out of those 267 that developed a rash after
16 exposure.

17 For all of these calculations -- you guys
18 are epidemiologists, you can do all of that.

19 But the point I wanted to make was the

1 median number of lesions even in those who had
2 developed disease after vaccination, those few that
3 had modified disease.

4 Yes.

5 COLONEL O'DONNELL: Is that administration
6 of vaccine after exposure?

7 DR. WHITE: No.

8 COLONEL O'DONNELL: Okay.

9 DR. WHITE: There are limited studies about
10 after-exposure published by Arbiter with a different
11 formulation of vaccine. And he found that if you
12 gave it -- I think there were about 30 individuals
13 in that study. Gave it within 72 hours, you did get
14 some protection -- actually pretty good protection
15 from developing disease. And those that did get a
16 modified disease.

17 This is the efficacy study, typical double-
18 blind, placebo controlled efficacy. They're
19 followed through two varicella seasons. The first

1 season we had 100 percent efficacy. The second
2 season, some vaccinated person, even with the 17,000
3 PFU lots, had a break-through disease that had only
4 40 lesions.

5 And if you're interested, that's published
6 in New England Journal of Medicine, 1984, with a
7 follow-up -- seven years follow-up in these same
8 individual by Kueter and others in Vaccine, 1991.

9 And you probably can't see this very well
10 in the back, but as I have told people that I've
11 given this lecture to, if you're a clever mother,
12 you can hide these up and send them right on to
13 school, because they usually don't get -- if you
14 have a speech to give that day, they're usually not
15 ill. Occasionally about 14 percent of children
16 -- this is a break-through case. This is somebody
17 who vaccinated. A couple of years later got
18 exposed. And sure enough they get a few spots,
19 usually not ill.

1 It can culture wild type virus from these.
2 And I know you can transmit it, because we had
3 break-through disease in a vaccine transmitted to a
4 mother. So I know this is contagious. If it's less
5 contagious, it's hard for do the studies. We
6 haven't done them. Maybe you guys taking a course
7 in the military know it's hard to do unless you have
8 a highly vaccinated cohort.

9 But you can see a few here. This fellow
10 had a few more lesions.

11 What you see in these is a little more
12 erythema around the base, probably because they had
13 some period of anemia to the antigen here.

14 And you usually don't have large vesicles.
15 You have very pinpoint vesicles.

16 And this just a close-up. I know that some
17 of the kids that we have in our regular slides of
18 both -- I was feeling a little cavalier one day when
19 I first came to America, there was a report of a

1 vesicle in between the fingers, one lesion reported
2 by the mother. And I remember I put down in the
3 database, that we'll wait. And sure enough, it was
4 varicella. One vesicle. And it had --

5 DR. ASCHER: Question.

6 DR. WHITE: -- so that you can have very
7 few lesions.

8 DR. ASCHER: Question?

9 DR. WHITE: Yes.

10 DR. ASCHER: The distribution of those
11 lesions suggests that's actual varicella and not
12 zoster from the vaccine?

13 DR. WHITE: Yes. You know, that's an
14 interesting point, because in our post-marketing
15 surveillance, it's going to be sometimes difficult
16 to tell between zoster and varicella. But usually
17 these are distributed on the trunk, and so you get
18 them on both sides.

19 If you only have one or two lesions, it's

1 tricky. But the -- we have had zoster reported in
2 vaccines and pictures taken. And usually they have
3 the classical zoster picture. We've grown wild type
4 from them incidentally.

5 DR. ASCHER: That's the real question.

6 DR. WHITE: Yeah. We've grown wild type
7 from the zoster lesion. I'm sort of jumping ahead.
8 In leukemics, you can get ocastrain out of it,
9 vaccine strains. It can happens both ways.

10 What's happened in those, in these kids
11 that have gotten zoster, some of them have had
12 break-through disease. So we know they've gotten
13 reinfected with wild type. And that's probably more
14 efficient than setting up latency, we think, from
15 our work and from Dr. Takahashi. And I'll tell you
16 why in a minute, or maybe if we have time at the end
17 for question and answer.

18 But usually trunk -- you're right, if it's
19 just one or two lesions. But we -- doctors aren't

1 usually reporting it as zoster unless you see
2 clustering of three or four little vesicles.

3 We'll talk a little about immunogenicity.
4 I know Dr. Ludwig is going to talk about serological
5 testing. I'll try to leave before that, because
6 there is loads about serological testing and what
7 test to use and all of the problems with sensitivity
8 and specificity.

9 So we got to design our own very sensitive
10 test because that's what you do when you're making a
11 vaccine, because you get low antibody levels and you
12 want to -- I guess I shouldn't say things like that.

13 Anyway, 97 percent sera-conversion rates,
14 we got from all lots.

15 With our new lots, 98 percent. And indeed
16 these did correlate with neutralizing activities.
17 So I know that these people actually are getting
18 antibodies that neutralizes the virus.

19 And also Ann Arvin and Stewart Star's roots

1 have tested CMI. And not only do we get antibody
2 production, but in these individuals we also get the
3 stimulated cell in the immune system.

4 So children respond very well to vaccine, a
5 very immediate response. That's why we vaccinate
6 children and not adults.

7 But this is a safety picture we had. The
8 placebo controlled part that I told you about. The
9 thing interesting to note on here is the only thing
10 that happened -- I don't have a key -- but more
11 commonly in the vaccine recipient in this placebo
12 controlled problem was the pain at the injection
13 site. So a very low reaction to the vaccine. You
14 do get a rash.

15 It's very difficult to grow the virus from
16 the vaccine associated rash. That comes in when we
17 talk about transmission.

18 You can culture. We've cultured it once, I
19 think, out of -- we must have cultured three or four

1 times these rashes. It's not hard to culture from
2 break through.

3 This is what's in the labelling. This is
4 the overall results from kids.

5 And then we'll talk a little bit about
6 transmission. We didn't do transmissions settings
7 in adults, but in the Armed Forces I think you could
8 probably equate it to -- well, like a daycare,
9 because most of the people are immune. We it in a
10 daycare and hospital setting and looked at
11 transmission from the vaccinate to susceptible
12 people and a daycare.

13 In that setting, that's published in the
14 Weigel paper as well. And it's in the package
15 circular.

16 It talks about there were sera-conversion
17 in six placebo recipients. And it goes that did not
18 receive the vaccine or were exposed to a vaccine,
19 that actually didn't develop a rash but they sera-

1 converted. And the person that sera-converted
2 didn't develop a rash, either.

3 Now, three of those were though to be mix-
4 ups in the field. And three of them they had no
5 explanation for. So we have in the package circular
6 -- and I think you have to say this about all live,
7 attenuated vaccine, there is a possibility that you
8 can transmit it. But the possibility is very low
9 and much lower than you see with natural infection.

10 We also did a study where we vaccinated
11 healthy children who lived in a household with an
12 immuno-suppressed sibling who is susceptible for
13 varicella.

14 I think the important group that you need
15 to consider when vaccinating -- and we saw no
16 clinical or sera-logical evidence of transmission in
17 this study. So they did not get any transmission in
18 this study.

19 DR. JOSEPH: How did you do that study?

1 DR. WHITE: Ann Arvin did it at Stanford.
2 In her group of 30 children, she found 30 families
3 where they vaccinated the healthy sibling that lived
4 in the same household as the susceptible leukemic.
5 Who asked that question? Yes.

6 They vaccinated the healthy person and then
7 they drew blood on the leukemic child.

8 DR. JOSEPH: I meant the IRB as for
9 example.

10 DR. WHITE: Well, I think we did this study
11 -- when was it done? Let me check the date. We've
12 had a lot of experience. Nineteen ninety-one. It
13 was done in like 1989. So we had seen the results
14 of the efficacy study with very minimal, if any,
15 transmission. And the IRB thought the risk of them
16 getting wild type varicella, the leukemic child, was
17 much higher than getting it from the child. And
18 obviously they were under constant, you know,
19 observation and for any signs of a rash they could

1 be brought in for IV cycle treatment.

2 DR. SCHAFFNER: This is one of the things
3 that pediatric hematologists want to do very much.
4 They want to vaccinate the leukemic child.

5 DR. WHITE: And, by the way, you can
6 vaccinate leukemic -- if you're taking care of
7 leukemic through a study protocol with vaccine free
8 of charge. It's in the package circular there. You
9 can vaccinate leukemic children after they've been
10 in remission for a year. But you don't want to do
11 it before that.

12 DR. JOSEPH: What about HIV?

13 DR. WHITE: HIV, we don't know what the
14 safety immunogistic profile will be in that group.
15 We're doing a study with the ACTGs. We have a
16 protocol that should start in the next few weeks. I
17 think it's reviewed. It's gotten through all of the
18 review cycles. It should start soon.

19 I expect -- you know -- we're using

1 -- we're vaccinating children who are asymptomatic
2 or mildly symptomatic to begin with. So I think
3 they should do fairly well and hopefully get a good
4 immune response.

5 So a lot of controversy has been brought up
6 about this transmission issue. And the way the AAP
7 approached it was they actually have recommendations
8 out in the May Pediatric Journal. They said the
9 spread of vaccine virus from healthy vaccines to
10 other persons is theoretically possible. Since the
11 vaccine has -- vaccine virus has been recovered in
12 vaccine recipients with skin lesions.

13 No clinical case -- then they go on to say
14 no clinical case of a varicella from contact with
15 healthy vaccines have been reported. Didn't want to
16 say this three that I told you about had sera-
17 converted.

18 And they go on to tell you the way of risk
19 versus benefit.

1 Now, if you want to get more complicated,
2 we know that it can be transmitted, because if you
3 vaccinate leukemic children who are sort of like a
4 growth media, sort of the immuno-suppressed, they
5 can transmit the vaccine virus if they develop a
6 rash. They don't do it from respiratory droplets
7 spread.

8 So, you know, we get into these arguments
9 about health care personnel. And I say, well, you
10 know, if the leukemic don't spread it by respiratory
11 droplets, if you have a health care person that you
12 vaccinate and they don't have a rash, I wouldn't
13 refer them. And you'll see the adults have a rash.

14 Anyway, so we know it's a live leukemia
15 vaccine and we know that if you give it to the right
16 person, it can suppress transmission. This
17 -- again, the ones that they transmit it to, they
18 get a modified disease.

19 Now, I'll just move forward to health

1 adolescents and adults, basically the same kind of
2 format. And I'll go briefly through that.

3 We didn't do a double-blind, placebo
4 controlled efficacy study. We should have done that
5 here, but it went away. So we would probably have
6 had to vaccinate the whole Armed Forces.

7 But we looked at protection rates on
8 household exposure and also protection of the time.
9 And I'll show you that first.

10 We first started just using one dose in
11 adults. Those studies were done by the NIH actually
12 way back in the early 80s. So we do have long-term
13 data on the one dose.

14 And it's pretty good, but two doses is a
15 lot better.

16 In adults, these are given two doses
17 followed three to four years. You can see the
18 break-through rates is fairly low.

19 They get -- they get a few more lesions

1 than kids, but they often don't come up with a
2 fever. About 40 percent will be a fever. And the
3 break-through is much less severe.

4 This is our new lots. We had three years
5 of following these. We are very pleased. The
6 break-through rates with these higher lots -- this
7 is following two days with very minimal break-
8 through.

9 And this is the efficacy following
10 household exposure. Perhaps a little lower than we
11 see in kids, but again the ones that do have break-
12 through have modified disease.

13 This is just a case. Again, you can see
14 the lesions, the break-through. Again, some on the
15 front. About 40, four 0, percent can develop a low-
16 grade fever. Some adults a little more with the
17 break-through disease.

18 When we went to the 1987 lots when we first
19 started using two doses, the reasons were pretty

1 apparent. Two doses because after one dose, it was
2 lower in -- one had a 75 percent sera-conversion
3 rate. And not only was the sera-conversion low, the
4 titer or the level of antibodies was about half of
5 what you found in kids.

6 The second dose brought it right back up to
7 the level of what we saw in kids. And those were
8 the studies that showed the protection rate were
9 pretty good.

10 These were our new lots. And, fortunately,
11 as I say sometimes, they acted a little bit too
12 good. So we were in quandary whether we wanted two
13 doses. We got a pretty good sera response rate from
14 one dose.

15 But I should caution you that the titer of
16 the anti-body and the level of CMR response was
17 lower in adults. It goes up a little higher when
18 given the second dose. So we thought that this
19 would be better for long-term protection.

1 Safety. We found out that adults
2 complained more than children. But we knew that
3 already. They're very mild complaints, pain,
4 erythema at the injection site. Can get an
5 injection site rash and can get a varicella like
6 rash. A few more adults than kids, but again
7 usually less than ten lesions. And temperatures
8 were reported, but a lot of those were associated
9 with other incombinant illnesses.

10 So in summary, we've shown the vaccine, I
11 think, from the clinical trials to be highly
12 efficacious. We have only done it with MMR. And
13 this will be a great challenge for you guys. You're
14 going to be giving them lots of vaccines. I don't
15 know what their sera-response is going to be if you
16 give them with other vaccines.

17 But I assume with other live vaccines, it
18 may dampen the response, but it's something that can
19 easily be looked at in a subset.

1 And generally well tolerant and no apparent
2 increase in zoster.

3 This is what it looks like. And we have
4 even more fun for you guys. You have got to keep it
5 frozen, unfortunately. And I've had people get real
6 angry with me about that. We didn't really want to
7 keep it frozen, but it was just the virus is. It's
8 not like measles, mumps and rubella. It's not
9 stable. We're working on new stabilizers.
10 Hopefully we'll have a refrigerator stable formula
11 in two or three years. But you've got to keep it
12 froze. A frost free will do. I mean, you could
13 probably keep it outside here at the Great Lakes
14 Naval Station probably most of the year, maybe not
15 today.

16 And this is what we're going to be doing as
17 time goes on. This will probably be the most
18 heavily studied vaccine post marking for obvious
19 reasons, because oftentimes people don't have long-

1 term sacculle from varicella. So we want to make
2 sure we don't make things worse.

3 CDC is doing surveillance studies. Murphy
4 is doing a large safety study at Kaiser Northern now
5 with 30,000 or 40,000 kids to see if we missed some
6 serious AEs. We're doing a field effectiveness in
7 daycare study. We're doing long-term effectiveness
8 studies in a subset here in both kids and
9 adolescents and adults.

10 We'll also case control studies if we have
11 any outbreaks. And we're looking at booster doses
12 when and if we need to give them.

13 I'll end with fortunately medical -- this
14 is a picture. I assume -- well, actually the
15 recruits probably look a little better than this guy
16 here. It says fortunately medical researchers have
17 been able to combine tetanus, smallpox and rubella
18 vaccinations into one shot. So that's probably
19 about as much progress we'll make in trying to

1 combine all of these things. But we're working on
2 it to combine it with MMR. So you can just have one
3 shot.

4 With that, I'll quit and I'll let Sharon
5 take over.

6 DR. BAYER: What kind of serious side
7 effects did you have with only one shot.

8 DR. WHITE: You know, we actually had no
9 serious -- believe it or not, we had no serious AEs
10 reported. Out of the 11,000 children, we had one
11 serious AE and that was a hospitalization for just
12 observation. We have had several seizures, about
13 three or four.

14 DR. BAYER: The Japanese, have they looked
15 at adult immunizations and how many shots have they
16 used?

17 DR. WHITE: In Japan, they do use adult
18 immunization. I think they only use one. They may
19 use a second for sera-conversion. And their

1 vaccine, depending on that may be a little bit
2 higher tiger. Most of those vaccinations are given
3 to children.

4 DR. HANSEN: You touched on this a little
5 bit, but is there any evidence of reversion to wild
6 type?

7 DR. WHITE: I haven't seen that. We looked
8 at the -- especially the ones at the Ann Arbor, the
9 transition ones, the open strain, to see if it was
10 more severe. We haven't seen it. It's a very
11 stable virus. So we don't expect that.

12 DR. ARDAY: Do you know if there is
13 anything that distinguishes the break-through cases
14 or if -- if there are any virologists -- I don't
15 know if there are any virologists here who know if
16 there is more than one particular type of varicella
17 wild type that, you know, might be a minor variation
18 of the strain and that particular strain is
19 responsible for the break-throughs or something?

1 DR. WHITE: Well, we know in the U.S. it's
2 mostly one or maybe -- Larry Gale has a description
3 and analysis of all of these different strains from
4 all over the world and the U.S. There are some
5 variations. We haven't seen any variations in vari
6 ones. In fact, we can tell the open strain from the
7 wild type simply because it came from Japan. And as
8 we see more continental mixing, I think we will see
9 less and less differentiation between different
10 strains world wide.

11 But you can tell a vaccine associated rash
12 from wild type by REA. And also Phil Lebrusic can
13 do that for you from a -- if you ever need to find
14 that out, he's at Columbia. And you can just do it
15 on a swab. It's amazing. He's got specific wild
16 type vaccines. Just do a swab and put it in an
17 envelope and send it if you have questions on a
18 case.

19 But there is not more than one different

1 -- one or two different ones in the U.S. They all
2 sort of have the same pattern.

3 DR. ASCHER: Natural immunity is not
4 absolute either. There are well described second
5 infections, besides zoster.

6 DR. WHITE: As we look more -- and
7 sometimes that happens in terms of families, the way
8 you respond to it. And a lot of people are
9 referring to the zoster as well.

10 AUDIENCE MEMBER: Do you have degradation
11 figures at all?

12 DR. WHITE: You mean, on antibody?

13 AUDIENCE MEMBER: Right. On antibody.

14 DR. WHITE: Yeah, that would be nice. I
15 think we will be able to gather that as we get a
16 more highly vaccinated population. But what happens
17 now is we get these lifts where people get exposed
18 and they get these huge responses. So if we don't
19 have an isolated group that hasn't been exposed.

1 AUDIENCE MEMBER: Well, the other thing is
2 -- (inaudible)

3 DR. WHITE: Actually we didn't do kinetics.
4 But if you look at one year, there is not much
5 difference.

6 MAJOR LUDWIG: I'd like to go ahead. I'm
7 glad to be here this afternoon with Dr. Joseph and
8 the rest of the Board. I'm Major Sharon Ludwig.
9 I'm at the Army Center for Health Promotion and
10 Preventive Medicine, which is provisional at this
11 point. And I'm in the Directorate of Epidemiology
12 and Disease Surveillance.

13 The first thing I'd like to say is an
14 apology for my title. I realized this not too long
15 after the slides were already made and it was
16 already pointed out to me once. The Army at this
17 point does not have a varicella vaccine policy. So
18 for those of you who have hand-outs, I'd like you to
19 please change it to just add the word "issues" after

1 that word "policy." We'll talk about the issues.

2 The other point about the title is that
3 although all of my data are from the Army. I think
4 based on my discussions with folks in other Services
5 and just on sort of an intuitive sense that these
6 are military wide issues, they're not just Army
7 issues.

8 The objectives of my talk -- and this will
9 lead to the questions that I would like to pose to
10 the Board. First of all, I'd like to try to
11 demonstrate the need for varicella prevention in the
12 military, determine the risk groups, determine the
13 most cost beneficial use of the vaccine in the
14 military, consider non-standard uses of the vaccine
15 if this is appropriate. And I will list some policy
16 recommendations that are based on my research and
17 they are not official Army policy recommendations.

18 Actually this point right here is one of
19 the questions that I want to pose to the Board. And

1 I will mention it again at the end. But it is to
2 consider non-standard use of the vaccine if it's
3 appropriate. It's not very severely non-standard;
4 nevertheless, we can talk about it.

5 And another question that I would like to
6 add to that, and I will mention again at the end to
7 ask the Board, may concern adding or establishing a
8 new way of doing things in terms of giving the
9 vaccinations to the recruits.

10 This graph shows the varicella
11 hospitalizations in the Army for active duty
12 personnel only for the last 15 years. And as you
13 can see, there is a blip here, maybe from '86 or
14 '87, to maybe something like 1990. And then a
15 decrease again, but not anywhere near the levels at
16 the beginning of this period. And what caused that
17 blip, I'm not exactly sure, but I think the Navy
18 experienced something very similar and we're going
19 to hear about that later.

1 Nevertheless, this -- this number -- let's
2 call it about an 80 -- it's a rate of 80 per 100,000
3 soldiers. It seems to be leveling off. And this
4 may not sound like too many, but it does work out to
5 an average of about 600 cases per year in active
6 duty Army.

7 And the important those of you who -- all
8 of you, I'm sure, are very familiar, that if these
9 cases are clustered, it may be a small number in
10 relation to the total population, but it can be a
11 very serious problem.

12 I am going to be focussing again on
13 varicella again in the military.

14 Joe, I think -- if I understand it right,
15 Army personnel are called soldiers. And I think
16 that Air Force is airmen, and Navy is seamen, if I'm
17 right. But anyway we're all troops.

18 When do active duty hospitalizations occur?
19 The first question I looked at is when in the

1 military career. And I think it's very revealing to
2 see that 24 percent or a quarter of these active
3 duty hospitalizations occur by the second month of
4 service and 90 percent of them by the second year of
5 service.

6 By the end of the second month of service
7 is when they're finishing basic training. So a
8 quarter of the cases in the Army that were
9 hospitalized -- and I'll talk about that a little
10 bit later, but anyway. By the second -- end of
11 basic training, in 90 percent, before they're even
12 finished with their first tour of duty.

13 And what age? This is not really very
14 surprising. Again, remember that the great majority
15 of varicella cases have already happened. Most of
16 the people who come to basic training are already
17 immune. But in those who get it while they're in
18 the military, 55 percent, over half of them by the
19 end of their 20th year of age -- and, again, that's

1 first termers for sure, mostly basic training. And
2 96 percent by the end of their 29th year of age.

3 Just some points. I think it's very
4 fortuitous that we took a tour this morning to sort
5 of demonstrate some of the things that are relevant
6 to varicella in the military. I think the situation
7 is very similar in the other services.

8 I wish that we had been able to see some
9 barracks and some of the way that people live,
10 because that's relevant also to the transmission of
11 varicella.

12 In any case, to review what Joe already
13 said, it's highly contagious. And I would just like
14 to emphasize that it has a relatively long and
15 partly sub-clinical communicable period.

16 And how that's relevant to Army or to
17 military training is that we have individuals who
18 come together from all over the United States.
19 Okay. They come from many, many different

1 communities and locations and environments. They
2 are housed in very close quarters. That is, a lot
3 of people in an open bay kind of situation. And
4 they're fixed cohorts. They do pretty much
5 everything together. And their interaction with
6 other units is limited. So whatever happens to one
7 unit is going to spread if they're susceptible
8 people.

9 And the third thing is that basic training
10 and in advanced training, and sometimes on farther,
11 as long as the soldiers are living in barracks, if
12 they are ill with a communicable disease, they are
13 almost always hospitalized. The reason for that is
14 that they need to be watched for complications.
15 They need to be quarantined or isolated from other
16 susceptible people. And they need somebody to watch
17 over them -- which is there is nobody to do that in
18 the barracks.

19 People later on in their military careers,

1 who are married or living on the economy or
2 whatever, aren't necessarily hospitalized for
3 communicable diseases unless they have serious
4 cases.

5 We saw a place where this happens in the
6 Navy this morning. The Army has six basic training
7 centers. And as I'll mention later, we train about
8 130,000 soldiers every year.

9 Some more points about varicella and Army
10 training. The clinical disease corps comp is at
11 least one week, that is, at least one week away from
12 the soldiers' regular daily duties. And as Dr.
13 White, there is greater morbidity and mortality in
14 adults.

15 This is important and relevant to Army
16 training, because as we discussed, training is
17 extremely demanding -- psychologically and
18 physically. The requirements are highly
19 standardized. It's not a good thing for people to

1 miss any of their training.

2 And missed training and what we call
3 recycling or sending them back through basic
4 training is, first of all, very expensive -- or it
5 can be.

6 And the point I want to make about
7 inadequate or inefficient training is that if they
8 miss training and they go back and make it up, then
9 it's inefficient, because they have to go back and
10 extra time is taken. Or it can be inadequate
11 training if they just decide to go on. All of these
12 things and the threat of being recycled lead to
13 decreased morale and loss of unit cohesiveness, all
14 of which are important points in terms of military
15 training.

16 AUDIENCE MEMBER: Sharon, that one week
17 would be sufficient to stir up the entire cycle.

18 MAJOR LUDWIG: Right. You mean, with new
19 cases.

1 AUDIENCE MEMBER: Yes. If you miss five
2 days out of --

3 MAJOR LUDWIG: Yes. Yes. Yes. I think
4 it's a maximum of three days. Maybe Dr. Bayer or
5 somebody here could go over that.

6 Rigorous training. An example of what the
7 Army does. It probably isn't very different.

8 Immunizations and Army training.
9 Immunizations need to be efficient, accurate and of
10 course safe. I'm not sure what was in my head when
11 I chose the word accurate, but I think what I mean
12 there is effective. You know, I had something in my
13 head, I'm sure, because I choose every word, but I
14 don't remember what it was.

15 The recommended varicella vaccine dose is
16 .5 mils per dose. And for children under 13 years,
17 again it's one dose. These are uncomplicated, not
18 high risk groups. I mean, the recommendations are
19 obviously much longer than these two points. And in

1 adults -- adolescents and adults 13 years and over,
2 two doses separated by at least four to eight weeks.
3 It can be longer than this. And how long I'm not
4 sure. We may talk about that a little bit later,
5 but at least four to eight weeks.

6 In Army training, immunizations are given
7 in large groups. They do it all at one time. And
8 try to get them over with and out of the way because
9 anything -- any medical in-processing that has to be
10 -- anything that they have to go back to the medical
11 processing station for is viewed as a training
12 disruption and is not seen very -- in very good
13 light. In fact, it's a real problem.

14 For Jackson, it's backwards there, but
15 they're getting their shots.

16 Varicella in the Army. Now, there are some
17 issues that aren't just training issues, the
18 training period. They persist a little bit longer
19 because not all of the cases do occur, as I

1 mentioned before, during training. An average of
2 600 soldiers per year hospitalized, as I mentioned.

3 I made an estimate of an additional 1200
4 per year recover as out-patients. I think -- I
5 consider this a very gross estimate. I base it on
6 the rates for the same age groups from the National
7 Health Information Survey. But they were unadjusted
8 rates for those age groups, which they would need
9 -- probably need to be adjusted to our population
10 and they weren't. It's really the question that was
11 brought up this morning about the problem of getting
12 out-patient surveillance. And we don't have it.

13 I made this estimate. And as you'll see in
14 my analysis later -- or as I'll just mention now so
15 you know it, the analysis is not sensitive to the
16 number of applications. So basically my conclusions
17 would not differ if we had only -- if we had zero
18 out-patients.

19 Relevance to the Army. Again, lost duty

1 time leads to decreased operational readiness. Even
2 small outbreaks can render an entire unit
3 inoperable. And I'm reminded --

4 I have a small story. When I was at Fort
5 Drummond, the preventative medicine officer there, I
6 got a telephone call from the holding area where
7 they were holding a patient whose unit had just
8 deployed that morning to a training exercise at Ft.
9 Irwin. And the patient that they had was diagnosed
10 with varicella. And there was a lot of concern that
11 there may be an outbreak in this unit that was going
12 to be living out in the desert and training out in
13 the desert.

14 I called ahead to the preventive medicine
15 officer out there, and it did turn out there was not
16 a problem. But if you can imagine, these people had
17 loaded their whole unit and all of their equipment
18 and gone from Fort Drummond, New York to Ft. Irwin,
19 California, with a huge operation. And if they had

1 an outbreak of varicella at that point, their
2 training exercise could have been jeopardized.

3 AUDIENCE MEMBER: Is that really true that
4 probably 90 percent of these --

5 MAJOR LUDWIG: The truth of it would be
6 -- it might depend, first of all, on who the people
7 were who were still susceptible. If there were some
8 key people in the unit, the MCIC and the officer in
9 charge, for instance, or operators of certain types
10 of equipment, it could cause the unit to be
11 inoperable. I'm not saying that there would be so
12 many people affected, but the people that were
13 affected, depending on what the mission was, could
14 affect the operability of the unit.

15 DR. JOSEPH: What does the experience show?
16 How many of those 600 cases, hospitalizations a
17 year, are in clusters and how many are sporadic
18 cases?

19 MAJOR LUDWIG: I don't know the answer to

1 that right now. I do know that there are clusters
2 in basic and advanced training. And out of those
3 600 per year, I'm not sure. We may have some more
4 information from the Navy. Do you have a break-down
5 that would answer that percentage that are
6 clustered?

7 AUDIENCE MEMBER: I make one other comment?
8 The other issue is the contact bracing. What do
9 you do when you get an index case? You then have to
10 try to figure out who already is immune. And if you
11 can't, until you can get the data, you sort of put
12 them in isolation or quarantine.

13 I think you mentioned the long incubation
14 period for the varicella. It becomes an issue in a
15 health care setting depending on the unit force.

16 MAJOR LUDWIG: Right. And large outbreaks
17 could possibly overwhelm health care resources. I
18 guess I'm thinking in a deployment situation if they
19 best they have is a battle aid station or something.

1 Or in a place like Fort Drum, where there is no
2 hospital right there, they do have an admission to a
3 community hospital. But I think they have like a
4 ten-bed holding area at Ft. Drum. It's possible to
5 overwhelm the health resources depending on what's
6 there.

7 AUDIENCE MEMBER: Let me give you a little
8 insight on the outbreaks? Several years ago
9 -- (inaudible)

10 MAJOR LUDWIG: Commander Bayer is the
11 commander of the hospital here at Great Lakes. I
12 met Commander Bayer recently at a recruit health
13 care symposium. I'm glad he's here today.

14 Varicella is again -- some more points
15 about varicella and relevance to the Army or to the
16 military in general. It's a disease that's easily
17 transmitted. It's contagious during part of its
18 sub-clinical phase. And it's particularly
19 concerning for immuno compromised persons and

1 pregnant women.

2 The reason that those issues are
3 particularly important is because of some of the
4 occupations in the Army. Susceptible health care
5 and child care workers are at risk of acquiring and
6 transmitting varicella to higher risk persons. An
7 exposed person -- a susceptible exposed person can't
8 go to work, especially health care and child care
9 workers. They basically have to be furloughed.

10 And pregnant women in these occupations are
11 appropriately given alternate duty so that they
12 don't expose or potentially expose other people.
13 And that can cause quite a problem.

14 AUDIENCE MEMBER: Could you clarify what
15 you mean by contagious as a part of the pre-clinical
16 period?

17 MAJOR LUDWIG: Could I clarify it?

18 AUDIENCE MEMBER: Yes.

19 MAJOR LUDWIG: Before the rash develops,

1 before it's actually diagnosed as a case of chicken
2 pox, I think up to a week or so before the rash,
3 they are contagious. Are you disagreeing with that?

4 AUDIENCE MEMBER: It's a little longer, I
5 think.

6 DR. WHITE: It's usually around two or
7 three days where they're more contagious.

8 MAJOR LUDWIG: You might be having a progen
9 at that point, but you might not have gone to seek
10 the medical care.

11 AUDIENCE MEMBER: The point I'm trying to
12 make is that if you have to take the time that the
13 rash is identified, back up about three days and
14 that's the point that the person is able to transmit
15 within the unit or within the closed quarters if you
16 have that. Any other period of time, nothing is
17 going to happen until those people that are
18 susceptible have an opportunity for the disease to
19 become apparent.

1 MAJOR LUDWIG: And that's the time during
2 which they cannot work in their jobs.

3 AUDIENCE MEMBER: They can't do anything.

4 MAJOR LUDWIG: If they're health care
5 workers.

6 AUDIENCE MEMBER: Right. They're not going
7 to develop disease and they can continue to work
8 even if they're sera-negative.

9 MAJOR LUDWIG: Between -- let me clarify.
10 Let me see if I understand what you're saying.

11 AUDIENCE MEMBER: The disease doesn't
12 develop immediately following exposure.

13 MAJOR LUDWIG: Right.

14 AUDIENCE MEMBER: And if you're
15 susceptible, you still can continue your duties.
16 But there is a point in time which one doesn't know
17 if you're going to develop the disease and you may
18 have to be separated.

19 MAJOR LUDWIG: Right. It's a puzzle in a

1 sense to work out.

2 AUDIENCE MEMBER: Susceptible individuals
3 are taken out of health care duties for 21 days
4 after exposure.

5 MAJOR LUDWIG: I think that's pretty
6 standard.

7 AUDIENCE MEMBER: Twenty-one days is the
8 upper limit.

9 MAJOR LUDWIG: Okay. The issues of
10 particular military concern are to eliminate
11 outbreak in basic and advanced training. Here is
12 where herd immunity is probably more important than
13 individual immunity, whereas other susceptible
14 personnel may be -- I think it's clear that
15 individual immunity is more important.

16 You want to minimize the disruption to
17 basic training. And you also want to try to do
18 something to eliminate the outbreaks that are
19 occurring during the first two years of service.

1 There are three options that I could think
2 of for trainees when I was working out my cost
3 benefit analysis. The first one is really what the
4 current policy is, which is no vaccine intervention.
5 The second one is universal vaccination, which is
6 bring everybody in like we do with so many of the
7 vaccines and just give them all a shot.

8 And the third one is selective vaccination
9 based on -- I say here -- what I say here is
10 serology, because that's what I've settled on. But
11 basically based on some evidence of whether they're
12 susceptible or not.

13 I have two slides of cost benefit
14 assumptions. I'm going to kind of go through the
15 analysis rather quickly because it's complicated.
16 But there are some handouts and if we need more, I
17 can make more. I just want to go through the
18 assumptions that I made a quick review of the
19 calculations.

1 It said 130,000 new trainees per year. The
2 varicella susceptibility rate -- gross -- or
3 unadjusted susceptibility rate is 9 percent.

4 Vaccine immunogenicity, as mentioned, I
5 said with one dose. I picked 78 percent out of the
6 studies that I looked at. That's close enough Dr.
7 White's 75 percent.

8 And with two doses, 95 percent. The
9 estimated vaccine efficacy or the percent of sera-
10 converters who are considered protected on the
11 package insert -- this is for adults, not for
12 children. And as was mentioned, there aren't any
13 perspective studies with adults. So the best that
14 could be done is really an estimate of efficacy.
15 And the lowest it would be in the studies would
16 -- or the study showed 70 percent.

17 DR. POLAND: Was that based on two doses?

18 MAJOR LUDWIG: The cost per vaccine dose,
19 the catalogue price is close to \$40 per dose. The

1 federal schedule, supply schedule of cost I just
2 learned was 29.37 or something like that per dose.

3 The cost per antibody screen -- and this is
4 really important here and I'd like to talk about it
5 just a little bit is estimated at really under \$3.
6 Many of you know Dr. Patrick Kelly, who has
7 addressed this Board many times. He's been very
8 interested in antibody screening and the effect that
9 it could have on immunization policy.

10 DR. POLAND: Is that total cost?

11 MAJOR LUDWIG: Yes, I'm going to go through
12 it in a minute here. What the would cover is the
13 cost of the equipment amortized over a certain
14 amount of time a year, let's say; the reagents; the
15 administration cost of drawing the blood, which we
16 do already anyway; and running the test.

17 It's very inexpensive to run the test,
18 because -- the one that I'm familiar from Bayer
19 Whittaker, they have -- it's mostly automated. They

1 can run, I think, 150 samples at one time. It takes
2 something like 45 minutes. And the specificity and
3 sensitivity are both high. I think 88 percent and
4 95 percent or something on the order of very
5 acceptable.

6 So this \$3 is, first of all, a little bit
7 high. It's more like 267. And that's total cost.
8 Okay.

9 The illness factors in the assumptions, I
10 got cost per hospitalization day and cost per clinic
11 visit from Walter Reed Army Medical Center. And
12 these are supposedly Army wide. They were for last
13 year, but I can't imagine they did anything but go
14 up. So I just left them with the same numbers.

15 The cost per duty day for in-patient and
16 out-patient is particularly important, because it's
17 very hard to estimate what -- it's definitely an
18 indirect cost, what you call -- you know -- what
19 does it cost the Army to have a patient or person

1 out of his normal duty?

2 Well, all I did was take the lowest
3 possible base pay for the ranks represented in our
4 in-patient data and came up with a daily base pay.
5 That's without any bonuses, so this is definitely a
6 conservative estimate of \$33. It doesn't take into
7 account anything like what it might do to the unit
8 or patient suffering or any of those costs that are
9 extremely difficult to estimate.

10 The out-patient was much, much more
11 difficult to estimate. So, again, I made it
12 extremely conservative. But the difference is that
13 the in-patients are of lower rank and the out-
14 patients tend to be of higher rank.

15 Number of in-patients per year is an
16 average. And the number of out-patients per year, I
17 mentioned before how I got this. And I'll also
18 mention -- I'll repeat that the analysis is
19 insensitive to this number.

1 The number of lost duty days per varicella
2 patient is seven. That's an average of six or
3 median hospitalization days and one con leave day,
4 convalescent leave. And I think from people that
5 I've talked to, the convalescent leave is likely
6 much longer than that for most people.

7 But I got this number off of the discharge
8 summaries. And the discharge summaries, a lot of
9 the people -- a lot of the positions don't even put
10 down con leave. So I suspect it's longer than that
11 for an average.

12 All right. The calculations -- I'll be
13 glad to talk these over with anybody. They are kind
14 of complicated. I'll just go through them kind of
15 quickly.

16 Hospital costs per year -- and that star
17 refers to this small equation down is how I figured
18 hospital costs per year.

19 Plus the cost of lost duty days. Plus the

1 cost of clinic visit, times two, because every sick
2 patient get at least two clinic patients, times the
3 out-patients and in-patients per year.

4 This is what it costs for no vaccine
5 intervention. That's what we do now.

6 One of the factors in the previous equation
7 was yearly cost of lost duty days. So this is how I
8 figured those. Hospitalization and con leave days,
9 I put a little note down here that that's total lost
10 duty days. Times the in-patients per year, times
11 the cost of their in-patient duty day plus out-
12 patients per year times the cost of their duty day.

13 And here is how I estimated the varicella
14 out-patient cases per year.

15 The second training option is universal
16 vaccination. This was an easy calculation to make
17 and an easy option to rule out. The number of
18 recruits per year times the vaccine cost plus the
19 cost of vaccine failures.

1 Here is how I figured vaccine failures.
2 It's one minus the percent of soldiers completely
3 protected from varicella times the cost of no
4 intervention.

5 I mentioned the percent of soldiers
6 considered completely protected from varicella.
7 It's one minus the susceptibility rate or one minus
8 9 percent. Plus the estimated vaccine efficacy
9 times the vaccine immunogenicity times the
10 susceptibility rate.

11 Obviously my saying this doesn't make sense
12 unless you see the parentheses and brackets and so
13 on, but I think you can at least have a rough idea
14 of how I did this and I can go through it more
15 later.

16 All right. Selected vaccination. Number
17 of recruits per year times the screening cost plus
18 the susceptibility rate times the vaccine cost and
19 plus the cost of vaccine failure.

1 The result. These are net costs; that is,
2 direct and indirect costs. Again, it doesn't
3 include the cost of suffering and some of those less
4 tangible factors.

5 No vaccine intervention. That is what we
6 do now. Costs the Army \$2.6 million per year for
7 varicella.

8 Universal vaccination with one dose would
9 be \$4 million. With two doses, it would be almost
10 \$8 million. That's why I said that one was a fairly
11 easy one to rule out. In the old days, it might
12 have been considered that was the easiest thing to
13 do so we'll do it anyway. I don't think these days
14 we could look at those kinds of numbers and choose
15 that option.

16 Selected vaccination. With one dose, it
17 was .8 million and with two doses it was 1.2
18 million. Now, remember that selected vaccination
19 includes the cost of screening.

1 I think things might have changed a little
2 bit since then.

3 So what I have for policy recommendation
4 -- let me go back first. I want to point out not a
5 huge difference in cost here between one doses and
6 two doses of the vaccine. But I want to add to that
7 the disruption to training, which we cannot minimize
8 what is considered disruption of training. To bring
9 people back. The complication of trying to figure
10 out who needs to go back to the processing station
11 to get a second vaccine.

12 And I worked out some calculations which
13 -- Percent of soldiers considered protected from
14 varicella. I should have another slide here that
15 showed what I came up with for this.

16 With two doses, if you take -- with this
17 calculation, which I think takes into account
18 everything you need to think of when you're trying
19 to figure out how many of the soldiers are actually

1 protected -- completed protected from varicella, it
2 worked out to -- and remembering, of course, that 91
3 percent of them are already immune from wild
4 disease.

5 It came out to a difference of only 2
6 percent. And something like 96 percent and 98
7 percent completely protected during the -- up to a
8 year or maybe two years after the vaccine, of
9 between one dose and two doses. That is, after one
10 dose, it looked like 96 percent of all of the
11 soldiers would be completely protected against
12 varicella.

13 And with two doses, it was like 98 percent.
14 Yes, ma'am.

15 DR. STEVENS: What's the timing of the
16 second dose and how much flexibility is there?

17 MAJOR LUDWIG: It is at least four to eight
18 weeks after the first dose. And the flexibility I
19 think is not -- the outer limit I'm not sure has

1 been determined. Dr. White, do you know?

2 DR. WHITE: We have vaccines to people who
3 have converted to sera-negative for several years
4 after the immuno vaccine. They usually sera-convert
5 at least --

6 MAJOR LUDWIG: The recommendation --

7 DR. SCHAFFNER: Just to pursue that line of
8 thinking, we saw today in video at least here in
9 Naval training, toward the end, people had a few
10 days off. They were hanging about playing guitars.
11 So, I mean, one could immunize then. And I think
12 anticipating your next slide -- well, Emerson said,
13 a foolish consistency is the hobgoblin of small
14 minds.

15 But I think you might get into some
16 consistency problems on how you dealt with active
17 duty personnel versus recruits. And, for example,
18 if you're concerned about making sure that women of
19 child bearing age --

1 MAJOR LUDWIG: May I go on to the next
2 slide?

3 DR. SCHAFFNER: Please. -- only get one
4 dose if they're recruits, but two doses if they're
5 active duty. Some people are going to be puzzled by
6 that.

7 MAJOR LUDWIG: Okay. Let me go through
8 these and say what I have to say. Then I'd like to
9 open up for discussion, because I would value the
10 comments. We haven't set the policy. Or, I should
11 say, they haven't set the policy. The policy has
12 not been set for the Army, yet. And these are
13 important considerations.

14 I'd like to recommend that we test new
15 accessions for antibody to varicella. This is an
16 ELISA test. It is a program that would have to be
17 set up. And that takes me back to a question I want
18 to address -- I want the Board -- I would like the
19 Board to address. And, that is, is it worthwhile

1 setting up a new program like that. It would be
2 some initial effort. I don't think a tremendous
3 effort, since we already draw blood for serum on
4 these soldiers and the equipment is not expensive
5 and is available. But I think it's something that
6 has to be addressed.

7 An additional point for that is that some
8 suggestions about testing -- and I think the Navy
9 already does this, test for MNR.

10 DR. PARKINSON: The Air Force does.

11 MAJOR LUDWIG: The Air Force does. Okay.
12 I knew somebody did. But anyway, if we added
13 testing for antibodies for those diseases, as well,
14 it's been suggested the money we would save by not
15 vaccinating people who don't need it would easily
16 pay for the equipment as well as the whole varicella
17 program. So I think that's something to keep in
18 mind.

19 I'm suggesting and open for discussion new

1 trainees who lack antibodies to get one dose of the
2 vaccine when they come in.

3 By the way, the new accessions could be
4 tested at the MIP station. That's one option. Or
5 at basic -- when they arrive at the basic training
6 centers.

7 I'm suggesting that other susceptible
8 personnel receive two doses. Remember, the point
9 that I made is that it's a difference between herd
10 immunity and individual immunity. And what I'm
11 suggesting is that the trainees -- the trainees in
12 the population, we're interested in a herd immunity;
13 whereas in the others, even one case could lead to
14 some very serious consequences. I'm suggesting two
15 doses.

16 This would include active duty -- these
17 categories of active duty and Department of Defense
18 civilians.

19 And considering active duty women of child

1 bearing age, of course, that might mean -- and we'd
2 have to consider whether that means that all females
3 within basic training would get two doses anyway.

4 As you remember, the difference in cost
5 between one and two doses was not huge. The main
6 consideration is the disruption to training.

7 And these I put in for completeness,
8 dependent children, follow the recommendations of
9 the American Academy of Pediatrics and other family
10 members of the ASIP.

11 Let me just repeat my questions to the
12 Board and make sure it's very clear. Can we
13 consider a non-standard use of the vaccine? I think
14 that discussion has already been done.

15 And I think we need to consider
16 establishment of antibody testing at either MIPS or
17 other basic war training.

18 Before I take any questions, I do have
19 Commander Gilcotter has a little bit of additional

1 data from the Navy.

2 How are we time-wise? Are we okay time-
3 wise?

4 COMMANDER GILCOTTER: Okay. I'd like to
5 thank Martin White of Navy Health Research Center in
6 San Diego who provided me with in-patient
7 hospitalization data and on Navy enlisted personnel.
8 The data you see here is only for Navy enlisted
9 personnel. I do not have Marine Corps data. I do
10 not have Navy officer data. But those numbers are
11 relatively small.

12 The Navy enlisted population seems to be
13 the area where we have a fair amount of problems.

14 The data here is for the period of 1980
15 through 1994. In this period of time, we had almost
16 9,000 hospitalizations for chicken pox. Almost 20
17 percent of the cases were relatively severe or had a
18 potential severe complications, post-varicella,
19 encephalitis and varicella hemorrhagic immunitis.

1 I do not know the degree of severity.
2 These are what they were coded for within the
3 database, and so that's how they fall out.

4 How does this break out by sex? Well, as
5 you can see, the vast majority of cases is in males
6 than in females. But then again they represent over
7 this period of time over 88 to 90 percent of the
8 population.

9 But the rate you can see is also higher in
10 males than in females.

11 How does it break out by rates? Well, the
12 rate in the caucasians was 91 per 100,000. You can
13 see in blacks or other or unspecified, it was a rate
14 of 230, 228-230. These were probably Filipinos,
15 Puerto Ricans, a few Hispanics.

16 So we have a sub-group that is at higher
17 risk than white males.

18 DR. WHITE: What time period is this?

19 COMMANDER GILCOTTER: This is 1980 through

1 1994.

2 DR. JOSEPH: A 15-year period.

3 COMMANDER GILCOTTER: Essentially the same
4 period that Dr. Ludwig showed. These are the rates.
5 And you'll see this is very similar to what we saw
6 in the Army. Now, for some peculiar reason, the
7 Army data has leveled out in five quarters on a rate
8 here with the Navy, once again fell back down to a
9 baseline.

10 These -- as we look at cases, they fall
11 about the same way. But you can see here '87
12 through '90 was a very severe problem. And I'll be
13 pointing out that a large part of this problem was
14 right here on the base on which you sit right now.

15 Who got the disease? Who was hospitalized?
16 As you can see, the primary problem was within our
17 junior ranks, E-1s, E-2s, and E-3s. E-1s, very high
18 rate. Who were they? They're our recruits, right
19 here in the training center with MCRD and RTC

1 Orlando and San Diego when we had those recruit
2 training centers.

3 The rates are very high when you consider
4 that when you look at the number of cases it would
5 flatten out a little bit. But you have to realize
6 that our E-1s are E-1s for a short period of time.
7 Many of them when they finish boot camp go on to be
8 an E-3, go on to school or something like that. So
9 it works out to be about six months as an E-1, nine
10 months as E-2, six months as E-3, before you're
11 eligible to be promoted. There are a lot of E-3s
12 with a number of years in.

13 But you can see the rates are very, very
14 high in our recruit populations. It falls off a
15 great deal.

16 If you'd look at this by age, you'd see the
17 same kind of curve.

18 Now, as I said, Great Lakes is a large
19 contributor to these curves, so if we looked at the

1 cases -- these are cases, not outbreaks, but cases
2 in that same time period. This is 1987 through
3 1994. The data I have from the database was
4 hospitalizations overall and not by hospital. I got
5 good data from Great Lakes because they started in
6 1986 when they saw that Pete started losing his
7 -- excuse me -- good recruits and have been keeping
8 the data pretty well ever since.

9 So you can see the dark and the black is
10 all other cases in all other facilities and
11 hospitals. The gray is what has happened at Great
12 Lakes.

13 So you can see in most years since '87,
14 somewhere between a third and a half, just about all
15 of the cases of chicken pox had happened right here
16 at RTC Great Lakes.

17 In 1989, I came up here to look at the
18 problem when it was first and initially identified.
19 So I tried to take a look at what was happening

1 here as well as what was happening at the other
2 training facility.

3 So in 1987 and 1988 we have these other
4 cases and the rate -- this rate is given as 1,000
5 -- I mean, the number for 1,000 recruits.

6 And you can see that once again the Great
7 Lakes -- the rate in Great Lakes was about five
8 times as high as any other training facilities. The
9 training facilities are the place where there is the
10 biggest problem for this as least as far as cases
11 being hospitalized.

12 The date -- there is supposed to be a
13 little asterisk here. The data for NTC and NCR San
14 Diego, that represents all hospitalizations at those
15 hospitals. So there may be a little bit high.
16 There may be a few non-recruits in there, but for
17 the most part, those were recruits in those
18 particular settings.

19 Now, it's interesting in what I found when

1 I came up here at Great Lakes. I was able to get
2 data for hospitalizations for a year and I got data
3 for the divisions and companies that were -- these
4 recruits came from. And in piecing those two pieces
5 of data together, I was able to look closely at 140-
6 some-odd cases in this group that occurred in the
7 period of February of '88 to February of '89.

8 I had eight divisions and 71 companies
9 included, which was 143 cases. Seventy-two percent
10 of those cases occurred in the latter half of
11 training with the onset of disease on the 39th day
12 of training. So it's kind of interesting with this
13 much disease circulating in the camp, you'd think
14 the people would come down if they were susceptible
15 right away. But they did not. They got well into
16 their latter half of training before they would come
17 down as a case.

18 Secondary transmission in companies was the
19 exception rather than the rule. Twenty-seven

1 percent of the cases was a single case that showed
2 up at a company. And in 38 percent of the cases,
3 the first case was the index case of a group that
4 was apparently exposed at a single time. Several
5 came down.

6 So -- and only 30 percent of the cases, of
7 the case companies had secondary transmissions. Two
8 companies experienced a third generation of cases.

9 So even with the very high rate that we saw
10 at Great Lakes at that time, we still had -- the
11 translation was the exception, rather than the rule.
12 But still with this many cases there needs to be an
13 intervention.

14 I wish that you could have gone through a
15 barracks today. We saw a lot of things here at
16 Great Lakes. But you did not see the barracks in
17 which these people live. If you saw that, you would
18 understand the tremendous problem we have. The
19 barracks are an open bay barracks, a little bit

1 longer this long, about as wide -- about as wide,
2 but a little bit longer. There is no air
3 circulation. There is no ventilation.

4 The heat is by steam heat, regulated steam
5 heat. The temperature control is how many windows
6 are open. I dare say in February there are not too
7 many windows open.

8 So you have a closed bay with 80 people
9 living in it, no air movement. They're there all
10 together, all of time, that they're in there.
11 They're together all of the time wherever they go,
12 but particularly in that particular setting in the
13 bay, in the barracks, they are particularly
14 vulnerable. A very, very bad situation.

15 As Dr. White leaves, I would like to say I
16 tried to get these folks on a protocol back at this
17 point in time. At that time, all of the protocols
18 were closed and not amenable, apparently all wanting
19 to look at it later, at which point the rate had

1 fallen enough that it didn't look like it was worth
2 following. But I just wanted to thank you.

3 DR. WHITE: Thank you.

4 COMMANDER GILCOTTER: The situation in
5 Great Lakes is my biggest concern. And I think you
6 can see from the data here it is a problem. I
7 concur, I think, in general with the recommendations
8 Dr. Ludwig made. I believe that for protection of
9 my troops, a single dose at boot camp would protect
10 and provide the herd immunity necessary to prevent
11 most of these cases of varicella, which are
12 occurring, I believe, in recruit camp.

13 DR. KULLER: We have some questions. We're
14 going to have to move fairly quickly, because we're
15 running out of time.

16 DR. ASCHER: Do you want to tell us about
17 the schedule so we know what's going to happen?

18 DR. KULLER: We'll do it in about 15 more
19 minutes. Okay.

1 DR. POLAND: What's the sensitivity and
2 specificity?

3 MAJOR LUDWIG: I mentioned 88 and 90. I
4 have to look up the study. It was a study that
5 Patrick Kelly did with some other people.

6 DR. POLAND: Those are sufficiently low
7 enough that with this low number of susceptible, I
8 suspect you're going to be immunizing a lot of false
9 negatives and converts.

10 DR. ASCHER: You can do better than that.
11 The problem is the commercial assay is not --

12 DR. POLAND: But that's because --

13 DR. ASCHER: Yeah, well, except --

14 DR. POLAND: The exceptions are sensitive
15 to a \$3 cost.

16 DR. ASCHER: You can make it yourself.

17 MAJOR LUDWIG: It belongs to that period of
18 history.

19 DR. POLAND: Well, that's the point. I am

1 concerned that you would use it in a non-standard
2 way. You have it modeled here, but have you
3 considered just asking whether they've had chicken
4 pox?

5 MAJOR LUDWIG: Yes. Several people have
6 asked me that.

7 DR. POLAND: And testing only those that
8 say no.

9 MAJOR LUDWIG: I think it's just a matter
10 of a short period of time before people learn that
11 if they say, yes, I have it, they don't get an extra
12 shot.

13 DR. ASCHER: Sharon, could you share with
14 the Board -- there is a question of whether you
15 order the test.

16 MAJOR LUDWIG: If they say -- you know,
17 what you're suggesting is that instead of testing
18 the serum, if you just ask them.

19 DR. ASCHER: No, no, you're drawing the

1 blood. You're going to have the blood on file for
2 the HIV. If they say they've had chicken pox, you
3 don't test them.

4 MAJOR LUDWIG: If they say --

5 DR. POLAND: If they say no or don't know.

6 MAJOR LUDWIG: Yeah, that was another
7 consideration. I mean, we'd consider it but it adds
8 another step to the logistics of figuring out how to
9 deal with this stuff in a non-uniform way for all
10 recruits. I decided that to me it seemed simpler to
11 standardize that and not ask for that history.
12 Somebody else may feel differently.

13 DR. ASCHER: The serology -- I won't
14 belabor it, but we're doing the Haines serology now
15 and we made our own reagent and it's easy to do.
16 And we do it for about \$4 on contract. But the
17 commercial reagents are not suitable for this large
18 scale screening because of what you say. And if you
19 want to --

1 DR. POLAND: I'll figure it out for you,
2 but you're going to --

3 MAJOR LUDWIG: I have to tell you the
4 numbers from the study. I have them over here. I
5 can look them up, but I don't know exactly what they
6 are.

7 DR. KULLER: I think your cost analysis was
8 interesting, but I don't think it really is very
9 meaningful. Or maybe it is. You know, the
10 presumption is that there would be about 3650
11 hospital days due to chicken pox, which means that's
12 about ten beds, 365 days of ten beds.

13 Now, if your analysis was -- the analysis
14 that you're using is realistic, it would suggest
15 that if we did the vaccine, that the Army would
16 close ten beds and all of the people attached to
17 them. But we know that's not going to happen, so
18 that in essence the savings to the military are non-
19 existent.

1 The only savings to the military that would
2 occur is that now this is different than the savings
3 due to the troops being out of service. There is no
4 question, therefore, of that situation potentially.

5

6 But even there, the money saving is kind of
7 limited because it would suggest that because they
8 weren't out of -- didn't have to be recycled, the
9 number of support people within the training
10 facilities could be reduced by X amount.

11 Now, if the military said they were going
12 to close ten beds and all of the people attached to
13 them, then I would agree. But I suspect -- I
14 figured out that the cost is really more close
15 -- for the Army is closer to perhaps \$100,000, which
16 is really the cost of the \$33 a day plus the X days.

17 MAJOR LUDWIG: And post-benefit analyses
18 are always controversial for that reason, as you
19 know, because there are so many factors that you can

1 factor in and factor out. And indirect costs are
2 the most controversial.

3 My boss, Dr. John Brunnage, who will be
4 here later, made that exact same point when I first
5 presented this. And the way that I addressed it
6 -- and I'll just throw it and you can think whatever
7 you think. But it would take a period of three
8 years before it was recognized that that many -- let
9 me say that that many cases were actually avoided
10 once we got that program going.

11 And if that's the case, then the budgets
12 can be altered. So it may not be the very first
13 year that you would actually alter the budgets,
14 change the manpower or the beds or however you want
15 to do it.

16 But I'm imagining that in the long term it
17 would show up in the --

18 COMMANDER GILCOTTER: At Navy Hospital
19 Great Lakes, there is a chicken pox ward that is

1 open about -- in what, November? About November.
2 And it stays open until about April. And it is
3 maintained for six months of the year, one ward of
4 chicken pox cases.

5 AUDIENCE MEMBER: There is not a chicken
6 pox ward.

7 COMMANDER GILCOTTER: In '87 to '88, there
8 was.

9 AUDIENCE MEMBER: There might have been at
10 that time.

11 DR. KULLER: But I think right now the
12 number of cases --

13 AUDIENCE MEMBER: At the present time, you
14 have four rooms that are negative pressure rooms
15 that are not -- wherever we find varicella, there is
16 --

17 COMMANDER GILCOTTER: At one time there was
18 a ward that was operated six months out of the year
19 at Great Lakes.

1 MAJOR LUDWIG: Colonel Diniega has been --

2 COLONEL DINIEGA: Just two comments. One
3 is that your data shows that 24 percent of the cases
4 that occurred in the second month of basic training.
5 So only 150 cases a year occurred during basic
6 training.

7 You know, is Bruce Jones in the room? I
8 remember exactly how much of that 150 that are
9 recycled in the training arena, training entry
10 arena, what comparison.

11 The other comment I had was, could you
12 share with the group two pieces of data? One is the
13 problems we've had with Puerto Rican troops from
14 Puerto Rico. And, two, Dr. Kelly's results in -- he
15 did the childhood immunization screens of selected
16 recruit populations several years back. But he did
17 find a difference in immunization from protection
18 rates by race or ethnic groups.

19 MAJOR LUDWIG: I'll address the first one

1 first, because it's the one that I am the most
2 familiar with. I think Dr. White touched on it.
3 The study by Janice Longfield and some others, of an
4 outbreak and some other data that showed that Puerto
5 Ricans in particular -- that is, Puerto Ricans from
6 Puerto Rico and possibly other populations from
7 tropical islands have higher rates of susceptibility
8 to chicken pox. And that rate, I believe, was 40
9 percent -- up to 40 percent susceptibility in that
10 population.

11 It's been suggested by a couple of people
12 that we focus on that population. And my comment to
13 that is, although 40 percent of that population was
14 susceptible, that's only a small percentage of the
15 total susceptible population in the military.

16 As far as Dr. Kelly's results, I'm familiar
17 most with his work on the antibody screening. But I
18 don't think that I know what the point that you're
19 making is. Can you clarify it?

1 COLONEL DINIEGA: Well, I think we found
2 that pretty much sustained micro-sensitive
3 susceptibility in the recruit population.

4 MAJOR LUDWIG: To varicella.

5 COLONEL DINIEGA: To varicella.

6 MAJOR LUDWIG: Right. That was from his
7 study.

8 COLONEL DINIEGA: And 6 percent in whites
9 and 15 percent -- and 20 percent in other ethnic
10 groups.

11 MAJOR LUDWIG: Right. And it's not, of
12 course, split out so that you can -- the only -- the
13 studies that have been done shows that it's
14 something like 40 percent susceptibility among
15 native Puerto Ricans, it was in an outbreak. So it
16 wouldn't show up in a population where you've got
17 black, white and other.

18 DR. KULLER: When you do the ELISA, do you
19 do it on the spot, so that that -- it's immediately

1 decided whether the person is going to get a shot or
2 not?

3 MAJOR LUDWIG: No.

4 DR. KULLER: So in other words, they'd have
5 to come back to the --

6 DR. ASCHER: Do it with HIV.

7 DR. KULLER: They'd have to come back to
8 get the shot.

9 MAJOR LUDWIG: Right. If you can do in the
10 first couple of days when they're doing -- it takes,
11 I think they said, two full days for medical in-
12 processing. So if you can fit it into that
13 schedule, it's not a disruption.

14 Anything that requires them coming back
15 again is a disruption.

16 DR. KULLER: But it must be a logistic
17 disruption, because somebody has to do the test,
18 enter it somewhere.

19 DR. ASCHER: No. You add it to the HIV

1 contract. You just say, do HIV and --

2 DR. WOLFE: Well, if it's done at MIPS,
3 that would be the best.

4 DR. ASCHER: That's what I'm saying. And
5 then you can --

6 DR. WOLFE: Then you can test four times as
7 many people than would show up.

8 DR. KULLER: In other words, is it easier
9 to test kids as a routine concept of giving
10 everybody the shot, which is part of the routine,
11 than going through its administrative course.

12 MAJOR LUDWIG: I feel strongly about that.

13 DR. PARKINSON: As an Air Force perspective
14 on this, we've been doing selective immunization for
15 years. It's been a policy that all recruits receive
16 screening serologies for measles and rubella. And
17 we only selectively immunize those who are
18 susceptible. And we would assume without going
19 further into it -- Gary is over here laughing. He's

1 heard it all before. But we don't really have -- so
2 much of what I see on this, my take on this is a lot
3 of this is environmental.

4 I mean, most of all of DOD's problems
5 completely relate to varicella on our Air Force
6 base. And it has to do with the way that we bring
7 recruits and the Navy has a higher proportion of
8 people from central Caribbean countries, from Puerto
9 Rico, than does the Air Force, for example. We
10 train a lot of people in San Antonio.

11 The other rates at Orlando, NTC San Diego,
12 probably are no higher than any other rates any
13 place else in the country for people who go off to
14 college.

15 So you've got the environmental piece up
16 here, which is one issue.

17 The other issue of selective immunization
18 is we could easily incorporate this for another two
19 or three bucks into our panel at Wilford Hall, that

1 we routinely do for our people.

2 And I think the other thing we're kind of
3 losing track up here in the joint operation, which
4 increasingly we're all doing together. It's as if
5 we have one force, not three. So one of the things
6 we should be thinking of as we're thinking of this
7 policy is would it make much sense to have -- we
8 should have some level of people protection, whether
9 that's through universal vaccination or selective
10 immunization with those found to be susceptible.

11 And generally our experience in the Air
12 Force is excellent in both cost benefit ratios for
13 measles and rubella. This would probably be even
14 more cost effective for us because the background
15 level of protection among the general population is
16 that much higher. It's even the smaller group of
17 people who are likely to need that immunization.
18 It's more universal.

19 DR. ASCHER: At our last meeting when we

1 discussed hepatitis A, it was clear that a single
2 program would be cost effective -- or may be cost
3 effective for hepatitis A. If you put the two
4 together, they would share costs.

5 MAJOR LUDWIG: And I would make a comment
6 that it would cost a couple of bucks extra if you
7 added varicella to the screening that you're already
8 doing. My understanding from Bio-Whittaker is that
9 this -- disregarding for the moment administrative
10 costs -- that is, the manpower to run the tests and
11 so on, the cost of one test including the cost of
12 all of the equipment and reagents and so on was only
13 a dollar per test.

14 So if you've already got the equipment, it
15 would be less than a dollar per test to add it to a
16 program that's already set up for an antibody test.

17 DR. ASCHER: And then do anything else free
18 on top of that, almost, because you've got the
19 blood.

1 DR. BAYER: We independently verified the
2 statistics.

3 MAJOR LUDWIG: I think the -- in my mind,
4 the idea of doing the antibody testing is not
5 questionable in my mind. I mean, I think that's the
6 way we need -- we need to switch that. The question
7 about whether to use one or two doses of varicella,
8 it was brought up earlier. And I think it's an
9 important point of vaccinating.

10 I do think that if it's decided that two
11 doses would be preferable for everyone, then it's
12 possible we need to look at giving the second dose
13 as they go to their next assignment or some way fit
14 it in so it's not a disruption to the cycle.

15 COLONEL TAKAFUJI: We have time in their
16 last week. They have time in their last week as
17 they're preparing for their graduation.

18 MAJOR LUDWIG: And it isn't that many
19 people that would have to do it any way.

1 COLONEL TAKAFUJI: Basically a sick call
2 visit. That's all it is.

3 DR. KULLER: We probably have to move on,
4 but I would suggest in your modeling of costs that
5 the largest, most important costs are going to be
6 the costs of disruption -- that are measurable costs
7 are going to be the cost of disruption of activities
8 within the military, I would bet. And I would like
9 to see some data where you could show you could
10 estimate the reduction of hospitalization costs.
11 It's such a small piece of the action, it's going to
12 be very hard -- and it's so widely distributed.

13 If there was a unit open here and there is
14 a lot of cases in one place, you'd be correct. But
15 the reality is that you're talking about ten days
16 and ten unit people going with that. And they're
17 scattered all over the military, so that it's very
18 hard to ever show an effect.

19 But there is a big effect -- potential

1 effect if by chance you disrupt the unit training or
2 subsequently somebody got on a ship or something and
3 you got a bunch of cases that caused some problems
4 of this sort.

5 In reality, most of these are fairly mild,
6 I think. So that's where --

7 MAJOR LUDWIG: I have that modeled on a
8 spreadsheet. It would be interesting to figure out
9 --

10 DR. KULLER: The only reason I'm saying
11 that is you might be better off getting the two-shot
12 approach only because you want to maximize the
13 increase in risk of infections of a clinical
14 disease, which can disrupt the activities rather
15 than worrying about it as a hospital cost.

16 DR. BROOME: If it's primarily 25 percent
17 of the cases are in recruits, it's not going to be
18 spread across -- evenly across bases. And we didn't
19 see the seasonality in terms of whether there is a

1 particular concentration. You know, just saying
2 that the savings on hospitalizations may be more
3 than a random distribution.

4 DR. KULLER: Oh, sure, but you're still
5 having it across three or four recruit bases, so
6 that's the equivalent of about less than a -- you
7 know -- two beds or so and whatever goes with it.
8 That's very, very hard to --

9 DR. BAYER: You can eliminate all of the
10 rest of those hospitalizations.

11 DR. JOSEPH: If the conditions that you
12 describe are true, the effective solution is almost
13 certainly to give everybody in all services one shot
14 with no prior history.

15 DR. ASCHER: These are also not
16 hospitalizations in the usual sense. These are just
17 separations.

18 DR. BAYER: You're correct.

19 DR. ASCHER: But it's not the IVs and all

1 of the overhead of antibiotics and stuff that you
2 normally associate with hospitalization. So the
3 overhead is way down.

4 DR. BAYER: That's correct.

5 DR. ASCHER: Would you like the disease
6 control committee to draft up a little statement?

7 DR. KULLER: Yeah, why don't we put that in
8 tomorrow morning.

9 DR. ASCHER: Brief statement.

10 DR. KULLER: Brief statement in tomorrow
11 morning. We've got to go on.

12 COLONEL JONES: In answer to Colonel
13 Diniega's earlier question, you know, it's hard for
14 me to see the great concern about an illness that
15 affects maybe 600 people per year, maybe 1800 when
16 we have the condition of injuries and the entire
17 budget spent on injuries is only \$500,000 in the
18 Army and it affects -- it propels higher every
19 cycle.

1 DR. KULLER: We're going to go on now to
2 -- I was saying that this is the best continuing
3 education course that I've had. It's quite
4 intriguing. We'll go on now to meningococcal
5 vaccines.

6 (A brief recess was taken.)

7 DR. KULLER: We're going to go on to Ebola
8 next. Don't get confused. This is not
9 meningococcal.

10 DR. TAKAFUJI: I'm Ernie Takafuji for those
11 of you are not familiar with me. I'm Commander of
12 the USAMRIID right now. In the USAMRIID, we deal
13 with many of these exotic infections, so it's
14 appropriate that we've been discussing this from a
15 USAMRIID perspective. But I want to at the
16 beginning first of all mention that this
17 presentation is really a presentation on behalf of
18 Dr. Peter Jarling who is my senior research
19 scientist at USAMRIID, as well as others who are

1 involved with the investigation of the Ebola crisis
2 that recently occurred.

3 And part of the investigating team includes
4 people from WHO, as well as the Centers for Disease
5 Control and Prevention.

6 The virus that we'll be discussing this
7 afternoon is Ebola or Ebola, depending on where
8 you're coming from -- if you're British or if you're
9 American, I guess. It's a filamentous looking
10 virus, as shown here. And it belongs -- the whole
11 category of viruses that are commonly referred to as
12 filoviruses because of the filamentous structure.

13 Filoviruses are zoonotic infections with
14 primates being particularly at risk. And, hence, of
15 course man being a primate, it's no wonder that
16 we're seeing some disease in human populations.

17 It's an RNA virus and there are some things
18 in the epidemiology that leave much to be desired
19 about these viruses, however. One being that there

1 is no natural host that has yet been identified.
2 And the fact that there are outbreaks that are
3 occurring, but the roots -- the routes of
4 transmission are ill-defined. We know that there is
5 direct person to person type contact, as well as
6 contact through blood and blood products.

7 But the issue that is probably one of the
8 most controversial has to do with the aerosolization
9 of this virus. It's very clear in a laboratory
10 setting that this virus can be easily aerosolized,
11 and indeed that does cause some issues to be raised,
12 especially when you're discussing a natural outbreak
13 and the risk of transmission.

14 As I'll mention a little later on in terms
15 of other routes of transmission, one of the concerns
16 has to do with ingestion. At the next AFEB Board
17 meeting, if you so desire, we will give you a much
18 more detailed update in terms of our research that's
19 continuing on.

1 But one of the concerns that I've had is
2 the possibility of ingestion of this virus. And, in
3 fact, some of the preliminary information we have on
4 simeangous monkeys does indeed confirm the fact that
5 it takes very little virus to be ingested to cause
6 infection. So, therefore, there is another route of
7 potential transmission.

8 There is no vaccine currently available and
9 there are no identified effective anti-viral drugs
10 at this point in time.

11 In terms of outbreaks that have recently
12 occurred, this is a synopsis. And these are in your
13 handouts of outbreaks that occurred in Zaire, going
14 back in 1976 when we had a large outbreak of 277
15 cases with a 92 percent mortality. Around that
16 time, there was also a second outbreak with a
17 different strain of Ebola in Sudan with lower
18 morbidity and mortality associated with it, but
19 nonetheless a significant outbreak.

1 And in 1977 another outbreak and again in
2 1979 and so forth, leading up to 1989 when we had
3 the problem with Reston, Virginia with Hazelton
4 Laboratories having an outbreak that was identified
5 to be a non-pathogenic from what we can best
6 determine -- realizing our numbers are small, a
7 less pathogenic or non-pathogenic strain of Ebola.

8 Finally, into 1995, where as of June we had
9 293 cases identified with an 80 percent mortality.
10 This is a map of Zaire. And just to give yourself a
11 perspective in terms of what has been happening,
12 back in 1976 when we had the outbreaks of Ebola that
13 are occurring in the northern portions of Zaire,
14 they occurred in the Yambuku region up here, near
15 where you see Mumba, this general region as well as
16 towards Sudan. That's where the disease outbreaks
17 were.

18 Recently when we had the military
19 deployment to Rowanda with the refugee situation,

1 there were some concerns raised -- and we had some
2 concerns, because you can see the proximity. No one
3 talked about it, because it never became a problem,
4 but we were very much concerned about the fact that
5 if we had troops living in the area or if
6 populations were migrating further into Zaire, that
7 there might be a potential risk.

8 Now, the area of involvement in 1995 is an
9 area called Kikwit. It's not shown here on the map,
10 but it's down here. So you can see it's pretty far
11 south.

12 What is important to remember about the
13 Kikwit outbreak is that the virus that we see and we
14 have isolated from this region is basically, with
15 the exception of maybe about four nucleotides,
16 basically identical to the strain that we saw in
17 Rambuku in 1976. So it's basically an identical
18 virus that seems to have reappeared for reasons that
19 are unclear way down south in this country.

1 This is a picture of Kikwit. And I must
2 say that these pictures were just recently provided
3 to me by Russ Coleman, who is one of the
4 immunologists from USAMRIID who was recently in
5 Zaire and has come back. And he will be giving you
6 an update at some future time. So I'm not going to
7 show some of his -- all of his slides. I'm going to
8 save the best for him to present to you.

9 I just want to give you a feel of the
10 environment that we're discussing as we talk about
11 the Kikwit area.

12 As you can see, it's really not that bad a
13 place in terms of remoteness and distance from
14 civilization. It's got some modern conveniences.
15 It's got some westernization influences and so
16 forth.

17 But the area immediately outside the area
18 of Kikwit becomes much more rural. But this is not
19 really deep jungle yet. This is really on the

1 fringes of the jungle. And the disease appeared to
2 have occurred in this region for unexplained
3 reasons.

4 The area, frankly, is relatively
5 inaccessible except through limited road systems,
6 but primarily through river navigation. That's the
7 primary way that people get around. And also goods
8 come up and down the river through this mode of
9 transmission.

10 This is -- I believe this is the house or
11 something very similar to where the first indexed
12 case occurred in this outbreak. And it occurred in
13 a charcoal gatherer, who was making charcoal
14 basically, living under remote conditions out on the
15 outskirts of Kikwit.

16 Now, a little bit about the epidemiology.
17 I don't have an epidemic curve, but it's a
18 traditional classic, bell-shaped, drawn out
19 epidemiological -- epidemic curve that we have seen.

1 The index case being this charcoal worker, living
2 in Kikwit, but working at the edge of the forrest.
3 In fact, that area around where he was working has
4 ended up being one of the foci where much of the
5 environmental efforts are being directed, looking
6 for natural posts and the like.

7 The index case was a 36-year-old laboratory
8 technician, which just added some more issues into
9 the picture. Initially it was suspected that maybe
10 he might have actually contracted his infection not
11 even related to the fact that he was gathering
12 charcoal, but more the fact that he was really a
13 laboratory technician and exposed to that mode.

14 Seventy percent of the first 70 patients
15 were health care workers, which adds credence to
16 these hypothesis about being a laboratory
17 technician. There is no question that some of whom
18 were exposed to blood, but there are cases among the
19 health care workers where direct contact in terms of

1 blood was not the situation.

2 The epidemic curve is now in its fourth
3 generation, meaning that it has gone through now
4 several cycles of secondary, tertiary and so forth,
5 in terms of the epidemic itself. The disease
6 continues to smolder on, but the number of cases is
7 much less than seen originally. And the quarantine
8 procedures has been anything but effective from the
9 standpoint of really limiting the migration of
10 populations from the area, both into the area as
11 well as out of the area.

12 One of the things that is of very much
13 concern to us -- I apologize for the spelling on
14 some of these slides. But one of the concerns is
15 very great among USAMRIID's personnel as well as CDC
16 is the fact that some convalescent blood is being
17 collected from the small number of cases and is
18 being used for therapy without any good evidence of
19 its effectiveness. I'm sure Cladd Stevens can

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1 relate to my concerns in that.

2 DR. ALLEN: Are they used in plasma
3 infusions?

4 DR. TAKAFUJI: Yes. They're plasma forcing
5 individuals and basically putting it right back,
6 untested, unscreened and so forth. I mean, it's
7 extremely dangerous.

8 DR. POLAND: These are two different cases
9 that you've got?

10 DR. TAKAFUJI: Which case?

11 DR. ASCHER: Yeah.

12 DR. TAKAFUJI: I'm sorry. Yeah, these are
13 two different cases. The reason I said that is that
14 this case was found out later after this case. In
15 other words, when we first found it first in this
16 case, this was a case. And then we found out about
17 the charcoal worker.

18 DR. ASCHER: Using the same hospital?

19 DR. TAKAFUJI: Yes.

1 DR. ASCHER: Would that individual lab
2 worker have been playing with this blood later?

3 DR. TAKAFUJI: Don't know. We don't know
4 the details on that. That's why there is some
5 confusion about --

6 DR. ASCHER: Hell of a gap.

7 DR. TAKAFUJI: -- where exactly this
8 happened. We think -- and when I say "we," this is
9 CDC and WHO -- thinks that this epidemic had been
10 actually going on for several months before it even
11 became recognized. And that's why the confusion
12 about what people are using as the index case and
13 the time and so forth.

14 Somewhere around the early part of the
15 year, somewhere between January and April is when
16 probably the first recognized case occurred.

17 In terms of the signs and symptoms, this
18 sort of gives you the picture. Fever, of course,
19 being a very conspicuous part of the clinical

1 picture, but some less specific symptomatology. I
2 don't put a lot of credence on this, because it's
3 only dependent on what questions were being asked,
4 but it gives you an idea of the non-specificity of
5 the symptomatology.

6 Again, more on the epidemiology: 293 cases
7 as of 27 June. And the median age being 37 years.
8 And most of it being in the Kikwit and surrounding
9 areas.

10 So what are we doing? When this occurred,
11 there was quite a bit of international interest from
12 quite a few nations sending in scientists and
13 individuals to do different things. We know that
14 one of the groups that went was Bob Swanipole from
15 South Africa. He was there doing some collections
16 and trying to assess what was going on.

17 And finally CDC received an invitation
18 through WHO. What, in essence, was put together was
19 a CDC USAMRIID team to go in and do an assessment.

1 These were -- basically what we set up were eight
2 person teams to assess the environment and to
3 continue this right through the next couple of
4 months.

5 Now, the environmental assessment has some
6 limitations because it's pretty limited to the
7 Kikwit area. That does not imply that the disease
8 really started in the Kikwit area. It's just that's
9 where the focus has been so far, part of it being a
10 limitation in terms of what the Zaire government has
11 permitted outsiders to do in the country.

12 For example, one of the concerns that I've
13 raised has to do with, well, what's been going on in
14 Yambuku further north when you see the same virus
15 appearing so far south or indeed are we seeing cases
16 that far north. And nobody seems to know at this
17 point.

18 But there is some interest now to send in a
19 team to take a look at the previous sites where we

1 have had activity in the past.

2 Much of the collections therefore in terms
3 of environmental collections have been directed at
4 small rodents, birds, bats and the like, as well as
5 the collection of arthropods, not ruling out the
6 possibility that there might be arthropod
7 transmission associated with the disease.

8 The monkey issue has been a very deep
9 concern. The teams that are in there have not found
10 monkeys, but we know that monkeys are present in the
11 environment. In fact, they are eaten quite
12 commonly. They're considered to be a delicacy by
13 the Zairians. So meat in general is hard to come
14 by. And monkeys, of course, are not found in the
15 immediate area of Kikwit. So they are gathered
16 further north in all probability in the jungles and
17 then brought in as imported meat to the area.

18 The animal tissues, they have been sampled
19 at the markets as much as what we can find. They

1 include everything from rats to cats to swine and
2 sheep.

3 Here is a picture that's actually from
4 National Geographic that came out several years back
5 that shows you, for example, a monkey that is being
6 singed -- the hair is being singed off the monkey
7 that is being prepared for a meal. This is to
8 attest to the fact that monkeys are part of the diet
9 of the Zairians. So you can see why my concerns
10 about ingestion.

11 In terms of the assessment, we are
12 processing, collecting and processing specimens.
13 This is a close collaboration between Archer
14 Laboratories. And the plans, as I stated here,
15 there will be some inoculation work done as well as
16 studies to look at trying to get a better handle on
17 the primate issue. I just wish we had more monkeys
18 to look at than what we've found so far.

19 One of the things that has come out of this

1 investigation, though, has been an offer from the
2 Russian government. The Russians have a hyper-
3 immune ITG serum against Ebola. Now, this hyper-
4 immune ITG serum is forced equain serum.

5 Now, how did they do that? What we've been
6 told is they immunized a bunch of horses sometime in
7 the past with live Ebola. And that's how they got
8 the hyper-immune serum.

9 They have approached WHO and said, we have
10 this serum. It might be of use. Would you like to
11 have it? And I assume there might be a price tag
12 with it, too. WHO has said, sure, let's have it.
13 We have agreed to test it. We have not seen it yet,
14 but we are supposedly going to receive it sometime
15 soon. We do not know much more about it, except we
16 have been told it may be de-speciated in terms of
17 reducing its risk in terms of serum sickness in
18 humans. But this is something we plan to take a
19 look at in the not too distant future.

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1 DR. SCHAFFNER; Ernie, you don't know which
2 Ebola virus was used as the antigen?

3 DR. TAKAFUJI: We think it was the -- from
4 the 1976 outbreak.

5 The strategic planning is continuing on.
6 In fact, next week there will be a meeting with CDC
7 to figure out where we're going to go. And one of
8 the efforts is also to look at potential anti-viral
9 drugs. But remember this is an RNA virus. And
10 unlike DNA virus, the RNA viruses are much more
11 difficult to approach in terms of anti-virals that
12 don't have a significant amount of ratogenicity and
13 side effects associated with those types of
14 approaches.

15 So the anti-viral drug effort with RNA
16 viruses is going to be a much tougher nut to crack
17 than with DNA viruses, such as smallpox and so
18 forth.

19 Here are some pictures just for your

1 general interest. Again, really more to set the
2 stage for the presentation that will be following at
3 a later meeting of the teams that are out there.

4 Production of rodent specimens and the
5 processing of the tissues from those specimens;
6 collections with mis-nuts and the like of bats and
7 other species, birds and the like. All of this
8 being catalogued and coming back to CDC and
9 USAMRIID.

10 One of the other issues that Dr. Joseph is
11 very familiar with is we were also asked to provide
12 support should the event occur where there were
13 casualties that needed to be evacuated from the
14 area. An AIT system was set up at one of the recent
15 Board meetings. You had an experience to see what
16 that capability consisted of. And indeed the teams
17 have been set up ready to respond and we are still
18 on alert status should the need arise to transport
19 individuals back to the United States.

1 And here are more details pertaining to the
2 specific plans in terms of the support that would
3 come probably through -- probably through Landstuhl
4 on back to the United States.

5 So in essence that summarizes where we are
6 with the situation in Zaire. It's a rather
7 formidable environment. We are coming in at the
8 time in terms of the seasonality of rainfall and so
9 forth that is not necessarily the same conditions
10 when the outbreak first occurred. So there are some
11 differences pertaining to what we're seeing in the
12 environment. That has some concerns, because what
13 we really need to do is an environmental assessment
14 through the year to really see if indeed there are
15 some differences. Perhaps a natural reservoir, for
16 example, has actually moved out of the area for all
17 we know. We just don't know.

18 But there are some interesting issues, and
19 this is our first opportunity to really get a better

1 handle on what may be actually occurring in terms of
2 how the outbreak actually started. It may give us
3 some clues as to what happened back in 1976.

4 DR. BAGBY: Ernie, have you seen any spot
5 maps showing concentrations of cases around that
6 area where there might be some indicator of a
7 certain environmental geographical area?

8 DR. TAKAFUJI: There are about four or five
9 villages in the Kikwit area that have cases reported
10 out of there. Some of them are family household
11 situations where there has been some evidence of
12 transmission or contact from case to case. It's not
13 clear, though, because oftentimes family members
14 take care of the cases and so forth. So whether
15 there is blood transmission going on or not we're
16 not very clear.

17 That's why the aerosolization issue is a
18 critical issue of concern. And it continues to be a
19 concern.

1 Yes, sir.

2 DR. KULLER: Are the sanitary conditions in
3 the hospital for the hospital workers defined well
4 enough to know whether the transmission would have
5 to be aerosolized or whether there is evidence these
6 people got to be infected because they've come in
7 contact with blood or serum or feces or urine or
8 something of this sort?

9 DR. TAKAFUJI: The situation with the AIT
10 being alerted was actually prompted by the fact that
11 there were a few nurses. The missionaries have
12 nurses -- nuns that were involved in the outbreak.
13 In fact, I believe it was two or three of them died.

14 There was one nun in particular that there
15 were some concerns about, perhaps even evacuating
16 her to South Africa, mainly because it was closer
17 by. It didn't happen.

18 The nuns live in a community sort of like a
19 little commune in one of the areas in Kikwit. And

1 some of those nuns had contact with patients. Some
2 did not. That's why the issue of aerosolization has
3 come up, because there may be more involved than
4 just blood transmission.

5 DR. BROOME: Two points that are relevant
6 to your question. First of all, retrospectively
7 we've identified a case that did occur. Negetu
8 Kenchasa, she was -- became ill in Kikwit, but was
9 evacuated to Kenchasa. This is back in April. And
10 there were no secondary cases, so apparently the
11 barrier and other precautions available in Kenchasa
12 were a step above what we know about the initial
13 situation in Kikwit.

14 And then I think last week June 30th MNWR
15 had an update. In there, the secondary attack rate
16 in households overall was 16 percent. Households
17 being defined as those sharing a household cooking
18 fire.

19 But of the -- I think this includes some

1 serologic back-up. But of the 78 household members
2 who had no direct physical contact with the person,
3 none developed viral hemorrhagic fever. So versus
4 the 16 percent overall known is 78.

5 DR. ASCHER: In this culture, is body
6 handling of death by family and all that?

7 DR. BROOME: The Kenchasa case?

8 DR. ASCHER: Yeah. In general, this
9 culture was washing bodies as well as contact in the
10 70s that -- in '76, didn't a woman get loose in
11 Kenchasa, as well, and was actually running around
12 for a short period. And then there were no such
13 cases.

14 DR. TAKAFUJI: I'm sure you've been reading
15 the papers that the government has had some trouble
16 in terms of implementing a quarantine policy.
17 Kikwit people are moving to the four winds
18 regardless of what they did. In fact, if anything,
19 it created a panic situation. So they just finally

1 lifted the quarantine procedure.

2 So there may have actually been more cases,
3 household cases and so forth, that frankly may have
4 disappeared that have never been identified. That's
5 part of the dilemma that we're dealing with here in
6 that whole environment. The 293 business is
7 probably an under-estimated number of cases.

8 DR. STEVENS: I'm trying to think of the
9 environmental sources. The question I have is
10 whether or not all of the cases from April can be
11 traced back to another original case or is there any
12 indication of a multiple --

13 DR. TAKAFUJI: I prefer not to comment on
14 that, because I haven't seen that data. We have not
15 seen all of that data. In fact, CDC hasn't seen all
16 of that data. They're trying to collect that data
17 now and get a better handle on some of that.

18 Some of them are direct -- I can tell you
19 that some of the cases are directly related to the

1 contact and they feel confident that that's the
2 route of transmission. Others remain ill-defined.

3 DR. POLAND: Has there been contact -- in
4 the community and in the hospital?

5 DR. TAKAFUJI: Yes. They're being done
6 right now. In fact, some of the human contacts
7 around the charcoal worker business, some of his
8 contacts and so forth are being looked at.

9 DR. POLAND: No data?

10 DR. TAKAFUJI: No data. I haven't seen any
11 data on it.

12 DR. BAYER: The 20 percent that didn't die,
13 are they dying or are they recovered?

14 DR. TAKAFUJI: No, they've recovered. The
15 outbreak is pretty much --

16 DR. BAYER: Any treatment at all?

17 DR. TAKAFUJI: No treatment.

18 DR. PARKINSON: You mentioned there were no
19 monkeys in the area. If there were a blood borne

1 infection, is this unusual that there are no monkeys
2 in the area? Did they die off? Or have there ever
3 been monkeys in that area?

4 DR. TAKAFUJI: Don't know. Remember, that
5 this is not in the jungle. This is on the fringes.
6 I showed you the slides deliberately to show you
7 it's really a sort of private fringes of where the
8 jungle begins and the grass lines.

9 DR. JOSEPH: One of the interesting points
10 with regard to the -- WHO asked us to make available
11 an isolation air-evac. It wasn't for American
12 citizens. It was for "international personnel."
13 And one of the interesting questions I think that
14 still is in the background is, who is that? The
15 nuns that Ernie was talking were Italian nuns.

16 Well, does it mean -- we clearly would
17 evacuate CDC personnel or U.S. Army personnel. But
18 would we evaluate Italians but not Belgians? No
19 Zaire unless they happened to be related to the

1 Minister? You know, where do you draw the lines
2 with that?

3 DR. TAKAFUJI: The reason I was very
4 careful in saying Americans is our mission is to
5 support U.S. citizens and not Italian citizens and
6 so forth, but --

7 DR. JOSEPH: The other one we never really
8 debated thoroughly was would the time required to
9 get there, no therapy a fatality rate of 80 percent,
10 if indeed you have -- let's make it the worst case,
11 a CDC case, is it really the best thing to do to
12 bring it to USAMRIID site?

13 DR. TAKAFUJI: There are several options in
14 terms of how you handle cases like this. One is you
15 are forcing the transport of an individual.
16 Obviously the individual needs to be stable before
17 he or she can be transported, because there is all
18 kinds of pressurization problems and the like as
19 well as contamination of equipment and so forth.

1 It's very complex.

2 But the other issue is where are you going
3 to deliver that individual to?

4 And most hospitals have the capability to
5 do isolation up to about the BL3 level. But when
6 you get into BL4 level type exposures, it becomes
7 much more of a serious issue.

8 Right now in the Army what we are doing is
9 looking at various options. In the Washington, D.C.
10 area, we have worked out at situation where the
11 WAMC, Walter Reed Army Medical Center, to be able to
12 handle these types of casualties, depending on the
13 severity of their illness. They can be housed at
14 Walter Reed, but basically it would be a bubble that
15 we would have to set up in a DL3 type suite. In
16 other words, taking it to another level of
17 protection. Or actually putting health care workers
18 in protective suits and having them operate in that
19 environment.

1 DR. JOSEPH: The MNWR that Claire mentioned
2 has some recommendations for initial isolation and
3 ongoing care at community hospitals that again raise
4 a series of interesting questions. The other thing
5 is that this summer we're also working with the Army
6 Medical Center to set up a capability to be able to
7 handle these types of casualties.

8 DR. BROOME: For a while, CDC actually
9 maintained --

10 DR. ASCHER: One problem is that if we were
11 ever to find the Reston vector, you can bring it
12 back to Hawaii.

13 (Laughter.)

14 DR. BROOME: For a while, we developed a
15 unit that had capability for highly restrictive
16 nursing. But for a variety of reasons, it really
17 did not appear to be the most logistically feasible
18 approach since you might be bringing these back in
19 your air-evac. But on the other hand, if worse came

1 to worse, you might have an importation almost
2 anywhere.

3 And I think what we know about the means of
4 transmission suggests that with exquisite attention
5 to the kind of precautions outlines in the MNWR,
6 it's not unreasonable --

7 DR. TAKAFUJI: Let me just comment on that.
8 If you recall back to the Ebola Reston outbreak,
9 there was no blood transmission among the monkey.
10 It was very evident that the only way it those
11 monkeys in the adjoining room got infected was
12 through aerosolization. That's very true.

13 That's why I feel very confident to say
14 there is no question about the Ebola virus being
15 aerosolizable and transmissible through that room.
16 Whether that occurs in a natural situation, we don't
17 know. But the potential clearly exists for that.

18 Now, clearly once you start saying in the
19 middle of an outbreak that this is an aerosolizable

1 virus, you can imagine what the toll that the outcry
2 is going to be and the panic situations you're going
3 to have to deal with. So there was some very
4 deliberate thought that went into what could be said
5 and what should be said and so forth. And clearly
6 the blood transmission is going to be a much more
7 direct root of transmission than through the
8 aerosolization. But it does not rule out the fact
9 that there could be potential aerosol transmission.

10 DR. ASCHER: At our visits to USAMRIID and
11 the small pox review, everybody that was here and
12 there knows that clearly the DL for capacity in this
13 country is stretched to the max. And you are to be
14 commended for really having a synergy with CDC on
15 this one. It's your survival strategy in both
16 hands, I'm sure. And smallpox is going to stretch
17 things even further.

18 If the Board could help you in any to call
19 to someone's attention with all of the media

1 coverage of all of this that this is really
2 stretched to the limit, you know, you have people
3 retiring and things like that which make a big
4 problem. I think we would be happy to go on the
5 record to get somebody's attention.

6 DR. TAKAFUJI: I'd appreciate that.

7 DR. ASCHER: Now that you're working
8 together, it would be really easy, I think, to get
9 an inventory and lay it all out and say, we could
10 only do this much.

11 DR. TAKAFUJI: Well, and it gets back to
12 the whole emerging infections issues and the
13 resources. And everybody is losing resources. And
14 how you can get people together to work on these
15 kinds of problems.

16 We are deliberately trying to work very
17 closely with CDC. And certainly on this problem it
18 seems to be working. But we just need to continue
19 using the best assets in this country.

1 DR. KULLER: In the same vein, I was
2 wondering is there any plan or approach to use -- to
3 develop some system where you would have an advanced
4 hospital -- if ever move a hospital not just to the
5 United States, but there must -- there is also
6 expertise in France and Britain and Germany and
7 other countries where you'd have the NATO based
8 approach where you would be able to move a whole
9 hospital down there to prevent the spread, or at
10 least instead of evacuating all of the patients, to
11 be able to move an effective unit in very quickly.

12 If this was a military encounter, certainly
13 we would have that capability. And yet it's almost
14 potentially as dangerous as a -- you know -- crazy
15 revolution or a crazy person trying to chase
16 everybody out of the country.

17 DR. TAKAFUJI: The air medical evacuation
18 handles the onesies and twosies, but it does not
19 handle the 10s, 15, 20 type outbreak situations. I

1 think if we have to respond to that, we are doing
2 that from the standpoint of looking at a doctrine in
3 terms of how we respond to viral scenarios and the
4 like.

5 It's very clear that we would probably go
6 into the modes where the health care operators
7 themselves would be the ones isolated and not the
8 patients.

9 DR. KULLER: Let me ask another question.
10 Where would you -- where would the epidemic go where
11 the need would occur for active intervention by
12 countries which have the resources to perhaps
13 quarantine, isolate the patients. Let's say if you
14 have 3,000 cases suddenly in Zaire, what would you
15 do?

16 DR. TAKAFUJI: It would be a problem. It
17 would be a problem.

18 DR. KULLER: I mean, where would you
19 -- where do you push the panic button and when? And

1 who makes that decision?

2 DR. BROOME: I think it may be really
3 important to have this kind of involvement of the
4 Department of Defense, because I think one of the
5 more important issues is the ability to import the
6 kind of medical supplies that simply were not
7 available at the outset of the epidemic.

8 So rather than think of very expensive
9 specialized units that won't necessarily deal with
10 large numbers, I think having the flexibility to use
11 military capacity as well as the specialized
12 laboratory expertise is really the way to go.

13 DR. JOSEPH: I would really like to see the
14 Board take on a longer, sort of rounder view of
15 this, because the talk we've been talking about in
16 the last five minutes is really global surveillance
17 in bio-defense. The Board ought to have a briefing
18 on domestic issues and domestic terrorist issues
19 from Frank Young. The Board ought to hear what

1 comes out of CSET, the National Security Council,
2 both international and national issues.

3 And I think it would be very helpful for
4 you to -- again, you can't do this in one meeting,
5 but to start to think with us about the more rounded
6 question here. I mean, that one situation that you
7 raised, sending an air transportable hospital to
8 Zaire to take care of 3,000 patients, I don't mean
9 this in any sense pejoratively, but it ain't as
10 simple as that.

11 DR. KULLER: Sure.

12 DR. JOSEPH: Would you do that? Would you
13 not do that? Under what circumstances would you do
14 that if you were going to do that? What do we need
15 in terms of on-line capacity, et cetera, et cetera.
16 And I think going back to this morning's discussion
17 about longer kinds of issues, this whole area -- I
18 guess I tried to say this this morning, this whole
19 area of how we ought to -- we in the military in the

1 larger ought to be positioning ourselves around the
2 emerging infection issues, whether they are bio-
3 defense issues or natural occurrence issues is worth
4 a good chunk of the Board's attention over a
5 sustained period of time.

6 But I think there is a lot of stuff you've
7 got to get before you're really ready to --

8 DR. TAKAFUJI: This outbreak has been a
9 difficult one for CDC, also, because CDC was not
10 initially invited in. It was a very complex
11 situation and they have a little sensitivity at the
12 WHO, because the request had to come originally from
13 Zaire and the like. And I apologize for the lack of
14 a more definitive epidemiology on what exactly
15 happened, but that's what we're dealing with right
16 now.

17 I think as this thing dies down, we'll be
18 able to hone in and figure out exactly what index
19 cases really are, exactly what the incidence rates

1 are in specific areas, populations, age groups and
2 the like. But that information simply is just not
3 available to us right now. I suspect over the next
4 couple of months it will be available.

5 So at your next meeting, I think that what
6 I would recommend is that you send an invite to CDC
7 or CJ Peters and his group. Tom Kaisen from CDC has
8 been one of the investigators out there in the
9 field, along with Peter Roulan and others from CDC.
10 And we have some people out there. And there is a
11 recruiter, in fact, that's going out. In fact,
12 Sharon Ludwig's brother is going to be one of the
13 mammalogists that's going to be heading out there in
14 the next couple of months to also assist with some
15 of the animal collections coming out of USAMRIID.

16 So there is a long list of projects that
17 are still going to follow on from this.

18 Carl Johnson, whom some of you may know,
19 he's involved in this thing, too.

1 So it should be a real learning experience,
2 not only in terms of the disease itself but how
3 systems get incorporated to respond to crises such
4 as this.

5 DR. KULLER: I'm still a little bit
6 confused. What happens -- there is no response from
7 any of the other countries?

8 DR. TAKAFUJI: No. There has been foreign
9 investigators going in. For example, Boen Eckleson
10 went in from Sweden as an investigator, who just
11 happened to be able to minimize the fever.

12 Bob Swanipole came up from South Africa
13 with his team and a bunch of animal traps because he
14 wanted to collect specimen. It's been that kind of
15 effort.

16 So when you start looking at the
17 epidemiology in terms of nicely defined
18 epidemiology, I think, which all of us would like to
19 see, it's just not there. It's not clearly defined.

1 DR. JOSEPH: But worldwide, the capability
2 is very, very limited. I mean, it's not just
3 sending all resources in. There ain't much
4 capability out there in terms of either for research
5 or --

6 DR. TAKAFUJI: From what I understand, the
7 whole intervention effort and the control measures
8 that was headed by the minister of Zaire, there was
9 some sensitivity about foreigners coming into the
10 country.

11 In fact, one of the problems we had was
12 there wasn't any motel rooms in Kenchasa. The press
13 showed up and the press just took over the whole
14 community. I mean, they took all of the cars. They
15 took all of the rooms.

16 With that, that completes my presentation
17 this afternoon. I have one more comment that I
18 would like to make to the members of the Board. And
19 as I mentioned, I'm at USAMRIID right now, but in

1 September, I will be leaving that assignment. And I
2 will be replaced by my deputy, Dave France, whom
3 some of you may know. And I'll be moving on to
4 command the Walter Reed Army Institute of Research.

5 So I will continue to be involved with the AFEB and
6 I certainly intend to continue my relationship with
7 this Board, which I think is very important to us in
8 the military.

9 Thank you.

10 (Applause.)

11 MR. BLACKWOOD: Just to do a little bit of
12 introduction, I'm Vaden Blackwood. I'm at Wilford
13 Hall, which is also a member of the 59th Medical
14 Board and the Directorate that takes care of
15 trainees and I work in the Division of Epidemiology.

16 The briefing day is going to be an update
17 on the meningococcal vaccine. It's going to be a
18 tri-force effort of myself; Dr. Reese, the
19 preventative medicine doctor from the U.S. Army

1 systems, will give us historical background of the
2 meningococcal disease. And Dr. Ryan, an
3 occupational medicine resident at Yuches, will give
4 us the epidemiological experience in the Armed
5 Forces from 1980 to 1990 with meningococcal disease.

6 So the question that we're going to address
7 overall is what is the appropriate link for re-
8 vaccination or re-immunization of military
9 personnel.

10 And here is Dr. Reese.

11 DR. REESE: I'm going to go through the
12 history fairly quickly so we can make up some time.
13 One thing about meningococcal disease, if you
14 compare it to something like adenoid virus,
15 respiratory disease, or injuries as Colonel Jones is
16 happy to point out, the impact has never been large
17 in terms of numbers.

18 However, if there has been -- the impact
19 has not been large in terms of numbers.

1 But when you review the history, you'll see
2 that the psychological impact of this disease and
3 some of the difficulties in dealing with it that the
4 Army has had, make it important to remember those
5 considerations.

6 Outbreaks occurred, and although we weren't
7 really -- outbreaks occurred, and although we really
8 weren't typing or doing bacteriologic confirmation
9 at this time, what we know from this time period
10 before World War I is that, yes, there were cases.
11 They occurred during periods of immobilization, but
12 they occurred in recruit training camps and not when
13 seasoned troops were forward deployed.

14 This is just an overhead which shows the
15 cyclacle nature of the disease and that military
16 epidemics had been generally concurrent with
17 civilian epidemics.

18 Next slide.

19 During World War I, again what was seen

1 with it, most of the epidemics when they occurred
2 were in the new soldiers who were in the initial
3 phase of their training; that if there were cases of
4 deployed soldiers, it was when they were crowded in
5 ports and ships and generally those cases occurred
6 when units had come from camps where the incidence
7 rate was high, as well.

8 The case fatality ratio at that time was
9 very high, treatment wasn't very good. And so this
10 was a problem for us.

11 Next slide.

12 Carrier studies became really common at the
13 time. The thing is no one really knew what to make
14 of them. It was very common to do lots of carrier
15 studies. But if you look at some of the old AFEB
16 reports and writings, interpreting this was rather
17 difficult.

18 Next slide.

19 This is one statement that was made. And

1 if you look at some of the old reports, really this
2 20 percent of carrier rate was treated as doctrine
3 and people were all concerned about when it rose
4 above that and when it stayed low. Yet, if you look
5 at it epidemiologically looking back at that data,
6 there were documented rates of 20 percent in health
7 communities. And really this rate wasn't useful in
8 distinguishing when an outbreak was imminent or not.

9 Next slide.

10 During the inter-war period, we did have
11 two epidemics, but they were concurrent with
12 civilian epidemics.

13 Next slide.

14 World War II, the peak occurred in 1943.
15 Again, most of the cases occurred in troops who were
16 in their entry phase of service. Large epidemics
17 were not reported in troops going overseas. And the
18 carriage rate again was found to be high.

19 At this time, though, the surgeon general's

1 commission on meningococcal, which was an AFEB
2 group, looked at all of that data and basically
3 said, the prevalence carriage rates are not really
4 all that useful. If you could keep someone who was
5 unexposed when they entered the service from
6 becoming a new carrier essentially, then you could
7 do something to reduce the incidence of disease.

8 And the most effective way to do that would
9 be if you just administered prophylaxis to people
10 without screening them first.

11 Next slide.

12 And basically this was based on that same
13 kind of information. That if you looked at where
14 outbreaks occurred and seasonality, you couldn't get
15 something from carrier prevalence that told you that
16 carrier prevalence was particularly useful to look
17 at risk. And part of that was also whether typing
18 was done in terms of carriers.

19 Next slide.

1 In 1943, sulfadiazine in terms of mass
2 prophylaxis was administered. And it was
3 administered in those settings where military
4 cohorts were crowded together. Again, this was done
5 without screening.

6 Next slide.

7 This is just a statement that came about
8 that time where people started to realize that
9 meningitis was not really a military problem
10 inasmuch as if you took all kinds of people from all
11 over the country and put them together in training
12 camps. Then the prevalences that were background in
13 their community were really what we were seeing in
14 our troops that developed meningitis.

15 After 20 years of prophylaxis, the
16 experience was in 1963 that we started to see
17 outbreaks of resistant sera-group B disease. And,
18 again, it was the same groups that seemed to be at
19 high risk, those soldiers who were in their initial

1 entry phase of training.

2 Next slide. Okay. Could you give me my
3 next overhead.

4 This was -- becaUse there were some
5 outbreaks of resistant disease, the Walter Reed Army
6 Institute of Research went to Fort Ord, which was
7 one of the installations that had problems and
8 really looked at the prophylaxis issue. And they
9 determined that when you prophylax people, what you
10 do is eradicate the strain, replace them with
11 resistant ones and people are carriers for longer.

12 So their recommendation at that time was it
13 probably wasn't a good thing to be doing in light of
14 the resistant strain.

15 That overhead just shows what was done at
16 Fort Ord kind of month by month. Those lines are
17 accumulations of cases. And everywhere there is an
18 arrow, they had tried either changing who got
19 prophylax, the whole post, they did basic training

1 at certain intervals, they did personnel that were
2 -- just when they were newly arrived. They tried a
3 bunch of different measures to see if they could
4 stop cases of resistant disease from occurring and
5 they basically couldn't.

6 And at point 10, that's where prophylaxis
7 was discontinued on the installation and cases
8 continued.

9 Next slide.

10 It was not only the military's problem.
11 And it was seen in civilian populations as well
12 during that year.

13 Next slide.

14 Fort Ord became rather significant. It had
15 the most number of cases in the first outbreaks.
16 And these numbers of cases cause a lot of media
17 attention. And the post was close to basic trainees
18 about that time because they needed to reassess the
19 situation. There is really a lot of hysteria

1 generated from these cases. And when people were
2 given orders to Fort Ord, it was almost as if they
3 were given a death sentence. And there were calls
4 to Army officials and letters and telegrams and
5 quite a lot of public relations to deal with that.

6 Once the installation was close to basic
7 trainees, the cases basically tapered off.

8 Next slide.

9 Looking at control measures, there -- there
10 were still -- even though the recommendation was to
11 not do prophylaxis any more -- this just shows -- I
12 didn't show these. This just shows that Fort Ord
13 had a disproportional number of cases. These are
14 numbers.

15 Next slide.

16 And that they clustered in the soldiers
17 with the short list of service they just entered.

18 Next slide.

19 And this is an old -- one of the messages

1 from the time that said, yes, at Fort Ord, we're
2 going to continue to use prophylaxis, even though
3 there was a lot of question about whether it would
4 work or not.

5 So the pre-Christmas mass prophylaxis
6 program was to get everyone sort of eradicate all of
7 the carriage and then let them go home on Christmas
8 leave and pass and so on.

9 Next overhead.

10 And there was actually a document that says
11 if you can eradicate carriage, they can't leave and
12 you need to think about discharging or transferring
13 them from the service, which was rather interesting.

14 The AFEB at that time recommended that
15 prophylaxis was really not working and that perhaps
16 they need to look at maybe other things that might
17 be done, such as environmental controls.

18 Next slide.

19 Those were really to just do what we had

1 talked about before. You get soldiers and you
2 cohort them. You keep them from interacting with
3 other groups. You basically -- other things that
4 were considered important or maybe contributory to
5 that, you let them rest, you let them eat well.

6 Next slide.

7 And that there were all sorts of things
8 that talked about, you know, how much floor space
9 per man was needed, ventilation rates that was
10 required, and then of course a prompt reporting to
11 sick call should a guy become ill. And there was a
12 very low threshold for admission to the hospital for
13 observation, as we talked about before in terms of
14 just keeping an eye on them if they became febrile
15 or sick.

16 Next slide.

17 One thing about the environmental measures,
18 they were never really systematically evaluated at
19 that time, but that was what was recommended as the

1 best action to take.

2 So what happened with Fort Ord? Well,

3 there was --

4 Can I have my next overhead.

5 There was a lot of discussion about what to
6 do. And this is a letter from the Chief of Staff of
7 the Army where he talks about angry mothers really
8 giving him a hard time and that they need to figure
9 out what they're going to do. And there was a plan
10 considered where you would take people who were
11 obligated, you know, draftees rather than
12 volunteered, and let them go to a different
13 installation and so on. And that was so of aborted
14 after it was considered that maybe that would create
15 a class system and some morale problems and probably
16 wasn't a good idea.

17 What happened eventually that cleared
18 everything up was that, you know, the facts came to
19 bear that California had been a typical focus of

1 infections. Fort Ord people had nothing to do with
2 most of the cases there. And basically, you know,
3 there was a problem in California, there was a
4 problem in the country, and Fort Ord was just one
5 part of it.

6 So basic training was again reopened.

7 I think that's just a little newspaper
8 article announcing that.

9 Okay. Everything sort of stayed quiet for
10 a while, except in 1964 to '69, that was the Fort
11 Leonardwood experience.

12 What happened in 1969 there was another
13 outbreak, although the epidemic strain had shifted
14 to type C. Again, it was in mostly basic trainees.
15 And there was a Congressional inquiry about this
16 time that looked into, well, why did this happen.
17 There was a lot of attention. This was the end of
18 the Vietnam build-up period. People didn't want to
19 get drafted. You know, they go away and they're

1 dying. So what are we going to do about this.

2 Well, at this time, really what was dragged
3 through the mud was the lack of -- the disregard for
4 environmental measures. You know, you had
5 commanders who were running their troops all of the
6 time and people were having to drag their rucksacks
7 here and there and wherever before they could go on
8 sick call and all of these sorts of things that
9 commanders like to be able to do with their people.

10

11 They were told, you know, they really
12 shouldn't have been doing that. They should follow
13 environmental measures and recommendations.

14 And the biggest concern out of this was
15 that Type C vaccine was available. It was only
16 being used in field trials. It was a rare developed
17 vaccine. At that time, it had shown already about
18 90 percent efficacy, but this was not one of the
19 installations where there were field trials going

1 on.

2 Next slide.

3 And this was the statement by the
4 Congressman that looked into it, that really we
5 should have done better and had that available for
6 them.

7 Once we started utilizing that vaccine,
8 this shows that military cases -- and it goes from
9 '67 to '84. But Type C cases tapered off for us but
10 continued to accumulate or occur in civilian
11 populations.

12 This was the time table for vaccine
13 implementation.

14 This slide just shows basically B is the
15 dark. C is the clear. This is Army only,
16 meningococcal disease incidence. And this is from
17 '64 to '84. And those lines are when the various
18 vaccines were implemented. And just a cross-hatch
19 of either not typed or type Os and B, C or Y.

1 Next slide.

2 Since mid-1982, we've had a predominance of
3 Group B strains. There have been really just two
4 outbreaks that -- rare or the Epicon service has
5 investigated. And they've written up some nice
6 reports looking at carriage rates and the dynamics
7 of carriage.

8 Next slide.

9 Looking at what seems to be important
10 -- and these are very small. Only a couple of cases
11 occurred. But basically they think that what
12 strains a group is seeded with initially is probably
13 the most important factor given -- there will be
14 cases given to susceptible people with a virulent
15 enough strain that's transmitted efficiently. And
16 those two outbreaks sort of differed in those
17 dynamics and were a little bit different than each
18 other and were kind of interesting. But I probably
19 don't have time to talk about them now because we're

1 trying to make up time.

2 So I think that's my last slide. And the
3 only point that I was trying to make with most of
4 this was that we never really had a lot of problems
5 with this disease in any group, other than basic
6 trainees. However, we've had some problems and
7 concerns about the psychological impact of having
8 cases.

9 Mortality or case fatality is not as high
10 as it was. But this disease does have a lot of
11 historic fear associated with it.

12 With that, we'll next have Dr. Buckwood.

13 MR. BLACKWOOD: This is the question,
14 what's the appropriate time to enroll for re-
15 vaccinating our personnel with the vaccine. And
16 I've gone over the agenda.

17 And the agent we're dealing with, I think
18 everybody knows, but neisseria meningitides. It's a
19 polysaccharide capsule and there are 24 serogroups.

1 There are four or five that are of clinical
2 significance. We immunized against four. And then
3 there are type or serogroup B.

4 And then it has an outer protein membrane,
5 which is important for evolving vaccines.

6 That's all right. Go ahead.

7 This is just to give you a little bit of
8 Air Force perspective. We don't seem to have the
9 same problem with infectious diseases as the other
10 services. But we are concerned. We had seven
11 deaths from 1952 to 1994.

12 And what is true is -- and I think this is
13 true in all of the services is that the parents, the
14 public and the Congressmen do not understand the
15 death of a young trainee. So every death is
16 important.

17 Next.

18 It does seem like a small number, but it
19 does seem to have a seasonal time in the spring.

1 The present policy is -- in the DOD, as far
2 as I can tell, is to give the vaccine within the
3 first three days of training, to give deployment
4 specific vaccination or boosters every three to five
5 years, depending on the hazard of the location that
6 you're deploying to or your occupational hazard.

7 The Army Special Operations Command has a
8 standing requirement to immunize every five years.
9 And this five-year period was just shortly -- just
10 recently established. They have that for 30,000
11 troops.

12 So the Army certainly could profit from
13 having an interval that's defined as longer than
14 five years if it's effective. And probably all of
15 the services would save some money.

16 Next.

17 For the cost for the Air Force for basic
18 military trainees, it's \$4.53 a dose delivered with
19 the jet. We have about 35,000 trainees a year. And

1 the cost is just under \$160,000, which is -- if you
2 think about one death, just the insurance is
3 \$200,000. And the cost to take care of it.

4 To make the point that meningococcal
5 disease is still a problem in the military
6 worldwide, this is an Italian Army recruit study.

7 They had a problem in the early 80s. They
8 had an attack rate of 17.3 per hundred thousand.
9 Ninety-five percent of it was caused by serogroup C.
10 They instituted vaccine treatment of prophylaxis.
11 And they had a dramatic reduction in the rate. And
12 it went down to 0.2 per hundred thousand in '88 and
13 '89. That's pretty dramatic.

14 Next.

15 They had the unique opportunity to look at
16 the vaccine's immunological effectiveness, because
17 in '87 they had 150,000 troops that were
18 unvaccinated and 150,000 that were vaccinated. And
19 they were -- found that they had a protective

1 efficacy of 91.2 percent.

2 DR. KULLER: Is it pardivil.

3 MR. BLACKWOOD: No, they weren't. They
4 were using the Italian vaccine and they were using
5 the ANC.

6 DR. CHIN: Is this the plan trial or did
7 they just run out of vaccine?

8 MR. BLACKWOOD: No. It was when they were
9 starting. It was when they were starting. It was
10 just that time in history that allowed them to have
11 that many. They were unvaccinated.

12 The sera-conversion was very good to the A.
13 It was 84 percent. In C, it was 91. The type of
14 response was oligoclonol. And the antibody response
15 induced was like that of natural immunity.

16 Next.

17 Their conclusion was they didn't have any
18 -- they were safe. They didn't have any internal
19 reactions, that it was effective in controlling

1 their meningococcal disease.

2 To make the point that it's still an
3 ongoing problem, the Israeli defense force has had
4 several outbreaks recently. Two in January of '92.
5 One in recruits. One in trainees. A high school.
6 And another one in February '93. Out of that,
7 they've got two cases, secondary cases that were
8 resistant to the rifampicin, which was of interest.

9 All of these cases were serogroup C and
10 they're now considering whether they should
11 vaccinate or not, things like that. A pretty simple
12 question.

13 To answer the question or try to get some
14 insight into what interval should the vaccine be
15 given, a study was done to look at the duration of
16 the antibody response after the vaccine and Air
17 Force personnel. It was a retrospective cross
18 sectional study. And the design -- there were
19 approximately 40 people, immunological response was

1 tested, at several different intervals.

2 Base line before the vaccine. At four to
3 six months after the vaccination. And then at two,
4 three, four, six, eight and ten years post.

5 Next.

6 With looking at the total meningococcal
7 anticapsule or antibody level measured by ELISA in
8 the serogroup A, you can see that it goes up quickly
9 in the one month. And then it comes down in the
10 first two years. But throughout every interval, it
11 was significantly -- it was elevated above base line
12 significant.

13 Next slide.

14 And the same with group C. It goes up
15 quickly in one month. It goes down in two years.
16 But even at the ten-year point, the -- it was
17 significantly elevated over the base line.

18 Next.

19 DR. SCHAFFNER: Could I interrupt just for

1 a moment?

2 MR. BLACKWOOD: Yes.

3 DR. SCHAFFNER: May I? If you go back and
4 look at those data, there is a compilation obviously
5 of 40 individuals.

6 MR. BLACKWOOD: Yes.

7 DR. SCHAFFNER: How much noise is there in
8 the system -- I guess I'm slightly concerned that
9 people might intermittently carry meningococcal
10 strains and then it might offer a booster.

11 MR. BLACKWOOD: Well, I may be able to
12 answer part of that with one of the upcoming slides.
13 I don't think I can answer all of that question,
14 all of that.

15 An appropriate serological measure for
16 protection against meningococcal disease hadn't been
17 clearly established. But it's been discussed. And
18 one of the measures that's been looked at is -- next
19 slide -- the meningococcal anticapsule or antibody

1 level as measured by ELISA. And there is at least
2 in discussion that level of two micro liters per
3 milligram or greater than that may be protected, may
4 be clinically protected.

5 And with that thought, at each interval,
6 they look to see what percent of the personnel had a
7 -- were above this level.

8 So part of the question you're asking
9 -- this is what they started off with at the base
10 line, about 25 or 24 percent serogroup A and about
11 15 percent for serogroup C. So that's probably the
12 best information I have for your question.

13 And you can see that it went up to 100
14 percent at one month for both groups and continued
15 to fall. But even at the ten-year level, the A was
16 75 percent and the C was about 85 percent.

17 Yes, sir.

18 COLONEL O'DONNELL: Were these sera all
19 saved and tested simultaneously?

1 MR. BLACKWOOD: These -- if the sera was
2 attained was selected because the Air Force started
3 HIV testing in '84. So they were able to use the
4 bank serum from '84 to '94 for the ten year look.
5 And then where I got involved was helping to obtain
6 voluntary specimens from the basic trainees for the
7 base line and the one month look.

8 COLONEL O'DONNELL: These are the same 40
9 people?

10 MR. BLACKWOOD: No, these are not the same
11 40 people. That's what -- they got the bank serum
12 and they got -- approximately 40 serums of a group
13 of cohort that was racially and similar and had a
14 similar distribution of sex. So these were not the
15 same people.

16 DR. TAKAFUJI: If I recall, there are no
17 data where the same cohort has been followed up
18 beyond five years.

19 MR. BLACKWOOD: No, there is not.

1 DR. TAKAFUJI: There is no such data.

2 MR. BLACKWOOD: That was the question.

3 That's the best I saw.

4 DR. TAKAFUJI: There are no such data. I
5 think five years is the farthest out that I've seen
6 anything go.

7 DR. BROOME: I think in terms of the ARISA
8 question, it's important to remember it's a
9 polysaccharide antigen rather than a protein. It's
10 not at all surprising that you'd see it.

11 COLONEL O'DONNELL: But one actually could
12 get serum from cohort people who stayed in the
13 service for ten years, the same people.

14 DR. TAKAFUJI: But you won't know whether
15 they got boosted in the interim or the interval in
16 between.

17 COLONEL O'DONNELL: Maybe even from
18 carriage.

19 DR. TAKAFUJI: Plus you have to start off

1 with a very large group since we lose a huge
2 percentage over time.

3 MR. BLACKWOOD: Yes, ma'am.

4 DR. STEVENS: What do you know about cases
5 that occur in vaccine recipients? Are they -- two
6 questions, I guess. One is are they people who
7 respond to the vaccine? The second question is, do
8 you tend to get so-called break-through infections?
9 Do they increase over time?

10 MR. BLACKWOOD: I'm not sure we have the
11 answer to that, but I'm going to defer that to Dr.
12 Ryan, because she has looked at immunological
13 experience. And you'll see that there are problems
14 in the lack of our information in some ways.

15 At least in the past the bacterial signal
16 activity was kind of the goal standard. As I look
17 at this in group C, somehow it's gotten even
18 lighter. This is serogroup C. And you can see
19 again the base line goes up. The one line comes

1 down at the end of two years. And it also stays
2 elevated through the ten-year period significantly
3 above the base line.

4 Next slide.

5 This is just to make the point that there
6 is a positive correlation between the capsular, the
7 total antibody capsular versus the bacteria sinal
8 activity. But it's not a working one. And the only
9 part of this activity is probably the bacterial
10 sinal activity.

11 Next slide.

12 Go ahead. We've already gone over that.
13 Just both of them. Both these measures were
14 significantly higher at each interval after
15 vaccination and persisted for up to ten years.

16 And if we knew that what was a clinically
17 protective level, then we could use this
18 information. If we had clinical epidemiology, we
19 could do some more with this information.

1 I think I should say a few things about
2 serogroup B, that we don't have a vaccine because
3 it's significant. It's on the increase in the
4 United States and Oregon and Washington particularly
5 and in other countries, the UK, Norway and many
6 more, Chile.

7 The ET5 is more invasive. And the attack
8 rate in the recruit age group seems to be
9 increasing. When you look -- I say that because in
10 the UK and Norway and in Washington, Oregon, there
11 is an increase attack rate in adolescents. And part
12 of our recruit population is this 17 to 20 or 21.
13 So they are -- they do have a higher attack rate in
14 that age group in the places where it's endemic than
15 the normal other population, excluding infants which
16 is the real problem.

17 There are clinical trials in various stages
18 for the Chilean, Cuban and Norwegian vaccines.

19 The CDC has initiated an investigational

1 drug application for the Norwegian vaccine. And
2 hopefully there will be some opportunities to get
3 involved in that.

4 An effective vaccine or vaccines may
5 increase the meningococcal disease in the military.
6 All three of these vaccines are effective against a
7 different type of serogroup B. And they may well
8 take multiple doses to give protection.

9 Next slide.

10 Well, I'll turn it over to Dr. Ryan and
11 we'll find out what our epidemiological experience
12 is.

13 DR. RYAN: This is the work that I did from
14 my MPH actually. And I give a lot of credit to Dr.
15 Feiner at USIS for starting this. You can go on.

16 This was a study that we did at the
17 epidemiology in the decade of 1980 to 1990. And
18 really just an observational epidemic study.

19 We wanted to ask the question, is it still

1 a significant threat in the military and what effect
2 do the vaccines have with this group of people
3 during this decade, that serving in that decade
4 would have received any of the various meningococcal
5 vaccines that first the univalent for serogroup or
6 the bivalent or the quadrivalent now.

7 And what's the appropriate use of the
8 vaccine on the population now?

9 The methods we used were just accessing in-
10 patient data systems records for the enumerator for
11 the decade. And then the denominator came from DMDC
12 data. You can move on.

13 The cohorts of -- the vaccine cohorts
14 decided who got what vaccine. We did by assigning
15 them based on their enlistment dates.

16 So if somebody enlisted after October of
17 '82, then we assumed they got the tetravalent or
18 quadrivalent vaccine. And the other enlistment
19 dates correspond to when they got the vaccine.

1 Next slide.

2 So there is assumptions inherent in the
3 study, of course, and that's -- the first assumption
4 is probably sound. That we're picking up all of the
5 cases from meningococcal vaccine from in-patient
6 data systems because in general they'll be
7 hospitalized. And in general they'll be
8 hospitalized in military hospitals.

9 The second assumption, that they're getting
10 vaccine is probably also a safe assumption.
11 Remember, we only looked at enlisted people. And
12 that was important because the policy on officers
13 varies a little bit between the services.

14 And then the vaccine corresponded to the
15 time of enlistment, which is probably also a fairly
16 safe assumption, since it was a DOD policy.

17 This one, though, they were not re-
18 vaccinated during that period. Of course, when you
19 get deployed to a meningococcal endemic area, you

1 get re-vaccinated.

2 We cut off the study purposely June 1990,
3 because that was the time of mass deployment to the
4 Gulf. So during that decade, many of the people in
5 our study will have been re-vaccinated. So the
6 cohort I've assigned them to may not really apply if
7 they've been re-vaccinated actually with an updated
8 vaccine.

9 But for the most part, especially in kids
10 and knowing that the average enlisted military
11 service is actually short, many of the people are
12 not re-vaccinated. So we can see where we have that
13 assignment anyway.

14 This was the rate of enlisted personnel
15 during the decade. And it's fairly constant with
16 maybe a little hint of going up in the last couple
17 of years of the decade.

18 Next slide.

19 The overall rate was 2.2 cases comparing to

1 CDC's data for civilians. That compares to about
2 one case per hundred thousand per year in civilians
3 in the United States. And in fact that's also about
4 the same age rate, too, about .9 per one case per
5 hundred thousand per year for this 18 to 25 age
6 group that the CDC reports.

7 Case fatality rate in the military for this
8 data was only 4 percent, which compares to about 12
9 percent in the civilian sector.

10 And we noted the same seasonally variation
11 that they also see in the civilian sector. Recruits
12 come in at all times of the year. Well, we have
13 people serving of course at all times of the year,
14 too. But we see the peak incidence in February,
15 which also mirrors the civilian experience.

16 Next slide, please.

17 By each service, I apologize it's a bit of
18 a busy slide. But there is a difference between the
19 services. And the Army, of course, is maybe the

1 most stable line here, has the biggest denominator.
2 The Marines have a very unstable rate, a very small
3 denominator. And you see that the actually
4 experience will epidemic towards the last part of
5 the decade.

6 The Air Force down here as Dr. Blackwood
7 implied has the lowest rate of the disease.

8 Next slide, please.

9 And there is a statistically significant
10 relative risk associated with service, the Marines
11 having the highest rates and the Air Force having
12 the lowest.

13 Next slide, please.

14 This is by racial group. The limitation
15 here is the racial groups assigned by what's in the
16 in-patient data systems record. And in general we
17 have white, black, other, without a really way of
18 validating of what the racial distribution is.

19 And you see -- now, other is also a very

1 small group. It's other, unknown. They're groups
2 that would not fit into the other two categories.
3 So that line is more unstable if you will.

4 Next slide, please.

5 There was a statistically significant
6 difference, though, between the black -- the
7 designated black racial group and the other racial
8 groups. And this experience is also mirrored in the
9 civilian sector.

10 Actually last CDCs active surveillance
11 reports gave a relative risk to the black rates as
12 about 1.5. But again it's a statistically
13 significance difference between the other racial
14 groups.

15 Next slide, please.

16 Now in the military, we also did this by
17 years of service. And assume that years of service
18 is a surrogate for age, is a surrogate for rank, as
19 well. But we thought that years in the service was

1 the most significant way to report this. And you
2 see the first year of service is when there's the
3 highest rate of disease.

4 I've included on the hand-out that these
5 blips out here, which we were just talking about re-
6 vaccinating or boosting, looks at 6 years and at 14
7 years actually are not statistically significant
8 increases in rate. And that the denominator is real
9 small out here.

10 Next slide, please.

11 If you do this by months of service and
12 actually blow up that first -- that first part of
13 that previous graph, this is up to four years. And
14 this has a little bit of assumptions in it because
15 not all in-patient data systems records have a
16 really delineation of length of service. Some of
17 you could say less than six months and so on.

18 Ones we could categorize as to their actual
19 length of time in service, we can graph out and show

1 that actually disease occurs in the first year and
2 actually it occurs in the first half of the first
3 year as we were just talking about. So in recruit
4 or just near -- just out of recruit camp type
5 setting.

6 Next slide, please.

7 And this is statistically significant in
8 terms of length of time in service, that 0 to 2
9 months, those are the kids that have really the
10 highest relative risk of disease. And as they get
11 out, anything past this is not significant. But in
12 the first two months, certainly. But even though we
13 now pass boot camp to their first duty stations.

14 Next slide, please.

15 This is maybe the most interesting finding.
16 And this is where the assumption comes in about
17 vaccine cohorts. This is where we assigned
18 everybody a vaccine cohort. And said that you're in
19 this cohort because of your date of enlistment.

1 So the kids who got petrivalent vaccine are
2 -- troops who got petrivalent vaccine are shown in
3 the red. And the troops that got bivalent vaccine,
4 who had been in service longer, are shown in yellow.

5 And the other two groups are shown here.
6 These are very small numbers for this study. These
7 are people serving in the decade 1980 to 1990,
8 sometime during that decade, that actually got
9 vaccinated with none which means they enlisted prior
10 to 1971. Or the univalent one, which means they got
11 vaccinated in the window of -- I mean, got recruited
12 or vaccinated in the window of '71 to '78.

13 So these two groups are probably a fair
14 comparison.

15 What's interesting is that in the first
16 year of service, they were controlling for a length
17 of time in service.

18 The people who got tetraivalent did a lot
19 better than the people who got bivalent. But beyond

1 the first year of service, actually the tetravalent
2 cohort had higher rates of disease, which was a
3 little hard for us to explain.

4 Next slide, please.

5 That's probably the best way to look at it,
6 but you can do some tests of significance.

7 Yes, sir.

8 DR. SCHAFFNER: I wonder if we could go
9 back?

10 DR. RYAN: Yes, page up.

11 DR. SCHAFFNER: Because those are also time
12 delineated, correct? I mean, the tetravalent folks
13 did not get their vaccine during the same period of
14 time?

15 DR. RYAN: Right.

16 DR. SCHAFFNER: And since this is not
17 corrected for meningococcal type, it may well
18 reflect a different prevalence, for example, group B
19 is in the community general during the efficacy

1 period.

2 DR. RYAN: Serogroup B. And actually the
3 very first slide we were considering a period
4 effect, because of course these people in red here
5 are the ones who were serving later. That very
6 first slide that showed the incidence is kind of
7 constant, but actually went up in the last part of
8 the decade may account for that difference and that
9 may be reflective of serogroup B.

10 Of course, we're interested in assigning
11 the actual disease to the people who got sick in the
12 study. And it's difficult to find all of that data.
13 We have a handful of it.

14 What I have is predominantly serogroup B.
15 And it's all Army data. So I don't have tri-service
16 at this point. I don't have the tri-service data
17 and I don't have -- I really don't have enough
18 numbers to say with any confidence what the efficacy
19 was for AC versus ACY W135 at preventing those

1 specific serogroups.

2 But it would appear to be exactly as you've
3 said. What we're seeing is what happens -- maybe
4 what happens to just serogroup B in our population.
5 And that maybe we've eliminated some Y. At this
6 time, it reflects what serogroup B is doing in the
7 community.

8 And again, just the difference between
9 these two cohorts, whether it means anything or not.
10 There wasn't enough weight here to say that it was
11 significant that the tetravalent cohort did better
12 in the first year and did worse after their first
13 year for overall disease. Next slide.

14 So from at least the small study we can
15 conclude that it's still a significant problem. Our
16 rates are more than double, the same age civilian
17 rates still. And we can also say that we still
18 continue to do well in terms of case fatality and
19 that may be because of our military vigilance for

1 disease.

2 Next slide, please.

3 But in the last decade we can see the
4 difference just in demographics between the
5 services, Marines and Air Force, if we're looking at
6 targeting and the interventions we may want to know
7 -- want to focus more on the Marines or the ones
8 that have the higher incidence of disease. But we
9 see the seasonal variation, which may also be
10 important in trying new vaccines and that
11 demographics of the racial variation which is
12 reflected in the civilian sector.

13 This may be hard to explain. When I asked
14 CDC how they explained the difference in racial
15 groups, they're not sure either. I thought actually
16 -- I hypothesized that maybe it was a difference in
17 response to vaccine, because there is racial
18 differences in response to HIV, which is another
19 polysaccharide vaccine. Native Americans actually

1 don't respond, as I understand, as well to HIV
2 vaccine. But in the civilian sector, that wouldn't
3 explain the difference in the civilian sector for
4 the difference in the racial groups.

5 Next slide, please.

6 You see the difference in length of time in
7 the service and the recruits at risk in their first
8 six months primarily.

9 And there was no epidemiologic evidence
10 from our study at least that overall rates of
11 disease, that there was an increase in rate of
12 disease at any particular point distant from their
13 initial group vaccination at recruit camp.

14 DR. TAKAFUJI: Did you differentiate
15 between meningitis and meningococemia?

16 DR. RYAN: No. It's all meningococcal
17 disease. The IC code include both and basic
18 disease.

19 And then the difference that we saw in this

1 cohort that got the tetravalent group.

2 Next slide.

3 Of course, the identification in the
4 serogroups is important to determine what the
5 efficacy of these vaccines were. And then as Dr.
6 Blackwood was talking about, that CDC is very
7 interested in the development of serogroup B
8 vaccines for kids or for outbreak and for conjugate
9 proteins for more measurable lasting immunity, if
10 you will. The CDC has a -- as Dr. Blackwood said,
11 for investigational drug, permitted to use the
12 Norwegian serogroup B vaccine and is interested in
13 trying that on whoever is game.

14 Next slide.

15 There is a quote about remembering
16 meningococcal disease.

17 I think Dr. Blackwood would like to make
18 some more concluding remarks.

19 MR. BLACKWOOD: Thank you for your

1 attention. It's been a long day, long afternoon.

2 The conclusion is that there is
3 insufficient information to determine the clinical
4 protective nature of the vaccine because we don't
5 have the serotypes. If we had the serotypes from
6 the epidemiological work that Dr. Ryan had done, we
7 might be able to do that. It depends on the leap of
8 faith you want to take if you consider that
9 information valid with the other information.

10 We don't have sufficient information to
11 determine the efficacy of boosters. And we don't
12 have enough information to determine a schedule for
13 re-immunization, although if you had the clinical
14 data, we certainly would like -- immunologically
15 they respond for at least up to ten years.

16 Next slide.

17 That was the quote.

18 We're available for questions. There is
19 certainly a lot of questions in this area.

1 Yes.

2 DR. PARKINSON: I think on behalf of I
3 think all three preventive medicine officers, I'll
4 kind of ask this question that's been brought up
5 before the Board. Let me just put in operational
6 context and in light of Dr. Joseph's comments this
7 morning about the role for the Board might be a
8 little different than what's been done in the past.

9 And that is, to serve as the role of a
10 scientific tie-breaker from ACIP or CDC or other
11 types of advisory bodies, to come out with
12 recommendations that currently exists for
13 meningococcal boosters that says, three to five
14 years.

15 That essentially is kind of based on
16 -- what we get is we get kind of a local option by
17 the various commands, unified commands, joint chiefs
18 of staff, as we build more preventive medicine
19 expertise throughout DOD, what we find is that

1 people say, well, you know, it seems -- I want to
2 really protect my people. So I want to go every
3 three years. Another command says, we'll do it
4 every five years.

5 And what essentially comes down to when
6 people go into theater, the people go into the
7 theater and they've got one person arriving with a
8 three-year booster and another person arriving with
9 a five-year booster going through a single funnel of
10 Colonel Albers' command that says, no, the only way
11 you get into our theater -- because we own that
12 command, we own that theater or operations. You run
13 into a conflict.

14 So what do we -- as we sat around one night
15 on the back of a napkin and said, one of the types
16 of issues where AFEB might be instructed is to look,
17 you know, not that we are the -- not that you all
18 are the ACIP. But there may be instances where
19 there may be pieces of data that if you could look

1 through an operational military perspective, that
2 you may help us develop a little more specific
3 guidelines about such things as periodicity of
4 boosters.

5 And we have various pieces of data that the
6 Air Force and others that on the face of them none
7 of them alone make a case for different periodicity.

8 But I guess I go back to some things like yellow
9 fever, where we know it's effective for ten years.
10 I mean, I'd like to go back and just where we have a
11 study, did we have ten years of perspective data
12 with clinical linkage on yellow fever to show that
13 it was effective that long.

14 I just don't know. So I guess that's kind
15 of why we brought it way.

16 Not a good way we traditionally do with the
17 varivax presentation, where the blood manufacturer
18 comes and presents it and we talk about a new
19 vaccine.

1 Kind of an ongoing issue that I can assure
2 you -- we have a deployment tomorrow, Colonel
3 Roudebush's command will be calling up Captain Trump
4 and talking to Frank O'Donnell and somebody else,
5 because everybody is going to be doing international
6 travel and it says every three to five years doing a
7 local option.

8 To the degree we can help smooth, whether
9 it's DOD immunization policy or chemo-prophylaxis
10 from malaria or whatever, we would like to try to
11 engage the AFEB in that.

12 COLONEL O'DONNELL: I just have a question
13 for those of you who have done their homework here.
14 Do we have any evidence there has been any vaccine
15 in any of the cases?

16 MR. BLACKWOOD: There was one -- this is
17 not a failure. There was one case of an officer
18 during Desert Storm. And it turned out that he
19 didn't get vaccinated.

1 DR. DINIEGA: I have a question for Dr.
2 Ryan and then a comment. Did you make any attempts
3 to look at officer cases? Because we generally
4 agree that basic immunizations for officers are not
5 well adhered to, to put it nicely.

6 DR. RYAN: We didn't because of that.
7 Because we weren't sure if we've gotten it. In the
8 Navy -- I've never been immunized. In the Navy, we
9 don't immunize officers.

10 MR. BLACKWOOD: The DOD policy is not to
11 immunize officers with meningococcal unless they're
12 going to an area of hazard.

13 DR. WOLFE: And the Navy only immunize the
14 men and not the women, because historically there
15 has not been a -- in recruit camp, first with the
16 female recruits.

17 DR. DINIEGA: The comment I wanted to make
18 was that with the low incidence of hospitalized
19 cases, it would be very easy to go back and pull the

1 hospital records to see if people were previously
2 vaccinated and what type of disease they ended up
3 having and what they were vaccinated with. We're
4 talking about a low incidence disease.

5 DR. ASCHER: But you've got to get the
6 strains in.

7 DR. DINIEGA: Right. That's why you go
8 back to the hospital records.

9 DR. ASCHER: We have a rather big problem
10 in California. About two to three cases a week of
11 severe disease. And that's a hundred a year or
12 something and it gets everyone upset, because
13 they're all sick people. That's .3 per 100,000.
14 It's no big number. And the strategy at this point
15 is to get all of the strains in and see if there are
16 any connections. They're all different at this
17 point. They're all from everywhere. There are no
18 clusters.

19 And Washington and Oregon had the B

1 clusters, which got their attention.

2 MR. BLACKWOOD: If I could -- I know the
3 biggest problem is we make -- pass on through the
4 records they could find, but they weren't
5 serogroups.

6 DR. ASCHER: You should be doing that.

7 MR. BLACKWOOD: Well, they should be and
8 probably now they are. But if you go back
9 historically, the information is not there. And
10 finding that person could be difficult. And finding
11 out if they were immunized is another significant
12 problem because we don't have an ongoing record.

13 DR. ASCHER: It's a classical Army
14 infections problem. You have a disease that's
15 vaccine preventable and there's not surveillance.

16 DR. REESE: In the Army, there is
17 instruction that any cases that occur, then the one
18 case, though rare. But people aren't familiar with
19 it and it generally doesn't just happen unless you

1 have the data. Since 1990, we've had 25 cases. One
2 death. And none of them were officers.

3 DR. TAKAFUJI: Part of it is also based on
4 the fact that the technology allows us to now at the
5 local level do PCR. So those specimens are not
6 necessarily coming in. That doesn't mean that they
7 haven't been tested or are serogrouped. But we're
8 not capturing the data.

9 So it gets back to Dr. Joseph's comment
10 about surveillance and the need for us to tighten
11 up, because we're speculating on what exactly is
12 going on and we really don't understand it.

13 The other issue, though, pertain to the
14 longevity of protection and so forth. I can assure
15 you that there are no data, because I remember
16 looking at this when we had to develop the policy
17 about three to five years. And it's just based on
18 pure speculation.

19 But there is two types of issues involved.

1 One is you're trying to protect the recruit during
2 his time as a trainee. That's one issue.

3 The second issue is you're trying to
4 protect the soldier for a 20-year career, where you
5 now are looking for something that's much more
6 prolonged where he or she could be the ploy to an
7 endemic area.

8 When you look at that second issue, the
9 fact that you don't see trainees with disease is a
10 non-issue. They're still going into the
11 meningococcal belt and so forth and they need to be
12 immunized.

13 So which question are you asking? I think
14 you need to ask that question, too.

15 DR. ASCHER: The present, more present.

16 DR. KULLER: I was just trying to get
17 -- you started to hit it, but I'm still confused.
18 What is the issue? I mean, you showed us data that
19 --

1 DR. ASCHER: The Rowanda deployment
2 commander --

3 DR. KULLER: I mean, there is no mortality
4 issue. The mortality rate is something like .8 per
5 million. So it's unlikely that with one death that
6 -- you know -- you may avoid that one death. By
7 chance, you may still have one death for some other
8 reason.

9 DR. BLACKWOOD: We can -- if we choose to
10 immunize, we can spread out the immunizing to every
11 ten years.

12 DR. KULLER: I'm talking about the current
13 public health issue. It seems to me that you're
14 dealing with a -- you want to make the success a
15 bigger success.

16 DR. ASCHER: No, no, no. They want a
17 consistent policy so they can maybe give less
18 vaccine.

19 DR. KULLER: That's what I'm saying. I

1 mean, the critical question is that right now you
2 have a very, very successful program. Agreed.

3 So the question now, it seems to me, is
4 whether you want to change the policy and reduce the
5 frequency of vaccine and take the risk that you
6 might have a less successful program, which is very
7 difficult to test.

8 DR. PARKINSON: The successful program is
9 measured by the fact that we don't have a lot of
10 meningococcal virus.

11 DR. KULLER: That's all you're really
12 concerned about.

13 DR. PARKINSON: But secondarily what we're
14 asking about is, is there enough data that we can be
15 more specific than the recommendation of three to
16 five years for a booster which logistically causes
17 the military a lot of time, effort and lost manpower
18 by coordinating messages because we don't have
19 consistent -- you know -- either three years or five

1 years or maybe is there enough evidence from what
2 you've heard today, but clearly there is not, to go
3 to ten years?

4 DR. KULLER: I understand that. But one of
5 the real problems in life is that it's very hard to
6 test the hypothesis in which the -- essentially the
7 alternative hypothesis is disaster. We go through
8 this all of the time. That is, we're testing the
9 hypothesis. It's not a benefit, but we're testing
10 the hypothesis of disaster, so that in essence if
11 the hypothesis turns out to be correct, we have a
12 disaster. It's very difficult to test that in any
13 real world, so that when you have a winner, it's
14 very, very difficult to test the hypothesis. But
15 you have less of a winner.

16 Although I agree with you, you're in a very
17 difficult situation. We do this all of the time.
18 We want to test. Somebody comes along and says, why
19 don't you test whether if you give this drug in

1 twice the dose, whether you're going to kill some
2 people. We tell the people that the hypothesis
3 we're testing is that if we double the dose, we're
4 going to kill some people. And it's very hard to
5 get people to participate in that study. But it's
6 also a very dangerous to hypothesis to test, because
7 we might be right. And if you're right, of course,
8 then you have to look for another job.

9 And that's the same problem here in the
10 sense that you have -- you've got yourself in a very
11 difficult political situation in the sense that if
12 by chance you test the hypothesis that you can do it
13 with less frequency and you get cases, you're in
14 deep trouble.

15 DR. STEVENS: What's the basis for the AICP
16 recommendation of three or five years?

17 DR. BROOME: You know, I actually do not
18 have the -- I think you're actually referring to the
19 foreign travel, yellow book, which is -- it's

1 basically, as Ernie said, in the absence of data, a
2 prudent course might be to consider re-vaccination.

3 But there actually are a couple of things I
4 think you can say that may help us. There is a
5 study that looks at duration of protection. We did
6 it in Bokina Faso. And we showed that in young
7 children, in fact, there is a very poor duration of
8 protection. But that's not surprising with the
9 polysaccharide group A vaccine.

10 In the older children, it was hard to tell
11 whether there was a slight decline -- I'm talking
12 about protective efficacy measured by a case control
13 study. But it was certainly nothing like in the
14 young infants.

15 Therefore, I think the study that Dr.
16 Blackwood is describing, that we did actually
17 collaboratively, was very important. And I think
18 the results in fact would lead me to think that
19 you're going to do pretty well by not re-

1 vaccinating. That it behaves like the
2 polysaccharide antigens that we've looked at like in
3 pneumonia.

4 The antibody, once you got over this
5 initial peak, stays pretty constant, stays well
6 above base line. Plus you've got the good
7 surveillance data that Dr. Ryan showed us to suggest
8 that there isn't some increase as you go out further
9 from the time of the initial vaccination.

10 I mean, I'll be happy to look at the exact
11 wording, but I don't think the AICP is recommending
12 based on -- you know -- some kind of data that there
13 be re-vaccination at those intervals.

14 And I'd like to just put one other issue on
15 the table. And that's the B vaccine. There is a
16 very strong reason to get strains, because if in
17 fact we move forward -- first of all, if this clone,
18 the ET5 which is showing up in Washington and Oregon
19 becomes more widely prevalent, it's a real bad

1 actor. That's the one that caused the Cuban and
2 Norwegian epidemic, the vaccines are not ideal.

3 The clinical efficacy studies, probably the
4 best guess is sort of 60 percent effective. So
5 these are not great vaccines. And they may well
6 illicit serotype specific protection, not serogroup.
7 It's serotype specific. So you've got to get the
8 strains to find out -- you know -- what group B
9 strains you're seeing. And they're going to have to
10 be essentially typed, because most labs will not
11 have the capacity to do sera and sub type specific
12 typing.

13 Now it's only relevant if you actually are
14 going to use this OMP based vaccine.

15 Finally, I think we should acknowledge the
16 Walter Reed efforts to develop improved vaccines.
17 There's really been a lot of investment by the Army
18 over the years to develop the initial vaccines and
19 to continue to develop and improve vaccines.

1 DR. TAKAFUJI: Going back to the point
2 about serums, I agree with you, there is a need for
3 us to do more in the surveillance. The AFEB can
4 certainly make that recommendation. It can help us
5 as we develop what our program should be.

6 The other thing, though, that was a
7 concern. I remember when we first head up the
8 policy, there was this very issue of polysaccharide
9 vaccines. And the concern really centered on the
10 experience that we had with the pneuma vacs. And
11 that is, if you recall, if you immunize too many
12 times, you're going to start seeing some very severe
13 reactions from the vaccine itself. And that is a
14 concern that we continue to have. It is a
15 polysaccharide vaccine. In fact, it's a multi-
16 polysaccharide vaccine.

17 So we're concerned about that when you have
18 now guys coming in for the third and fourth shot.
19 Do you have any thoughts on that as far as a concern

1 that we should have?

2 DR. BROOME: The really severe adverse
3 reactions were with the original 14 valent pneuma.
4 And at least you're a mere four in this one. But I
5 think -- I think again you sort of have to say,
6 well, how much data are sufficient. But the kind of
7 antibody data that's been developed and the
8 epidemiologic data would suggest to me that you
9 probably don't need booster, certainly not at three
10 years. And, you know, it looks pretty out to ten.

11 Now, if you're going to send a bunch of
12 people to Bokina Faso in the midst of an epidemic,
13 you know --

14 DR. SCHAFFNER: Applicable to Dr.
15 O'Donnell's last comment and I'm persuaded that Mike
16 made a reasonable statement of an issue that we
17 might address. And at the risk of burdening the
18 good Dr. Ascher and the rest of us, is this
19 something that the disease control subcommittee

1 could work on in a more deliberate fashion rather
2 than -- because there is a series of nested
3 questions. And we could address them kind of
4 sequentially.

5 DR. ASCHER: We've also got a presentation
6 from the repository asking for things to do. We
7 have pre-recruitment sera. And you've seen it. And
8 a follow-up annual or every other year on 2 million
9 sitting in Rockville. Why can't you do your
10 longitudinal study? Do you want us to recommend it?
11 I mean, do you want us to say that the proper
12 longitudinal study is --

13 DR. TAKAFUJI: Yes.

14 DR. BROOME: I think -- how many -- yeah,
15 because the repository goes back how long? Eighty-
16 five. So you have a pretty good --

17 DR. SCHAFFNER: This would inform civilian
18 practice, also.

19 DR. BROOME: That's why --

1 DR. KULLER: I thought we don't know the
2 level, which is basically protective?

3 DR. BROOME: There is some reasonable
4 assumptions. In fact, probably the two micrograms
5 per milliliter is, if anything, a conservative
6 level. I mean, it's not directly analogous. But if
7 you look at pneumonia or HIV, you know, one is fine. I
8 mean, it's very hard to quantitate these, so I
9 wouldn't put a lot of weight on that.

10 But I think there is -- you know it's a
11 protective antigen. You can look at it versus the
12 base line. And we're doing some efforts to try to
13 get the implementation of the quantitation down.
14 You've got the side. I think's a perfectly
15 reasonable study. And it would be nice in terms of
16 confirmatory, having more than one study in which to
17 say don't bother with a five year booster.

18 DR. ASCHER: Or whatever the result is.

19 DR. BROOME: Right. Not prejudging.

1 DR. ASCHER: There must be people in there
2 the have it. So look at that factor, as well. If
3 you could get the medical records linked.

4 DR. KULLER: My concern with this is
5 basically you're dealing with what I would call the
6 one event. And that is, if you have one adverse
7 event, you're in deep, deep, deep trouble. So you
8 have to be absolutely certain. It's unfortunate,
9 but you know when you have the success that goes
10 well and you have one bad event, because you change
11 policy, you have a terrible problem.

12 DR. SCHAFFNER: I think we're on slightly
13 different wavelengths. What we have now is a series
14 of different policies that are occurring. And I
15 think what the military is looking for is a little
16 bit more coherence and approach.

17 DR. BROOME: As to what should the policy
18 be.

19 DR. SCHAFFNER: And interpretation of what

1 they see as a recommendation.

2 DR. KULLER: Well, I think for that we'd
3 have to know what the policy is across the military
4 right now and how -- and then basically from there
5 try and see if you could simplify it and see whether
6 any new data would be helpful.

7 DR. SCHAFFNER: I think we ought to chew on
8 this.

9 DR. PARKINSON: I think what you could do
10 is if you took Dr. Broome's statement, which is
11 literally lifted out of the yellow book, which is
12 clinically proven every three to five years and you
13 gave that to all of the major commands and units and
14 public health officers and preventive medicine
15 officers in the three services and said, apply that
16 to the military, going to Bokina Faso -- we've got
17 some saying three, some saying five.

18 And where this costs us in the logistic
19 credibility. We want some credibility. And that's

1 where we say, if the AFEB is not for this issue,
2 what is it for. Help us on scientific credibility
3 as a kind of beholden to them. I mean, the Army
4 said they were trying. But I don't think we should
5 -- you know. So I think it would be useful to have
6 more.

7 DR. BROOME: CDC recommendations aren't
8 carved in concrete. We're equally interested in
9 these data in terms of trying to think about what
10 should our recommendations be.

11 AUDIENCE MEMBER: If I'm not mistaken, the
12 reason for the recommendation was a political one
13 and not scientific or medical. It was because Saudi
14 said, when people come to the Haj, you have to have
15 the mening vaccine. If I'm not mistaken, isn't that
16 the reason?

17 DR. ASCHER: That's part of it, but that
18 wasn't the only reason.

19 AUDIENCE MEMBER: It's every two years for

1 that.

2 DR. ASCHER: How often are we going back?

3 (laughter)

4 AUDIENCE MEMBER: As we've sat around here
5 and said, there appears to be no scientific upon
6 which the recommendations were made. It's not a
7 recommendation of the AICP. It appears to be a
8 political recommendation. Can we make a scientific
9 recommendation?

10 DR. KULLER: I think you can collect very
11 good scientific data on which to improve the
12 recommendation. And that I think is very good
13 priority. I think to think that a group of people,
14 because they're very smart, can sit around a table
15 and make a scientific recommendation based on non-
16 existent data is again become just political. But
17 we can certainly make a recommendation to collect
18 quality information, which may improve the
19 recommendation. I think that's important.

1 But I think it's difficult to make a policy
2 change when you have a successful policy, not based
3 on any -- unless you have very good strong new data.
4 Because otherwise if it doesn't work, somebody is
5 going to say, who made a policy change.

6 AUDIENCE MEMBER: Without a policy, there
7 is no way you can that this was a successful policy.

8 AUDIENCE MEMBER: The recommendation during
9 Desert Storm was in fact related to those forces
10 that might penetrate the border into Iraq because of
11 the increased incidence of meningococcal disease
12 among the Iraqi population. And it really wasn't
13 directed so much towards the Saudi Arabian issue. I
14 mean, you can't disregard that, but operationally
15 the issue was those forces that might even go across
16 the border be shot down and wind up in the Iraqi
17 area.

18 DR. KULLER: I think the infectious disease
19 committee can certainly take a very good look at

1 this and make recommendations about what needs to be
2 done to evaluate the data and improve the data base.

3 DR. ASCHER: This is another issue. When
4 we were always asked questions, which were very
5 limited, as Steve said, it really didn't give us
6 comprehensive views of this. We might need a
7 statement on this, which might have many of the
8 issues nested as you say that really is a
9 meningococcal statement. And if it changes anything
10 -- if it doesn't, it doesn't matter. We're just
11 saying where we are today. I think it's time to get
12 some of this written down.

13 MR. BLACKWOOD: There are some hand-outs
14 here for people who didn't get them. Colonel
15 O'Donnell, you had your hand up and then you kind of
16 backed out of it.

17 COLONEL O'DONNELL: No, I didn't have my
18 hand up. Or if I did, I've forgotten what I was
19 going to say.

1 MR. BLACKWOOD: Well, I think it's a good
2 time to move on. Thank you very much.

3 (Applause.)

4 DR. KULLER: Thank you very much. We're
5 going to walk over now to Building 1. Is that
6 right?

7 (Whereupon, at 5:30 p.m., the meeting was
8 adjourned, to reconvene on Friday, July 7, 1995, at
9 8:00 a.m.)

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