

ARMED FORCES EPIDEMIOLOGICAL BOARD

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DALRYMPLE CONFERENCE ROOM 1425
U.S. ARMY MEDICAL RESEARCH INSTITUTE
OF INFECTIOUS DISEASES
FORT DETRICK
FREDERICK, MARYLAND

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TUESDAY, MAY 30, 2000

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ATTENDEES :

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AFEB Executive Secretary

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COL. JOHN GRAHAM

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P R O C E E D I N G S

(7:45 a.m.)

DR. LaFORCE: As was pointed out to me by Ron Waldman, I'm late. There's a certain precision about starting. It says 7:30, and it's now 7:44 and a half, Ron. My apologies, and to everyone else. Good morning. It's my pleasure to call to order the Spring AFEB meeting here at Ft. Detrick. Welcome to everyone, and thank you all for coming.

I want to begin by thanking Col. Parker for hosting the group at USAMRIID. Thank you very, very much for having us here.

COL. PARKER: We are honored to host the meeting, so the pleasure is ours.

DR. LaFORCE: The last time I was here, I was telling Pierce Gardner coming up on the -- when we got lost getting here -- that, it was probably 35 years ago I was delivering some plague samples from a plague outbreak in Nepal, and I remember coming up here and wandering through these bucolic highways to find Ft. Detrick. And at the time security was actually very, very tight here. And I remember being assigned some poor soul who was a Ph.D., who followed me all day long. So, 35 years later I find myself coming back and, if anything, there have certainly been a lot of

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1 roads built. But, again, thank you very much for your
2 courtesy.

3 We've got new members that are added to
4 the group -- Linda Alexander. Linda, you are from?

5 DR. ALEXANDER: Chapel Hill, North
6 Carolina. I run ASHA, the American Social Health
7 Association.

8 DR. LaFORCE: Super. Dr. Bill Berg.
9 Bill?

10 DR. BERG: I'm from Hampton, Virginia, and
11 I run the Hampton Health Department.

12 DR. LaFORCE: Welcome. Phil Landrigan.
13 Phil's not here, I don't think. And Pierce Gardner, an
14 old friend.

15 DR. GARDNER: I'm from the State
16 University of New York at Stonybrook.

17 DR. LaFORCE: Departing members from the
18 Board, we've got several this year. Andy Anderson, who
19 is here; Ron Waldman is here, and Sue Baker, Dick
20 Jackson, Judith Larosa, Art Reingold, and Neil
21 Weinstein, who are not here.

22 We also have a couple of Preventive
23 Medicine Liaison Officers who are leaving. Capt.
24 Trump, I didn't realize you were leaving as the Liaison
25 Officer.

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1 CAPT. TRUMP: I'm waiting for orders, sir.

2 DR. LaFORCE: Waiting. Orders for where,
3 or is that a secret?

4 CAPT. TRUMP: No. Hopefully to the
5 University, Uniformed Services University of Health
6 Sciences.

7 DR. LaFORCE: Thank you. And Cdr.
8 McBride.

9 CDR. McBRIDE: Yes.

10 DR. LaFORCE: Ah, come on.

11 CDR. McBRIDE: I'll be transferring this
12 fall to the National Naval Medical Center in Bethesda.

13 DR. LaFORCE: So both of you are going to
14 be in the D.C. area.

15 CDR. McBRIDE: Yes.

16 DR. LaFORCE: Okay. We do hope that we
17 are able to keep some sort of contact. The Board
18 really thanks you both for all of the time that you've
19 put into AFEB activities.

20 Lastly, LtCol. Souter from Canada.

21 COL. DINIEGA: He's not here.

22 DR. LaFORCE: Okay. And a welcome to Col.
23 John Graham. Yes. Col. Graham, welcome.

24 COL. GRAHAM: I'm a stand-in for Col.
25 Andrew Ward.

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1 DR. LaFORCE: Andrew Ward, a famous
2 golfer. Actually, quite skilled golfer. Out of
3 personal terms, I know that.

4 Let me pass this on to Ben Diniega, who
5 has got some administrative comments and remarks to get
6 us started.

7 COL. DINIEGA: Good morning. As most of
8 you know, I am the Executive Secretary, and I have some
9 administrative remarks.

10 First, I want to thank Col. Parker and his
11 staff for hosting the meeting and making, essentially,
12 all the arrangements. I never had to do an onsite
13 visit, and that's very nice.

14 We are asking for donations for the
15 snacks, though -- a couple dollars to help defray the
16 cost of that. Otherwise, I'll be using my kids' college
17 fund.

18 We have some honored guests. First, Rear
19 Admiral Jarrett Clinton. Some of you may recognize
20 him. He previously at one time was assigned to the
21 AFEB, and he's familiar with how the AFEB works, and
22 we're very honored to have him. Later on, we'll be
23 hearing from him on the agenda on antibiotics and BW
24 agents.

25 Ms. Margaret Thompson, from Army Committee

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1 Management Office. She's attended some of the meetings
2 in the D.C. area to see how we're doing as an advisory
3 board, and she keeps me straight.

4 A special thanks to Ms. Teresa Howe for
5 working with Jean Ward from my office to put the
6 meeting arrangements together, and special thanks to
7 Jean Ward for her administrative support in getting
8 ready for the meeting. All of the handouts and things
9 that were sent out to special committee members, the
10 Infectious Disease Control Subcommittee and the
11 Committee on the Squalene Review got a lot of handouts,
12 and I think everybody got handouts to read ahead. So,
13 I hope everybody had the chance to review the handouts
14 and read-aheads to save some time and be thinking about
15 recommendations for the issues we have today.

16 A reminder to sign in. Outside, we have
17 sign-in sheets. Please sign in. That's the only way
18 we know who attended the meeting and who has interest
19 in the meeting.

20 Snacks and lunch -- I mentioned the
21 donations for the snacks. There are soda machines, but
22 they are down the hall past the secure door, so you'll
23 have to ask somebody from USAMRIID to let you through
24 the door, and it's to the left after you go through the
25 door.

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1 Lunch is on your own. We have about 75
2 minutes for lunch. There's an NIH cafeteria behind the
3 Headquarters Building this way. Ask people in, I
4 guess, Army uniforms, and they can help you, or we can
5 lead a caravan over or something at lunchtime. There's
6 also a McDonald's that you saw just off-base in the
7 strip mall.

8 The restrooms are down this hallway. When
9 you go out, turn left and make a right before the
10 secure door. The restrooms are located there.

11 The telephones are outside. There are
12 local calls, VSN and credit cards -- or telephone
13 cards.

14 Messages, two numbers for incoming
15 messages, goes to Col. Parker's office -- (301) 619-
16 2833 or 2772, and if you need to fax, it's the same
17 prefixes and the extension for the fax is 4625.

18 A reminder to the Board members, in order
19 to get reimbursed for your travel costs, don't forget
20 to send in your 1352s, and once they pay you, you get a
21 white paper that says that you got paid and things were
22 deposited into your account, please send us a copy of
23 that, too, so we'll know what the actual cost was for
24 the travel.

25 If you take a look at the agenda, the

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1 agenda is very, very full. We're trying to hold a
2 regular meeting along with our annual task to review
3 the Chairman's BW Threat List.

4 Today, we have three questions to the
5 Board to respond to, and you can see what they are on
6 there. One has to do with ergonomics, another with a
7 Squalene Review of a paper, and then the third is BW
8 agents and licensed antibiotic use.

9 Tomorrow's session is closed to the Board
10 members, Preventive Medicine Liaison Officers, and the
11 speakers that have been invited, and any other
12 specifically invited guests. For those people that
13 were invited to tomorrow's session, make sure your
14 security clearance was sent in to the Security Officer
15 up here at USAMRIID. You will need that to be in on
16 the closed session.

17 Subcommittee meetings where the
18 appropriate subcommittees will discuss responses to the
19 questions will be held from 3:15 p.m. to 5:15 p.m., or
20 longer if you need. I would recommend that any further
21 discussions be done as a subcommittee group in the
22 evening over dinner or before dinner. We would like to
23 have draft recommendations presented at the Executive
24 Session tomorrow for the rest of the Board to approve.

25 The subcommittee rooms, two subcommittees

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1 will meet here, Disease Control and Health Promotion
2 and Maintenance can meet here, and then we have -- I'll
3 find out the location of the second room for
4 Environmental Occupational Health to meet this
5 afternoon.

6 If anybody is interested in a tour of the
7 facilities here at the U.S. Army Medical Research
8 Institute for Infectious Diseases, Col. Parker is
9 willing to take people on a tour. Just by a show of
10 hands, who would be interested in a tour so we can fit
11 that into the schedule. It would have to be at the end
12 of the day. Can I see that show of hands again?

13 (Hands.)

14 About ten. So, at the end of the day,
15 about 1715, 5:15.

16 A reminder to speakers on the table and
17 questions from the audience, the speakers on the table,
18 around the table, are for both amplification and also
19 the transcriptionist. The meeting is being
20 transcribed. If you have something to say, please
21 state your name first and then ask your question or
22 make your comments. If you are in the audience, come
23 up to the corner and lean into one of these mikes on
24 the corner. They are voice-activated, so if you tap on
25 it -- if you're not sure, tap on it and it will

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1 activate the microphone.

2 The handouts -- we normally -- the order
3 for handouts will be one to me, one to the
4 transcriptionist, then the head table, and then the
5 rest of the audience. I asked the speakers to bring 70
6 handouts each, so there should be more than enough to
7 go around.

8 And, lastly, a reminder that the press,
9 members of the media are usually present at our open
10 meeting.

11 I personally want to thank the departing
12 members for all their service to DoD. We've changed
13 our style of trying to get things done over the years,
14 and e-mail has made that a little easier, and I know we
15 all have full-time jobs, but it's been good that
16 everybody has participated in reviewing and making the
17 recommendations on policy and program reviews.

18 The Preventive Medicine Officers leaving,
19 in my tenure, my two years so far at the Board as
20 Executive Secretary, I've had a great group of
21 Preventive Medicine Officers to work with, and they are
22 all members of the Joint Preventive Medicine Policy
23 Working Group under DoD, and a great bunch of people,
24 and I will certainly miss Capt. Trump and Cdr. McBride,
25 and I hope their replacements are just as able and easy

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1 to get along with as this group has been. So far,
2 we've been very lucky, and I look forward to working
3 with them all in the future, and also with their
4 replacements.

5 With that, we can start the meeting. Are
6 there any questions first?

7 (No response.)

8 DR. LaFORCE: We will begin with
9 introductory comments from Col. Parker, Commander of
10 USAMRIID.

11 COL. DINIEGA: Before you start, I just
12 want to say that this is Col. Parker's last meeting
13 also. He is getting -- they are firing him from his
14 job to go to the Army War College this summer, in July,
15 and he will be replaced by Col. Ed Eitzen, whom some of
16 you know. Ed is standing over here in the corner. And
17 I personally would like to say thanks to Gerry not only
18 for the time he's been up here and his support of the
19 meetings, but I've worked with him in the past on
20 special issues, the BW and chem issues, and we've had a
21 great time, and I certainly will miss him being around.

22 COL. PARKER: Thank you, Ben, and the
23 feeling is mutual, and we been working some of these
24 issues for a number of years. First, I want to also
25 welcome everybody to Ft. Detrick, and specifically here

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1 to USAMRIID. It is an honor and a pleasure for us here
2 at USAMRIID to host the Armed Forces Epidemiology
3 Board.

4 I was asked to give a short command
5 briefing, and I'll do that. Since we're running a
6 little bit late, I'm going to go through some of these
7 fairly quickly so we can try to get you back on
8 schedule because there is a full schedule. Go ahead
9 next slide.

10 (Slide.)

11 Well, first, my boss -- I just want to let
12 you know we all have our chain of command -- but my
13 boss is Major General John Parker, Commander of Ft.
14 Detrick and the U.S. Army Medical Research and Material
15 Command, and his boss is the Army Surgeon General, Lt.
16 General Ron Blank. But we have a lot of bosses. Our
17 funding comes in from a different source. Policy comes
18 in yet from another vector, and so forth. So life is
19 complicated down here in the lab but, nonetheless, this
20 is my straight chain of command. Next slide.

21 (Slide.)

22 Just a little bit about Ft. Detrick. We
23 are right here. This is our main building in USAMRIID.
24 We also occupy this laboratory, and we share some
25 laboratory space with USDA.

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1 A little bit about the history of Ft.
2 Detrick, which was brought up just a minute ago.
3 Before 1969, the U.S. had an offensive program, and
4 that offensive bio program began in the early '40s here
5 at Ft. Detrick. It involved a lot more locations other
6 than Ft. Detrick but, anyway, it began here at Ft.
7 Detrick, and now the National Cancer Institute is
8 located in this part of Ft. Detrick, and that's where
9 most of that offensive program was located when the
10 U.S. did have such a program before 1969. This
11 building is about 30 years old, opened up in 1969. Our
12 other lab is about 45 years old. So they are not new
13 buildings anymore. Next slide.

14 (Slide.)

15 Our mission, we're a tech-base research
16 organization, 6163 funding. We are the science
17 component, we are not the operators. We are the
18 science. Our job is principally to develop new vaccine
19 candidates, diagnostics, therapeutics, and, just as
20 importantly, the information, the underpinning
21 scientific information that supports the products we
22 are trying to develop. Ninety-nine percent of our
23 funding is in the Medical Biological Defense Research
24 program, a very small part also comes down under the
25 Endemic Infectious Disease Research Program principally

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1 for work on viral agents requiring to be worked on in
2 our maximum BL-4 containment. Education is also a big
3 part of our mission, and I'll talk about that more in a
4 minute.

5 Some of the unique capabilities that we
6 have here to conduct our overall mission. One of those
7 is the ability to put these agents up in an aerosol
8 form, and be able to understand how these diseases
9 cause their effects after an aerosol exposure, and then
10 to, just as importantly, evaluate our vaccine
11 candidates our therapeutics, or look at the kinetics
12 for diagnostics after that aerosol exposure. So we are
13 routinely working with anthrax, plague, hemorrhagic
14 fever viruses and so forth in an aerosol exposed
15 format, and developing the requisite animal models to
16 do that.

17 Diagnostics is a growing part of our
18 research portfolio, and we also serve as a reference
19 laboratory to support either the Public Health
20 community or the law enforcement community for working
21 up unknown samples.

22 Operational Medicine Division here is a
23 key component in the medical management of biological
24 casualties and education. And, of course, we are the
25 only maximum BL-4 biocontainment lab in the Department

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1 of Defense.

2 We have about 550 people employed here
3 right now. We have an authorized level of 420 people,
4 and in that delta between 420 and 550 we have a number
5 of onsite contractors now, NRC post-doctoral research
6 fellows, and in summer particularly we will bring on
7 some students.

8 It is multi-disciplinary. Our molecular
9 biologist expertise is in most demand today, but it
10 takes a multi-disciplinary approach, as you well know,
11 to accomplish the research mission that we do have.

12 As far as our unique facilities, we have
13 50,000 square foot of BL-3 laboratory space, and 10,000
14 square foot of BL-4 laboratory space. We even have a
15 BL-4 capable patient containment ward. And you will
16 see this, those of you who want to take the tour later
17 today, we'll be able to walk through the lab and see
18 some of these things up close.

19 The bottom line, our tech-base mission --
20 and we've had a heavy investment in developing new
21 vaccine candidates over the last several years -- but
22 we first have got to understand how these pathogens
23 cause disease. In this case, we have anthrax spores,
24 and we have to understand how it causes disease at the
25 molecular level and, in the case of anthrax, we have a

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1 lot yet to learn at the molecular and the whole-animal
2 level of disease pathogenesis. But then we have to
3 understand what parts of that can elicit protective
4 immune responses that can serve as the basis of new
5 vaccine candidates. And then we've got to be able to
6 test that, as I mentioned earlier, in our aerosol
7 exposure models to ultimately get something in a
8 bottle.

9 And this is just an example of some of the
10 vaccine candidates that are either transitioned from
11 the tech-base into advanced development, or very mature
12 in the tech-base and we hope to transition in the very
13 near future.

14 There is a cell culture-derived smallpox
15 vaccine candidate that transitioned actually back in
16 '94 to advanced development. Recently we had a
17 transition of an infectious clone for Venezuelan Equine
18 Encephalitis into advanced development, and also a new
19 recombinant Botulinum vaccine. Still in the tech-base
20 is a new plague vaccine candidate based on F1-V and
21 this is actually a F1-V fusion protein, and we have a
22 recombinant protective antigen vaccine candidate that
23 could serve as a new vaccine for anthrax. We have a
24 robust program in staph-enterotoxins into a good
25 candidate recombinant products for SEB and SEA.

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1 And then we're also looking at multiple-
2 agent vaccine and looking at different ways to deliver
3 vaccines. And one of those that we're most -- two
4 major approaches we're looking at here, DNA-based
5 vaccines, but the one we're most excited about is a B-
6 replicon vaccine delivery vehicle, and one of the
7 candidates that looks very promising is a Marburg-
8 replicon vaccine candidate that we've demonstrated
9 protection against a Marburg challenge in a non-human
10 primate.

11 But we're also looking at treatments, and
12 we'll look at, say, antibiotics against the bacterial
13 threats. Now, we don't develop antibiotics here, but
14 we do leverage what's coming out of industry and test
15 the newer generation antibiotics in the relevant animal
16 models against the inhalation challenge.

17 We're also increasing an investment in
18 antivirals and actually have some candidates that have
19 some hope for promise against both the orthopox viruses
20 and the viral hemorrhagic fever viruses. And as we are
21 speaking right now, there's a group collaborating from
22 here at USAMRIID and the CDC actually working with a
23 Varicella virus down at CDC this spring and through
24 parts of June, principally to look at antiviral
25 research specifically against Varicella. And we are

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1 also looking at novel therapeutics specifically for
2 some of our toxins and Botulinum neurotoxins, trying to
3 develop and discover compound that can interrupt the
4 enzymatic activity, the BOT neurotoxin, but also be
5 able to deliver the new compound into its target, the
6 presynaptic nerve terminal.

7 We also need to begin to think about new
8 threats, emerging threats. We have our classic BW
9 threats and we're going to hear more about that
10 tomorrow, but it's time for us to also begin to
11 consider how we're going to deal with emerging or
12 genetically engineered threats, and that's very
13 difficult to get your hands around that. And it's hard
14 to identify what the threat is. And we've been
15 participating in a number of committee meetings to try
16 to address that. But the bottom line, our approach
17 right now is to develop the tools and have the
18 databases and have the collaborations so we can first
19 be able to identify that we, in fact, may be dealing
20 with something that's new.

21 Diagnostics is, again, a growing part of
22 our investment portfolio, trying to develop small,
23 sensitive and specific medical diagnostics, not
24 environmental detection, but medical diagnostics that
25 can be fielded in our forward deployed laboratories.

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1 And, of course, USAMRIID also serves as a reference
2 laboratory for the Department and also in collaboration
3 with our colleagues, either with the CDC and Public
4 Health and Law Enforcement and a few other customers.
5 But, again, our job is to develop the sensitive and
6 specific diagnostic platforms.

7 And we have a very close relationship, a
8 unique relationship, with the Army's only deployable
9 medical laboratory, the 520th Theater Army Medical Lab,
10 and this has been a very valuable interaction for us at
11 USAMRIID. In fact, I often talk about this as being
12 USAMRIID Forward, and it allows us to insert some of
13 the newest technology that we're developing in the
14 laboratory into a field environment. It's good for us
15 because often in the laboratory we don't anticipate
16 what it's going to be like in the field, and more often
17 than not we may think something works great in the lab,
18 we put it in the field and it falls apart.

19 So this has been very valuable to have our
20 scientists working in this environment, and it's been
21 very good for the Field Laboratory because they could
22 not be able to get the latest and greatest technology
23 with the standard sets, kits and outfits in our TO&E
24 environment. So, it's been a good way to get the
25 equipment into the field.

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1 And this is just a photograph of the unit
2 as deployed to Kuwait in real honest to goodness
3 situations, and the value of a deployable laboratory
4 has proven itself.

5 We're also now working stronger than ever
6 -- for years, we've had strong collaborations with our
7 colleagues in the Public Health community, specifically
8 at the NIH and the CDC, but as now there is a growing
9 concern of bioterrorism in the United States and the
10 CDC now has a new mission in bioterrorism preparedness,
11 our collaborations have just grown even stronger. And
12 so we are working very hard to try to support them in
13 their new mission and endeavors, and trying to link up
14 the expertise because when you get down to it we really
15 do have limited expertise in our country that are
16 familiar with working with some of these pathogens.

17 Just an example, some of the areas we're
18 working on, collaborating with the NIH and we will be
19 as well with the CDC, on a new recombinant protective
20 antigen vaccine candidate for anthrax. As I mentioned,
21 we have collaboration on smallpox, specifically
22 antivirals, but it's also looking at vaccines and
23 diagnostics. And then we've also been able to work
24 closely with Law Enforcement, Public Health in the
25 laboratory support.

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1 Occasionally, we do get called upon to
2 support the Public Health community in disease
3 outbreaks, and this is just a list of some of the
4 outbreaks that we've participated on through the years,
5 and just when we had expertise and it's asked, then we
6 usually provide them. Most recently, of course, was
7 the West Nile outbreak last summer, early fall.

8 We get involved in supporting the
9 Department and U.S. Government Interagency in
10 bioterrorism preparedness. We're not shooters, we're
11 not operators here, but we often get tapped for the
12 scientific and medical knowledge. And so we serve as
13 medical and scientific consultants and reference
14 laboratory support. And we have physicians and
15 scientists assigned or tapped to respond to several
16 emergency response teams, like the Chem/Bio Rapid
17 Response Team supporting the FBI through the DEST,
18 Domestic Emergency Support Team, and State Department
19 through the Foreign Emergency Support Team. And this
20 is a number of organizations that we have supported
21 through the years and support now.

22 Education is very, very important, and for
23 years we've conducted the Medical Management of
24 Biological Casualties Course right here in this
25 conference room, but three years ago we put this course

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1 on a Satellite Distance Learning venue, and last year
2 we also did this in partnership with the CDC. The
3 information is basically very similar whether it's a
4 military audience or civilian audience, health care
5 audience. There are some different twists for DoD and
6 civilian, but the basic scientific medical knowledge is
7 the same.

8 And some of the other products produced by
9 the Institute and our sister lab, the Institute of
10 Chemical Defense. Of course, the textbook on Military
11 Medicine is devoted to chemical and biological casualty
12 management, and then the handbooks. I think there's a
13 copy of the blue book at your table.

14 But the bottom line, we have a number of
15 vaccine candidates that are fairly mature in the tech-
16 base, but one of the things that keeps me awake at
17 night is making sure that we maintain the underpinning
18 scientific expertise so we are able to work on the
19 problems that haven't even been identified to us yet,
20 and there are going to be not only the classic BW
21 agents that we need to know more about today, but there
22 are going to be the emerging threats that we are going
23 to need to be able to respond to in the future.

24 And so we are a tech-base organization.
25 And we are committed to improving readiness.

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1 Sometimes, though, it may take ten, 15 years for
2 something we're working on today to have a direct
3 impact on readiness, like a new vaccine candidate, but
4 our folks here, our scientific staff here, works pretty
5 hard in making sure our knowledge can be tapped today
6 and have an effect on readiness today.

7 So, with that, I will conclude, and if
8 there's any questions I'll be happy to answer them
9 right now; otherwise, we can talk more when we take a
10 tour later in the day.

11 DR. LaFORCE: Thank you, Col. Parker.
12 Questions?

13 (No response.)

14 If not, again, thank you. Let's go on to
15 the Preventive Medicine Officer updates. The first
16 presentation, Capt. Trump.

17 COL. DINIEGA: While Capt. Trump is
18 getting up, the blue book, copies of the blue book are
19 on the back table here, and extra copies of the agenda,
20 if anybody needs those.

21 CAPT. TRUMP: Good morning. I'll keep
22 this first brief short. You've already been introduced
23 to RADM. Jarrett Clinton. He is the Deputy Assistant
24 Secretary of Defense for Health Operations Policy, and
25 within Health Affairs he really is the responsible

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1 person for Operational Medical Policy, the preventive
2 medicine policy as it applies to the operating forces,
3 to those who are in uniform. He is the key person for
4 biological warfare defense issues, including the
5 anthrax vaccine program, and also the medical research
6 initiatives as far as health affairs involvement in
7 health policy oversight. And you'll be hearing from
8 him and Col. Takafuji later on today about anthrax
9 vaccine and about biological warfare defense issues.

10 Anthrax vaccine is one thing that
11 obviously continues to be of interest throughout the
12 Department of Defense, and I'll just touch on two
13 issues this morning. One is to call your attention to
14 an April 28th issue of the Morbidity and Mortality
15 Weekly Report, which reported on some DoD surveys for
16 anthrax adverse events, and summarized work that had
17 been done at the Tripler Army Medical Center and also
18 in Korea that was really a joint effort of many within
19 the Department, headed by Naval Health Research Center,
20 but also with a lot of support from staff here at
21 USAMRIID, others within the Army Office of the Surgeon
22 General that has oversight for the anthrax program,
23 vaccine program of implementation, and others within
24 all three services.

25 The other role I have as the DoD

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1 representative to the Advisory Committee for
2 Immunization Practices, and the ACIP does have a
3 working group that is looking at the biological warfare
4 defense vaccines and revising the pertinent ACIP
5 recommendations for those vaccines, to include their
6 use for bioterrorism response within the United States.

7

8 The anthrax vaccine recommendation is
9 probably as close to a final draft as the working group
10 can get it, and that will be presented to the ACIP at
11 their meeting at the end of June, and we're hoping for
12 a decision at that time or shortly thereafter about
13 acceptance of that and application to follow.

14 The other effort they've started is with
15 the smallpox vaccine and started to work on that
16 recommendation. And, again, that's one that although
17 the CDC National Immunization Program has the lead for
18 these efforts, they are turning towards many within the
19 Department of Defense, including staff here at
20 USAMRIID, for key parts of the scientific expertise to
21 bring to making those up-to-date recommendations.

22 Within Health Affairs, we're a small
23 staff, but prevention initiatives fall across many
24 different parts of the organization, and even within
25 Health Operations Policy, several of us -- Col.

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1 Takafuji in particular and I -- look at different parts
2 of the preventive medicine issues. Within other parts
3 of Health Affairs, we have the clinical and program
4 policy, and you'll hear later this morning from Lynn
5 Pahland who is on that staff, which really has
6 oversight for the prevention initiatives that are much
7 more broadly applied both to the active military force
8 and also to our other beneficiaries, family members and
9 retirees, in the areas of -- and you'll hear more about
10 that with the tobacco prevention and DoD alcohol and
11 suicide programs.

12 And then, finally, just a reassurance to
13 Dr. LaForce and Col. Diniega, I've been attending Armed
14 Forces Epidemiological Board meetings long before I
15 represented either the Navy or DoD here, and I suspect
16 that as long as I'm in uniform I'll continue showing up
17 at these from time to time. Thank you.

18 DR. LaFORCE: Thank you, David. The next
19 speaker is Ben Withers, Preventive Medical Officer at
20 the Army Surgeon General's Office.

21 COL. WITHERS: Good morning, and thank
22 you, Dr. LaForce. I'm Col. Ben Withers, Army
23 Representative to the AFEB. Next slide, please.

24 (Slide.)

25 I'll be covering these topics this

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1 morning. Next slide, please.

2 (Slide.)

3 Okay. West Nile Fever surveillance, the
4 North Atlantic Regional Medical Center, that's Walter
5 Reed in the region, has developed this plan for
6 prevention, surveillance and control of West Nile
7 Virus. I covered this last meeting, as you will
8 recall.

9 Additionally -- and this is the last
10 bullet -- starting in June, reports will be provided
11 weekly to the Department of Defense Global Emerging
12 Infection System, which will then collect and pass the
13 information to the CDCP for use in their national West
14 Nile surveillance effort. Next slide, please.

15 (Slide.)

16 On the topic of Varicella Screening and
17 Immunization, we are still developing this policy,
18 coming a little slower than we wanted. We didn't want
19 to go full serology like our sister services, but money
20 has become an obstacle, mainly in the laboratory. We
21 are at five locations instead of one, it would have
22 meant that we had to gear up five laboratories, hire
23 five new people. It all gets expensive quickly, and so
24 I'm sure we're going to go with a blended approach
25 involving history, records, and serology for those that

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1 are still in question.

2 One thing we're going to discuss with the
3 sister services is doing serology on everyone at the
4 recruit station -- not at the boot camp level, but at
5 the boot station. We can all get away with that for
6 about \$2 a test. It would be cheaper for all of us, so
7 we actually may go that way, but we'll have to see
8 about that. Next slide, please.

9 (Slide.)

10 Okay, chlamydia screening generated a lot
11 of discussion when I spoke last meeting. As you
12 recall, the AFEB recommended that we screen all females
13 on accession and with each yearly GYN exam through the
14 age of 25. Now, for the Army, this is turning out to
15 be a complex issue that will require an incremental
16 approach. The most expeditious and efficient first
17 step is to implement screening for females through age
18 25 during routine GYN exam. Fulfillment of the full
19 AFEB recommendations will require study of STD
20 education programs, male screening programs, and other
21 Chlamydia-related interventions. We'll have to bring
22 CHBM (phonetic) into this, and in the long-term it will
23 also require the deployment of what we call "chcs-ii".
24 That's an acronym which is really our master computer
25 with which we run peacetime medicine, hospital-based

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1 automation.

2 Eventually, we want to screen new female
3 recruits during basic training using urine
4 amplification. This avoids a negative impact on
5 recruitment, while at the same time having minimal
6 effect on training time. However, many issues have to
7 be addressed. The cost is approximately \$1.5 million a
8 year, we think. Again, we have to deal with lab
9 resources, whether we want to do this inhouse or
10 contract it, confirmatory testing and public health
11 reporting and tracking has to be dealt with.
12 Nonetheless, we expect to have a policy by the end of
13 the summer. Next slide, please.

14 (Slide.)

15 I thought I'd tell you about a recent
16 outbreak we had of acute respiratory disease. This
17 occurred at Ft. Benning, one of our five training camps
18 in southern Georgia, in late April of this year, and
19 was investigated by our epidemiological consultant
20 service. What you are seeing here is the epidemic
21 curve. You can't really read it, but the five lines
22 are -- well, as you see there, numbers of soldiers per
23 hundred trainees, so we had a balance from about .5 to
24 1 up to 2.5 all of a sudden at the end of April. Next
25 slide, please.

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1 (Slide.)

2 By the time it was over, we had 195
3 trainees admitted to our hospital over a three-day
4 period with no deaths. The initial presentation was
5 consistent with either influenza or adenovirus and, in
6 fact, 29 of 43 rapid diagnostic tests for influenza
7 were positive; however, they were falsely positive. In
8 the end, viral cultures were all positive for
9 adenovirus. Selected findings include no particular
10 hangups or problems with our medical in-processing,
11 overcrowding in the barracks was not a particular
12 problem, although there was a linkage with sleeping
13 density, and poor air quality was noted. Next slide,
14 please.

15 (Slide.)

16 Influenza vaccine extension. As some of
17 you may not be aware, we give influenza vaccine year-
18 round at training camps. It sort of caught all of the
19 services by surprise that the manufacturers labeled the
20 '99-00 vaccine to expire June 30th whereas September
21 30th had been customary in the past. I contacted the
22 Shelf Life Extension Program Office at the U.S. Army
23 Medical Materiel Agency right here at Ft. Detrick, and
24 asked them to intervene on our behalf.

25 The process is that the FDA can and will

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1 review manufacturer data and can extend a product.
2 However, in this case the manufacturer won't warrant a
3 product which has already been released out of their
4 control. They will provide the data which is
5 essentially good for stocks they still have, but they
6 won't warrant things that are already out of their
7 control. Therefore, the FDA won't extend an
8 unwarranted product. So we're sort of in a Catch-22.

9 The '00-'01 vaccine, however, we've
10 already been told will be labeled such that it expires
11 on August 31st. The FDA does strongly desire a gap
12 between one year's vaccine and the next to avoid
13 confusion. Next slide, please.

14 (Slide.)

15 Okay, this is a quick one. Meningococcal
16 Immunization Policy, I expect us to get this signed and
17 distributed this week. This is a minor expansion of
18 current policy which follows the ACIP recommendation to
19 provide information and an offer of meningococcal
20 vaccine to college freshmen. Next slide, please.

21 (Slide.)

22 I thought I'd just tell you about this.
23 In fact, some of you AFEB Board members are on this
24 committee and so you know about it, but recently the
25 Medical Research and Materiel Command requested, if you

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1 will, contracted the Institute of Medicine to review
2 the naturally-occurring infectious disease threat to
3 military operations on a two-year time line. Subtasks
4 include to define and prioritize the diseases of
5 relevance, to determine the status of available
6 vaccines, and to examine the Military Infectious
7 Disease Research Program, looking at its priorities,
8 vaccine development, and role. The eventual product
9 that MRMC is looking for are recommendations for a
10 comprehensive strategy that Medical Research and
11 Materiel Command and Department of Defense could adopt
12 to best apply their resources toward development,
13 licensure, production, stockpiling, distribution, and
14 use of vaccines against naturally-occurring diseases of
15 military importance. Next slide, please

16 (Slide.)

17 That's all I have to say today. Are there
18 any questions?

19 DR. ALEXANDER: I have a question
20 regarding chlamydia. I guess it had been my
21 understanding that military health care, at a minimum,
22 was consistent with civilian guidelines and practices
23 in terms of infectious diseases. And, frankly, coming
24 from the military, I always thought the military was
25 more on the cutting edge than the civilian sector. So,

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1 I'm a little aghast at where you are with chlamydia
2 screening, given that the standard of care in civilian
3 settings is for routine screening using amplified
4 testing for women. Why is it that it's not in place
5 for the military?

6 COL. WITHERS: I honestly don't know how
7 it compares to the standard in the civilian community.
8 That's one thing I'm not sure of.

9 DR. ALEXANDER: Well, CDC guidelines and
10 HDIS (phonetic) guidelines have recommended routine
11 screening now for quite a long time. In fact, we've
12 even been successful in ensuring that amplified testing
13 be the standard of care in Medicaid and Medicare
14 populations. So to have the female soldier portion of
15 our population subjected to less than standard care, to
16 me, seems somewhat egregious.

17 COL. WITHERS: I must admit, I don't have
18 a great answer. When we are looking at it all at once
19 in terms of getting into it, so to speak, or
20 implementing it, it's a resource problem. That's my
21 easy and quick answer. Why we didn't do this a long
22 time ago, I honestly don't know.

23 DR. ALEXANDER: Chlamydia is particularly
24 intriguing, given that the investment of \$1.00 up front
25 in screening saves \$12 down the road in treatment

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1 costs. So, the cost-benefit analysis with chlamydia is
2 pretty well established globally.

3 COL. WITHERS: I don't know. Perhaps my
4 other service colleagues would answer for me, or at
5 least help me out here.

6 CDR. McBRIDE: Let me respond to that, if
7 I may. For some years, we have done chlamydia
8 screening at the Recruit Training Center in Great
9 Lakes, and then through this effort we are very pleased
10 with the results. We felt that it was money well
11 spent. And it came to the attention of the Armed
12 Forces Epidemiological Board that the screening policy
13 within the services was not consistent, and so this
14 became an issue over the last couple of years, and this
15 has come to our mind, and we are trying to correct
16 this.

17 I don't know why this has been overlooked
18 in the last few years. Some of the concern has been
19 that there had been no controversy or difficulty as to
20 where would we do the pelvic examination and pap smear
21 of women entering the military services, and I think
22 some of it had to do with -- there were some concerns
23 it should be done at the military entrance processing
24 stations where they get their prephysical exam before
25 they even go to boot camp, and then in some services

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1 they were doing it at boot camp. And so there was some
2 difficulty and some challenges as to when they would
3 time this, and then do the chlamydia screening at that
4 time. But that was not entirely correct because you
5 could do a chlamydia screening without the benefit of
6 the pelvic exam, and so that kind of raged for a year
7 or two. But we're happy to say that regardless of
8 what's happened over the past few years, we now have a
9 recommendation from the AFEB, and I think the services
10 are moving forward to everyone now do chlamydia
11 screening. And so we're moving forward in that regard.

12 DR. LaFORCE: Do you have a comment, Ken?

13 And can you say your name before you make your
14 comments?

15 CAPT. SCHOR: This is Capt. Schor. The
16 only thing I would add to Wayne's comment is that from
17 a standard of care standpoint, at the annual pap and
18 pelvic exam of active duty women, I think we meet and
19 exceed the standards of care in the civilian world.

20 What this question and this issue has
21 addressed is at points of accession when you're
22 bringing large numbers of women in, what is the most
23 effective and efficient and cost-effective time and
24 means to screen women for chlamydia. It may not be the
25 best time to do that when they are doing their recruit

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1 accession. You may need to wait until they get past
2 boot camp. There are a lot of different issues that
3 have been addressed in this issue, and I think that,
4 again, yes, money does drive some of this, but I think
5 that when it gets down to the annual pap and pelvic
6 exam, those standards are met.

7 DR. ALEXANDER: I would emphasize that
8 urine-based screening is pretty normative globally now.

9 Even in developing countries, we're going to urine-
10 based screening. So the idea of withholding the
11 testing for GYN exam really -- and the reason I'm, I
12 guess, being a little assertive here is that as we look
13 across the spectrum of other STDs, the opportunity in
14 the future for multiple testing with a single specimen
15 is very real. So if this were implemented now, the
16 infrastructure would be in place to include a battery
17 of testing in the future, which would be obviously
18 advantageous to the service as well as the
19 participants.

20 COL. WITHERS: Thank you for your
21 comments. I'm sorry I don't have a lot more to say
22 about it.

23 DR. GARDNER: Pierce Gardner, Stonybrook.
24 Last week I participated in a conference call from the
25 Advisory Committee on Immunization Practices that

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1 indicated that this year there's a major problem in
2 influenza vaccine production, and that they are
3 expecting to be significantly late, and that only about
4 50 percent of the targeted production will be available
5 on time. So, you need to plan on that, and whether it
6 has effect on stockpiling neuraminidase inhibitors or
7 other approaches is an interesting question that
8 perhaps should be considered.

9 COL. WITHERS: Thank you.

10 DR. LaFORCE: Another thing is, Colonel,
11 do you have any data from the Fort Benning outbreak in
12 terms of cost and disruption of training?

13 COL. WITHERS: No, sir, I don't, not more
14 than I presented. Reviewing that, the epidemic was
15 concentrated in one battalion and in even one company,
16 or about 100 man units. So, if we had -- and I'm sort
17 of extrapolating here from what I said, but if we had
18 195 admissions, that would be in a training battalion
19 of about 500 men.

20 DR. LaFORCE: Do you know if there was any
21 recycling that had to occur as a result of the
22 adenovirus?

23 COL. WITHERS: Yes. I heard that
24 discussed, and it was minimal. We got away with it
25 because the epidemic was up and down quickly enough

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1 that few, if any, were recycled in this case.

2 DR. LaFORCE: Thank you.

3 COL. WITHERS: I think that was just a
4 lucky stroke, Dr. LaForce, on our part.

5 COL. DINIEGA: The issue of ARD will be on
6 the agenda in September, and we have about four talks
7 on the status of ARD in the services, so that's a big
8 topic for our next meeting.

9 DR. BERG: Bill Berg. Col. Withers, you
10 mentioned that there had been tests done for influenza
11 virus and they were all falsely positive. Could you
12 elaborate a little bit on that and what test you used
13 and what is the role, and particularly the future role?

14 These tests are becoming more and more widely used,
15 and you've raised some questions as to their validity.

16 COL. WITHERS: Well, yes, sir, I did.
17 Unfortunately, I don't know anymore details about this.

18 Obviously, somebody there had a test and applied it to
19 roughly a quarter of the soldiers that came in, and
20 with a lot of false-positives. I'm afraid I don't know
21 what test or what the screening parameters were for
22 that.

23 DR. LaFORCE: Could you get that for us,
24 please?

25 COL. WITHERS: Yes, sure can.

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1 DR. LaFORCE: If you would, and then we'll
2 get it back to you because this sort of thing isn't
3 supposed to happen with current testing stuff, and you
4 sense that somebody just got it wrong at that
5 particular lab because these are very -- they've got
6 pretty good sensitivity and pretty good specificity in
7 terms of the testing.

8 COL. WITHERS: I'll get a little fact
9 sheet up on that and distribute it to the Board.

10 DR. LaFORCE: Okay. Thank you, Ben.

11 COL. WITHERS: Thank you, sir. Let's go
12 on to the next presentation, Cdr. McBride.

13 CDR. McBRIDE: Thank you. Let me just
14 review several things. I have no slides, and so I'll
15 go swiftly through a short list that I have. Let me
16 follow up on a couple of issues that Ben brought up
17 regarding some of the programs that the Army is engaged
18 in.

19 I'll give you a quick review of the
20 Varicella program in the Navy. Several years ago, we
21 started Varicella immunization as a routine at the
22 Recruit Training Center in Great Lakes. Many of you
23 know of this and the success we've had with that
24 program. I'm pleased to say that the two Marine
25 Recruit Depots, San Diego and Parris Island, have now

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1 started this. San Diego has embraced, at least
2 initially, a form of doing history on their incoming
3 recruits and then immunizing those that report they
4 don't know or they have not had a previous infection.
5 We're following that. It's a little earlier yet to see
6 what kind of data we're going to get from that, but
7 we'll follow that with interest and perhaps report that
8 to you as to what their experience has been.

9 The Marine Corps Recruit Depot in Parris
10 Island has recently obtained a machine to do the
11 serologies there onsite, and they are moving forward
12 with doing 100 percent serologic determinations and
13 then, of course, immunizing the sero-negatives.

14 Meningococcal vaccine is now a requirement
15 at the Naval Academy, and that's going well. With
16 regard to the Naval Academy, they are also giving
17 Varicella vaccine, but they find that in the
18 registration papers that are given to the incoming
19 Midshipmen, they ask for very specific information on
20 immunizations, and they find that the data that they
21 come back with when they come to Annapolis is very
22 accurate, and so they only find that there is about 1
23 percent of the incoming Midshipmen that have not had
24 the vaccine or have not had a doctor-confirmed history
25 of Varicella, and so they give the vaccine to less than

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1 1 percent of their incoming freshmen, and that's been
2 very successful.

3 Just an aside here, we've looked at
4 obtaining records of immunization from our recruits in
5 a way to lower the cost of vaccinating our recruits in
6 the Navy and the Marine Corps, and it's been very
7 difficult even to get the recruiters to help the
8 incoming recruits bring very good records, and that's
9 not been very helpful. We found that the information
10 on these little sheets, you know, different forms and
11 papers that they come in, have not been very helpful,
12 and so we've found that we have not been able to rely
13 on immunization information from the recruits. The
14 numbers have been very low and the quality of the
15 record has been very poor. And so we've not been able
16 to find it of great benefit in obtaining records of
17 immunizations from our Navy and Marine Corps recruits.

18 You'll be interested to know that we are
19 in the Navy undergoing a comprehensive review and
20 update of our tuberculosis control program instruction
21 reflecting the most recent recommendations that have
22 come forward from the American Thoracic Society and the
23 CDC, and we hope to have that out this summer.

24 A comment about West Nile Fever
25 surveillance. We're joined today by one of our senior

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1 entomologists in the Navy, Cdr. Michael Mann on the
2 side there, from the Navy Environmental Health Center.

3 He and the entomologists from Jacksonville, our
4 Disease Vector Ecology Control Center in Jacksonville,
5 have already started a vigorous program of West Nile
6 Fever surveillance among all of the Navy bases on the
7 eastern coast here, and liaising closely with local
8 authorities and jurisdictions, and this has just
9 recently started and we hope to be able to provide more
10 information on that, but we have embarked on that
11 important effort.

12 Let me give you a quick update on our
13 hepatitis-B immunization policy. You may remember that
14 in the Navy and Marine Corps recently we've tried to
15 enlarge and expand our hepatitis-B vaccination policy.

16 I'm pleased to say that this was among a number of
17 initiatives that have been approved by the Bureau of
18 Medicine and Surgery for funding, but unfortunately we
19 have yet to see any dollars. In the vagaries of this
20 budget process, this can take some time, but we're
21 hopeful that we'll be able to move forward in expanding
22 the hepatitis-B vaccination to many of our Marines,
23 particularly those who operate in the Asian Pacific
24 area, so we're moving forward with that.

25 We've been very supportive of the Army's

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1 efforts to extend the shelf life of influenza vaccine,
2 and particularly with what Dr. Gardner has indicated,
3 we hope that that will be successful.

4 I don't see Col. Bradshaw with us. I'll
5 just make a quick plug. He has led an effort within
6 the Joint Preventive Medicine Policy Group to revise
7 and update the Joint Service Immunization and
8 Chemoprophylaxis instruction. This is a comprehensive
9 instruction that provides the services guidance on our
10 immunization programs that is consistent throughout the
11 Department of Defense, and the Coast Guard benefits
12 from this instruction as well, and we are nearing the
13 completion of a vigorous effort to update that, and we
14 want to commend Col. Bradshaw for his remarkable
15 efforts in leading that.

16 Those are the issues I wanted to share
17 with you this morning. I neglected to say that on
18 behalf of the Preventive Medicine Liaisons, I want to
19 welcome the new AFEB members, particularly Capt. Berg,
20 Navy Retired, glad to have him with us, but as I
21 transition off of my position later this fall, I
22 express my appreciation for the opportunities to
23 contribute to the AFEB and would welcome additional
24 association in the future. Are there any questions or
25 comments?

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1 COL. DINIEGA: I do have a comment. Cdr.
2 McBride talked about the test management side of the
3 house and entomologists increasing their surveillance
4 for West Nile. I talked to Col. Don Driggers
5 (phonetic), who is on the Armed Forces Pest Management
6 Board, and he along with all the services have notified
7 their installations to increase their surveillance for
8 West Nile Fever carriers.

9 DR. LaFORCE: I also would make an
10 observation, Cdr. McBride, on the whole issue of
11 accurate vaccine information that is person-specific.
12 The National Vaccine Advisory Committee met last week,
13 last Monday and Tuesday, and devoted almost a half a
14 day to the whole issue of vaccine registers, and this
15 is an effort that began a while ago but has had a lot
16 of -- Steve would know about this in terms of CDC has
17 actually become very involved in this -- and it was
18 based on the huge success of vaccine registers in
19 England, in terms of using vaccine registers to achieve
20 rather astonishing immunization coverage. If you know
21 what's happened to an individual, you can really focus.

22 And there is now a major effort to actually get this
23 funded across all 50 States. And if that were to
24 happen, then what would naturally unfold would be a
25 person-specific record that would be available when

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1 somebody is 18 years old through an organized database
2 that actually talks to itself.

3 And during the course of discussion, I had
4 the opportunity to bring up the issue that had come up
5 here several times, which is the fact that at the time
6 of accession, information in terms of immunization
7 status per inductee is woeful -- not that it hasn't
8 been done, it just hasn't been codified in any way that
9 is of value to military public health officials.

10 So there may be some progress along this
11 line. If that were to happen, I think this is an
12 issue, as the effort matured, would disappear obviously
13 as these cohorts matured so that it would be over
14 within 15 or 20 years.

15 CDR. McBRIDE: I appreciate that. Let me
16 make a followup comment, if I may. I know there are
17 many states that do have a vigorous immunization
18 tracking program, at least for their children and
19 infants, and in the Navy some of our medical treatment
20 facilities are embracing this. And even though for the
21 last three years the DoD has been working on and
22 improving our immunization tracking systems within the
23 services -- and as you may know, all active duty
24 immunizations, or at least certainly anthrax, are being
25 pushed up to the DEERS -- some of our hospitals in

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1 Florida and California, that I know of, are seeking
2 liaisons and working with these state immunization
3 registries so that the immunizations given to children
4 are recorded in the state where they are administered.
5 And we are hoping that this will enlarge and we can
6 only benefit from continued efforts in this regard.

7 DR. LaFORCE: Thank you.

8 DR. GARDNER: Could I ask a brief question
9 to Cdr. McBride? You were talking you're expanding the
10 hepatitis-B immunization program. As a newcomer, I
11 assume that hepatitis-B would have been a bedrock of
12 immunization. What is the current policy that needs to
13 be expanded?

14 CDR. McBRIDE: Many of us are familiar with
15 this, but I'll share it with you quickly in the
16 interest of time. For many years now, hepatitis-B has
17 been routine immunization within the services for only
18 specific indications. All Medical Department personnel
19 are routinely immunized, and others who have
20 occupational risks, and then those who are evaluated
21 for asexually transmitted disease are given the
22 immunization. And that has been the policy for many
23 years.

24 DR. GARDNER: I would have thought that
25 all members of the Armed Forces would be at

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1 occupational risk.

2 DR. McBRIDE: Well, this has been
3 something that has been very controversial over the
4 last several years. You may or may not know that many
5 years ago the AFEB gave a recommendation that all
6 individuals in the military would be immunized
7 routinely, but this was not embraced by the services at
8 the time. And though there have been those who have
9 sought to have this policy enlarged, it has not
10 received funding, and largely because of the cost-
11 benefit considerations on this. And it's been
12 difficult to show that a vigorous immunization policy
13 with hepatitis-B would really result in some cost-
14 savings. Well, notwithstanding that we in the Navy and
15 particularly the Marine Corps and Ken's efforts here
16 have been trying to push this forward, and I think we
17 are finally getting there.

18 I don't know, other than because of cost
19 considerations and the lack of a convincing cost-
20 benefit analysis within the services, that this has not
21 been embraced heretofore, but we are hoping to correct
22 that as well as we continue with this effort.

23 DR. LaFORCE: It may well be that the cost
24 of hepatitis-B vaccine has gone down rather
25 dramatically in recent years, and I know that this was

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1 a very contentious debate that occurred, I don't know,
2 maybe ten or so years ago, and it may well be that --
3 we'll talk to Ben -- that maybe this needs to get
4 looked at again in terms of it because the cost-benefit
5 analysis is going to be a bit different now because of
6 the cost of vaccine that has gone down rather
7 dramatically over the last several years.

8 CDR. McBRIDE: It has, and I think that we
9 could only benefit -- the services could only benefit
10 or our efforts to enlarge this program could only be
11 benefitted by a reinforcement of the AFEB of their
12 long-standing recommendation. And given that the cost
13 of vaccination has significantly diminished for
14 hepatitis-B, that's another consideration.

15 DR. BERG: Bill Berg. My Health
16 Department is gearing up to immunize all the fifth
17 graders in the city of Hampton next fall because it's a
18 state requirement. All sixth graders will be immunized
19 against hepatitis-B. I think it's -- having spent 24
20 years in the Navy and always thought of the military
21 services as being on the cutting edge of immunization,
22 it's a little distressing to hear that they may sort of
23 be falling behind the civilian standards. And I
24 realize I'm preaching to the choir, but I would hope
25 that this program could move forward and it would

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1 continue to fight for this immunization.

2 CDR. McBRIDE: Thank you. David?

3 DR. ATKINS: In the discussion, you raised
4 a sort of a general point about the cost-benefit
5 analysis, I mean, I think it's probably given that with
6 the military a lot of things that are cost-beneficial
7 from a societal perspective are not going to save the
8 military money and -- maybe the Board needs to weigh in
9 somehow on what we think an appropriate approach to
10 really evaluating the true cost-effectiveness or cost-
11 benefit should be.

12 DR. LaFORCE: Remember, we visited this in
13 great detail when we talked about chlamydia, in terms
14 of the benefit accruing to a gender -- obviously, over
15 a period of time -- that would be in large measure
16 after individuals had completed military service. And
17 so there was clearly a societal benefit, and no one
18 would want to demean the importance -- or diminish the
19 importance of the societal benefit. But it is an issue
20 that turns out to be of relevance as you have these
21 particular discussions. Yes? Stan?

22 DR. MUSIC: Stan Music. I want to get
23 back to West Nile. I'm very interested to know about
24 plans that you have for things beyond surveillance for
25 the virus. In birds, are there plans to issue Deet

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1 and, if so, are you also going to have some kind of
2 surveillance for overuse or toxicity and those kinds of
3 issues because when the cases start we can have ready
4 access to --

5 CAPT. TRUMP: It's interesting. To my
6 knowledge, no, Dr. Music. Most of our -- I did say
7 that the program was designed for prevention,
8 surveillance and control but, frankly, it's weaker in
9 the control. It's strong in the education in two
10 areas, knowledge of the disease itself amongst
11 clinicians and, secondly, personal protective measures
12 on military community members. And it's strong in
13 surveillance for disease in humans and in birds and
14 mosquitos, but I have to say the area you bring up,
15 toxicity associated with personal protective measures,
16 I don't know that we've really anticipated that.
17 Scott, am I wrong on that, or am I right? Col. Stanrick
18 (phonetic) is agreeing with me. He's the author of the
19 program, and I'm afraid we haven't really reckoned with
20 yet. Good thought, though.

21 DR. LaFORCE: Let's go on. The Marines
22 have been waiting very patiently.

23 CAPT. SCHOR: Sometimes we don't wait very
24 patiently.

25 (Laughter.)

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1 CAPT. SCHOR: I'm Ken Schor. I'm with
2 Health Services, Headquarters Marine Corps. Next
3 slide.

4 (Slide.)

5 We'll change gears here just a little bit.
6 This is the thought for the day from the current
7 Commandant. It just shows his analogy from Kipling's
8 Wolf Pack, the concept of the Marine, the individual
9 and the group. Next, please.

10 (Slide.)

11 Let's change gears here a little bit.
12 I've chosen three fairly hot topics for us in Health
13 Services there, and we'll move along. Next slide.

14 (Slide.)

15 This builds on some things that Wayne
16 McBride talked about and has come before this Board
17 before. I just thought I'd let you know that the
18 Commandant gets e-mail from Lance Corporals, and he
19 takes it very seriously -- that is a very important
20 avenue of communication to him. And this Lance
21 Corporal felt he got Lyme Disease during Marine combat
22 training, which every Marine goes through. He did the
23 short course, which is 16 weeks; others do much longer
24 courses if they are a machine gunner or that sort of
25 thing, or fire team. And he felt -- he was a very

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1 thoughtful young fellow, and felt that we should
2 increase our training primarily. He had some concerns
3 between the sentences, between the words, about whether
4 he was treated as aggressively as he perhaps should
5 have been, but our response to that is, as I note in
6 the bottom bullet, we've asked the hospital to do a
7 case review to see if they were as aggressive as they
8 should have been, if there are any lessons to be
9 learned from that, because this individual did his
10 Marine combat training in a much more endemic area than
11 where he is currently doing military police duties and
12 undergoing his treatment for arthralgias and arthritis.

13 So that proves the issue that we all have to be very
14 alert and aware of infectious diseases even if they are
15 not significantly endemic where we are stationed.

16 And I'm going to bring this next week to
17 the Navy Epidemiology Board and ask the basic question,
18 something that I found out during my MPH study that I
19 did on training, and that is, do we need to systemize
20 the training better?

21 We do a very good job predeployment, just
22 going into a threat area, but I'm not so sure we are
23 very systematized as we send Marines to schools, as
24 they transfer to bases, and do they need sustainment
25 training? Does that need to be organized?

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1 And the issue here is that this crosses
2 over Navy and Marine Corps lines. This crosses over
3 the folks that look over the hospitals and the stations
4 and NEHC, Navy Environmental Health Center and their
5 Preventive Medicine Units, and also the Operational
6 Preventive Medicine officers. And so we are going to
7 start asking that question and see if we can get more
8 systematized training. Next, please.

9 (Slide.)

10 Here is a different issue on immunization
11 delivery. About every three or four months we've had a
12 problem with folks out in Okinawa, Pendleton, Lejeune,
13 saying, you know, we're having some trouble getting the
14 vaccines that we want. The hospital is saying that it
15 costs too much, they don't have the money to buy it.
16 Adm. Clinton, this is not an issue for you at this
17 point, I don't think. It's an issue of the fault line
18 between Navy medicine and the operating forces in the
19 Marine Corps. Those are two different pots of money,
20 and it's taken us a while to actually figure out that
21 Navy BUMED actually buys the vaccines, they don't buy
22 the consumables -- the syringes, the alcohol wipes.
23 And the supporting hospitals are facing an increasing
24 budget deficit as we go into tri-care and managed care.
25 And so they are saying, "We need to know what we have

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1 to budget for vaccines".

2 It was more in the past, you'd come up and
3 just tell us what you want and we'll give it to you.
4 There is no concern that they will not support the
5 operating forces, that is not an issue. The real issue
6 is that perhaps the contact point between the
7 warfighters, the operating forces, and the suppliers,
8 the hospitals, isn't really worked out so well, the
9 communication isn't as good as it should be in terms of
10 planning and communication. And you see in that fourth
11 bullet the fact that that's sort of the string we have
12 to put together, and we really haven't had to do that
13 before. Now we're going to start doing that better,
14 and we're going to start fostering communication,
15 improve communication and try to optimize that.

16 And the basic question that's being asked
17 is, should there be central funding for immunizations
18 in the Navy and Marine Corps? Next slide.

19 (Slide.)

20 And this is something new. The CINC
21 Surgeons meeting last week first heard about this. I
22 bring this up because it's a different kind of weapon.

23 It's a weapon that may well be employed against us in
24 the "3-Block War" of urban warfare where you're
25 shooting and fighting vertically, when the bad guys --

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1 or maybe the good guys, let's hope are on the top floor
2 and the bad guys are on the bottom, and you're just
3 blasting out in between. That's a vertical battle
4 zone.

5 These things work very well in enclosed
6 spaces by shockwave. And the issue is on injury
7 epidemiology. We think of penetrating wounds, not so
8 much blasts in contained spaces, and that changes how
9 you may have to treat these folks. I'm not a surgeon.

10 I don't know the whole epidemiology here, but I would
11 just like to mention that here are some folks that are
12 using these things. And they are shoulder-fired. They
13 weigh 22 kilos with the explosive of about 2 kilos, and
14 they go about 1 to 6 football fields. So they are a
15 new threat. And I think that's all I have except for
16 the last slide.

17 (Slide.)

18 That is just to remind us of the pointy
19 end of the spear. Any questions, please?

20 DR. LaFORCE: What does "schmel" mean?

21 CAPT. SCHOR: That means bumblebee,
22 apparently, in Russian.

23 DR. LaFORCE: And that's what that weapon
24 is called?

25 CAPT. SCHOR: By the folks that

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1 manufacture it, yes, sir.

2 DR. LaFORCE: Questions? Yes, Steve?

3 DR. OSTROFF: I'm curious have you seen
4 -- Steve Ostroff -- any Lyme Disease at Camp Lejeune?

5 CAPT. SCHOR: We asked the hospital.
6 They had about 35 antibody screens -- I guess they were
7 ELISAs -- and none of them were positive on Western
8 Blot. So it does not appear to be the case, at least
9 in one calendar year recently. Very little disease
10 overall.

11 DR. LaFORCE: Cdr. McBride may wish to
12 comment on this. He's presented data on this at our
13 last briefing.

14 CDR. McBRIDE: I'll just remark briefly on
15 this for the benefit of the new members. At our
16 previous meeting, we reviewed data that was -- there
17 were over 9,000 sera from members of the Armed Forces
18 that were obtained from the Armed Forces Serum
19 Repository, and of these we did ELISAs on all of them,
20 and over 1,000 were positive on ELISA determinations.
21 And then on all of those, they were submitted for
22 Western Blot determination, and only 12 were found to
23 be positive. Of those 12, we had -- I'm trying to
24 remember -- about 9 or 10 that had antecedent serum
25 specimens that were available to us, and they showed

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1 that they had pre-existing antibody positive, so
2 suggesting only 2 of over 9,600 servicemen and women
3 had sero-converted while on active duty, suggesting
4 some fairly compelling data that indicated, at least in
5 that sample which we think was representative of the
6 Armed Forces, that it's very uncommon indeed to sero-
7 convert while on active duty, suggesting that there was
8 really no need to embrace a real vigorous policy for
9 the use of the Lyme Disease vaccine, and that was kind
10 of the question that we were seeking an answer from,
11 suggesting that Lyme Disease was not a significant
12 issue in the Armed Forces.

13 CAPT. SCHOR: And I think the overall
14 issue is tick-borne disease prevention. That is the
15 career-long issue here, not just Lyme Disease. Of
16 course, it depends on geographic threats, and it could
17 be very, very simple, you know, a two-minute stand-up
18 brief in recruit training or some of the early training
19 phases, but then it becomes more specific with more
20 data and more information provided.

21 So, I'm not suggesting we need a big,
22 heavy educational push that takes up hours and days of
23 training, but very specific and a more systematized
24 kind of approach than we perhaps have.

25 DR. LaFORCE: And when we discussed this

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1 the last time, we were actually, I thought, quite
2 specific about separating out the two themes. One
3 theme was, was there enough disease burden to warrant
4 the issue of a DoD recommendation for Lyme vaccine, and
5 that was totally different from what the obligatory
6 nature of the counseling in terms of wearing proper
7 clothing, using the insect repellents, whatever, to
8 protect forces not only from Lyme Disease because we
9 know that the European strain wasn't going to be
10 prevented at all with even if troops were immunized
11 here in the States. So, we would agree with you
12 completely. And I can't tell you how useful the study
13 was now when this point now comes up, is that the risk
14 is not zero because you do have troops that are working
15 in areas or doing maneuvers in areas where we do know
16 there is Lyme Disease. So, to expect that the rate of
17 disease is going to be zero is frankly too much to hope
18 for, but does that now impel us to be that much more
19 aggressive in terms of counseling recruits? I think
20 the answer is clearly yes, and I would agree with the
21 strategy that you've proposed completely.

22 CAPT. SCHOR: This invincible Marine Lance
23 Corporal, his wife is a biologist that felt that if we
24 scared him with the symptoms of Lyme Disease that would
25 have made him more vigilant. I'm not sure that that's

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1 going to work against the Lance Corporal Marine, but I
2 think perhaps just a little bit more screening would be
3 called for.

4 DR. LaFORCE: Thank you, Capt. Schor.

5 Next, LtCol. Kimm, Medical Readiness
6 Division.

7 LtCOL. KIMM: Yes, sir. Good morning.
8 Some of you may recognize me. In the past, I've had
9 the luxury of sitting in the back against the wall, but
10 at the last meeting Col. Diniega suggested that perhaps
11 there might be some value in me giving you the Joint
12 Staff perspective at these meetings, and I hope it
13 will. Since this is my first shot, I've just put a
14 list together of some current issues that I'd like to
15 bring up, just a very short list. Next slide please.

16 (Slide.)

17 Starting with some good news, based upon
18 your recommendations, I think we've come to some
19 solution, not without some arm-twisting and education
20 on my part with my J-2 Intelligence and J-3 Operator
21 counterparts. Col. Takafuji and I will be discussing
22 this in more detail tomorrow.

23 We are also very interested in the anthrax
24 vaccination program. From our perspective, we are
25 closely monitoring vaccine stockpile and production

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1 issues as they may impact current operations, as well
2 as planned operations. Also, based upon -- really, the
3 instigating factor was a letter to the Chairman from
4 Representative Ike Skelton, who had proposed that we
5 have a stand-down day for anthrax and for a variety of
6 reasons, mainly, that it was not practical or feasible
7 to do so. We came up with what we think is a very
8 valuable contribution, that is, working together with
9 the Program Office, we are making available to all of
10 the Active and Reserve Component Forces an anthrax
11 educational videotape. As you are aware, in the past
12 our focus has been pretty much "just in time
13 training", and we think there may be some value in
14 providing up-front training to all of our Forces
15 through this videotape.

16 Also, several policy issues. A current
17 policy in staffing right now is an anthrax vaccine
18 refusal tracking, the very small number of refusers.
19 There's a policy in staffing right now on that issue.

20 As Capt. Schor mentioned, last week was
21 our CINC Surgeons Conference, and one of the agenda
22 items was a PB protocol, recognizing the potential that
23 we might need to use PB in the future, and the fairly
24 stringent FDA regulatory requirements as well as the
25 recent Executive Order signed by the President. We had

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1 the Medical Research and Materiel Command come and
2 discuss with our CINC surgeons some of the issues
3 involved, and so we're going to be working with them
4 and the services on the detail so that we can have a
5 protocol in place that would meet all those
6 requirements so we can do the right thing.

7 You are certainly aware of the variety of
8 RAND papers that are out there. There is one out for
9 staffing right now on pesticide use during the Gulf
10 War. This paper is just that, a study of pesticide
11 use. It doesn't go to the next step and try to
12 correlate potential Gulf War illnesses with pesticide
13 use. It's a survey-based paper, and we should have
14 that staffed in the next couple of weeks.

15 The Naval COMEDS, that is the Committee of
16 Medical Surgeons General, met -- the plenary session
17 met several weeks ago, and the way that committee
18 operates, there's -- MPM stands for Military Preventive
19 Medicine. There's a MPM subgroup under the COMEDS
20 plenary. The plenary has to essentially bless the work
21 of the subgroups, and there were several items that did
22 receive blessing at this last meeting listed here.
23 Working together with our UK counterparts late last
24 year, we had an initial meeting about working together
25 on Standard Disease Non-Battle Injury Report, using a

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1 EPI-NATO format which is slightly different from our
2 Joint Staff format, so we're going to be working that
3 at the next meeting which is to occur the end of June
4 in France.

5 Also, depleted uranium, a significant
6 issue on a variety of fronts not only from a potential
7 health standpoint or perception of health standpoint,
8 also a very politically charged issue, as I'm sure
9 you're aware. They recommended that we work together
10 and prepare a NATO standardization agreement on
11 depleted uranium, all aspects of it. And, also, I'm
12 sure you're also aware of the environmental health risk
13 assessments that have been done not only in Southwest
14 Asia, a significant amount of work done in Bosnia, but
15 there's also a draft report that's been prepared on the
16 United States sector in Kosovo. The NATO committee is
17 very interested in developing some sort of mechanism
18 for us to share our information with them as well as
19 any information that they may have with us, so we're
20 going to put that on the table to discuss some
21 potential solutions there, be they web-based or
22 otherwise. Next slide, please.

23 (Slide.)

24 A document that we're very excited about
25 is our Force Health Protection Vision document. Not

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1 all of you may have seen this. I'll pass it around
2 when I'm done. This document represents the
3 culmination of about three years worth of work.
4 Several subgroups made up by representatives of the
5 CINCs and services subject matter experts in a variety
6 of areas.

7 What this document is really our Force
8 Health Protection Vision in support of the Chairman's
9 Joint Vision 2020, very much forward-looking. And in
10 the back of it is a very large chart -- I won't pull it
11 out, but you can take a look at it over the break --
12 that is our roadmap out to, at this time, 2010. It is
13 now officially Joint Vision 2020, and it's a list of
14 over 100 critical success factors, technologies, CINC
15 and service initiatives that we feel we need to have by
16 2010 or 2020 to get to where we need to be. There was a
17 list of ten that's also in the back of here that
18 represents our priorities, and we're working together
19 with a contractor in our office to put together those
20 interim milestones, figure out where we are on these
21 various success factors today, and hopefully we'll get
22 to where we need to be.

23 We're also excited about the Institute of
24 Medicine's final report which is due out later this
25 year, the title listed here, we've been actively

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1 involved with them as have several others in the room,
2 over the past two years. They had a meeting last week,
3 final technical review session out in California. For
4 the most part they've been very supportive of all that
5 we're doing in this area, and they also have some
6 suggestions. We're looking forward to seeing what
7 their recommendations are, and hopefully they'll fit
8 together with our plan and we can act on them to make
9 our program better.

10 Presidential Review Directive 5 did many
11 things, but another thing we're excited about is the
12 creation of the Military and Veterans Health
13 Coordinating Board. My boss, Adm. Mayo, is the
14 chairman of one of the work groups under that. There
15 are three. He chairs the Deployment Health Work Group,
16 the other two being a Risk Communication Work Group and
17 a Research Work Group.

18 What is exciting about this is that the
19 chairpersons of the Board are actually the Secretaries
20 of Defense, Health and Human Services, and Veterans
21 Affairs. So for the first time we're going to be
22 getting together with our colleagues and counterparts
23 from those organizations to hopefully build a strategy
24 that can truly make our longitudinal approach to Force
25 Health Protection a reality, taking care of service

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1 members from asession -- you could look at that as
2 Health and Human Services -- through their time with us
3 in Department of Defense, and work for a smooth
4 transition to when they are being taken care of by
5 Veterans Affairs.

6 Our Joint Staff Memo on Deployment Health
7 Surveillance, which was issued about a year and a half
8 ago in December '98, even though it's only a year and
9 a half old, for a variety of reasons we're working on a
10 modification, MOD 1 to it, which we expect to be ready
11 perhaps by the end of the year. It was initiated by
12 some administrative changes, one, to take out the
13 middleman, if you will, for the pre- and post-
14 deployment health assessments. Those are now being sent
15 directly to the Army Medical Surveillance Activity.
16 And also it presently requires a weekly reporting to
17 higher headquarters, Joint Staff, CINC Surgeons Staff,
18 and we think it may be more practical to go to a
19 monthly reporting, although we still strongly recommend
20 and will, in fact, require weekly reporting at the
21 field level.

22 Also, at the time that Joint Staff Memo
23 was issued, the Environmental Surveillance
24 Requirements, although they are in there, are fairly
25 generic because at that time there hadn't really been

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1 much consensus among the services on what the minimum
2 requirements are. Since then, through the Joint
3 Environmental Surveillance Work Group, we have come to
4 some consensus on things like minimum analytes and
5 minimum data elements for reporting purposes, so some
6 of that is going to be incorporated in the
7 modification. And, also, we're going to strengthen the
8 operational risk management focus, putting
9 environmental health risks into perspective with the
10 many other risk decisions that the commanders out there
11 face. This is a language that they understand, and we
12 think that that will make it a much more effective and
13 valuable tool. Next slide please. That's all I have,
14 unless there are any questions.

15 DR. LaFORCE: Questions?

16 (No response.)

17 If not, let's go on to Cdr. Tedesco of the
18 Coast Guard.

19 CDR. TEDESCO: Good morning. I'm Mark
20 Tedesco. I'm with Coast Guard at Coast Guard
21 Headquarters. I oversee medical readiness. As you may
22 be able to tell from the acronym under my name, like
23 Adm. Clinton in the back of the room, I'm a Clinician
24 Public Health Service Officer, although I wear the
25 Coast Guard blue uniform because I've been detached

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1 from the Public Health Service and detailed over to the
2 Coast Guard. Unlike my sister service medical
3 representatives who are commissioned in the service
4 which they represent, the 160 health care professionals
5 in the Coast Guard are actually commissioned Public
6 Health Service officers, all of us detached and
7 detailed over to the Coast Guard.

8 Because of the number of comments and
9 questions I've had over the last couple of years as a
10 member of the Board, or liaisioning with this Board, I
11 thought I'd do something a little different today and
12 kind of bring you through what is the Coast Guard, how
13 they are made up, especially since recently this --
14 even after "phone a friend" and "ask the audience" --
15 this question as to what Federal agency the Coast Guard
16 was in was answered in incorrectly on "Who Wants To Be
17 A Millionaire." So I thought we would go through this.

18 The Coast Guard is one of the five Armed
19 Forces of the United States, by law. It is a military
20 service in and of its own right, which is oftentimes
21 not understood, but falls under Department of
22 Transportation rather than under Department of Defense.

23 So military and Armed Forces isn't necessarily
24 synonymous with Department of Defense.

25 The Public Health Service, one of the

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1 seven uniformed services of the United States, is not a
2 military service, it is not part of the Armed Forces
3 other than the 160 of us who are detailed over to the
4 Coast Guard. We do fall under Uniform Code of Military
5 Justice. Next slide, please.

6 (Slide.)

7 Again, the Commandant of the Coast Guard
8 falls under the Secretary of Transportation, however,
9 he also sits with the Joint Chiefs of Staff as a
10 member. And in time of war, the Coast Guard, by
11 definition, can fall under Department of Navy.
12 However, that hasn't happened since World War II. Next
13 slide, please.

14 (Slide.)

15 Just briefly, the history -- and you can
16 see a number of the different missions in these
17 predecessor services to the Coast Guard. Lighthouse
18 Service started well before this country was actually
19 the United States and we were still part of Britain.
20 The Revenue Cutter Service -- because of the need for
21 trade, this country's Federal Government first made
22 money off revenue tariffs, and it was important for our
23 own merchant marines to be able to trade, the Revenue
24 Cutter Service was formed.

25 About eight years later, the Marine Health

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1 Service was formed, which was the predecessor of the
2 Public Health Service, and one of their tasks, as well
3 as to care for merchant marines, was to care for the
4 Federal employees of the Revenue Cutter Service, and
5 that's where the relationship originated between the
6 Public Health Service and the Coast Guard. Next slide,
7 please.

8 (Slide.)

9 The Coast Guard was formed in 1915 as the
10 Revenue Cutter Service and the Lifesaving Service
11 combined into one group. And then later on was added
12 the Bureau of Navigation Steamboat Inspection, and in
13 1967 we became part of Department of Transportation.
14 We have been working under the Navy, as a service under
15 the Navy during the two World Wars. However, we
16 haven't functioned specifically that way since then.
17 Next slide, please.

18 (Slide.)

19 It is said that we would function under
20 the Navy in time of war, however, there's been several
21 wartime experiences since World War II where the Coast
22 Guard's has had a significant presence where we haven't
23 officially been part of the Navy, although detached
24 units may function under part of the Navy.

25 It's my personal feeling, given the

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1 missions that the Coast Guard now has, that we may
2 never fully operate under the Department of Navy, but
3 will have assets that may be attached to the Navy or to
4 the other services. As such, that's why more and more
5 I think it's important, and we have been trying in the
6 medical perspective to become a member of Boards like
7 this and also other working groups in DoD so that we
8 can keep our forces always ready to go with DoD to
9 various contingency missions. Next slide, please.

10 (Slide.)

11 Some of the various missions and, as you
12 can see, military operations is just one of the many
13 missions that the Coast Guard has. Next slide, please.

14 (Slide.)

15 Some of the other missions the Coast Guard
16 has. Three years ago today, I was still an Army
17 Medical Officer, so it was quite eye-opening to me to
18 come over to the Coast Guard not quite three years ago
19 and see the variety of missions as well as military
20 operations that the Coast Guard did. Next slide,
21 please.

22 (Slide.)

23 And, again, we are about 10 percent of the
24 size of the Army, but we have about 1 percent of the
25 health care professionals that the Army has. That kind

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1 of illustrates for me how we got to spinning a lot more
2 quickly than some of the other services in order to
3 keep up with the things we need to worldwide -- 60
4 doctors, 55 dentists, pharmacists, sanitation officers
5 are the officers. As you can see, we don't have a
6 single RN other than the few Nurse Practitioners we
7 have who function as Medical Officers, but we don't
8 have a single commissioned officer RN in the Coast
9 Guard. We also don't have hospitals. We've got 30
10 clinics worldwide, but no hospitals, two infirmaries at
11 the Coast Guard Academy and our Recruit Health Base.

12 I thought I'd spend today kind of bringing
13 the whole group up to the level of knowledge as to the
14 Coast Guard and how we fit into the scheme of things as
15 part of the Armed Forces. Subject to your questions,
16 that concludes my briefing today.

17 I'll add one comment -- and, Col. Diniega,
18 I apologize for not bringing this up earlier. This
19 will be my last meeting also officially as a member of
20 the Board. LCdr. Ludwig -- this decision was made in
21 the last few days, so I didn't have a chance to bring
22 it forth earlier, but I will be sitting in the
23 sidelines, I'm sure, at future meetings, but LCdr.
24 Sharon Ludwig, who sits at the desk next to mine, will
25 be taking over officially sitting here in front of the

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1 podium. Thank you.

2 DR. LaFORCE: Is there a message? I mean,
3 is this a sinking ship here?

4 (Laughter and simultaneous discussion.)

5 DR. LaFORCE: Let's close with Col.
6 Graham, the British Medical Liaison Officer.

7 COL. GRAHAM: Good morning, sir, ladies
8 and gentlemen. I'm delighted to be at my first AFEB
9 meeting. I regret that it's going to be my last AFEB
10 meeting. I'm deputizing for Col. Warde and just raise
11 a few publications -- mention a few publications which
12 have come out in the UK within the past few weeks which
13 may be of interest to you.

14 Professor Simon Wesley who was funded by
15 the U.S. Department of Defense to study patterns of ill
16 health in British Gulf veterans published his first
17 paper, provided two months ago, in which, like the Iowa
18 study, Pennsylvania study, Canadian Gulf study, he
19 found that Gulf veterans were more likely to report ill
20 health across the full range of symptoms than Bosnia
21 veterans or nondeployed British veterans.

22 In that first paper, he mentioned an
23 association between reported ill health and
24 immunization histories. He looked at that in more
25 detail and about ten days ago in the BMJ published

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1 another paper, and he had used the personal records of
2 immunization which you have in the British Army to
3 validate the reported immunizations by Gulf veterans,
4 and he found in the second paper that Gulf veterans who
5 were immunized in-theater who had their anthrax,
6 plague, pertussis vaccines -- what was our biodefense
7 program, the veterans who had those vaccines as an
8 emergency procedure in-theater were more likely to
9 report ill health than veterans who were immunized
10 before they left the UK.

11 I have not mentioned this paper because of
12 its scientific value, but I think it's going to be
13 picked up in -- it's certainly been picked up in the
14 UK, and it will probably be picked up in the media in
15 the current debate about anthrax immunization in our
16 forces.

17 There was an editorial in the BMJ in the
18 same week questioning the conclusions of the Wesley
19 paper. So, as I say, from a scientific point of view,
20 it will be questioned, but it will certainly be picked
21 up in the anthrax immunization debate.

22 I've also given the URL of the website of
23 the week from that issue of the British Medical
24 Journal, and it gives the URLs for the British Gulf
25 veterans websites, the DoD and the VA websites.

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1 The second paper I mentioned is an
2 information paper published two weeks ago by Ministry
3 of Defense on the biological detection program which we
4 used in the Gulf. It may be of interest to the Board
5 members. That site also contains papers on how the
6 British immunization program in the Gulf was
7 implemented, papers on chemical defense in the Gulf.
8 So there is some other material there which might be of
9 interest.

10 The third paper was a critique of the RAND
11 PB paper which the Ministry of Defense produced again
12 two weeks ago. We had been asked by Parliament to
13 comment on the RAND PB paper, and we referred it to the
14 chemical and biological defense sector of the Defense
15 Evaluation Research Agency. The scientists there came
16 back with their views. They felt that the review had
17 not been carried out in an orthodox way, that they had
18 not considered all the relevant material, that some
19 material which was included was unpublished preliminary
20 material, that the hypotheses which were generated were
21 generated on the basis of equal weight being given to
22 publications of different stages in terms of their
23 publication or peer review. And, overall, we did not
24 feel that it was a considerable advance in our
25 understanding of issues.

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1 My contact details are at the bottom. If
2 any of you would like any more information about these
3 papers or any others in the UK, I would be delighted to
4 provide them.

5 DR. LaFORCE: Questions? Everybody got a
6 copy of this? Fine. I just wanted to make sure.

7 DR. BARRETT-CONNOR: I have one question.
8 Are there differences between the people who went to
9 war without their immunizations? I mean, what were the
10 circumstances in which one would have been immunized
11 there as opposed to in the UK?

12 COL. GRAHAM: The British deployment to
13 the Gulf was in two waves. In September-October of
14 1990, we deployed seven armed brigade groups, which was
15 combat troops with a very light logistic tail. When
16 Desert Shield became Desert Storm, we then augmented
17 seven brigades with four brigades, plus their logistic
18 groups, plus then a huge logistic tail. So the troops
19 who went out early were much more likely to have been
20 regimental combat troops rather than service support
21 troops, and their experience in many ways was
22 different. On the one hand, they went out earlier, the
23 preventive medicine arrangements were more rudimentary.
24 They were living in much poorer accommodations,
25 feeding and water provision were difficult. The people

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1 that came out later had more training in-country. Not
2 only were they given their immunizations, they were
3 trained on chemical defense, biological defense. They
4 were worked through training programs. Some of them
5 were given very little. We had more reservists in that
6 second batch. So, I think for a lot of reasons, from
7 a scientific point of view, I don't think we were
8 comparing like-for-like in that paper.

9 Also, although Professor Wesley said there
10 was a trend that the more vaccinations people had, the
11 more likely they were to report symptoms. In fact, it
12 was a fairly flat graph with a blip at the end. If you
13 took out that small subset of individuals, the paper
14 isn't as robust. I think it's because of the public
15 debate rather than the scientific content of the paper
16 that would be important.

17 DR. LaFORCE: Other questions, comments?

18 DR. ANDERSON: So just to clarify that
19 point, so it was the early deployed people who were
20 getting vaccinated in-theater?

21 COL. GRAHAM: Yes.

22 DR. LaFORCE: Thank you, Col. Graham.
23 There's a little bit of delay in terms of the Healthy
24 People 2010 presentation, and what I want to do is ask
25 Ron Waldman who has asked for a few minutes to address

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1 the Board in terms of humanitarian issues.
2 Unfortunately, Ron was not able to make the San Diego
3 meeting when this was discussed in some detail. Ron?

4 DR. WALDMAN: I just wanted to bring up
5 this one issue very quickly to see if I could elicit
6 any remarks, comments, or reactions. This is my last
7 meeting on the Board, as has been said many times, and
8 I'm being joined by a rather large quantity of my
9 colleagues.

10 The reason I was initially nominated for
11 the Board four years ago is that at that time there was
12 a lot of interest, I would say at that time new
13 interest, in DoD particularly, in regard to activities
14 that they had been or anticipated undertaking in the
15 arena of humanitarian assistance overseas in response
16 to international emergencies or complex humanitarian
17 emergencies, as they have been called. This is an area
18 that I've been working in for some time, and it was one
19 of the Preventive Medicine Officers at the time who had
20 also worked in a number of these theaters, who felt
21 that there would be some movement in this direction,
22 particularly in the Public Health sphere, and that it
23 might be useful to have a civilian advisor on the AFEB
24 who could participate in those types of discussions.
25 To my disappointment, those kinds of discussions never

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1 really took off, and I haven't -- I feel disappointed
2 and sorry that I haven't been able to make, I don't
3 think and by my own estimation, an adequate
4 contribution to the deliberations here.

5 I think by way of background, it is
6 important to say that as these complex emergencies
7 unfold, it seems to be the rule rather than the
8 exception that the most coordinated, the most active,
9 and the most effective sector, at least in an emergency
10 phase of these operations, is the Public Health sector.

11 It's one where there is a certain epidemiological
12 background that's been established. I can't quite say
13 that it's become a science, a scientific endeavor, but
14 it's more of a discipline, and there is more discipline
15 in the Public Health sector than there seems to be in
16 many of the other kind of operations that are required.

17 Well, lo and behold, over the course of
18 the past few years, it's been everyone's perception
19 that the military presence in these emergencies and the
20 interest of both the U.S. and its Allies from the
21 military standpoint has increased many, many fold. And
22 it is unusual now for one to operate in a complex
23 humanitarian emergency without having to have
24 substantial contact with armed forces.

25 As you might well imagine, the cultures

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1 which dominate in the civilian relief community are
2 antithetically opposed at times to the kind of culture
3 that exists in the Armed Forces, and this makes
4 relationships between the civilian and military sectors
5 extremely dicey.

6 There is one -- let me cite a very brief
7 example, but there is a rainbow, an umbrella
8 organization of nongovernmental relief organizations in
9 this country called Interaction. The topic of
10 Civilian-Military Cooperation, or CIMIC as it's called
11 in the trade, came up at the last meeting of its
12 Disaster Response Committee, and based on the
13 deliberations that were held, and when it was learned
14 by some of the member organizations of Interaction
15 that, in fact, money was being spent by Interaction on
16 trying to learn how to work more with the military, how
17 to incorporate military operations into its own
18 operations, a number of the prominent civilian
19 organizations, including Doctors Without Borders, which
20 is the Nobel Prize winner for Peace last year, resigned
21 from the Disaster Response Committee, so opposed are
22 they in principle to cooperation with the armed forces
23 in any way in humanitarian operations. Putting it very
24 briefly, the rationale for this is that the military
25 obviously, by definition, is an extension of bilateral

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1 foreign policy, and it is important in the eyes of
2 these NGOs to remain entirely neutral in these
3 operations and never to be perceived as a tool of
4 bilateral foreign policy.

5 Anyway, these are important issues in this
6 field about which books have been written, although not
7 very good books and not very many books. At any rate,
8 because the Public Health sector is the most advanced,
9 because the military is always present, I asked Marc,
10 as sort of my parting shot from the AFEB, feeling
11 guilty as I did, if it would be possible to see whether
12 or not the current direction of preventive medicine
13 activities in, I'll say, the Armed Forces rather than
14 DoD, to include our colleagues from the Coast Guard,
15 whether there has been any perception of heightened
16 interest in participating in humanitarian assistance
17 activities. I know there must be in other parts of the
18 military, and I just received yesterday a typical
19 example of invitations that people like myself get at
20 times.

21 Here is an e-mail that I got from someone
22 at East Carolina University, talking about
23 effectiveness of distributed medical intelligence
24 systems to be measured during an unprecedented
25 humanitarian exercise. And these kinds of exercises,

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1 or simulations, or games, have been becoming
2 increasingly frequent as part of the preparatory
3 process for these interventions in humanitarian
4 emergencies. This is one where -- this is being done
5 off Hawaii, I believe. There are 55 ships involved in
6 this simulation -- 55 Naval vessels, 26,000 Sailors and
7 Marines will participate in this six-day exercise which
8 is largely going to be a display of the military's
9 telemedicine capabilities. On the list of nonmilitary
10 invitees are the World Food Program, the International
11 Federation of Red Cross, and the United Nations High
12 Commissioner of Refugees, along with others. This is
13 called "Operation Strong Angel". Participants of
14 Strong Angel are hoping to benefit from the transfer or
15 knowledge and experience between the militaries and the
16 civilian organizations of the seven participating
17 nations.

18 So, to make a long story short, therefore,
19 I guess I asked Marc for this time to ask whether or
20 not on the one hand AFEB would be interested, on the
21 other hand if the Preventive Medicine Departments of
22 the Armed Forces would be interested in pursuing an
23 exchange of knowledge and experience in the area of
24 Public Health interventions in these complex
25 humanitarian emergencies which seem to be becoming,

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1 first of all, much more frequent occurrences for those
2 of us working in the civilian sector, and there's a lot
3 of activity there, but by my perception at least, and
4 by my experience, a much more prominent area of
5 endeavor for the Armed Forces as well. And if so, how
6 could one go about playing a leadership role as is done
7 in the field, here back home in the inter-epidemic
8 period, if I could say so, in pushing the envelope
9 forward a little bit in education, in training, and in
10 determining what the more common priorities encountered
11 in Public Health in these humanitarian emergencies
12 might be.

13 DR. LaFORCE: What I would propose is --
14 Ron is here. We are scheduled for a ten-minute break.

15 I wanted him to present this prior to the break so
16 that the discussions could continue during the course
17 of the break. So, what I would propose is just break
18 for ten minutes and then continue discussions during
19 the break. Thank you.

20 COL. DINIEGA: I am setting my timer.

21 (Whereupon, a short break was taken.)

22 DR. LaFORCE: I would like to introduce
23 one topic that Julian Haywood just brought to my
24 attention. He said that the AFEB should not miss the
25 opportunity of the turnover of several Preventive

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1 Medical Officers who are rotating off the Board, and
2 ask those Preventive Medical Officers that are rotating
3 off the Board specifically if they had one or two
4 recommendations for the Board. They come with obviously
5 a wealth of their own experience, and also worked with
6 the Board several years.

7 So, I would ask the three or four who are
8 rotating off and I will find you personally, or Ben
9 will find you personally, and if you just have a
10 sentence or two or an observation -- it doesn't have to
11 be written down -- please give us that feedback, that
12 would be very helpful. Thank you, Julian.

13 Okay. Let's move on to DoD Plans for
14 Healthy People 2010. Lynn Pahlund, the Health
15 Promotions Programs from DoD Health Affairs. Lynn.

16 MS. PAHLAND: The two topics that I just
17 wanted to touch on are the DoD Prevention, Safety and
18 Health Promotion Council, and also to talk about
19 Healthy People 2010 and what our strategy is for
20 incorporating the 467 goals and objectives that are in
21 the 28 specialty areas into our system. That's a
22 formidable task, it's something that will take many
23 years, it's something that I don't think we'll be able
24 to accomplish next week, but we're certainly going to
25 try.

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1 I've been at Health Affairs for three
2 years, and since I have come there certainly has been a
3 great shift in the focus of prevention, wellness,
4 health promotion, trying to solidify the concept of
5 wellness and health promotion so it is not seen as
6 something that is fluff, that it is the basis for our
7 entire MHS. That's very important.

8 Approximately three years, the Under
9 Secretary of Defense for Personnel and Readiness, Mr.
10 DeLeon, selected three topic areas that he felt were
11 very important for us to address across the DOE, not
12 just within the Military Health System, that would
13 actually impact the effectiveness and the readiness of
14 our fighting forces, and those three topics were
15 tobacco cessation, alcohol abuse, and injury and
16 illness prevention.

17 From that concept, he asked Gen. Roadman,
18 by name, who was the Surgeon General of the Air Force,
19 to be the champion of these three particular efforts.
20 Our original concept was we were going to have groups,
21 that we were going to have little committees, we were
22 going to figure out the best way to do business, and I
23 started to develop a charter.

24 As the charter originally was going to be
25 signed by Dr. Bailey and Gen. Roadman was going to be

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1 the head of this particular group. As we developed the
2 charter, as we looked at our intent, what it was we
3 wanted to accomplish, it became more apparent that we
4 had to really broaden our scope of involvement with
5 people across the DoD because the important thing is
6 that injury and illness prevention and alcohol abuse
7 prevention and tobacco prevention are not necessarily
8 Health Affairs responsibilities alone, it's something
9 that cuts across the entire Department of Defense.

10 So, over the many months that we developed
11 a charter and it went through many fits and turns, it
12 became apparent that we had to go across the entire
13 DoD. And in my formal slides, it identifies the people,
14 the representatives that we currently have on this
15 Council.

16 We developed a Flag-level council. We have
17 a charter -- I'll pass out a copy of the charter --
18 that really seeks to have a unified effort to
19 originally hit these three topics.

20 We added a couple other committees to
21 that, but they still are our three main driving forces.

22 Again, as this concept grew, we had these committees
23 addressing these three areas, and we pulled in people
24 from across the Department of Defense, and over a
25 period of a year and a half we now have very mature

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1 programs that Capt. Murphy and LtCol. Talcott will
2 address more in depth. We have action plans and we
3 have charters for each one of these committees. And
4 the important point is that this Prevention, Safety and
5 Health Promotion Council now has got to a level where
6 it was actually signed by the Secretary of Defense.
7 So, it has a great deal of visibility. It was signed
8 in July of '99. And, again, it's been interesting as
9 this Council has developed. The important thing to
10 know is that this isn't another "stovepipe," this isn't
11 another organization, but it certainly is an
12 opportunity for collaboration.

13 And another one of the important things
14 that we want to focus on is linking research, linking
15 prevention to our entire DoD focus on keeping our force
16 constantly fit and ready. That's another very
17 important topic.

18 As far as Healthy People 2010, the
19 Department of Defense has been involved with Healthy
20 People 2000 probably for the last eight or nine years,
21 and the way they chose to approach their interface with
22 Health and Human Services Healthy People 2000 was to
23 identify 48 of the goals and objectives that were in
24 2000 to be targets for the Department of Defense, and
25 they chose targets that were different from Healthy

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1 People 2000.

2 A list was developed, a list was put into
3 place, but then I never really heard that we had a
4 total DoD-wide strategy to put these targets and goals
5 into effect and to actually monitor our progress. Some
6 of them do live in some of our existing performance
7 measurements, but some of them do not.

8 What we are hoping to do now with our
9 interface with Healthy People 2010 is to actually
10 develop a DoDD, which is going to be 1010.10, which
11 currently used to be the DoDD for Health Promotions.
12 We have a statement in there now that is in the process
13 of being coordinated, but we want to identify the fact
14 that we want to support the achievement of all these
15 targets and goals even though there's 467 of them in 28
16 different areas, but that as a system we should be
17 moving toward achieving those goals and exceeding them.

18 The importance of our talking about the
19 DoD Prevention, Safety and Health Promotion Council is
20 that eventually we want that Council to get to the
21 point where it would be the organization or the body
22 that would identify those areas where the Department of
23 Defense might want to have a target or a goal or
24 objective that would be different. We are very aware
25 that in our culture, because of the nature of the

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1 beast, that we are going to have a different injury and
2 occupational health incentive targeted or identified
3 within Healthy People 2010, so it would be incumbent
4 upon that particular body to identify something based
5 on research, based on evidence, based on fact, that
6 would be the appropriate goal for the Department of
7 Defense.

8 So, these two particular activities, the
9 development of the DoDD that identifies an interface
10 and are working with Health and Human Services Healthy
11 People 2010 and the DoD Flag-level Council, are two of
12 the very important initiatives that are impacting the
13 development of DoD-wide policy for health promotion and
14 for wellness.

15 Again, not knowing what your level of
16 current interaction is with DoD Prevention, Safety and
17 Health Promotion Council, or in your interaction or
18 knowledge of Healthy People 2010, I really wanted this
19 to be a dialogue. I'd like to know if there is some
20 way in writing the DoD that I could incorporate some
21 systemwide language or have some sort of methodology so
22 that we could utilize this body in some way to, again,
23 help us advance our objectives in meeting these goals.

24

25

DR. LaFORCE: Any questions? Carol?

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1 DR. RUNYAN: It's been a while since I
2 looked at the charter of this organization, but in
3 looking at the charter that you just showed us, it
4 sounds the same as my understanding of this Board. And
5 so I'm a little bit confused about the relationship
6 between these two organizations, or more the potential
7 for tremendous overlap, and if somebody could help sort
8 that out, I'd appreciate it.

9 DR. LaFORCE: Lynn?

10 MS. PAHLAND: I think that's one of the
11 reasons that we are here because I think that everyone
12 in the room will admit to the fact that within the
13 Military Medical Services, as good as they are, we have
14 tremendous overlap or partial overlap, in many areas.
15 And there's so much work to do. It's not a good idea
16 to have two separate groups doing the same thing and
17 not be interfacing or interacting.

18 So, as this Prevention Council occurs and
19 develops, it would be appropriate for us to identify,
20 for example, what things this body would do and what
21 things the DoD Prevention, Safety and Health Promotion
22 Council would do. Again, the membership of the Council
23 are Flag-level personnel. I've listed the different
24 areas that they are from, and it's really to identify
25 priorities, plus it works together. This is not

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1 necessarily a body that has an authority. The
2 authority is incumbent and in place with the
3 participants on the Board. I believe Dr. Murphy is
4 going to talk a little bit about the activities of the
5 Board down to the actual how we get things done, but I
6 haven't seen -- I don't sense that there really is
7 duplication. Right now, we've identified six areas
8 that are listed in your briefing chart -- sexually
9 transmitted disease prevention, injury, tobacco,
10 alcohol, ways Preventive Medicine can work with them,
11 and all of these groups report through the committees,
12 and then the Council decides if there's a way that they
13 can intervene to make that work group's activities and
14 programs be effective.

15 DR. LaFORCE: Ben?

16 COL. DINIEGA: I'll take the first stab at
17 this because as I found out about the group, the same
18 concerns came to me -- you know, what do they do, what
19 do we do, what do the -- but as a little bit of a
20 history.

21 The Board, in the past, has made
22 recommendations on tobacco cessation and alcohol abuse
23 prevention and injuries, and those have gone forward to
24 the services, and sometimes we haven't really heard
25 what is being done in the services.

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1 What I see happening between the PSHPC --
2 the other thing that has happened is the formation of
3 the Joint Preventive Medicine Policy Working Group has
4 been a very good thing for the services and for DoD
5 because we could hash out potentially service-wide
6 issues during that body, and in the past the only way
7 to do that was through the AFEB. So, there is a
8 diminishing role for the AFEB.

9 With the PSHPC, I think we have already
10 set a precedence when Col. DeFraithe brought his DoD
11 Occupational Illness Prevention Action Plan to the AFEB
12 for comment. And when I went down to brief the PSHPC
13 about the AFEB, what I told them, as I see the roles of
14 the two organizations happening, is we continue to make
15 policy recommendations and program review
16 recommendations to the services and to Health Affairs,
17 and it is up to the services and Health Affairs to
18 implement. It will always be that. We just make
19 recommendations. However, as things trickle and they
20 are widely accepted by the services, a lot of the push
21 will come from the PSHPC because these are Flag Officer
22 and three-star General level, and a mixture of
23 nonmedical Flag Officers and senior executive service
24 personnel who are at the meeting and can make things
25 happen on a service DoD-wide. So you have the safety

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1 community there, and the medical community. You have
2 the Community Services group there, and the medical
3 community, trying to get and accomplish an approved
4 plan that everybody has bought into. Now, they don't
5 control monies and they also make recommendations, but
6 they try to coordinate the implementation of things.

7 So, I see the AFEB's role as continuing to
8 make policy and recommendations on prevention in
9 certain arenas, but as the DoD community picks it up
10 and wants to go ahead and implement and develop action
11 plans and further policy, they then come back to the
12 AFEB to run it by for our input into what they have
13 thought about implementing service-wide prevention
14 programs.

15 RADM. CLINTON: I think you stated it very
16 correctly from my perspective. One is an external
17 advisory group that we depend on extensively, one is an
18 internal implementation process which we hope will be
19 more powerful than things that have not worked quite as
20 well with this arrangement, in the past. It may be
21 that the internal group might turn to the AFEB to
22 pursue a particular question that may arise beyond
23 their capacity and need the external validation or
24 external review process that AFEB affords.

25 MS. PAHLAND: That is certainly our

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1 intent. And as I was trying to point out when I was
2 talking about how this whole Council evolved, initially
3 we thought it was very microscopic, that it would just
4 be between the services, and then it just blossomed,
5 and it cuts across the entire DoD. And as we are
6 developing the Council -- and we're rewriting even now
7 the charter, and we're making it more inclusive, we're
8 adding more staff and we're adding the Military
9 Veterans Coordinating Board officials, Gen. Claypool,
10 Dr. Claypool -- and if there is a role that we can
11 define that formalizes an interface with your group, I
12 think that would be superb because, again, in the three
13 short years that I have been in Health Affairs, I have
14 seen so much good work being done throughout the DoD
15 and within the services that sometimes they are
16 operating not as a set of gears that are interfacing
17 and meshing and moving our mission forward, but they
18 are almost little independent gears. They are doing
19 wonderful work and they are working so hard, but unless
20 you engage the system we are not going to be effective.

21 So, I just see this as a splendid opportunity to
22 formalize hopefully an interaction with this group.

23 When we were developing the Alcohol Plan
24 and the Tobacco Plan and the Injury Plan, we tended to
25 go out in the areas that we happen to know people who

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1 were subject matter experts. My guess is we had such a
2 wealth of knowledge that we'd be very much of
3 assistance here. So the more we all know about one
4 another and can work with one another, that's certainly
5 what we're trying to do from our perspective. And I
6 never wanted the concept for somebody to say just
7 because Health Promotion policy is written at a desk in
8 a cube that I sit at, that that's where it belongs. It
9 belongs to the system, and if there is a way that we
10 can advance your recommendations and advance best
11 practice, that's all we're looking for. And we're
12 identifying and modifying and formulating this approach
13 as we go along, so please don't feel left out, that was
14 never an intent.

15 Now we are in the process of rewriting our
16 charter, and I think there is very much a role that you
17 can identify, and as we bring our plans together we
18 don't necessarily want to send them here for a
19 rubberstamp approval. I would think that you would
20 want to be involved perhaps in the development of some
21 of our further plans. The next area we're looking at
22 taking under the Council is probably suicide, and
23 that's a very important topic.

24 CAPT. SCHOR: Capt. Schor. Let it not be
25 said that anything done in the Beltway can ever be

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1 called community-based preventive health services, but
2 I would suggest and say that the PSHPC is the closest
3 thing that we can come up with within the Beltway to
4 actually try to do community-based health services.
5 It's probably the only group that I'm aware of -- and I
6 belong to two or three of the subgroups underneath --
7 that actually tries to bring in folks outside of the
8 medical community, other stakeholders, the broadest
9 range of stakeholders available, to see if we can move
10 certain initiatives along. So, it's very positive from
11 that standpoint.

12 My only concerns at this point, with the
13 fairly short exposure to it, are that, again, as
14 different Boards arise and different functions come
15 out, there is some concern of dual tasking and multiple
16 tasking and overlaps and confusion as to who does what
17 to whom, or can't do what to whom. That issue is one
18 issue.

19 The other issue is that the subgroups
20 underneath the Prevention, Safety and Health Promotion
21 Council are very different. When you look at the
22 universe encompassed by injury prevention versus the
23 Joint Preventive Medicine Policy Group, two groups that
24 I know very closely, and compare that to some of the
25 smaller carved out areas such as alcohol and tobacco

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1 cessation, and then self-reporting instruments, those
2 are vastly different entities and functions and
3 outcomes.

4 So, I find at this point that there's a
5 wide variance into the kind of subgroups that are part
6 of that Council, and I think that just needs to be
7 recognized very overtly.

8 COL. DINIEGA: I have another comment. In
9 response to Dr. Runyan's concerns, I know that Col.
10 DeFraites' work group, he did ask for an AFEB member to
11 sit on the committee, and Sue Baker did that, and I
12 also sit on that and try to get to some of the other
13 work groups' meetings so that if there are issues for
14 the Board, I can be there to be the proponent for them.

15 MS. PAHLAND: When this Committee came up
16 -- or the Council -- we took the three areas that the
17 Under Secretary of Defense for Personnel and Readiness
18 identified -- tobacco, alcohol and injury -- but then
19 we also subsumed some existing committees to begin to
20 focus on wellness and improving health status of
21 individuals and populations, and pulled that under.

22 This Council -- we never want it to get
23 too huge -- and the priorities over a period of, say,
24 five to seven years perhaps needn't change. It is
25 certainly my hope that we really could make a dent in

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1 alcohol abuse or tobacco use, and gradually have those
2 things then walk away from Council business, and
3 perhaps another very important topic -- I don't know
4 what it would be at the time -- but that would then
5 become the center of it.

6 When we had the first Council meeting, and
7 all the Council meetings, when we have our Flag-level
8 personnel leaving, we've got very positive comments in
9 that this is the first time this group has been
10 together, and they feel a sense of fortitude from one
11 another that they now can reach out to the medical
12 community. For example, one of the things that we're
13 looking at is hearing loss and development of
14 particular weapons.

15 So, again, what is it now? It is not
16 necessarily what it is today, and the particular
17 committees under it now are not the way they have to
18 be, but it certainly has been a very, very powerful
19 pull for us to get our message or to get the attention
20 of the Secretary of Defense who is very pleased with
21 the work that's going on in that Council.

22 DR. LaFORCE: David?

23 DR. ATKINS: I wasn't clear. Is there a
24 plan in place to do something to identify objectives
25 within the 430-plus Healthy People 2010 objectives --

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1 MS. PAHLAND: Yes.

2 DR. ATKINS: -- that are relevant to the
3 military, and then a commitment to track them with data
4 sources, or what's the process by which that happens?

5 MS. PAHLAND: As I said, that could be a
6 two- or three-hour talk in and of itself. It's very
7 difficult to talk about such a broad subject in five or
8 ten minutes, but we don't want to take quite the
9 approach that we did before, a small group of people
10 identifying these four main areas. We really do want
11 to develop a forum and a methodology to identify things
12 that are going to be important to the military, but
13 right now there are 467 goals and objectives. We went
14 through every one of them. It was a bit tedious, but
15 interesting. But, you know, quite frankly, we really
16 do have an impact on the majority of them.

17 So the methodology of looking across the
18 entire Department of Defense and identifying who is
19 going to be responsible for what -- for example, water
20 fluoridation doesn't fall under the MHS. It falls
21 under Environment Security. Right now, we're asking
22 for a 75 percent target to have water fluoridation. We
23 know we want more. But that belongs over in Environment
24 Security. So it's going to take a very thorough,
25 systematic approach to figure out exactly how we would

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1 recommend doing it.

2 Right now the language in the DoDD just
3 says "We support the achievement and proceeding of
4 Healthy People 2010 goals", but, of course, the devil
5 is always in the details. The methodology is going to
6 be cumbersome and it's going to take a while, and we
7 certainly do have an idea of what we would do within
8 the MHS, but when you're talking about multiples of
9 these 467 goals and objectives that are outside the
10 purview of the MHS, the directive will be there and
11 hopefully it will be signed, but I can't describe their
12 methodology.

13 Our methodology in the MHS for those
14 activities where there are goals and objectives that we
15 think are medically based, then that process is going
16 to be developed within the confines of the Prevention,
17 Safety and Health Promotion Council, because all of our
18 Surgeons General are members of the Council, and our
19 ASD for Health Affairs and people from the J-Staff and
20 Dr. Claypool, but the exact process, we don't know that
21 yet. But right now we do have existing tools,
22 performance measurements that have taken heavily from
23 Healthy People 2000, and they are a part of our goals.

24 But we've already identified some of them. Some of
25 them are tobacco, some of them are alcohol abuse. If

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1 you go down the ten leading health indicators -- you
2 see the topics there. We have committees that address
3 just about every one of those topics. So, I think
4 we're very much well on our way to -- we've identified
5 those ten areas as Department of Defense areas also.

6 DR. LaFORCE: It is clear that there is an
7 important overlap in terms of the committee structure
8 within AFEB, and I would make a plea that as you
9 develop your working groups, that you either give Ben a
10 call or me a call, because I think that there is merit
11 in having representation from AFEB members to
12 individual working groups. I assure you it would
13 facilitate in the same way that you are talking about
14 facilitating communication amongst the different
15 service groups. This would facilitate the level of
16 collaboration across the AFEB and your group. So I
17 would make a recommendation or I think I'm speaking for
18 the AFEB when I say I. I think the AFEB would make a
19 recommendation that as you establish working groups
20 that you make it as a matter of policy to either
21 contact -- certainly Ben would be the focal point and
22 discuss in terms of representational issues because I
23 think there is a level of expertise and here certainly
24 is a level of interest within the AFEB to not get in
25 the way, that in point of fact this is a process that

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1 might help accelerate things.

2 MS. PAHLAND: I absolutely concur. That
3 is why we are here and we are all a part of this
4 evolution to increasing health status and consider it
5 done. Absolutely, we will develop close contact.

6 DR. LaFORCE: Super. We should go on
7 perhaps to Capt. Bob Murphy's presentation on the DoD
8 Alcohol Action Plan. Capt. Murphy is a staff officer
9 in the Air Force Surgeon General's office.

10 CAPT. MURPHY: Good morning, everyone.
11 Adm. Clinton, members of the Armed Forces Epidemiologic
12 Board. On behalf of the Council and LtGen. Kaufman
13 (phonetic), we'd like to thank you very much for the
14 opportunity to come and address you this morning. Col.
15 Diniega had the opportunity to address us at our March
16 meeting and, again, Ben, thank you very much for the
17 opportunity to attend the meeting. Next slide, please.

18 (Slide.)

19 A little bit of background -- Lynn has
20 touched on this a bit -- background for the Prevention,
21 Safety and Health Promotion Council occurred at the
22 direction of the then Under Secretary of Defense for
23 Personnel and Readiness, Mr. Rudy DeLeon, who now is
24 the Deputy Secretary of Defense, and he called together
25 a group from across the DoD to a first meeting in June

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1 of 1998. As you can see, it was a pretty eclectic
2 group from Personnel, Services, Education and Training,
3 Safety, and the Medical community. Mr. DeLeon did this
4 very intentionally because in the past there had been
5 tried groups of this nature, but they had failed
6 because they had been largely medical in nature.

7 Subsequently, after a two-day meeting,
8 they did develop what they felt were their three top
9 priorities -- that being alcohol abuse, tobacco use,
10 and unintentional injuries. From that came the first
11 meeting of the Council. Next slide, please.

12 (Slide.)

13 As you can see again, the Council
14 membership is by a very eclectic group. I won't
15 delineate the bullets, but certainly the people who
16 have the power to effect change within the Department
17 of Defense are represented. We have recently added Dr.
18 Claypool from the Military Veterans Health Coordinating
19 Board, and it's nice to see Col. Kimm here from the
20 Joint Staff because an invitation has been extended to
21 LtGen. McGovern, and it is the intention that Adm.
22 Mayo, CJCS, Deputy Director for Logistics, will be the
23 member on the Council. Next slide, please.

24 (Slide.)

25 This clearly delineates what we feel the

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1 purpose of the Council is in terms of talking about
2 advancing policies and practices that lead to health
3 and safety promotion, and injury and illness
4 prevention. It's spelled out very clearly in the
5 National Defense Strategy and Policy. It is our role
6 in the DoD to deliver a fit and ready force, and
7 certainly concurring with the concept of population
8 health, we want to build healthy communities at home
9 and abroad, and certainly in peacetime and conflict,
10 and therefore it was very important that we include our
11 friends from the J-4. Next slide, please.

12 (Slide.)

13 Certainly in terms of our scope of
14 activity, we want to make recommendations in terms of
15 Health Promotion and Prevention Policies and Programs.

16 We can't do this without involving our line commanders
17 and community leaders from all across the spectrum of
18 Department of Defense. We certainly want to place an
19 accent on Putting Prevention Into Practice. We want to
20 certainly talk about successful deployment, the HEAR,
21 which is now known as a self-reporting tool. Next
22 slide, please.

23 (Slide.)

24 As Lynn has talked about a little bit, the
25 charter is signed by the Secretary of Defense. This is

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1 the request of Ms. Goodman (phonetic), who is the
2 Deputy Under Secretary of Defense for Environmental
3 Safety, who had been at the January 1999 meeting, felt
4 that in order for the Council to have any significant
5 effect in terms of changing practice, that it had to
6 gain the attention of the Secretary of Defense. He did
7 sign this on the 28th of July, 1999. We currently are
8 in the process of preparing a revision to the charter
9 which hopefully will be approved before the end of the
10 year because, by statute -- if you will read in the
11 charter -- we have a charter review to coincide with
12 the new Chairman being appointed in January of 2001.

13 The Under Secretary of Defense is the
14 overseer of the Council. He approved the plan
15 originally for Injury and Occupational Illness in
16 September of 1999, and then Alcohol and Tobacco were
17 approved in October of 1999. While the Executive Agent
18 is the Assistant Secretary of Defense for Health
19 Affairs, the appointment of the Council Chair is done
20 by the Under Secretary of Defense for Personnel and
21 Readiness. Because of Dr. Roadman's specific interest
22 and advocacy in the areas of preventive medicine, he
23 was asked to chair. And when Gen. Roadman retired,
24 Gen. Kaufman, at Mr. DeLeon's request, was asked to
25 complete Gen. Roadman's term. Next slide, please.

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1 (Slide.)

2 To show you that they were very prescient
3 in terms of picking out those areas which were
4 important, it's interesting that when the DoD's
5 worldwide survey was released that the three top areas
6 were exactly the same as noted by the Prevention Group
7 at their initial policy meeting, that's the area of
8 heavy alcohol use, tobacco use, and hospitalization for
9 injuries. Next slide, please.

10 (Slide.)

11 Now, this data is taken -- I'm sure many
12 of you have seen this -- from the DoD worldwide survey.

13 It's not important for you to look at the individual
14 services. What is important is the fact that across
15 the DoD we have not changed the rate of abusive use of
16 alcohol in the course of the last 20 years. So this
17 means that we have to come up with something new. The
18 strategies that we have designed in the past are simply
19 not working. Next slide, please.

20 (Slide.)

21 And, again, the demographic data certainly
22 shows that our high risk groups -- that's between the
23 ages of 18 and 25 in all the services -- but, more
24 importantly, compared to our civilian counterparts in
25 that particular age group from 18 to 25, we are

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1 significantly higher, and this is the group at risk
2 that we need to address. Next slide, please.

3 (Slide.)

4 Now, this is the bottom line. We're all
5 here in physically constrained environments, but
6 alcohol costs us nearly \$600 million a year. This is
7 data taken from Dr. Helyer's study which was published
8 in Military Medicine in January of 1999, but it's
9 attributable to 3 percent of our deaths on active duty
10 but, more importantly, it doesn't even address the cost
11 associated with fetal alcohol syndrome, and this data
12 does not include the cost associated with homicides,
13 injuries and suicide. And a very interesting study has
14 come out to show that -- it's published in the Annals
15 of Emergency Medicine -- which very clearly shows
16 significant rates of alcohol abuse in the areas of
17 injury, suicide and homicide. Next slide, please.

18 (Slide.)

19 Now, anybody that's been in the Beltway
20 for the last year has seen this slide a significant
21 number of times in terms of iteration. Col. Talcott
22 will take the option for this because he did this for
23 Gen. Roadman, but what has been important is the change
24 in our culture, the change in our attitude.

25 Previously, we had been pretty much

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1 concerned with the bottom two on the continuum in terms
2 of accession and duty, but across the Department of
3 Defense we have two missions. First, the Force Health
4 Protection Mission, which CJCS -- that is our
5 Deployment Health Component -- and then also the
6 Prevention for Force Enhancement and Peacetime Benefit.

7 When we come home following deployment, what type of
8 illnesses are we going to deal with, plus, the family.

9 So, what the change has been is that we
10 are now considering all the way from accession, to
11 retirement, separation, and beyond. We realize that
12 many of our people leave after the first term, however,
13 if we can develop healthy habits with regard to them,
14 they will carry that on into their civilian life. Next
15 slide, please.

16 (Slide.)

17 Now, in terms of goals, we talked about
18 alcohol ongoing surveillance, better education and
19 training. Dr. Talcott is going to talk to you about
20 accessibility and availability because it's really more
21 germane to the Tobacco Plan. It was originally part of
22 the Alcohol Plan, but after considerable discussion and
23 review of the literature, we found that there is still
24 controversy in terms of that area. We talked about
25 identification of our high risk groups, and we've

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1 already alluded to that in terms of the 18 to 25 year-
2 olds, and talking about assessing and developing
3 evidence-based tests for action. Next slide, please.

4 (Slide.)

5 Now, subsequently, in terms of the Alcohol
6 Abuse Reduction Plan, the Alcohol Abuse Reduction Plan,
7 the Alcohol Abuse/Tobacco Use Reduction Committee,
8 which Col. Talcott and I co-chair -- well, fortuitously
9 because we are right next door to one another in the
10 cubicle -- was originally established in September of
11 '98. Dr. Talcott was the first chair, and then when I
12 arrived from Pearl Harbor in November of '98, we made
13 the decision to co-chair, and I usually run the
14 meetings.

15 We did brief the time line of our plan to
16 the Prevention, Safety and Health Promotion Council in
17 July of last year. As you can see, the Under Secretary
18 of Defense for Personnel and Readiness approved that
19 plan in October of 1999, and then subsequently we set
20 about to complete a significant number of the goals
21 associated with that plan by February of this year.

22 We did conduct an Alcohol Abuse Policy
23 Reduction Seminar here in Washington, D.C. in January
24 of this year. Next slide, please.

25 (Slide.)

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1 Subsequently, this is the plan, as you can
2 see, as we briefed to the Council. The white stars
3 represent those areas which we had already completed by
4 the time of the briefing to the Council. The green
5 stars represented areas that we had to plan for and
6 hope to accomplish at the time we set them up. Next
7 slide, please.

8 (Slide.)

9 Again, as you can see, according to our
10 time line, at the time that Under Secretary DeLeon
11 approved the plan, we had a significant amount of work
12 to undertake. Next slide, please.

13 (Slide.)

14 And this, again, shows our long-term
15 range, July to October 2000. Many of these items that
16 need to be addressed are wrapped up in the Put
17 Prevention Into Practice session which we hope will be
18 through coordination in the latter part of this year.
19 Next slide, please.

20 (Slide.)

21 As you can see, in terms of our seminar,
22 we had DoD, Service Secretary, Service Offices
23 representatives. For the first time, we had Service
24 Alcohol Program Managers in the same room, talking with
25 one another, sharing what they were doing

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1 independently. We had Service Personnel, we had the
2 Education and Training representatives, plus we had
3 civilian consultants to give us a broader, better based
4 perspective. We had Dr. Paul Sobel (phonetic) from the
5 Bovie University in Miami, Florida, and we had Dr. John
6 Baer (phonetic), a very noted alcohol individual from
7 the University of Washington.

8 Our focus was on prevention. We've got
9 great tertiary care programs, there's no doubt. In
10 each of the services, if you are identified as an
11 alcohol abuser, you need treatment, we can get you in.
12 But it's a very cost-effective, time-intensive program,
13 and it doesn't reach a broad base of people. What we
14 want to talk about is a primary or universal
15 intervention that we could reach a broad group of
16 people, talk about identifying a high risk group. Each
17 of the individual services -- this is what Dr. Sobel
18 addressed -- would then pick the time and the place to
19 give that primary intervention. Then once we were
20 looking at some of our research projects, we could
21 develop targeted intervention -- and this is Dr. Baer's
22 area of expertise, especially in the area of
23 motivational interviewing. Next slide, please.

24 (Slide.)

25 We were very successful over the course of

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1 a period of approximately three days. Dr. Mazzuchi
2 was our keynote speaker. We were able to identify a
3 high risk group. We were able to review existing
4 service programs for getting down to the bottom line
5 individual unit, and we do an excellent job in that.
6 We talked about developing a mechanism to track adverse
7 alcohol events, and that was the decision that we
8 reached. Alcohol Incidents mean different things to
9 different people, so we came up with the current
10 adverse alcohol events, which means based upon security
11 police information, an adverse alcohol event is
12 identified when alcohol plays a significant role in
13 that event occurring. We talked about a centralized
14 database, but all these services do a very good job in
15 terms of tracking these alcohol events, and why should
16 we reinvent the wheel; why should we put in another
17 redundant system? So what is going to occur is that
18 the Council will receive a report on an annual basis
19 based upon a compilation of the service data.

20 Now, what elements are in that data we are
21 still discussing, and hopefully we will have that
22 resolved within the next two or three weeks. Next
23 slide, please.

24 (Slide.)

25 We are in the process of preparing a

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1 policy to address formal intervention, referral and
2 treatment. We talked about in terms of service
3 education and training, changing the cultural norm.
4 Our studies show that more people are absent, more
5 people are going -- we're trying to get the message
6 that it's okay not to drink, that alcohol is not
7 necessary to have fun. We have nothing against
8 alcohol. What we have is we are against the abusive
9 use of alcohol. We talked about reviewing service
10 policies for early intervention. We do a very good job
11 largely mandated referral. I'm part of a guidelines
12 committee that's working on substance abuse for both
13 the DoD and the VA, and this information is being
14 incorporated in both guidelines. We talked about
15 desired funding for the studies -- one, for best
16 practices but, more importantly, studies. We talked
17 about changes in our leadership culture. We talked
18 about early assessment of some of our pilot study
19 programs. The Air Force has the SHARP (phonetic) and
20 the SHARE Program. Dr. Rick Schaffer (phonetic), from
21 the Naval Health Center for Research in San Diego, has
22 just presented to Ms. Carolyn Becraft (phonetic) the
23 results from his study done on the Marines in Okinawa.
24 Next slide, please.

25 (Slide.)

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1 So here is where we stand right now. The
2 Council has not even seen this briefing, other than
3 Ms. Carolyn Becraft, the Assistant Secretary of the
4 Navy for Manpower and Reserve Affairs. You can see
5 that we have accomplished a good number of our goals in
6 our first area. We have kept the green stars for the
7 last few elements because they are ongoing studies that
8 we need to address. Next slide, please.

9 (Slide.)

10 And as you can see, we have completed a
11 large number of the second page. Dr. Talcott is
12 involved with the development of the next generation of
13 the worldwide survey. We've already been in contact
14 with our friends at CMA. We do an annual survey of all
15 our beneficiaries. While it is largely related to
16 customer satisfaction, it does address tobacco, and we
17 are in the process of having one or two questions
18 incorporated that address alcohol abuse so that we
19 could have a steady time line of data. And, obviously,
20 at the bottom we are looking, talking to our friends at
21 the War College and other institutions to talk about
22 development of an awareness package. Next slide,
23 please.

24 (Slide.)

25 As you can see, we've already talked about

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1 the July to October time frame. We are very much
2 interested in the Put Prevention in Practice that is
3 coming out that will address a good number of those
4 items. Next slide, please.

5 (Slide.)

6 So, the bottom line, ladies and gentlemen,
7 is the fact that we want a healthy population across
8 all the services. Leadership is a very, very important
9 role with regard to this. And Dr. Talcott doesn't let
10 me tell too many stories. I just want to give you one
11 anecdote -- or two anecdotes.

12 First of all, I commanded three Military
13 Treatment Facilities. The last time I commanded was in
14 Pearl Harbor, Hawaii. I had 250 enlisted people, total
15 number of 500 people, 85 officers. My last 19 months
16 in command, we did not have one alcohol-related
17 incident, and that's because I made it a significant
18 priority with my senior leadership. That continued for
19 another five months. So, Pearl Harbor was free for
20 over two years of alcohol-related incidents.

21 The second, my good friend, Capt. Chuck
22 Pierce, who is now in the Educational Department of the
23 Surface Warfare School in San Diego, was Commander of
24 the U.S.S. Cromley (phonetic). They went on a six-month
25 deployment. They set all sorts of records but, most

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1 importantly, during that six-month deployment, Chuck
2 did not have a single alcohol-related incident, and his
3 crew had a great time. And I'd like to attribute that
4 to the fact that Chuck told his kids the problems that
5 they could have, the negative effects that they could
6 have upon themselves in terms of their health.

7 And, lastly, probably in October, as Dr.
8 Roadman was getting ready to retire -- and if you've
9 ever listened to Dr. Roadman - he puts up his hands --
10 I've got it -- takes off his glasses, "What don't you
11 understand," and then -- I'll calm down the language --
12 Wayne and I were trying to update him on our
13 accomplishments, and he said, "You got one lousy thing
14 in a year, what are you doing for me lately." But then
15 after, of course, we had all melted down and our
16 shields had all been taken off, he said, "Who would
17 have ever figured a year ago that an orthopedic surgeon
18 from Pearl Harbor and a behavioral psychologist would
19 get this far." And there's a lot of impetus, a lot of
20 interest in the Council. We very much appreciated them
21 coming and talking to us. There is a significant role
22 in terms of the AFEB working with the Injury and
23 Occupational Illness Committee, and also the Joint
24 Preventive Medicine Committee. Adm. Johnson sits on
25 the Council as a member, so there is a broad spectrum

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1 of representation. We are looking forward to working
2 with LtCol. Kimm and Dr. Mayo to do that and, again,
3 thank you very much for the opportunity to share some
4 work in regards to one, the Council and number two,
5 what we're doing in alcohol.

6 I'd be happy to entertain any questions,
7 but LtCol. Talcott is going to let you know what we are
8 doing in the area of tobacco cessation. And, of
9 course, we've worked with Wayne McBride very
10 extensively. So, thank you very much for the
11 opportunity of coming and addressing the Board. Are
12 there any questions?

13 DR. LaFORCE: Any questions for Capt.
14 Murphy?

15 DR. BARRETT-CONNOR: I have two questions.
16 One is, how do you do these heavy alcohol use surveys?

17 CAPT. MURPHY: At the present time, we use
18 the -- the major tool is an anonymous survey, the DoD
19 worldwide study, and there are specific questions asked
20 with regard to that.

21 DR. BARRETT-CONNOR: But what percentage
22 of what units get asked questions?

23 CAPT. MURPHY: It's a sampling that's
24 extrapolated across the services. It's done by the
25 Research Triangle Institute, Dr. Gray.

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1 DR. BARRETT-CONNOR: My other question is,
2 when we discussed alcohol reduction earlier, I don't
3 know how many years ago on this committee, we talked
4 about the fact that alcohol was so cheap -- it was
5 actually cheaper in some Officers' Clubs that I've been
6 in to drink scotch of a better quality than I can
7 afford to buy than to have a Coke. And it seemed like
8 that was a very mixed message also. Has anything
9 changed with regard to the pricing?

10 CAPT. MURPHY: Well, there is -- Assistant
11 Secretary of Defense Muldon (phonetic), who is, of
12 course, Management and Policy. We do have a specific
13 policy with regards to packaged alcohol, distilled
14 spirits and other forms, and we are within 10 percent
15 of the competitive price.

16 DR. BARRETT-CONNOR: You mean the
17 nonmilitary price.

18 CAPT. MURPHY: The nonmilitary price,
19 correct. And that policy was -- as was testified in
20 front of the Senate Armed Services Committee, that
21 policy is going to continue.

22 DR. BARRETT-CONNOR: When did that start,
23 because there is nothing shown on this heavy
24 drinking --

25 CAPT. MURPHY: What we are saying is that

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1 that -- that policy has been in effect for at least the
2 last four or five years, that I'm aware of. I can get
3 you when that policy went into effect, but you are
4 absolutely right. We have to develop new strategies in
5 terms of addressing the 20.8 percent.

6 DR. BARRETT-CONNOR: I don't want to be
7 the only person asking questions, but I don't
8 understand what you mean by you've kept the price
9 competitive on packaged alcohol. Is that what they buy
10 at the PX, or is that -- I mean, what is served in the
11 places where the military can buy alcohol on the base?

12 CAPT. MURPHY: Everything -- beer, wine --

13 DR. BARRETT-CONNOR: I understand, but is
14 that also competitively priced?

15 CAPT. MURPHY: Beer and wine are not, that
16 legislation has not gone forward. And according to
17 Assistant Secretary Muldon, that is not going to be
18 addressed at the present time. That's his testimony in
19 July.

20 DR. OSTROFF: Steve Ostroff. This is
21 clearly not an area of my expertise, but I'm curious as
22 to -- I mean, in terms of identifying the high risk
23 groups for intervention, you mentioned the 18 to 25
24 year olds. Clearly, within the military, this is a
25 behavior -- drinking is a behavior that's acquired very

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1 early once somebody comes into the service, and I'm
2 wondering what else you've done to attempt to identify
3 even at the time of accession who the high risk
4 individuals are so that you could potentially intervene
5 as quickly as possible.

6 CAPT. MURPHY: There is a study which
7 talks about -- which measures high school students -- I
8 think it was from Michigan or other places which Mike
9 Beech (phonetic), the Alcohol Manager for the Navy,
10 discusses, and they are already identified by the time
11 they finish high school a significant number -- 30 or
12 40 percent -- are already at high risk. So the point is
13 in an universal intervention which hopefully will
14 gather some momentum, this will be addressed by the
15 individual services. Maybe in our discussion, we won't
16 manage the individual service policy in terms of doing
17 that, but it probably will be given in boot camp, it
18 will be given in our schools. Each of the services
19 does it a little bit differently, but it is certainly
20 addressed if the -- the Marine Corps does it best
21 because they address it at each level of their
22 leadership training all the way to their Command and
23 Staff College. I'm in the process of finding out what
24 the Naval War College does now. I'm not sure what we
25 even do at the Captains Course. Again, the Air Force

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1 does a very good job in terms of addressing at their
2 schools. The Navy doesn't do quite as good a job in
3 terms of addressing it. Does that answer your
4 question?

5 DR. RUNYAN: I have a couple of questions.
6 One is on your cost data. Does that include the cost
7 for family members?

8 CAPT. MURPHY: Yes, but it does not
9 include, as you will note, costs associated with
10 suicide or homicide, and some injuries.

11 DR. RUNYAN: Which would greatly increase.

12 CAPT. MURPHY: Yes, ma'am.

13 DR. RUNYAN: The other question I have, I
14 couldn't read all of the small print, but I did notice
15 that addressing the relationship of alcohol and
16 domestic violence was one of the issues. Are you also
17 looking at the relationship between alcohol and child
18 abuse?

19 CAPT. MURPHY: Yes, that certainly is one
20 of the elements. As I said, we have not determined all
21 of the elements that we're going to take from the
22 Security Police, but one of the suggested elements is
23 child abuse, sexual abuse, family violence, crimes
24 against property, crimes against people. We're just in
25 the final negotiation stage of that. We already did

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1 traffic, DUIs, and traffic related fatalities. The
2 Annals of Emergency Medical Study very clearly shows
3 significant relationship between alcohol and incidents
4 of domestic and spousal abuse, child abuse.

5 Several years ago, Adm. Clemens
6 (phonetic), who was then Commander-in-Chief of Pacific
7 Fleet, sent out a message to the entire Pacific Fleet
8 talking about incidents of sexual assault. Ninety
9 percent is associated with that. So we are looking at
10 that.

11 DR. WALDMAN: Now to come back to Dr.
12 Barrett-Connor's point for a minute, I thought I heard
13 you say in your presentation that it had been
14 determined that access and availability issues were
15 more important to tobacco than alcohol.

16 CAPT. MURPHY: That is correct.

17 DR. WALDMAN: On what basis do you say
18 that?

19 CAPT. MURPHY: The research and the
20 literature is still -- in terms of alcohol availability
21 and access, is still very controversial. There have
22 been --

23 DR. WALDMAN: In general. Is that in the
24 general population or in the military population?

25 CAPT. MURPHY: In general.

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1 DR. WALDMAN: Because I think it's fairly
2 logical in one's mind that if you say that you're
3 practically giving this stuff away on the base, that
4 there just seems to be some dysjunct there that, on the
5 one hand, it's okay to practically give it away to a
6 population that has the potential at least to abuse it,
7 on the other hand to be putting a great emphasis on it.
8 There seems to be a contradiction.

9 CAPT. MURPHY: To follow up your question,
10 the question was asked of me by Ms. Becraft, are we
11 getting a subset of high school students. I don't
12 think that's the case. I don't think there's been
13 anyone to say that we get a specifically different
14 subset than the average college student. You see, our
15 young officers mimic their civilian counterpart the
16 same as our young people would mimic their counterparts
17 who aren't going on to college.

18 DR. WALDMAN: I think most would agree
19 that there's a problem in that particular population
20 even in situations where it's not being given away for
21 free to them. So, again, to me it doesn't make very
22 intelligent sense.

23 CAPT. MURPHY: However, that's where I
24 think leadership plays a very important role. If I
25 have -- I got the kids right out of course school,

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1 right out of field medical school, if I make it
2 important -- I'm not saying my kids didn't drink, I'm
3 not that naive, and maybe they just didn't get caught.

4 But I made it very clear when they came in to
5 interview with the Executive Officer and myself, I told
6 them the rules, and I reinforced them. I never banned
7 alcohol at any of our command functions, but I can tell
8 you over the course of the last two and a half years,
9 the amount of alcohol present at any command function
10 was much less. And when I was the ExO at Bremmerton,
11 we stamped their hands for those over 21, and the Chief
12 monitored them. And I'm sure that the same is true in
13 the Marine Corps with their corporals and above, it's a
14 leadership issue and I think it's an education issue,
15 and we need to have our senior people let them know
16 what the ramifications are.

17 DR. BERG: Bill Berg, Hampton. I'm
18 puzzled why the price is being raised on spirits but
19 not on beer, since beer is the drug of choice. And I
20 understand that the literature may be conflicting about
21 what effect access has, but if you're going to say that
22 price has little effect on it, why are you raising the
23 price on spirits but not on beer?

24 CAPT. MURPHY: That is a political rather
25 than a medical decision. The fact is that the Congress

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1 of the United States is not willing at the present time
2 to talk about beer and wine.

3 DR. BERG: Are you saying that there is
4 congressional pressure, because I remember a few years
5 when some of the Navy ships were trying to go entirely
6 smoke free, there was a lot of congressional pressure
7 from the tobacco states threatening to cut
8 appropriations.

9 CAPT. MURPHY: I can tell you right now --
10 and I don't want to steal Dr. Talcott's thunder --
11 there is already been congressional modification of our
12 intent to raise tobacco prices even further. And I
13 think the link between tobacco pricing and access in
14 terms of tobacco is much clearer, and he is behavioral
15 scientist and he can address the question, but I'm not
16 saying -- it is still controversial, there is still not
17 enough pressure by the Congress to be willing to adjust
18 the price of beer. That was discussed in terms of the
19 original plan, and that was taken out.

20 DR. LaFORCE: We probably should move on a
21 little bit, but I would say, to answer Elizabeth's
22 question, the survey, the alcohol-related survey was
23 discussed, I believe, at the last AFEB meeting, and it
24 is a stratified random selecting -- it's actually
25 statistically -- it was very, very well done, this

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1 self-administered --

2 DR. BARRETT-CONNOR: I was trying to get
3 him to say that. I was going to say that no matter how
4 good your anecdotes are, the data don't look like
5 anything's changed.

6 DR. LaFORCE: The other thing is, it's
7 important to link, I think, your activities with what
8 is happening in the U.S., particularly with the issue
9 of binge drinking because that clearly, on a college
10 campus, on a high school level, or in young Americans,
11 is the greatest risk to unintentional injuries or
12 alcohol-related injuries, abuse, et cetera. After
13 comes the more hard core alcoholic issues that are
14 frankly quite different. And what's been learned --
15 particularly at Robert Wood Johnson Foundation and also
16 a lot of others say is there really some interventions
17 in terms of this binge drinking that appear, as you've
18 pointed out, to bear real fruit, not the least of which
19 is the issue of leadership and also within peers, that
20 it's okay not to do something.

21 CAPT. MURPHY: You're correct. And a last
22 comment, the Congress of the United States last year
23 allotted about \$14.5 million to study 14 conditions, of
24 which alcohol and tobacco, amongst other diseases,
25 were. Dr. Talcott and his group, the only tobacco

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1 funded one which I'm sure he'll talk about, and seven
2 of the 31 alcohol projects were funded. I don't know
3 who those researchers were or what their research is,
4 but it's not been released.

5 This year Congress has gone to \$25
6 million, so there is certainly intense congressional
7 scrutiny and interest as regards that, and we are more
8 than happy to -- that decision is made by the ASRAM,
9 we're more than happy to help any researcher, supply
10 them with the information. The RFPs were supposed to
11 be by tomorrow, but I haven't seen them on the Website.

12 So, there certainly is interest, and we would
13 incorporate any data gleaned from the civilian sector
14 with regards to strategies that we might want to
15 recommend to the Council for DoD.

16 DR. LaFORCE: Before you begin, Col.
17 Talcott, I want to introduce a new guest, LCdr. Johns,
18 from the Office of Emergency Preparedness for Health
19 and Human Services, who is the representative of Dr.
20 Satcher's (phonetic) office.

21 LtCol. Talcott.

22 LtCOL. TALCOTT: Thank you. Let me first
23 begin by making some corrections for authorship sake,
24 the Lifecycle slide you saw earlier, I did borrow
25 whoever created that slide actually, and edited some of

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1 the boxes, but I am not the creator of that, although I
2 wish I was the creator of that.

3 A couple of things with the comments, I
4 guess the thing I want to tell all of you here, just
5 observing the interaction that's going on in the room
6 is exactly why you need to be integrated and connected
7 in some way with our Council, because this is just the
8 kind of thing that we need in our meetings. At the
9 subcommittee level, but even on the Council, it would
10 be very nice to have somebody sitting to kind of help
11 out with these kind of problems. I mean, that's my
12 perception, sitting on the outside of the room.

13 I'm here today to talk to you about the
14 tobacco side of the Alcohol Abuse/Tobacco Use Reduction
15 Committee. Next slide, please.

16 (Slide.)

17 You've seen the goals -- deliver a fit and
18 ready force, build healthy communities, and advance
19 policy and practice are the three that we have
20 determined in our charter that we'd go after, so what
21 you hear after this should be supporting that. Next
22 slide, please.

23 (Slide.)

24 Again, this is from the 1998 survey of
25 Health-Related Behavior. These are smoking rates. And

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1 what you can see is we've got nice reductions from 1982
2 until 1995, probably largely attributable to secular
3 trends, probably not attributable to any specific
4 programs that we've had in DoD.

5 From 1995 to 1998, however, we've not seen
6 significant reduction and, again, that's probably more
7 related to what's going on nationally than it is
8 something specific to the DoD, that we're not doing
9 something new to encourage tobacco use or to discourage
10 whatever we were doing before that was reducing it, but
11 the concern that in the last three years not just in
12 the military, but for those outside the military that
13 we're not seeing continued reductions in tobacco use
14 even though the literature more and more points to the
15 fact that tobacco use is the single most preventable
16 cause of premature death in the country today. Next
17 slide, please.

18 (Slide.)

19 We're hemorrhaging in the DoD to the tune
20 of \$548 million annually which, you know, honestly
21 doesn't seem to impress too many people. I mean, it
22 just seems like an awful lot of money to me, but you
23 don't get a lot of strong reaction to that.

24 Now, one of the criticisms of this slide
25 is, well, that's the whole military health system, so

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1 that's retirees, that's -- but what about those young,
2 healthy active duty people who smoke, I mean, let's be
3 honest with them -- I mean, this is kind of the stuff
4 that goes on outside the briefing -- let's be honest,
5 you know, they're going to report to work and while
6 they're young they are not going to get these horrible
7 diseases until later. So is this something we really
8 should be paying attention to? Next slide, please.

9 (Slide.)

10 A study just released. These are just the
11 bottom line just released at MMWR Thursday of last
12 week. It's a study that took a sample, actually a large
13 sample but not a random sample, of health care
14 beneficiaries who were active duty personnel from
15 Region VI in TRICARE, and then matched them to the
16 stratifications we have in the military, and looked at
17 smoking stats. And what they looked at were -- because
18 these were all young, active duty military people, men
19 and women, under the age of 36 -- that was the cutoff,
20 so they are young smokers. And then they looked at the
21 differential cost of the delta between health care
22 cost, indirect and direct cost, to the Department of
23 Defense -- this specifically concerning Air Force
24 personnel. And what they calculated, if you look at
25 the costs of the clinic visits, those

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1 hospitalization/clinic visits and lost time to smoke
2 breaks was about \$107 million annually. So these are
3 for young, healthy smokers' differential costs, not for
4 older, chronic diseased people.

5 If you turn that into full-time
6 equivalents, in others, workforce, you could buy about
7 3,573 people every year for the cost that we spend for
8 smoking, or basically you could take one of our Air
9 Force Bases away. That's basically, the number of
10 people we usually have on active duty to man one Air
11 Force Base like Whiteman. So even if you take out all
12 the chronically diseased smokers and you just look at
13 the young healthy smokers, you still get a significant
14 cost delta between healthy smokers and healthy
15 nonsmokers. Next slide, please.

16 (Slide.)

17 I think one of the problems and one of the
18 things that I think the Council, from the very
19 beginning, that I've been excited about, is this new
20 approach, and different approach to health care
21 problems or health risk factors.

22 Typically, what we do, traditionally what
23 we have done -- if you smoke, that's okay, it's your
24 right to smoke, it's not illegal. I certainly have
25 heard that many, many times, especially when we staff

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1 the Tobacco Use Reduction Plan through the DoD, how can
2 you tell people they can't smoke.

3 What we have done traditionally is we just
4 let them smoke until they get diseased and they come to
5 a Medical Treatment Facility, and that's when we engage
6 them and tell them they shouldn't have smoked in the
7 first place, and we treat their diseases, and we give
8 them their health care if they can get in to see us,
9 and then we send them back out to do their duty until
10 they get sick again from whatever chronic disease they
11 have. It's a high cost. And to be honest with you, if
12 you really think about the goal of the United States
13 Armed Forces, it's really to maintain a healthy force,
14 not to treat the force that got sick. Well, it's not
15 as cost-effective and it probably doesn't meet the
16 needs of the military services. What you want are
17 people that are healthy and ready to go all the time,
18 not sick and recovering or needing care. Next slide,
19 please.

20 (Slide.)

21 So what we are opting for is a little bit
22 different view with the goal not being to cure disease,
23 but the goal being to maintain health and function,
24 which changes a lot of the things that you're going to
25 want to do, which brings up the issues of the pricing

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1 of alcohol products, the pricing of tobacco products,
2 the messages we give young people when they come into
3 the military about the way in which they choose to live
4 their lives. But the goal here from this slide is that
5 disease and health care, although very important, is a
6 very small part of the whole picture for why people
7 might choose to behave the way they do and why they may
8 or may not be fit and ready to go when they are being
9 called.

10 So the main thing in health and function,
11 what we're arguing is, a number of things have to be
12 addressed that we can't address in order to actually
13 deal with the problem -- for instance, the problem of
14 tobacco use. Next slide, please.

15 (Slide.)

16 So, basically what we are trying to do is
17 focus on -- and thank you for saying it's as close to a
18 community approach as we can come -- we're trying to
19 get as close to a community approach as we possibly
20 can, and the questions you all are asking, what I was
21 fascinated by and excited by, quite honestly, was that
22 they directly assuming that of course we'd use this
23 kind of an approach. Of course we want to be concerned
24 about selling cheap alcohol if we don't want people to
25 use it. I mean, it just makes sense to me, too.

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1 So if you think about like tobacco use and
2 you take all our TRICARE beneficiaries, what you want
3 to do is intervene in multiple locations. You don't
4 wait for them to come into the MTF. If I want to make
5 this a healthy function, then I probably don't want to
6 wait until they come to the MTF because that almost
7 assumes there's something wrong with health and
8 function already by the time they get there.

9 So what I want to be able to do is
10 intervene in the workplace, recreational facilities,
11 training. When they come for training, we have one of
12 the greatest opportunities in the country where young
13 people actually -- 19-year-olds -- actually make the
14 decision to make a shift in the way they live their
15 lives. I mean, actually sign on the dotted line saying
16 "I'm willing to do things very differently than I've
17 done them before," and they are 19 years old. So, we
18 teach them how to eat differently. We teach them how
19 to make a bed. We teach them how to fold their
20 underwear differently. We teach them how to march in a
21 straight line. Why can't we also teach them something
22 about a healthy lifestyle, something about, you know,
23 well, maybe this is the way you did it when you were 18
24 and in high school, maybe all your friends did smoke,
25 maybe 80 percent of the people from your perception in

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1 your school were smoking, but not in the military. And
2 I don't know why we haven't taken advantage of that.
3 And, again, they have multiple training opportunities
4 throughout the course of their career, so that just
5 should be repeated multiple times.

6 And then, finally, we want to have a
7 multi-faceted approach. So what I'm going to do now is
8 walk you through the plan -- I didn't get as detailed,
9 Bob gave you the details, that's the kind of briefing
10 slides we introduced to the Council, but you have read-
11 aheads. I did not bring read-aheads, I apologize, but
12 I'll make my slides available to you if you can get
13 them electronically, but I do have mine in big print so
14 you'll be able to read them, and I just highlighted the
15 big ones in the action plan.

16 The idea behind the whole action plan
17 which did not -- they all had good intentions, but
18 unless -- my brief experience in the Beltway is, once
19 you have a specific action item that is somewhat clear
20 and that has a time line attached to it, and someone
21 you have to report to, it is very difficult, with all
22 the other things you have to do, to put the focus on
23 those particular topics. All these things that Bob
24 showed you, all of our action items of all of our
25 action plans have time lines. And the idea is that the

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1 Project Officers, like Bob and I, have to stand up in
2 front of the Council and say we're late and this is why
3 we're late, or we're not late and this is why we're not
4 late, which in my experience has really increased the
5 interest in people working together and actually has
6 worked very well toward the completion of some of these
7 goals.

8 We wanted to establish goals. I must say,
9 we have admirable goals -- not very realistic, but
10 admirable for tobacco. Reduce access to tobacco
11 products was one of the things we wanted to do. We
12 believe that access to the product itself probably
13 increases the likelihood you're going to smoke.

14 Integrate with training and education. So
15 anywhere we could build it in as a part of what we were
16 training you to do, and the model we used was really
17 pretty simple, and that was we trained, we trained. We
18 assume when you come here that you don't know how to
19 load bombs. You don't have the technical skill to load
20 bombs. So, the weapon system you're going to work on
21 if you're a bomb loader in an aircraft, you have to be
22 good at that skill, and so we give you training and
23 practice, and you have to show some level of
24 proficiency. And the idea is, if we do that, it's
25 prevention from dropping big bombs and them blowing up

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1 and having accidents.

2 So, we kind of looked at the person the
3 same way. We looked at one of our soldiers as a human
4 weapon system, much like we want to do preventive
5 intervention on all our jet engines, we don't want jet
6 engines stalling out in the sky and saying, "Look, we
7 really wish you would have done something to keep it
8 flying." We build in routine prevention episodes for
9 that engine. Why not also for the person, and why not
10 in training?

11 So, there are things you can learn about
12 yourself that might help you project yourself through
13 your career in the military that will increase your
14 likelihood of being successful. And, oh, by the way,
15 here's what some of those are. Why not build that in
16 just like we build in the other technical skills?

17 We wanted to integrate for possible
18 medical care. Obviously, you do have the opportunity
19 to get into the MTF, what ten-second interventions do
20 you do? We've adopted HCPR guidelines, the first
21 round, and we're about to hit the second round, I
22 think. With that, what kind of things can happen in
23 the medical center, and that's kind of the way we've
24 gone in the HCPR, and I'm sure most of you are familiar
25 with that. And then provide access to cessation

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1 programs and products. One of the other things we were
2 concerned with is if I did want to quit smoking and I
3 didn't want to quit on my own, where do I go and what
4 am I going to get? And kind of what we're finding is
5 you just flip a coin and -- I mean, I could get
6 anything.

7 The good news is lots of people are doing
8 smoking cessation across the Department of Defense.
9 The bad news is it's really, really busy. I mean, you
10 might get hypnosis in one place. In another place
11 you're going to get a very good behavioral program with
12 NRC that's right out of a manual, it's excellent. Next
13 slide, please.

14 (Slide.)

15 So here are the goals. The goal for the
16 actual whole smoking plan is to reduce smoking rates by
17 5 percent per year. It would be a wonderful goal to
18 achieve, but probably not going to happen. The reason
19 we settled for this goal is we wanted to impress the
20 people on the Council who wanted an aggressive goal.
21 They'd rather fail to meet an aggressive goal than set
22 one so low.

23 We want to reduce smoking rates by 15
24 percent by the year 2001, and we obviously are going to
25 be adopting Healthy People 2010 goal of 12 percent. If

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1 you remember, Healthy People 2000 had two goals, one
2 for civilians and one for the military because we were
3 so far behind. Now we're not so far behind. In fact,
4 we know right now we actually are lower. If you match
5 with gender and age, we actually have lower smoking
6 rates than our civilian counterparts, which is good
7 news. I don't know whether we can take credit for it,
8 but it's still good news. Next slide, please.

9 (Slide.)

10 What about reducing access to tobacco
11 products? These are all items on the plan, by the way.

12 We want to match state and local laws for restricting
13 tobacco use, the local standards are more restrictive.

14 We've changed so that one of the things we do now is
15 talk to all of our commissaries and exchanges and ask
16 them what are your goals, and do they match up with
17 ours, and they have to report back so we can actually
18 get a listing of what's the problem with this and are
19 we really doing it. Prohibit tobacco use in all common
20 areas so that we're just taking it out of places where
21 you might have one smoker. If limitation in Executive
22 Order 13058 -- I know you're familiar with that --
23 that's the President's Executive Order for tobacco
24 smoking, taking it out of all DoD facilities, and
25 implementation of these. What we're trying to do is

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1 just to drive the message down. As you know, what
2 happened to that was the NWR facilities exception was
3 approved by Secretary of Defense which said, well, if a
4 commander at an installation wants to stop smoking in
5 all facilities, they can by saying we're going to stop.

6 However, if they want to allow smoking in family
7 recreational facilities like bowling alleys and
8 whatnot, clubs, they can for a period of three years,
9 and during that three years they have to basically
10 install airflow rooms in the building -- you know,
11 those smoking rooms where the air is being sucked out.

12 So, a number of bases -- and I don't know
13 the number -- actually have opted to do that. So they
14 are allowing smoking, it's going to continue for three
15 years from the time Mr. Cohen signed the order. At the
16 end of that three years, though, everybody goes smoke
17 free.

18 Pricing is back to no more than 5 percent
19 below the competitive price. Again, the good news is
20 that has all been approved by all our exchange people.

21 It's not done yet. Obviously, as you all know,
22 Congress determines the pricing of these products, we
23 do not, so we have to wait on Congress. We have not
24 heard back from Congress. But the DoD has signed off
25 on it.

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1 Prohibit single-serve access, single-serve
2 tobacco products sold by self-serve sold at the
3 checkout register -- I said I would make it in English,
4 but this is the language the Navy uses. What that
5 means is you don't have tobacco with things sold in the
6 impulse line. So if I just got through -- if I'm
7 trying to quit smoking and I'm having to wait in this
8 line and I've got tobacco all around me in single
9 packs, I'm much more likely to grab one. So what this
10 requires is now they all have to be back behind the
11 cash register. They have to be in back so a customer
12 can't actually reach and grab one. You have to ask for
13 it.

14 Display tobacco cessation products to
15 provide maximum visibility. The reason for that is we
16 want them to show us that where they place tobacco
17 cessation products, they're going to be more likely to
18 be bought, most likely to be purchased, and that they
19 should be below the local competitive prices, and they
20 are. Actually they've reported back and you can buy
21 Nicorette gum and what not, its' right now below the
22 local competitive price. If you went to WalMart to try
23 to buy it, it would be cheaper onbase than it would be
24 offbase. Next slide, please.

25 (Slide.)

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1 Continuing to reduce access to tobacco
2 products. We want promotional programs like working
3 for smoking cessation. That's been approved by our
4 personnel people across all four services, it's just a
5 matter of ramping it up and deciding -- and, again, we
6 cannot vouch for the regularity of what are these
7 programs, what should they look like, and we have
8 gotten approval by all four service Personnel
9 Departments that we can move on this, and they agree
10 that this is something we can do.

11 Regular counter-advertising by Public
12 Affairs for tobacco cessation. Next slide, please.

13 (Slide.)

14 So that's reducing access. In terms of
15 integrating with education and training. What we would
16 like to do is we've targeted educational programs. We
17 have some now. We actually have an National Institutes
18 of Health grant funded by NHLPI (phonetic) for basic
19 training for all our Air Force accessions. And what we
20 are trying to do is to build an intervention there.
21 The one advantage is everybody has to quit smoking
22 during basic training. All four services disallows
23 smoking or tobacco use during basic entry training for
24 Airmen, and the other services' new entries. So we
25 thought what a great opportunity. No. 1, everybody

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1 already knew they were going to do that, it's not
2 surprising. So they've already done the hardest thing,
3 they've all quit smoking. So what we've done is built
4 an intervention in six-week -- Air Force basic training
5 is six weeks long. We built an intervention and we've
6 said basically that's a prevention. Everyone is a
7 nonsmoker, so now what do you tell nonsmokers who have
8 quit for six weeks. Some plan on going back and some
9 don't. What do you do in an intervention to try to
10 help them keep from smoking. We did one grant with
11 NIH. What we found was since the policy change
12 resulted in about almost an 18 percent decrease in one
13 year for that population of smokers, which is huge,
14 absolutely huge, after the policy decision.

15 The intervention which is a one-hour
16 intervention initially resulted in a significant
17 difference, but only for the one-hour intervention, but
18 it really had an effect for those smokers who came in
19 saying that they didn't intend to stay quit. So if I
20 intended to go right back to it when I got out of basic
21 training and I got the one-hour intervention, I'm much
22 less likely to start back than if I didn't receive it.

23 Prohibition of tobacco use for students
24 during the duty day informal military training. A lot
25 of the basic military training targets absolutely know

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1 what we are trying to do. What we are trying to do if
2 the policy doesn't exist but the practice does, is
3 ramping up the policy so there's something in writing
4 that says this will not happen in these settings. But
5 a lot of them are finding, or some of them are finding,
6 are just practiced. Somebody decided that on their
7 command they did it, but there was no regulation change
8 to make it that way. Next slide, please.

9 (Slide.)

10 This is the policy that the DoD intends to
11 be smoke free, which we do not have right now. Next
12 slide, please.

13 (Slide.)

14 What do we want to do in our medical
15 facilities, we want to develop centralized monitoring
16 of tobacco use, which we do not have, some way of
17 keeping track so if we do get reductions we can name
18 those. I don't know how successful we're going to be
19 in that.

20 Now, this is in the plan, but the Army has
21 developed DOD-VA guidelines. The Veterans
22 Administration and Department of Defense have joined
23 forces where the primary care intervention is modeled
24 after the guidelines. Next slide, please.

25 (Slide.)

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1 And the fifth vital sign is make it a
2 fifth vital sign. So everyone is going to be asked
3 about their smoking status when they come in for a
4 visit.

5 Access to cessation programs and products.
6 What we are concerned about is we want to create the
7 climate so that people are less likely to start smoking
8 after basic training since all accessions are
9 nonsmokers after basic training. We want to maintain
10 that. But if you are a smoker -- let's say you slip
11 and go back -- how do you help them to quit. So we
12 wanted to develop interventions for high risk groups,
13 like in tech schools where, believe it or not, that's
14 where everybody starts up again. Almost everyone goes
15 to basic training, and then they go to a technical
16 training school where they learn a skill, whatever
17 their job skill is going to be, and that's where we get
18 huge initiation rate. About 85 percent of all the
19 initiation of tobacco, if it's going to occur, is going
20 to occur in tech training, and so that's a high risk
21 group and a high risk location for new intervention.

22 It could fall to the cessation programs.
23 We've done that in a couple of ways. One thing we've
24 done -- and, again, I think the advantage to this
25 group, if you can do this, you have all four services

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1 with their personnel people, with their medical people,
2 all sitting at the same table so we could work this
3 together. What we did was line up all the
4 installations across all four services and said, what
5 are doing in smoking cessation.

6 We had a panel we invited Sue Curry and
7 Harry Lanville and a whole bunch of folks to come in
8 and they basically told us, these are the things you
9 should have in a smoking cessation program. They
10 itemized them. We went out and asked the people who
11 were doing it whether they were, which of these --
12 actually, what we said was, which of these would you
13 like to help with, rather than which are you doing
14 because if you ask which you are doing, then they ask
15 what are they supposed to be doing. And we identified
16 that actually it's really a mixed bag. Depending on
17 where you are, you are going to get something very
18 different. Some programs have high mobility, the
19 people are there and then they can TDY a lot or TAD.
20 But the only program we have available is 12 weeks
21 long. It's a good 12-week program, but not many people
22 can attend it. So you have a low attendance rate. So
23 one of the things we're trying to do is to fit the job.
24 Where you have a high TDY group, you might want a
25 shorter cessation program. You might get lower quit

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1 rates, but you might get better access.

2 We just got a \$2.8 million from a
3 specially mandated funds grant, actually Harry Landon
4 got that at University of Minnesota. So that's going
5 to be a joint military effort, all four services are
6 playing in this. Basically, we're going to select 16
7 facilities, two are experimental and two are going to
8 be our controls, and we're going to go in and do
9 community marketing for smoking cessation and doing the
10 assessment up front, and then we're going to train
11 whoever it is that's doing smoking cessation at that
12 location. It's just a model that was designed by our
13 working group. And we're going to come back to you
14 later and do some followup, but we're also going to
15 provide ongoing training to those groups. Next slide,
16 please.

17 (Slide.)

18 This is just a working group, I told you
19 about that. We received a grant. What we're trying to
20 do as much as possible is to join academics and
21 scholars from civilian communities who know an awful
22 lot about the content area, to bring them to the table
23 along with kind of what I see our role is as kind
24 intermediaries, and we kind of help them begin to talk
25 to the military. That's all I have. Questions?

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1 DR. LaFORCE: Yes, Steve?

2 DR. OSTROFF: Steve Ostroff. One question
3 I would have is, it seems to me that probably both of
4 you are targeting many of the same individuals and that
5 the same person who has a cigarette in one hand is
6 likely to have a beer in the other hand. And I guess
7 you've got your strategies and he has his strategies,
8 but what assurance do you have that you're trying to
9 coordinate your activities since you're probably
10 targeting a lot of the same people.

11 CDR. TEDESCO: Good question. And what we
12 did actually -- we were going to have all these
13 separate committees, and we realized between alcohol
14 and tobacco, with the exception of accessibility and
15 availability -- which by the way, we did have the
16 original plan and we got beaten up so badly for having
17 it in the plan, it actually was redacted -- but,
18 otherwise, they look the same. Rather than have people
19 go to two meetings, they go to one meeting and we go
20 through all the items together.

21 DR. LaFORCE: Julian?

22 DR. HAYWOOD: Do you anticipate any
23 differences between the services -- approaches,
24 resistance, culture.

25 LtCOL. TALCOTT: Yes, absolutely. The

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1 culture, the history, and the way the services have
2 developed -- you're talking about not just getting a
3 couple of physicians or a couple of medical -- you're
4 trying to touch the institutions, and you have to
5 depend on -- and it's varied. And what happens is you
6 find that some services are better prepared to do some
7 of these things, just the way they are organized. I
8 think in the Air Force we have some advantages, for
9 instance, because we're relatively small compared to
10 the Army, so we don't have the history of 200 years of
11 organizational structure where in the Army sometimes,
12 for them to go out to everybody is much more complex, a
13 much more challenging job. We're not there to point
14 fingers at one service or another, we are working every
15 goal. Our person at the table says, well, it's much
16 harder for me in the Army, our job is, well, who do we
17 need to talk to to help get this done.

18 DR. HAYWOOD: I want to congratulate you
19 on the broad program that -- both in NMC what we've
20 recommended here or talking about here for the last
21 three years. I'd like to also point out one example,
22 for instance, how the Navy promotes smoking by giving
23 smoke breaks to shipmates aboard ship, but not to the
24 nonsmokers, which is a typical example of difference in
25 culture.

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1 DR. RUNYAN: Along those same kinds of
2 lines, I'm just curious, are there possibilities of
3 restricting advertising or vending machine access that
4 might not draw the attention of Congress in the same
5 way that pricing does.

6 LtCOL. TALCOTT: Vending machines I'm not
7 sure about, but I don't believe we have -- I don't know
8 if there is policy or if that's in our plan. That's an
9 excellent question.

10 DR. RUNYAN: About whether advertising of
11 alcohol and tobacco products is --

12 CAPT. MURPHY: To answer your question,
13 there are specific guidelines regarding commercial
14 sponsorship by alcohol and tobacco, and all the
15 services are in compliance with that. In Pearl Harbor,
16 they had a Hydro-Fest, which is the hydroplane, and in
17 1998, RJR, Smokin' Joe was entered -- in 1998, my last
18 tour there, all tobacco sponsorship was withdrawn.
19 Smokin' Joe did not race. We never heard Peter Coors
20 and Augustus Busch, III and IV, talk about how they
21 cooperated with Adm. Nelson in terms of that, so they
22 certainly are working. And Peter Coors' message was
23 very clear. On the message he said, wait until you are
24 21. So they are certainly working with us on that.

25 DR. RUNYAN: It might be interesting to do

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1 a cost-analysis in that domain.

2 DR. WALDMAN: Do you have dose line rates
3 for smokeless tobacco products? You show those
4 impressive declines in smoking, and you had a target, a
5 goal for smokeless, but you didn't --

6 LtCOL. TALCOTT: Smokeless is a huge
7 problem.

8 DR. LaFORCE: We need to move on. Do you
9 have one more?

10 DR. WALDMAN: I just want to know, when
11 you talk about competitive pricing, because there's a
12 lot of tax burden on these products, obviously. Are
13 you talking about the cost to the consumer?

14 LtCOL. TALCOTT: The cost to the consumer.

15 DR. LaFORCE: Thank you. the next item on
16 the Board's agenda is a question posed to the Board on
17 the Ergonomics Action Plan, and it was a question that
18 specifically came up from Curtis Bowling, the Assistant
19 Under Secretary of Defense, that said specifically, and
20 I quote: "We need the AFEB to answer the following
21 questions: (1) What does the AFEB recommend for
22 determining the relative contribution of ergonomics to
23 the development of back pain and carpel tunnel
24 syndrome? (2) Can this be extrapolated DoD-wide for the
25 cost-benefit model, and how? (3) Does the AFEB have

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1 any recommendations for the DoD Ergonomics Working
2 Group Action Plan for installation-level and DoD-wide
3 ergonomic program development? (4) What measures of
4 merits should local economic, ergonomic and service-
5 level programs in DoD establish?"

6 To initiate this the presentation from
7 LtCol. Lopez, a physical therapist, Chair of the DoD
8 Ergonomics Working Group.

9 LtCOL. LOPEZ: Thank you. I appreciate
10 the opportunity to come and address this group.
11 Ergonomics is a developing area in the Department of
12 Defense, and we really value your feedback and your
13 suggestions for us so we can develop this program the
14 right way. Next slide, please.

15 (Slide.)

16 Our working group has been established
17 since 1994. If you remember, in the early '90s there
18 was a lot of talk from OSHA about establishing an
19 ergonomic standard. Now it's 2000 and they still talk
20 about it from OSHA, but we recognized as we started
21 looking among the services that there was a lot of
22 duplication of effort, so we decided to pull together
23 and maximize our resources.

24 We have members from all of the major
25 services -- Army, Air Force, Navy, Marines -- as well

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1 as the smaller agencies -- DISA, DFAS, DECA. We have
2 GSA, we also have OSHA and NIOSH participating in our
3 working group, and it's a very healthy working group.
4 We have a fair representation from physicians,
5 therapists, safety professionals, personnel specialists
6 and other organizations.

7 We are trying to attack ergonomics from
8 all directions, and I will address each one of these as
9 we go through the presentation. Next slide, please.

10 (Slide.)

11 From the top down. We are the only
12 organization in the United States that has a firm
13 ergonomics policy. The Department of Defense, out of
14 Ms. Goodman's office, did sign out a policy, DODI
15 6055.1. DoD the only federal organization that has
16 a firm ergonomics policy. It's stronger than the
17 proposed OSHA standard. It's stronger than the
18 California regulation. It requires every installation
19 to have an ergonomics policy.

20 The Navy has an ergo policy in their
21 NAVOSH standard, the Army has a policy letter that will
22 be signed within the next few months. The Air Force
23 has a Surgeon General policy memorandum, and I also
24 mentioned the OSHA proposed standard. In general, the
25 DOD policies are more proactive and protective than

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1 because we have set elements at all installations that
2 we are requiring. Next slide, please.

3 (Slide.)

4 From the top down, the thing that is
5 getting commanders' attention is data. We've worked
6 very hard with the DMSS systems and the ICUC, (Civilian
7 Injury/Illness Compensation System), to get some good
8 solid numbers. We selected ICD-9 codes which are
9 commonly associated with ergonomics as well as the
10 Department of Labor Nature of Injury Codes, and those
11 are included in your handout.

12 We found when we looked at the DMSS data
13 that for the military these codes represented at 20
14 percent of the clinic visits and 49 percent of the
15 limited duty dispositions, and that's significant in
16 that this number doesn't even represent the number of
17 days that are lost. The limited duty disposition data
18 only means the that patient left the clinic with a
19 limited duty disposition, so the number is probably
20 even more significant.

21 From the civilian side, we picked nine
22 Nature of Injury codes out of a total of 74 which are
23 typically related to ergonomics. Those represented 50
24 percent of the claims, 50 percent of the costs, for a
25 total of \$275 million in medical and in compensation

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1 costs in fiscal year '99.

2 We are working hard to get the raw data
3 out of the Department of Labor data and transfer it
4 into the DOEHRS system so that we can look closer at
5 that information. So, again, our primary problem is the
6 causal link and I'll talk about that in just a minute.

7 Next slide, please.

8 (Slide.)

9 We do have some results. Now, one of the
10 problems I always have when I talk to commanders is
11 that we don't have a lot success stories in DoD
12 ergonomic programs. The program is too new. There's a
13 GAO report that came out -- and I'll pass this around
14 for your information -- that did show that you can have
15 significant results from ergonomic programs.

16 We are looking at cost benefit analyses,
17 which is one of our major issues, and that's what I'm
18 coming to the Board about. We do have a preliminary
19 analysis looking at just injuries for the Army. The
20 Navy has a corporate ergonomics program, which is
21 looking at base-level results. The Air Force is
22 looking at activity-based costing, and then we're
23 trying to pull together a DoD cost benefit model. Next
24 slide, please.

25 (Slide.)

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1 The model inputs deal with the task, tool
2 and equipment information. We're going to categorize
3 the thing that they're doing in terms of material
4 handling, office, or some other kind of risk category
5 as well as get information about the frequency and
6 exposure both in terms of the task frequency and the
7 duration during the day that they're actually doing
8 this thing or working with that piece of equipment.
9 And we're also collecting production information.

10 Demographic information. Also falls
11 within this input, we want to get an idea of the
12 occupational classification. For example, if you have
13 soldiers at a high risk -- infantry is actually a very
14 high risk MOS -- they would actually have a greater
15 risk as you walk through that model.

16 Gender. We know that women have a great
17 risk of musculoskeletal injuries than men do. Age and
18 rank. The lower ranks are usually at a higher risk
19 because they are doing more of the material-handling
20 activities.

21 We also want information about the service
22 command because those injury rates can vary by service
23 command location.

24 On the health outcome side, we want to
25 look at severity and probability and the body parts

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1 affected in this model. Next slide, please.

2 (Slide.)

3 I've already talked about the diagnoses.
4 We did select several ICD-9 codes, Department of Labor
5 Nature of Injury codes and VASRD codes. When I talk
6 to audiences and we talk about the cost benefit model
7 and the impact, there's always a question that's raised
8 about who is, responsible, the line versus the medical
9 community. As I have gone through the funding process
10 and submitted requests to our medical folks. They are
11 always telling me, "Well, that's a line
12 responsibility", and the same with the line, they say
13 that they view ergonomics as a medical responsibility
14 because it crosses both accounts. So this model is
15 designed to identify the line-related costs and the
16 medically related costs. One thing I didn't mention as
17 I started out talking about this cost benefit model is
18 that ergonomics is the only profession or element in
19 the health care field that actually has a production
20 impact. And a lot of my working group is saying that
21 it's probably better to include talk about the
22 production-related effect than the health care effect.
23 For example, if I go into a work area and I reengineer
24 a process, I can make that process more productive, I
25 can make the reject rate go down, I can make the

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1 quality of the work better with the side benefit that
2 you see injury rates decrease.

3 So this is what that model is trying to
4 balance, both the health outcomes and the production-
5 related benefit.

6 We're looking at several health-related
7 costs: the disability cost in terms of payments and in
8 lost productivity as you see on that handout. Health
9 care cost includes hospitalization and clinic visits,
10 but our primary issue as Curtis Bowling referred to in
11 the memorandum, is to determine the ergonomic-related
12 portion of those health costs. As I said, I can pick
13 out the ICD-9 codes that are specifically related to
14 ergonomics, but we all know that there are other things
15 that can cause those conditions, like physical
16 training; sports-related injuries; smoking can also be
17 a risk factor; predisposition; as well as the ergonomic
18 piece of it. So we want to have a model that will
19 stand up to scrutiny. I need to be able to say my
20 piece of these costs are related to ergonomics. We
21 have several options, I think, to look that, for
22 example, selective sampling or some other kind of
23 surveys. And I'll show you one thing that we've been
24 using in just a second. But this is my big question:
25 How can we identify the number of work-related

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1 conditions? Next slide, please.

2 (Slide.)

3 On the cost benefit model, on the post-
4 intervention side, we are looking at residual risk
5 because we know that we can't solve all of the
6 problems. We won't be able to eliminate all of the
7 costs. So we're considering residual risks, in terms
8 of severity and probability. And then the production,
9 chain, as I was talking about. The production effects
10 are very important. Can we do it faster, and then the
11 total cost of that thing that we did. Next slide,
12 please.

13 (Slide.)

14 I know you'll have questions about the
15 cost benefit model as we get to the question and answer
16 time, but let me go on through our action plan and
17 things that we're doing. Most of our programs are in
18 the early startup stage and that's okay, actually,
19 because it's a slow-growth process. If we take a
20 policy and we work it down in installations, there will
21 be a effect, and then once you take the pressure off,
22 they'll stop doing it. So a slow-growth process is
23 okay, as we're building support for the case that
24 ergonomic design, work-related injuries, are
25 significant problems for the Department of Defense.

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1 Our primary problem when we talk to the installations
2 is the staffing and resources, and we've found
3 repeatedly that all of our policies must be accompanied
4 by tools. Without the tools, the policies will never
5 get carried out, and you will only end up with very
6 frustrated customers. We've worked very hard to
7 develop many products. We have templates, we've
8 collected data, we've had success stories, we have
9 technical guides, we have program management guides, a
10 lot of flow charts.

11 This is one instrument that I was
12 wondering if it would have any value towards
13 determining work-relatedness. This is a formula that
14 was developed by the Air Force which DoD turned into a
15 bubble form that looked at the risk factors for the
16 development of musculo-skeletal conditions in
17 connection with work design. It is being studied in
18 several research studies and is forming up very well as
19 a good predictor of those people who will be injured,
20 especially with the back scale. So, again, we're
21 getting some good validation of it.

22 The DOEHRs system is another tool that
23 we're working. We have a Level 1 guide which
24 streamlines the ergonomic assessment process. Again,
25 one of the things we really have to look at is the

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1 personnel available to conduct the assessment. We
2 believe this is a successful tool which will allow a
3 technician or other person to go in and assess a work
4 area in a fraction of the amount of time than it would
5 take another person to go in and do the evaluation.
6 We've printed a spinoff of the VDT program which is a
7 European community requirement that every single
8 European National employed by the Department of Defense
9 have a one-on-one workstation assessment. And when
10 Americans particularly started looking at the cost of
11 that which would be \$75-100 for an ergonomist to come
12 and sit at these workstations, the costs were
13 prohibitive. So we developed this expert system, this
14 VDT assessment system which we could have technicians
15 do and they could do the assessment in about 10-15
16 minutes with a little bit of practice so there was a
17 significant cost-savings and again it addressed some of
18 the critical issues from the field. And we have
19 developed the ergonomic risk assessments which right
20 now based on safety graphs but we're trying to move
21 into the health-based graphs with thresholds. But as
22 you know, it's very, very difficult to set specific
23 thresholds for musculoskeletal conditions.

24 It's just like with cigarette smoking, how
25 many cigarettes do you smoke before you develop lung

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1 cancer? How many times do you have to move your wrists
2 before you develop carpal tunnel syndrome? Eventually
3 you will develop it, but you just don't know how many.

4 So the thresholds that we're looking are based on the
5 NIOSH risk equations and the recent ACTIH TLV for hand
6 activity. Hopefully, we will be able to move it into
7 that health based graph. We are looking at the
8 deployed environment because repeatedly we're finding
9 that musculoskeletal conditions in the deployed
10 environment is one of the most significant problems
11 that people have. And it doesn't take a genius to see
12 this. If you have a soldier with full gear on, the
13 helmet, the protective gear, the flak jacket, having to
14 fill sandbags with a trenching tool and stacking
15 sandbags up to a certain height before he's permitted
16 to take off his equipment, you know why you're having
17 people have back injuries and shoulder problems. A lot
18 of the activities and equipment that are given to folks
19 in deployed environments are causing the injuries that
20 we see. Next slide, please.

21 (Slide.)

22 In the hazard prevention and control, we
23 talk a lot about the low-cost solution and the
24 administrative solution because we found that if you
25 re-engineer a process and the tasks included, you can

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1 significantly reduce risk without having to purchase
2 special equipment and those high-priced things that
3 most of the people are worried about with ergonomics.

4 On the health care management side, we are
5 working on the clinical practice guidelines initiative.
6 In particular we've worked on the low back pain
7 clinical practice guideline, and we included the risk
8 management process. The problem we've had in the past
9 is that there's been a disconnect between clinical
10 management and addressing the causative factors for
11 back injury carpal tunnel syndrome and cases like that.

12 So the best medical management is not going to be as
13 effective if that soldier goes back to the same work
14 environment that caused the problem in the first place.

15 So with our involvement in the clinical practice
16 guidelines, we are included in the process with the
17 work-related ergonomic evaluation are I think that's a
18 significant step. We are starting to get into the
19 work-related musculoskeletal practice guidelines and
20 that should start in the fall. And that will look at
21 other musculoskeletal conditions in the risk management
22 process. The tools that the practice guidelines have
23 developed are very important and, again, it includes
24 some very basic self-management solutions for those
25 patients. Next slide, please.

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1 (Slide.)

2 Education and training. We have developed
3 a 40-hour course and trained a heck of a lot of
4 personnel, and we're moving into a Web-based training
5 so that we can get that message to the field in a more
6 effective way. We have worker/supervisor materials
7 including posters, fact sheets, information, general
8 awareness and special training programs out there. One
9 of the most significant things we are doing in terms of
10 training is establishing a concentration in
11 occupational ergonomics in the USUHS MPH. This will
12 start in the Summer of 2001, and we see that as an
13 important initiative because it will help change the
14 staff mix in the field. Next slide, please.

15 (Slide.)

16 In terms of acquisition, our immediate
17 issue with acquisition is bottom line purchaser. We
18 have a lot of supervisors in the field at installations
19 who have IMPAC card purchasing personnel and they can
20 go out and buy furniture and equipment and things that
21 they see advertised that will solve all their ergonomic
22 problems. But we've found repeatedly that they buy the
23 wrong furniture, they buy the wrong kind of keyboards,
24 they have expensive retrofit, they buy equipment that
25 is too heavy. So one of our big issues is informing

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1 the people with those credit cards how to make educated
2 purchases. UNICOR is a particular problem because we
3 are all under the UNICOR restriction in terms of
4 chairs. We recently published a fact sheet on UNICOR
5 chairs. The problem with UNICOR is that they have one
6 chair that they call Classic ERGO Chair, and we have
7 supervisors who say I need an ergonomic chair, and
8 they'll go out and look at the UNICOR list and they'll
9 just kind of go with the faith, you know, purchase that
10 one, whereas UNICOR has a better chair called the
11 Legacy Series that will give him better results. So,
12 we're trying to inform our consumers on purchasing.
13 But the larger issue, the more significant issue we
14 have in terms of acquisition is getting into the
15 acquisition cycle. Ergonomic injury prevention really
16 needs to be at ground zero in the acquisition cycle
17 because we've repeatedly seen systems and equipment
18 coming out that are obviously injury-positive things.
19 For example, we recently evaluated the LSTAT litter.
20 They took a basic litter and added all of this high-
21 tech material to it. They made it, essentially, a
22 mini-ICU for cardiac monitoring. Well, they've
23 increased the weight of the litter up to 175 pounds.
24 Now, if you take a fifth-percentile female and put that
25 person on the litter, you might have a four-man team

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1 who could lift that. But if you put a 95th-percentile
2 male on that litter, that weight could only be lifted
3 by the top fifth-percentile strength male population.

4 So we know this very expensive piece of
5 equipment will probably be sitting on the ground
6 someplace. It looks nice but it's really not a
7 functional piece of equipment because it's just too
8 heavy. We also have the MILES gear which is one of
9 our best success stories. It's a special laser-tag
10 system and it has computerized readouts, a GPS system,
11 it has battery packs on it. The problem is that it's
12 unbalanced.

13 The battery packs hit you in the leg. In
14 fact, the computer readout flips up sometimes and will
15 hit them in the face and chip teeth. It's a big
16 problem. This is a \$25,000 piece of equipment. We've
17 had soldiers we're told who wade through the swamp and
18 get the batteries wet so the thing shorts out and they
19 have an excuse to take it off. Now, that's not a
20 functional piece of equipment. And I'm sure you've all
21 had examples like this. But we really need to look at
22 how we're positioned in the acquisition cycle. Next
23 slide, please.

24 (Slide.)

25 Research. We're really looking at a lot

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1 of research projects to translate these kinds of
2 effects. That's our number one priority. We have to
3 translate every single research project into practice
4 and to get that information down to the field level.
5 We have a lot of partnership projects going on,
6 including a back injury prediction study. I'll pass
7 around the results of that. In essence, looking at
8 risk factors for back injury in high-risk job series.
9 And the nice thing about this is that it is
10 multifactorial. It looks not only at ergonomics but
11 also looks at physical fitness and training, it looks
12 at the stress and psychological component of it, and
13 tries to balance that. The result was a very brief
14 ergo scheme on the very back page of this handout you
15 can see that there's a spreadsheet that unit commanders
16 can use to help prevent infinite numbers of back
17 injuries. This study was concluded so we have not
18 deployed this yet and that's another. Another question
19 I have with my action plan is if you have any
20 recommendations for distribution channels of better
21 ways to employ our information down to the field, I
22 would greatly appreciate it.

23 We have a demonstration project down at
24 Fort Bragg because the unit commanders have always
25 said, all of these studies like the GAO report, is

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1 great for the civilian world, but it doesn't mean
2 anything for the military, so the demonstration project
3 is looking at the effect of integrating an ergonomics
4 program for the active duty unit. And those results
5 are very promising because, again, we've done very low-
6 cost basic changes. For example, we looked at a
7 parachute shop, and one of the things we changed was
8 the lighting so the soldiers could see their work
9 better and they didn't have to bend over all the time
10 to look at it. The color of the thread changed, the
11 basting thread, so that they could see it better. The
12 height of the table. Very, very basic changes that the
13 post engineers were able to fix with a fraction of the
14 cost and it has had significant results.

15 The secondary prevention predictor study
16 is a feedback from the low-back pain clinical practice
17 guideline in that when a patient comes into the clinic,
18 if that provider can identify which patient is at
19 greater risk for long-term disability, we can intervene
20 at an earlier point and prevent long-term disability.
21 Again, it's to get them back to physical therapy
22 sooner, to get them back to work sooner and to talk
23 about stress management earlier. And I think we've
24 seen a significant reduction in long-term disability.
25 Again it's to get them back to physical therapy sooner,

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1 to get them back to work sooner and to talk about
2 stress management earlier. And I think we've seen a
3 significant reduction in long-term disability.

4 Hand and power tool replacement is a study
5 looking at the effects of replacing tools as a way of
6 reduction in injury. Tele-ergonomics, is looking at
7 the most effective way of having a soldier in an
8 existing environment do an assessment of an ergonomic
9 problem and sending the results back to a central
10 location. The importance of this is that we can use
11 those same tools in the deployed environment. We're
12 identifying the best assessments and technologies that
13 we can use in the deployed environment. And then again
14 the cost benefit models have cost savings. Next slide,
15 please.

16 (Slide.)

17 Our strategy has been to leverage
18 resources as much as possible and to partner with every
19 organization we possibly can. We've partnered with
20 NIOSH OSHA as well as our sister services I think we
21 are positioning ourselves fairly well in terms of the
22 policymaking side of it here. For the first time we're
23 invited to participate in OSHA policymaking activities,
24 as well as the NSA study. But our main thing is to
25 develop installation programs, to get that

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1 institutionalized so that we do have the culture change
2 so it's not always that tougher is better.

3 Now I'm not saying that tough isn't good
4 because a certain level of challenge is appropriate for
5 units. It builds morale. But we really need to look
6 at culture change for long-term injury prevention.

7 I'm really sorry about the rotten startup
8 I had with the speaker. I'm sure you have questions
9 for me. I'm sure I've missed something, so please ask
10 me if you have any questions.

11 DR. LaFORCE: This is an excellent
12 presentation.

13 (Simultaneous discussion.)

14 And it follows presentations that we've
15 had over the last two AFEB meetings in terms of the
16 ergonomics, and also I'm particularly impressed with
17 the cost-benefit general model. And this is where you
18 want feedback from the AFEB? That's our number one
19 task, is that not right?

20 LtCOL. LOPEZ: Yes, sir.

21 DR. LaFORCE: Stan, would you want to make
22 any comments? You represented the Board at the recent
23 ergonomics meeting they had. I think it was in April.

24 DR. MUSIC: I think this presentation
25 really summarizes it well. The fundamental problem is

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1 that we've got preventable injuries, and how do we get
2 to maximize the preventability. Culture change seems
3 to be the most important thing because of the attitude
4 of people who think that macho is good and you get no
5 gain without pain. And, in fact, what you want is the
6 opposite, and this came out in the conference. You
7 want no pain is gain, and you want ergonomics to be
8 perceived as macho and not as wussy. So you need a
9 culture change. And now technology, as we just heard,
10 is getting in the way with 175-pound litters and
11 helmets that push your head in the wrong place so you
12 can't run and see and shoot the way you're supposed to.

13 And the other problem that was partially
14 alluded to is that the medical records are not designed
15 so that you can easily get information or data that are
16 readily useful for ergonomic application. So they are
17 looking for guidance, and I must admit, it's a very
18 complex issue, and I think part of the reason that
19 NIOSH or OSHA have been so long in developing something
20 definitive is that we have yet to arrive at the place
21 where anybody has anything definitive. But we've got to
22 put some common sense into this, and maybe we can make
23 a contribution.

24 DR. LaFORCE: Common sense, I'm going to
25 define that in terms of the Environmental and

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1 Occupational Health Subcommittee that's going to
2 wrestle with this with input, I think, from Health
3 Prevention and Maintenance. But I do think that this
4 is an important issue and particularly when I hear the
5 story of \$25,000-piece of equipment being soaked so it
6 can short so that they can get rid of it and avoid
7 getting their teeth chipped. I would say that soldiers
8 always find a way --

9 DR. BARRETT-CONNOR: It is creative, you
10 have to admit.

11 DR. LaFORCE: It is creative, that's
12 right. That's what I said, soldiers always find a way.

13 DR. MUSIC: There are also stories of a
14 \$25,000-piece of equipment that was not bought for a
15 repetitive something. It was for fixing an engine
16 part, and they were all doing it manually, and as you
17 watched this from a distance and over time, they would
18 have saved the \$25,000 many times over if they just
19 bought it right up front and not had the injuries that
20 resulted from trying to do it by hand.

21 DR. LaFORCE: I was also intrigued by the
22 fact that apparently the European military forces that
23 contract out this work apparently have managed to find
24 the funds to be able to ergonomically evaluate how
25 these things are done. I'm trying to figure out how

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1 they do that and we can't.

2 LtCOL. LOPEZ: It's a different culture
3 system.

4 COL. GRAHAM: Perhaps I might help. In
5 the Ministry of Defense, the ergonomic characteristics
6 of our workstations are assessed by a self-administered
7 questionnaire. Obviously, the incentive to say there
8 is something wrong, you just say no, it's fine, that
9 the wire I trip over when I get up is not important.
10 We meet the legislative requirements but don't
11 necessarily honor the spirit of the law.

12 COL. DINIEGA: I have a few comments. You
13 know I wrestled with the ergonomic issue, and we talked
14 about what the question should be to the Board, et
15 cetera, et cetera, and there are several areas that are
16 very difficult, I think, in this arena. One is how do
17 you sort out very easily from the overall injury issue
18 ergonomically related injuries. I mean, it's very hard
19 to find a specific ICD-9 easily. So how do you do
20 that?

21 And then the other part of it is, as we
22 all know in the military, occupational health for a
23 long time had a double-standard of application. One was
24 that in the initial years occupational health programs,
25 the OSHA programs, were primarily aimed at our civilian

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1 population and workers, and very little was addressed
2 on the active duty side. Well, that's changed now. But
3 I think on the ergonomic side, it's still sort of a you
4 say ergonomics and things, and people think of civilian
5 workers rather than the military workers.

6 And then a third area that I think is
7 confusing is in the research and development arena.
8 There is an office that looks at the hazards
9 associated with any new weapon system or widget out
10 there, and I'm not so sure if ergonomics evaluation has
11 been a routine incorporation for that part of the
12 evaluation. But I think the biggest problem is how do
13 you sort out what is truly ergonomically related
14 injury.

15 And then another comment I have is that in
16 my 20-some years in the military, nobody has ever
17 evaluated my workstation.

18 DR. RUNYAN: Carol Runyan. It seems like
19 another element that I'm sort of picking up on but not
20 sure I'm hearing fully developed is the appropriateness
21 of bringing some behavioral science understanding to
22 the issue as well because it sounds like the cultural
23 norm issues and the adoption of these innovations is a
24 stumbling block. And I haven't heard very much -- and
25 maybe you could help me understand -- how those

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1 elements of understanding are being brought to
2 developing the plan and evaluating the implementation.

3 LtCOL. LOPEZ: You're right. It's
4 behavioral because you want in some ways a behavioral
5 change or a mindset change or an anticipation change.
6 We have psychologists involved with our committee, but
7 in terms of actually being useful in the field, we're
8 talking more about marketing than behavioral science
9 because we're talking about what our customers
10 understand and what our target audience will understand
11 and the best way to get that message across. I hope
12 that answers your question.

13 DR. LaFORCE: Let's break for lunch. It's
14 now almost 12:15. I propose we break for one hour and
15 reconvene promptly, please, at 1315, and we'll begin
16 then. We've got enough give this afternoon that we'll
17 pick up the 15 minutes this afternoon.

18 COL. DINIEGA: I'd like to encourage all
19 of those interested in the ergonomics and the injury
20 issue to stick around for the subcommittee because my
21 guess is they'll need all the help they can get.

22 (Whereupon, at 12:15 p.m., the lunch
23 recess was taken.)

24
25

AFTERNOON SESSION

(1:15 p.m.)

1
2 DR. LaFORCE: If I could call the group to
3 order, we will begin this afternoon's tasks. The
4 afternoon sessions will rotate around and through two
5 questions that are being posed to the AFEB. The first
6 is the issue of antibiotics and biologic warfare threat
7 agents, and the presentation will be given by RADM.
8 Clinton.

9 For those of you who don't know, RADM.
10 Clinton is in the Health Care Operations Policy within
11 DoD Health Affairs.

12 RADM. CLINTON: Thank you. It's great to
13 be here today and have an opportunity to meet this
14 group again. I had been in Health Affairs some years
15 ago and enjoyed it greatly. We were struggling with
16 issues of HIV and we were also struggling with some of
17 the alcohol and tobacco issues. It's interesting to
18 see what has been done despite some of the statistics
19 that continue to really be challenging to us.

20 I've been with the Health Affairs Office
21 now about three months. Obviously, for anyone who is
22 reading The Washington Post and military newspapers,
23 the issue of the anthrax vaccine has been probably the
24 number one operational medicine issue for sometime and,
25 to some extent perhaps, has taken off the table some of

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1 the other discussions we need to have, and it was for
2 this reason we wanted to raise with you the whole issue
3 of antibiotic use.

4 Biological weapons and a completely
5 different set of issues, chemical weapons, continue to
6 take a great deal of DoD's biomedical discussions time.

7 Hardly a week has gone by since I've been here in
8 three months that there isn't another meeting about
9 biodefense in some way -- national security issues,
10 research issues, where do we invest the next dollar.

11 Most recently, those of you from the
12 Washington area know that we had this major national
13 exercise, required by the Congress, funded in part by
14 the Congress, managed predominantly by Department of
15 Justice and FEMA, but DHHS had a very active role in
16 it, and it was to respond to this new -- they are not
17 new -- both chemical, radiological, and certainly the
18 bioweapons.

19 The bioweapon that was used in this topoff
20 exercise was in Denver, Colorado, where I first heard
21 in our own Operations Room that it was anthrax, and was
22 greatly disappointed because anthrax, because of the
23 need for vaccine, gave me double heartburn than one of
24 the others. Well, we certainly learned very quickly,
25 in consultation with CDC colleagues, that it was

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1 plague. And it may be that that's an example of what
2 we're faced with.

3 From our perspective, what we do is
4 population-based medicine. Indeed, with people who
5 have plague or we are pre-treating them
6 prophylactically against plague, we are having to make
7 decisions for a group of people and, therefore, we are
8 expected to be in compliance with all FDA regulations
9 about what drugs you use, what is on label, and are
10 presented with extraordinarily complex legal and
11 procedural issues if we are talking about an IND
12 arrangement or anything that gets into that general
13 realm.

14 Obviously, we were approached about
15 antibiotic use, but there's a national stockpile that's
16 maintained by CDC, so those of us in the medical world
17 got that routed and we did what we needed to do with
18 regard to Denver. But if you open any of the books,
19 and you see that some of the preferred drugs in the
20 management of plague cases -- and we were talking about
21 hundreds and hundreds and hundreds of plague cases by
22 the latter part of the exercise -- they talked about
23 streptomycin and gentamycin, as well as others. I
24 doubt that there are very many stockpiles of
25 streptomycin and this presents its own set of problems,

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1 and therein lies the issue that we want to raise with
2 you -- the use of antibiotics in a population-based
3 program, which is certainly what DoD is faced with, and
4 my guess is that CDC, because it maintains the national
5 stockpile and would be responding to a population-based
6 issue, might have to struggle a bit more with the off-
7 label use increasingly. We'll hear about that.

8 We have cost issues, obviously, in
9 pretreating anyone with doxycycline. We have an easy
10 cost issue. If it's ciprofloxacin, we have another
11 cost issue. So we need you, as we've indicated in the
12 letter, to look at the use of microbials and bacterial
13 and rickettsial diseases that are on the Threat List,
14 and we appreciate your help with the previous work on
15 that alone. What are the drugs? What are the clinical
16 issues in the management of the disease when it
17 presents? What are the clinical issues that we need to
18 think through in the indications where we're using them
19 in a pretreatment standpoint, like putting all the
20 folks in the Denver area prophylactically on an
21 antibiotic for a period of time? We need it in the
22 post-treatment period of something like anthrax.
23 Unlike the traditional warfare weapons, these might be
24 used against a population that is not just of military
25 age, but could include dependents -- so we would have

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1 gender specificity -- and might include older and
2 younger people either as our dependents because it's to
3 a whole community of people, not just on a military
4 battlefield, and I would imagine that CDC is going to
5 be greatly more engaged in that same issue, and we
6 welcome their consultation in that also.

7 The FDA then. What's on the label and
8 what's not on the label does make a difference. We
9 need to know that in advance and try to work our way
10 through whatever needs to be done, subject to your
11 recommendations on that.

12 So, in summary then, while there have been
13 a number of work groups that have looked at the issue
14 of antibiotics, and there are good tables, good
15 articles in JAMA, good articles that come from this
16 institution and others about how one manages it, I
17 think we need the AFEB position and the issues
18 identified then that go across the spectrum of
19 population-based medicine health focusing which drug
20 under which indication, gender and age-specific, what
21 about the FDA restrictions on this or that, what are
22 the general cost issues. And we look forward to your
23 very helpful advice. Thank you.

24 DR. LaFORCE: Thank you, Admiral.
25 Questions for Adm. Clinton before we go on?

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1 (No response.)

2 If not, the next speaker is LtCol.
3 Christopher, who is, I believe, is from USAMRIID and is
4 the primary coordinator for BW activities here.

5 COL. DINIEGA: Before Col. Christopher
6 talks, I passed out to the Board members and the
7 Preventive Medicine Liaison Officers, an FM on BW
8 management. That is a final draft, and we'd like to
9 keep the circulation limited. I think, if I'm not
10 mistaken, George, that's going to be published this
11 summer?

12 LtCOL. CHRISTOPHER: This has a
13 publication date of 17 July.

14 COL. DINIEGA: Okay. So if we can keep
15 that to limited circulation until then, I'd appreciate
16 it.

17 COL. EITZEN: Ben, could I just comment?
18 If it wasn't for Col. Christopher, that document would
19 have never been written. He has been the driver behind
20 that. We all owe him a great round of thanks.

21 (Applause.)

22 COL. DINIEGA: And I fully concur with
23 that because I remember talking to George about four
24 years ago about how we needed this and we needed to
25 turn the blue book into something official, and he made

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1 it happen.

2 LtCOL. CHRISTOPHER: Thank you. Good
3 afternoon. I'd like to thank Col. Diniega and Dr.
4 LaForce for the opportunity to join you this afternoon
5 to discuss the role of antibiotics and medical
6 biological warfare countermeasures to be used as either
7 prophylaxis or therapy. Next slide, please.

8 (Slide.)

9 Essentially, the key requirement is that
10 these antibiotics be clinically effective as either
11 prophylaxis or therapy in a biological warfare
12 scenario. There are certain considerations that we
13 need to address up front. One is that the severity of
14 a disease following a biological warfare delivery might
15 be more severe than the naturally occurring disease.
16 For example, most of the biological warfare threat
17 agents are zoonotic pathogens which cause human disease
18 after cutaneous or percutaneous vector-borne
19 transmission. Examples: plague, tularemia, anthrax.

20 Now, the naturally occurring disease then
21 might result from a relatively small inoculation in the
22 skin, while on the battlefield the disease would follow
23 the inhalation of a large inoculum. So the disease
24 seen on the battlefield then might be more severe than
25 the naturally occurring endemic disease: inhalation

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1 anthrax rather than cutaneous anthrax, primary
2 pneumonic plague as opposed to bubonic plague,
3 inhalation tularemia versus ulcer or glandular
4 tularemia, all of the latter examples having a higher
5 case mortality rate than the naturally occurring
6 disease.

7 The second point Col. Parker addressed
8 this morning. In this day and age of genetic
9 engineering, we might be faced with the challenge of
10 microbes that have been genetically altered for either
11 enhanced virulence or antibiotic resistance. Next
12 slide, please.

13 (Slide.)

14 Other issues to be addressed: the safety
15 profile of the candidate drugs, the ease of
16 administration. Oral administration is clearly
17 necessary to be effect as a prophylactic agent. Long
18 half-life drugs would be preferred so that the dosing
19 could be less frequent.

20 Broad spectrum. Clearly, if we have a few
21 drugs that cover the broad spectra of bacterial
22 biological warfare threats, that would be preferable to
23 distributing numerous numbers of drugs for specific
24 agents.

25 Logistics. Some of the issues that Adm.

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1 Clinton has just addressed, the availability of these
2 drugs, the ease of distribution, certain logistic
3 considerations.

4 And last but not least, as Adm. Clinton
5 has just raised, the administrative or regulatory
6 issues. While all the drugs that we are going to
7 consider today are already FDA-licensed and -approved,
8 they are not FDA-licensed or -approved for biological
9 warfare countermeasures for the inhalation version of
10 these diseases, so there are considerations in the
11 context of the Executive Order mandating special
12 authorization for a non FDA-approved indication.

13 Use during pregnancy and pediatric use.
14 Not of primary concern for troops on the front line in
15 the battlefield, but certainly a consideration if
16 military installations, if our bases, our garrisons, et
17 cetera, are attacked. Next slide, please.

18 (Slide.)

19 How can efficacy be determined? Again,
20 most of these diseases are infrequent even in the
21 naturally endemic forms. Certainly, the inhalation
22 forms of these diseases are very infrequent, so we
23 really do not have well conducted clinical trials to
24 demonstrate efficacy for these particular diseases.

25 Other issues: Our clinical experience

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1 with many of these diseases -- for example, inhalation
2 anthrax -- is very limited and for the most part
3 anecdotal.

4 So the recommendations that are found in
5 the field manual, FM 8-284, which were adopted by the
6 Medical/Biological Defense Materiel Board, are based on
7 the prevailing standards of medical practice, in some
8 cases the clinical guidelines for laboratory exposures
9 to specific pathogens, in some cases animal models, and
10 in others in vitro susceptibility. So these are the
11 bases for coming up with our clinical practice
12 recommendations. Next slide, please.

13 (Slide.)

14 Let's begin with our main, number one
15 threat, inhalation anthrax. Next slide, please.

16 (Slide.)

17 Of course, pre-exposure prophylaxis is
18 based on immunization as our primary mode of pre-
19 exposure prophylaxis. If we have intelligence that an
20 attack is imminent, that an attack is about to occur,
21 we can begin antibiotic chemoprophylaxis before the
22 attack. The drugs recommended, ciprofloxacin or
23 doxycycline.

24 For post-exposure prophylaxis, we would
25 add those same antibiotics, either doxycycline or

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1 ciprofloxacin, even if those individuals are fully
2 immunized. Now, animal models suggest that pre-
3 exposure immunization protects the nonhuman primates
4 exposed to over 900 LD-50s. So then why add another
5 layer of protection? Simply, we want to add every
6 potential layer of protection that we can for our
7 troops. Next slide, please.

8 (Slide.)

9 Dr. Ostroff will address the civilian
10 guidelines recommendations, so I'll simply skip over
11 this slide. Next slide, please.

12 (Slide.)

13 Same with the pediatric recommendations.
14 I'll focus today on the recommendations for active duty
15 military. Next slide, please.

16 (Slide.)

17 As we move from prophylaxis to therapy, we
18 see the same drugs listed, however, given parenterally
19 rather than orally. Penicillin we would reserve for
20 cases that are known to be susceptible as determined by
21 in vitro susceptibility. Next slide, please.

22 (Slide.)

23 These are the civilian recommendations
24 found in the JAMA article from last summer, and again I
25 will leave this for Dr. Ostroff to discuss. Next

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1 slide, please.

2 (Slide.)

3 This is the intestinal tract of a monkey
4 who died following inhalation anthrax here at USAMRIID,
5 and as you can see the gut is grossly edematous.
6 There's areas of hemorrhagic necrosis involving the
7 intestinal tract, as well as hemorrhagic necrosis in
8 the omentum near the omental lymph nodes.
9 Histologically, this will demonstrate infection in the
10 submucosal layers rather than involvement through the
11 intestinal epithelium supporting hematogenous
12 dissemination rather than a primary oral inoculation.
13 So, we feel that GI tract involvement will be a sequel
14 following inhalation challenge. This might affect the
15 bioavailability of oral drugs. So, even though oral
16 ciprofloxacin, other quinolones, have excellent oral
17 bioavailabilty, we are concerned that they might have a
18 decreased bioavailability for cases. So these drugs
19 might be adequate for prophylaxis when given orally,
20 but possibly not for therapy. That's why we recommend
21 parenteral therapy and oral prophylaxis. In fact, at
22 Sverlosk 39 of the 42 victims undergoing autopsy had
23 these findings in the intestinal tract grossly and
24 histologically. Next slide, please.

25 (Slide.)

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1 This is a list of the drugs that are being
2 considered for prophylaxis and therapy of inhalation
3 anthrax. As we can see, the betalactam drugs,
4 penicillin and cefazolin, are active in vitro. We have
5 in vivo data, animal experiments done here at USAMRIID,
6 only data available for penicillin among the betalactam
7 group. The extended-spectrum cephalosporins do not
8 appear to have adequate in vitro activity against
9 bacillus anthracis. All of the oral quinolones are
10 active in vitro. However, we only have animal data
11 available to us for ciprofloxacin. Next slide, please.

12 (Slide.)

13 Tetracycline, doxycycline, clindamycin are
14 all active in vitro, as are the macrolides and
15 diazolidone product, azithromycin, however, again in vivo
16 activity using animal models is exceedingly scarce, so
17 we definitely need more information regarding the
18 efficacy of these in vivo. Chlorphenicol, rifampin
19 are active in vitro.

20 DR. LaFORCE: There is clinical experience
21 for doxycycline.

22 LtCOL. CHRISTOPHER: Doxy?

23 DR. LaFORCE: Oh, yes.

24 LtCOL. CHRISTOPHER: Very good. For
25 cutaneous anthrax?

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1 DR. LaFORCE: African data, Stanford
2 Medical Journal about four or five years ago.

3 LtCOL. CHRISTOPHER: Great. Thank you.
4 Next slide, please.

5 (Slide.)

6 New candidates being considered:
7 vancomycin and aminoglycosides are active in vitro.
8 Cinocid, quinopristin, dalfapristin active in vitro;
9 daptomycin highly active in vitro. However, again, we
10 do not have in vivo activity for these new candidate
11 drugs.

12 As Col. Parker alluded to this morning, we
13 are actively partnering with the pharmaceutical
14 industry in testing new candidate antibiotics. Our
15 Bacteriology Division has an agreement with
16 pharmaceutical firms to obtain all of the drugs
17 currently in Stage 2 and Stage 3 trials to test those
18 drugs in vitro. And those drugs that appear promising
19 in vitro will then be used for in vivo testing. So we
20 will have further models, further information to work
21 with. Next slide, please.

22 (Slide.)

23 This slide simply lists candidate drugs
24 that are under consideration, again, those drugs that
25 are active in vitro will be used to study animal models

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1 in vivo. And further revisions to FM 8-284, for the
2 most part, we will need to at least have good animal
3 data prior to making additional recommendations to
4 advise for the drugs. Next slide, please.

5 (Slide.)

6 I'm sure you're all aware of the
7 antibiotic-resistant live attenuated spore vaccine that
8 was developed in Russia. Essentially, the live
9 attenuated spore vaccine was genetically altered so
10 that it was resistant to multiple antibiotics. And
11 they made a presentation here at USAMRIID, and we asked
12 why did you want to do that. And they said, "Well,
13 suppose there is an epizootic of anthrax among an
14 unimmunized herd of cattle, sheep or goats. We would
15 want to both immunize and chemoprophylax the herd
16 simultaneously. So if antibiotics are given
17 concurrently with the current live attenuated spore
18 vaccine, the antibiotic would kill the vaccine, thereby
19 preventing the vaccine take." So by developing this
20 vaccine, they have "developed" a better vaccine. Of
21 course, we are concerned that those same genetic
22 modifications could be used in a fully virulent weapon
23 strain. It certainly poses some problems, some issues.

24

25 Are there any questions at this point on

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1 anthrax?

2 DR. LaFORCE: Have those resistant
3 isolates been cultured?

4 LtCOL. CHRISTOPHER: To my knowledge, we
5 at USAMRIID have not been able to access this strain
6 for experiments.

7 DR. LaFORCE: But there's rumor amongst
8 the community that either through reverse transcriptase
9 or some other biological or molecular biological
10 technique they are able to take Sverdlosk tissue and
11 demonstrate that that isolate did have either plasmids
12 or genetic material that was consistent with it being a
13 resistant strain. Is that true?

14 LtCOL. CHRISTOPHER: Not to my knowledge.
15 I'm aware that a Los Alamos group obtained tissue from
16 Sverdlosk victims and demonstrated that there were four
17 different strains in those victims, four different
18 fully virulent *Bacillus anthracis* strains. They also
19 identified the attenuated spore vaccine strain at
20 vaccine sites in some of the victims. So they
21 demonstrated genetic diversity, but to my knowledge
22 we're not aware of the phenotypic correlates of that
23 genetic diversity.

24 DR. LaFORCE: Thank you. Let's touch on
25 plague. Next slide, please.

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1 (Slide.)

2 Primary inhalation is what we would be
3 faced with on the battlefield, a rapidly progressive
4 necrotizing pneumonia. Next slide, please.

5 (Slide.)

6 Pre-exposure prophylaxis.
7 Chemoprophylaxis with ciprofloxacin or doxycycline.
8 This is based both on vitro data and animal studies.
9 Post-exposure prophylaxis, doxycycline, a very
10 conservative recommendation even for post-exposure
11 prophylaxis in the epidemic setting. For household
12 contacts, cases of pneumonic plague, doxycycline for
13 one week, again supported by animal data.
14 Ciprofloxacin, new recommendation, again, based on in
15 vitro data in animal studies. Next slide, please.

16 (Slide.)

17 Therapy. Very conservative
18 recommendations following the standard care.
19 Streptomycin, gentamycin. Next slide, please.

20 (Slide.)

21 Doxycycline, with the addition of
22 ciprofloxacin. This is a new addition. We made this
23 recommendation again based on in vitro susceptibility
24 in animal models. Chloramphenicol recommended for
25 patients with meningitis. On the basis of animal

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1 studies done here, the betalactam drugs actually were
2 not very effective. In fact, the betalactam drugs
3 carried a higher case fatality for treating animals
4 with meningitis, higher case fatality than the
5 bacteriostatic drug, chloramphenicol. Next slide,
6 please.

7 (Slide.)

8 These are the antibiotic candidates.
9 Again, the aminoglycocides, tetracycline, quinolones
10 looking very promising in vitro. We have animal data
11 for these drugs. Next slide, please.

12 (Slide.)

13 Some drugs we need some further
14 information on, as you see here. So at this point, it
15 would appear that doxycycline and the quinolones appear
16 to be our most promising candidates at least for
17 prophylaxis and possibly for therapy according to the
18 information that we have today. Next slide, please.

19 (Slide.)

20 I'm sure you all are aware of the multi-
21 antibiotic, Madagascar, reported in the New England
22 Journal in 1997. This isolate was highly resistant to
23 multiple antibiotics and, interestingly, all of these
24 antibiotic-resistant genes were carried on a single
25 transferrable plasmid. The patient survived after

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1 having been treated with trimethepram sulfa possibly
2 because the isolate was still susceptible trimethepram.

3 So we have a resistant isolate from nature, so of
4 course we are concerned that a resistant isolate could
5 be developed by a potential adversary. Next slide,
6 please.

7 (Slide.)

8 Melioidosis and glanders. Next slide,
9 please.

10 (Slide.)

11 We really could not come up with a pre-
12 exposure prophylaxis regiment for FM 8-284 based on
13 clinical experience. It is interesting to note that in
14 our laboratories we do have chemoprophylaxis
15 recommendations based on in vitro data, as you see
16 here. Next slide, please.

17 (Slide.)

18 Therapy of glanders and melioidosis is
19 somewhat controversial. For FM 9-284, we adopted very
20 conservative standard recommendations found in the
21 leading medical textbooks. At this point, one may note
22 that we have had a case of laboratory-acquired glanders
23 here recently. The patient was treated with emipenum
24 and doxycycline and responded very well to that two-
25 drug combination. Next slide, please.

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1 (Slide.)

2 Tularemia. Post-exposure prophylaxis
3 regimen was outlined, again on the basis of animal
4 models and in vitro susceptibility. There are really,
5 as you know, no recommendations for post-exposure
6 tularemia for other than laboratory exposures in the
7 community. Next slide, please.

8 (Slide.)

9 Therapy. Very conservative
10 recommendations, with the exception of the addition of
11 ciprofloxacin. This recommendation is based on in
12 vitro animal data and very limited clinical experience.
13 Seems to be highly effective based on that limited
14 experience, so we adopted that as one of our potential
15 therapies. Next slide, please.

16 (Slide.)

17 Brucellosis. As you know, no pre-exposure
18 prophylaxis. Post-exposure prophylaxis, we would just
19 advocate, following inhalation of a high inoculum, a
20 full course of two-drug therapy, doxycycline plus
21 rifampin. This is based on experience with use of
22 Brucelli live attenuated vaccine used in veterinary
23 use. It can cause human disease after accidental
24 inoculation. A three- to six-week course of post-
25 exposure prophylaxis is recommended. That was the

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1 basis for our recommendation here. Next slide, please.

2 (Slide.)

3 Coxiella burnetii. Post-exposure
4 prophylaxis is problematic. Prophylaxis is effective
5 if given within a certain window between 8 to 12 days
6 post-exposure. If given before that, it simply
7 prolongs the incubation time. So there would be an
8 issue about identifying the time of the exposure in
9 order to identify the course of post-exposure
10 prophylaxis. Fortunately, Q fever responds very well
11 to antibiotic therapy. Next slide, please.

12 (Slide.)

13 So, future prospects. Certainly the new
14 quinolones are very promising agents because of their
15 very broad spectrum of activity, and possibly also
16 because of the long half-life. Some of these drugs,
17 sparfloxacin, for example, can be given once daily and
18 would be convenient to use on the battlefield. Other
19 drugs being considered as outlined on this slide.

20 At this point, I'll take any questions.

21 DR. LaFORCE: Questions?

22 DR. GARDNER: I might just ask a question.

23 I did read the Field Manual before I came, and
24 listened carefully to your presentation, and then also
25 was sent to me an analysis of drug costs by LtCol. Carl

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1 Curling.

2 DR. LaFORCE: Who is here, incidentally.

3 DR. GARDNER: He's here -- good. My
4 question, I guess -- I was trying to weigh the merits,
5 obviously as you were, of quinolones versus
6 doxycycline, and in your presentation it looked pretty
7 even-Steven, although I gather there's a fairly strong
8 sense that for inhalation anthrax the quinolones look
9 better. Is that because efficacy or because of the
10 concern about mutants being generated. That's my
11 question. Because there is, I think, about a 25-fold
12 difference in the cost of these drugs, so you're
13 looking at a -- is there a 25-fold difference, I guess,
14 in the risk, and I think you're into some significant -
15 - when I got through all this, I said, well, how come
16 we just don't use doxycycline for everything versus
17 using quinolones, and I'd like to hear a little more
18 discussion as to what really -- what is the proven
19 benefit of the quinolones.

20 LtCOL. CHRISTOPHER: Well, the first
21 consideration, efficacy in an animal model using the
22 nonhuman primates, both drugs were highly effective for
23 post-exposure prophylaxis in monkeys containing very,
24 very high inocula. So they both appear to be effective
25 for that particular indication.

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1 As far as resistance, we saw the
2 antibiotic resistance on the genetically engineered
3 live attenuated vaccine. Tetracycline, doxycycline was
4 among those drugs to which the isolate was resistant.
5 Quinolones were not. Now, do we have any information
6 that a quinolone resistant strain is being developed,
7 can be developed? I don't know the answer to that.

8 DR. GRAHAM: But there's concern that the
9 bioterrorism bug might be altered rather than the fact
10 in our current isolates there's any real difference, is
11 that a fair statement?

12 LtCOL. CHRISTOPHER: Yes, sir. So we're
13 concerned about the genetic engineering for resistant
14 strains. Another consideration for the quinolones is
15 the broad spectrum of activity. Here we have a
16 bacteriocidal drug that can be active against *Bacillus*
17 *anthracis*, also *Yersinia pestis*, *Francisella*
18 *tularensis*, in vitro even *Coxiella burnetii*, so the
19 broader spectrum of activity might be a consideration
20 when comparing these two drugs. But as far as efficacy
21 in the animal models, both appear equivalent.

22 DR. LaFORCE: Other questions?

23 (No response.)

24 The other point of view is it's also nice
25 to have two things in the bank rather than one.

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1 LtCOL. CHRISTOPHER: Right.

2 DR. GARDNER: But you're making a choice
3 -- I gather the choice has been made -- to pick the 25-
4 fold more expensive drug and, again, not based on
5 current efficacy, but based on the concern that it's an
6 easier one to manipulate the resistance.

7 LtCOL. CHRISTOPHER: The animal data does
8 suggest that ciprofloxacin might have superior activity
9 against *Yersinia pestis* following inhalation.

10 DR. BARRETT-CONNOR: If you're talking
11 about prophylaxis, it looked like doxycycline would be
12 -- if you didn't know what you had but you thought you
13 had something, that that would be the way to go. Is
14 that part of the recommendation?

15 LtCOL. CHRISTOPHER: Doxycycline is listed
16 as a potential drug for almost all of them.

17 DR. BARRETT-CONNOR: It's a very fabulous
18 review that you just did. It was really nice for those
19 of us who haven't kept up.

20 LtCOL. CHRISTOPHER: I think if we saw
21 large numbers of casualties coming in with an
22 inhalation disease of something that we could not
23 identify, doxycycline plus gentamycin -- that would
24 cover *Yersinia pestis*, it would cover most of the
25 agents on the list.

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1 LtCOL. CURLING: I'm LtCol. Carl Curling.

2 I was formerly the NBC Defense Staff Officer for the
3 Army Surgeon General, I now work for the Assistant to
4 the Secretary of Defense for Civil Support, Ms. Pam
5 Berkowski (phonetic), as her R&D Deputy, as well as
6 addressing medical aspects for Civil Support.

7 To address the question of cost, the
8 recommendation I left the Surgeon General with for
9 future budget years was rather than buy 100 percent of
10 the requirement every year of each year's requirements
11 for ciprofloxacin, that we did a review of the cost,
12 and by cutting out 25 percent of the annual purchase of
13 ciprofloxacin -- in other words, buying enough for what
14 we anticipate could be 75 percent of the maximum
15 requirement -- we can buy another 50 percent of the
16 maximum requirement with doxycycline. And that was the
17 recommendation that was left: we actually buy both
18 antibiotics, neither one of them at all of what we
19 would need to dose 370,000 soldiers, but each of them
20 sufficient to respond to a large fraction, a
21 contingency portion of that population. And that is how
22 the recommendation has gone to the Surgeon General to
23 address the issue of cost and efficacy. Rather than
24 rely on one very expensive antibiotic, we're relying on
25 two, one expensive and one not so.

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1 DR. BERG: Bill Berg from Hampton. You
2 personally answered the question I was going to raise.
3 Could we have a little discussion about whether we're
4 in an all-or-nothing situation, whether we have to go
5 with one drug or the other, or whether we can get both,
6 or whether it's a mixed bag, as you suggested. Has
7 there been much thought given to that?

8 COL. DINIEGA: I have a comment before
9 somebody answers that specific question. I think the
10 tasking to the Board is to look at treatment, potential
11 chemoprophylaxis use and combination use with vaccines.
12 That's the general tasking.

13 The other issue is, I don't think we want
14 to get into stockpile issues or anything here. The
15 discussions have all pointed to let's make the best
16 medical recommendation, but the fact remains that
17 sometimes for large organizations out in the field,
18 handling two, three multiple lines is very difficult,
19 and you want to have as few lines as possible -- this
20 is of pharmaceuticals. To carry into battle five lines
21 of antibiotics is a lot more difficult than just
22 carrying one or two.

23 DR. LaFORCE: Why don't we go on and hear
24 a CDC perspective from Steve Ostroff, and then we'll
25 open this up to more general discussion for both Dr.

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1 Christopher's and Dr. Ostroff's presentations.

2 DR. OSTROFF: Well, thanks. It's nice to
3 take my West Nile hat off occasionally and do something
4 else. I'll start by saying that the pharmaceutical
5 stockpile isn't primarily an issue that my center deals
6 with except from the scientific point of view at CDC.
7 The pharmaceutical stockpile is handled by the National
8 Center for Environmental Health, and my only
9 significant involvement is that I got the nice task of
10 having to testify before Congress about how we were
11 developing our pharmaceutical stockpile after a General
12 Accounting Office report came out late last year that
13 was, to say the least, somewhat critical of the other
14 stockpiles that were in the process or had been
15 developed, one of them from the Office of Emergency
16 Preparedness at Department of Health and Human
17 Services, and the other the CBIRF stockpile. Both of
18 those stockpiles are primarily developed for chemical
19 weapons exposures. Our stockpile, which is
20 significantly larger in terms of its size, volume and
21 cost, is primarily geared towards exposures to
22 biologics, particularly microbial exposures. And so
23 ours is very appropriately geared around the issue of
24 antibiotics.

25 Let me just start out by -- next slide,

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1 please.

2 (Slide.)

3 Next one after this.

4 (Slide.)

5 CDC was given a significant role in terms
6 of bioterrorism response only in 1999 when we had a
7 significant windfall of funding for an agency that has
8 a budget that pales in comparison with DoD. There was
9 a total of about \$121 million that became available in
10 1999 for work on the array of different activities that
11 you see listed here, and as you notice down at the
12 bottom, was overseeing and mobilizing the National
13 Pharmaceutical Stockpile for use in civilian
14 populations. And I will say that the issues related to
15 the civilian sector are significantly more complicated,
16 I think, than in the military sector where you have an
17 array of individuals, you have to deal with pediatric
18 issues, you have to deal with issues related to people
19 who are immunocompromised. There's not a uniformity
20 concerning vaccination, and certainly the threat agents
21 that one would have to potentially deal with could be
22 different in the civilian side than they would be in
23 the military side, so there's not a 100-percent
24 analogy.

25 I will point out that in the packet of

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1 materials that were distributed to you, that part of
2 the way that we went about developing the priorities
3 for the National Pharmaceutical Stockpile was based on
4 a meeting of external experts that came to provide
5 advice to us about what the priority agent should be,
6 and I think that as you can see at the end of the day,
7 that the list that was developed based on the expertise
8 from these individuals was really not significantly
9 different than the list would be from the military
10 point of view. And we've used that to prioritize what
11 we would then procure for the National Pharmaceutical
12 Stockpile.

13 One thing that's worth pointing out is
14 that the 1999 funding that we received was in an
15 emergency line and, as such, is no-year funding, so it
16 could be spent over a prolonged period of time. In
17 Fiscal Year 2000 when we got roughly the same amount of
18 money which for the Pharmaceutical Stockpile was \$52
19 million, that must be spent this year. And so we've
20 actually been doing most of our procurement in 2000 and
21 been holding in abeyance some of the 1999 funding for
22 what I would consider to be sort of the "800-pound
23 gorilla" that's waiting in the background, which is
24 smallpox vaccine. But let me move on to the next
25 slide.

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1 (Slide.)

2 The role of the National Pharmaceutical
3 Stockpile is to maintain a national repository of
4 lifesaving pharmaceuticals and medical materiel that
5 will be delivered to the site of a bioterrorism event
6 in order to reduce morbidity and mortality in civilian
7 populations, and this is the basis by which we've been
8 acting. Next slide.

9 (Slide.)

10 The program itself has a variety of
11 different elements, and when you think about deploying
12 this within a civilian sector where you can't very
13 readily predeploy any of the elements, there are a
14 number of different things that need to be developed.
15 This includes the logistical management, the contract
16 management for the materials themselves; issues related
17 to quality assurance which was a particular area that
18 the GAO was highly critical of; technical assistance
19 training and education because one of the peculiarities
20 of the way that we would dispense the pharmaceutical
21 stockpile, we actually wouldn't be the ones that would
22 be distributing the pills to the individuals, but we
23 would rely on our partners either in other Federal
24 agencies or our partners at the State and local level
25 to actually do the distribution, and so there's a fair

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1 amount of training and education that needs to be done.

2 Operational research, to figure out how to
3 best move the stockpile and how to best distribute the
4 stockpile; and, of course, response to incidents in
5 field exercises, and I must say that for us the TOP-OFF
6 Exercise from a week ago was quite edifying in many of
7 the issues that were raised about how the stockpile
8 would move because our whole basis of operation has
9 been to basically move it through commercial
10 transportation, particularly through UPS and FedEx, and
11 the planners for the exercise were acting under the
12 presumption that this would potentially move by
13 military aircraft and end up at Buckley National Guard
14 Base outside of Denver, so we were acting actually on
15 two completely different pathways, and part of our
16 evaluation was that we certainly could have gotten it
17 there a lot faster through FedEx, and they could have
18 unloaded it at Denver Airport within a period of 38
19 minutes where it would have taken the military probably
20 five to six hours to be able to offload the same amount
21 of material because when you do this for your living in
22 FedEx, you make sure you do it quickly and you make
23 sure you do it efficiently, so that was certainly one
24 of the things that we learned. Next slide.

25 (Slide.)

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1 There are a number of very critical
2 elements, and I think some of them were touched upon by
3 Col. Christopher. One is the issue of stock rotation,
4 keeping the materials fresh; one is the issue of
5 storage and the security around storage; and certainly
6 the one that's been quite difficult for us because we
7 would have to move this to the site of an incident, is
8 the transportation issues. Next slide.

9 (Slide.)

10 We've had certain issues that we've tried
11 to deal with. We've played a whole series of what I
12 call the "end games", which is trying to decide what it
13 is that we're developing the stockpile for. And as you
14 can see on the left-hand side, for the potential
15 biological we've based most of our planning notions on
16 having to have a stockpile of either vaccine or
17 antibiotics for smallpox to be able to use in a
18 population of 40 million individuals. And I think as
19 most of you know from a number of discussions that have
20 occurred over the years, we certainly have only a
21 fraction of that vaccine currently available.

22 For anthrax, the planning notions are to
23 be able to treat or prophylax a population of 10
24 million; for pneumonic plague, the scenario calls for 1
25 million; for tularemia, it's the same. We've still

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1 been working on the issue of BOT-TOX, and that's a
2 priority for probably next fiscal year. And, of course,
3 with the potential chemical agents, the numbers that
4 we've been looking at are considerably smaller than
5 that with about 10,000 for a nerve agent such as sarin
6 and for the respiratory irritants. Next slide.

7 (Slide.)

8 Our pharmaceutical stockpile is basically
9 composed of two parts, one of them is what we call the
10 12-hour Push Packages, and these Push Packages are
11 basically a set group of antibiotics, other types of
12 pharmacologic agents, as well as all the logistical
13 material needed to actually deliver and to also treat
14 seriously ill individuals, and so it includes things
15 like ventilators and IV solution and bandages and all
16 kinds of things like that. And what you see in the
17 handout that I've provided is the current list of what
18 is contained in the 12-hour Push Packages. These are
19 meant for an unofficial response to an incident when
20 you may or may not necessarily be certain of what the
21 agent is that's producing illness, all you know is that
22 there are a lot of sick people. We know from some of
23 the presentations that Col. Christopher made that the
24 number of antibiotics that one would have to be
25 concerned about is rather limited, and so these can be

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1 put together as a package and the entire package
2 basically delivered to the site of a biological
3 incident. And then as you refine over time and
4 determine what the causative agent is, you can then
5 refine what additional procurement is necessary
6 specifically geared towards that agent.

7 And so we currently have a total of four
8 of these 12-hour Push Packages. They are all currently
9 in one location, which is in the VA system, but they
10 over the coming months will be deployed in four
11 different areas around the United States so that they
12 would be in a position to be able to reach anywhere in
13 the country within a period of 12 hours.

14 What we would then follow on with -- and
15 similar to the thinking in the Department of Defense --
16 what's called the vendor-managed inventory, which is
17 that you actually don't buy the materials themselves,
18 what you buy is you buy a placeholder so that what the
19 vendors or the manufacturers themselves do is that they
20 keep an extra bubble of inventory for gentamicin or for
21 ciprofloxacin or for whatever, and then if you
22 specifically need additional ciprofloxacin, they
23 guarantee to you that that additional bubble of
24 material would be available, and they would then make
25 it available to you. Of course, they charge to

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1 maintain this extra bubble, and so again you try to
2 limit the number of potential agents that you would
3 have in the vendor-managed inventory to the minimum
4 necessary.

5 This is meant to be onsite within 24 to 36
6 hours, and so the 12-hour Push Packages are meant to be
7 the initial materials that are needed and then you
8 follow up with the more nuanced vendor-managed
9 inventory packages. The advantage to this, of course,
10 is that the stuff doesn't expire and the vendors
11 constantly rotate the materials, and over time it's
12 significantly cheaper to be able to work through a
13 vendor-managed inventory than it is to actually procure
14 them and have them onsite. Realize one of the major
15 distinctions between CDC is that we don't, as a rule,
16 treat people on a day-in and day-out basis like the
17 Department of Defense does and like the Veterans
18 Administration does, and so we don't have a readily
19 made mechanism to be able to constantly rotate these
20 antibiotics as they get near their expiration dates.

21 Next, next slide.

22 (Slide.)

23 So this is the content of the National
24 Pharmaceutical Stockpile -- ciprofloxacin, doxycycline,
25 gentamicin, erythromycin -- and in addition you see the

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1 materials for chemical exposures -- various IV
2 supplies, airway supplies, other emergency medications,
3 bandages and dressings, and the available smallpox
4 vaccine that we've maintained over the years and this
5 constantly gets re-examined and the expiration dates
6 get pushed back further is now officially a part of the
7 National Pharmaceutical Stockpile.

8 In response to the comments that were made
9 about the previous presentation -- and as you can tell
10 from some of the materials that I've distributed --
11 cost is a significant consideration for us. And so
12 what we have done in the case of the potential anthrax
13 exposure -- and this has its own set of potential
14 complications -- is that initially we would provide for
15 prophylactic use ciprofloxacin, and then once the
16 information is available about the susceptibility
17 patterns we would then switch over to doxycycline for
18 the duration of the course, if the organism was
19 susceptible to doxycycline, precisely because of the
20 issue that was raised, which is that the doxycycline is
21 so much cheaper.

22 I think one of the considerations that
23 wasn't brought up, which I think is a very serious
24 consideration, is that I personally have told them
25 repetitively that if I was the people developing the

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1 stockpile, I would also provide compazine because one
2 of the things that we know is that a significant number
3 of individuals that take either doxycycline or
4 tetracycline will have gastrointestinal upset, which is
5 far lower if you use ciprofloxacin. And so I think
6 that the side effect profile is actually a significant
7 consideration.

8 The other problem that I've seen
9 repetitively -- and I think in terms of some of the
10 decisionmaking that's been made in DoD is -- I
11 personally have difficulty in a civilian setting,
12 thinking about using one antibiotic and then trying to
13 switch over on a large-scale basis because we may be
14 talking about treating tens of thousands of
15 individuals, trying to switch them over simultaneously
16 to a different antibiotic after a period of four to
17 five days, and when you think about many of the
18 logistical issues surrounding doing that it can be very
19 formidable to make those decisions. And so I've
20 actually been -- I mean, if we could throw cost
21 considerations out the door, I would have been one that
22 would also have made the same recommendations that DoD
23 has made, which is to use ciprofloxacin for the entire
24 duration because I think the side-effect profile as
25 well as the potential broad spectrum of coverage is

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1 certainly supportive of potentially using that, but we
2 didn't necessarily have that luxury and so our
3 decisionmaking has been based on initial use of
4 ciprofloxacin and then switching over to doxycycline,
5 but I certainly empathize that one could come to
6 somewhat different conclusions. Next slide.

7 Well, I don't quite know what happened.
8 Next slide. No, there you go.

9 (Slide.)

10 So the way that we would deploy the
11 stockpile would be that there is an incident and the
12 local and State public health agencies respond to that
13 incident and identify that the local medical facilities
14 are being overwhelmed in terms of the availability of
15 the local antibiotic supply. They could then make a
16 request for deployment of the stockpile. This could be
17 made independent of the actual implementation of the
18 Federal Response Plan around bioterrorism, and this
19 request could come either to the FBI, it could come to
20 FEMA, or it could come directly to CDC. And if you can
21 continue. Keep going. This is on my nuances of Power
22 Point.

23 (Slide.)

24 And then these would be deployed through
25 the direction of CDC in consultation with the Surgeon

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1 General. And the stockpile is meant to move with
2 personnel, such as pharmacists and logisticians, et
3 cetera, that would actually be able to assist with many
4 of the issues that will come up at the other end where
5 these materials are meant to deploy. Next slide.

6 (Slide.)

7 And this is just to describe the array of
8 individuals that would actually move with the stockpile
9 so that it could be used most efficiently at the other
10 end. Next slide. I think yes -- That may be it.

11 One of the things that I wanted to briefly
12 comment upon was the issue that has been raised
13 repetitively, and that is the issue of off-label use.
14 This is a very problematic issue, one that we've been
15 dealing with for about a year and a half with the Food
16 and Drug Administration. We at CDC have actually been
17 dealing with them on two closely related issues. One
18 of them is that the rapid diagnostic assays, which
19 we've been making available through the network of
20 State Public Health Laboratories, are also not licensed
21 assays, and so you have many of the same issues that
22 come up concerning the forward use of these rapid
23 diagnostic assays that you do with the off-label use of
24 a variety of these antibiotics.

25 For us, being that FDA is a sister agency,

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1 we've been engaged in a dialogue with FDA for, as I
2 mentioned, about the last year, year and a half, or so,
3 to try to figure out how we could best resolve this
4 issue. In some of our discussions, you know, we
5 clearly agree with them that if you have a material
6 such as a vaccine or antitoxin that's not a licensed
7 product and it's certainly entirely appropriate to do
8 that through an IND mechanism and to have appropriate
9 informed consent, the difficulty that we have is that
10 clearly many of these agents are agents that we have
11 been in common use for extended periods of time --
12 doxycycline, gentamicin, ciprofloxacin -- there's a
13 vast experience with these agents, and using them in a
14 setting like this can be done with a fair degree of
15 confidence.

16 And I think that even the FDA realizes
17 that some of the logistical issues that would surround
18 doing these activities through an IND mechanism with
19 informed consent in a setting where basically you have
20 to get these materials into people's mouths within a
21 matter of hours, can be quite problematic. And so we
22 actually have had discussions with them as recently as
23 the last two to three months, along with Bill Route
24 (phonetic), who is the Science Advisor and the
25 Assistant Secretary for Planning and Evaluation in HHS,

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1 whereby they would agree to a very simplified consent
2 procedure, which is basically that all we would need to
3 do is, as we would identify people who would be
4 receiving these materials, they basically would be able
5 to sign a sign-up sheet and include both their name,
6 their address, a way of contacting them, and that would
7 be considered sufficient in terms of them giving
8 informed consent to be able to receive those materials.

9
10 And we've had these discussions orally
11 with FDA, we have yet to see anything in writing. We
12 hope that that will get through the Office of the
13 General Counsel in the Food and Drug Administration,
14 but we think that that's probably quite appropriate
15 because certainly the way that we anticipate using the
16 stockpile where we would have to get back to many of
17 these individuals within a matter of days to
18 potentially switch them over to some other antibiotic,
19 we need to get that information anyway. And what we
20 would do is in -- and I have some copies of them so you
21 can see some of the patient information that would be
22 provided -- you can just pass it around -- we would be
23 providing a great deal of information about the
24 product's side effects, et cetera. And I think from the
25 standpoint of the Food and Drug Administration, as long

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1 as we hold some sort of an official IND, this would
2 likely be satisfactory for those purposes.

3 We've always maintained that until we get
4 all the i's dotted and the t's crossed, if we had an
5 incident where we had to deploy the stockpile, that
6 even if it was for an off-label use, we would go ahead
7 and use it, and worry about the potential consequences
8 afterward.

9 So, I think that I'll stop there and open
10 it up to any questions there may be.

11 DR. LaFORCE: Questions for either Drs.
12 Ostroff or Christopher? Yes?

13 DR. TSAI: I have a question for both of
14 them. On this last point, Steve, would there be a plan
15 for adverse events, and particularly serious adverse
16 events? And then for Col. Christopher, you cited the
17 lack of information on clinical efficacy data on some
18 of the antibiotics for some of these conditions. Would
19 there be a contingency plan to collect efficacy data as
20 you use these particular antibiotics for a given
21 syndrome so that one could make a rapid assessment of
22 antibiotic resistance and perhaps switch therapies --
23 make a recommendation for switching therapies? Sort of
24 related questions having to do with --

25 DR. OSTROFF: Let me just answer that

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1 first. I mean, this is the point that the FDA has
2 raised with us, is that you really would want to do
3 things through some sort of an IND mechanism because
4 then you have the potential to collect information that
5 might be helpful over the long-term, not necessarily
6 about the efficacy of your prophylactic measures, but
7 at least information about side effects, tolerance, et
8 cetera, which might eventually lead to potential on-
9 label use. So, in other words, it's actually licensed
10 for that particular use. And I think that that
11 theoretically sounds quite good, but I think in the
12 settings in which these materials are going to be
13 deployed, the likelihood that we would have the
14 personnel available to be able to meticulously collect
15 that type of information and collect it in a way that
16 the Food and Drug Administration would find acceptable
17 is probably going to be fairly low down the priority
18 list in terms of other things that need to be done in
19 the emerging setting.

20 And in addition to that, we can't, of
21 course, petition for labeling changes, only the actual
22 manufacturer can petition for labeling changes, and
23 we've not heard -- and maybe DoD has heard differently
24 -- but we have not heard that there is a great deal of
25 interest in actually submitting proposals to change the

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1 labeling to include some of these indications.

2 DR. LaFORCE: I would point out that if --
3 I hope these never -- these reservoirs, or these
4 stocks, never get used for the purposes for which they
5 are intended, but if they were, I must admit, I
6 consider an R&D mechanism, signing things, with all the
7 chaos that's going to be going around, with all of
8 that, to be absolutely ridiculous to think that that's
9 going to be, number one, respected and, number two,
10 makes common sense. It just really stretches the
11 regulatory issues to a level that is -- that I find a
12 bit --bewildering --

13 DR. OSTROFF: Well, actually, I think we,
14 in general, being very practical in terms of especially
15 situations like this, are in agreement with you. We,
16 quite frankly, have been very surprised about the issue
17 of the rapid diagnostics. And the thought of getting
18 informed consent from someone who may be in an
19 intensive care unit on a ventilator with undiagnosed
20 illness, quite frankly, has sort of boggled the mind.

21 COL. EITZEN: Yes. Col. Ed Eitzen. From
22 a military perspective, I think, though, that we're in
23 a little bit different situation based somewhat on our
24 experience from the Gulf War, the use of IND drugs in
25 the Gulf War. And we have quite a problem here because

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1 -- I believe I'm correct in saying that there was
2 actually an Executive Order published last fall by the
3 President which says that, in fact, you have to get
4 presidential approval for using the IND -- or maybe --
5 and some people have interpreted this as off-label,
6 also, drugs in a wartime environment in servicemen.
7 So, it's a significant problem.

8 COL. EITZEN: What I was going to say,
9 just to finish the comment, is that I do think that one
10 of the things that we found is that FDA, I think, is
11 aware of this problem, which is why I think it's good
12 that we've been able to find some sort of a middle
13 ground that apparently would be acceptable from our
14 point of view in terms of things that we would need to
15 be doing anyway, and I think would be acceptable from
16 their point of view that we've met their regulatory
17 requirements. I mean, in general, we would need to
18 have people at least put down their name and how to
19 contact them in a situation where we're actually
20 handing out material. So I don't view that as being
21 such a huge potential obstacle as I would actually
22 having them sit there with an informed consent form and
23 having to read through the entire thing and make sure
24 that it's signed and have somebody available to answer
25 any potential questions they may have, et cetera.

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1 And, similarly, with the rapid diagnostic
2 assays, what we've been able to do is to reach a middle
3 ground whereby they would only make those requirements
4 in individuals who weren't ill in which you are
5 collecting specimens to see if potentially they've been
6 exposed to anthrax or whatever it happened to be, but
7 in a situation where you have somebody that's ill, they
8 would waive those requirements, and they have the
9 capacity through the Secretary to be able to do that.

10 DR. LaFORCE: Again, the only point is --
11 not to be argumentative -- but the civilian sector and
12 the military sector are really quite different, and the
13 President, as Commander-in-Chief, can in a nanosecond,
14 all of a sudden decree something and that's the green
15 light, et cetera, whereas in the civilian sector it is
16 pretty messy.

17 DR. OSTROFF: Let me just say I think that
18 right now this is not going to be an insurmountable
19 issue.

20 DR. MUSIC: Even in a military situation -
21 - this is Stan Music -- there is chaos. And when we
22 went back and did the pyridostigmine bromide, there
23 were troops who took that stuff the way they were
24 supposed to -- probably very few. There were some who
25 took much too much. There were some who took none at

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1 all. And there were some who went back and forth, day
2 to day, depending on how scared they were. And then
3 you try to reconstruct this after-the-fact -- forget
4 it. It's not going to happen.

5 DR. BERG: (Inaudible) Regarding the issue
6 of informed consent, one of the concepts of an informed
7 consent is that it is really voluntary, and I don't see
8 how you're going to get around the issue of somebody
9 saying, "What? You're not going to give me this pill
10 after I've been exposed to plague unless I sign this
11 consent?"

12 DR. OSTROFF: Well, I think that my take
13 on that would be that everybody is going to want it.
14 And so if that's the only way they can get it, they
15 probably would sign it. And I think it will be a
16 little different situation than the theoretical with
17 anthrax vaccine or something like that. I think if
18 people really think they are exposed and at risk,
19 they're going to want these products.

20 DR. BERG: You said that nobody was
21 interested or thinking about studying the efficacy of
22 this. I would hope some thought would be given to that
23 both in the military and on the civilian side because,
24 otherwise, we're going to be in the same situation we
25 were after the Persian Gulf. People are going to say,

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1 I was in perfect health until I took ciprofloxacin for
2 this bioterrorist incident, and I've had heart failure
3 and all sorts of other problems since then, and one of
4 the criticisms that has come up after the Persian Gulf
5 is there was no decent data on which to draw any
6 conclusions.

7 DR. OSTROFF: Let me just say I don't
8 think that I said that no one was interested, I think
9 that I said that probably in the setting in which we
10 would be distributing these materials, it's not our
11 highest priority.

12 DR. BERG: You'd have to bring in a
13 special teams to concentrate just on that.

14 DR. OSTROFF: Right. I mean, it would --
15 the circumstances under which any of these materials
16 would be deployed would be so extraordinary, and the
17 amount of panic, the amount of concern -- I mean, you
18 know, just thinking through many -- I mean, we've tried
19 to think through -- and that's why I think the TOP-OFF
20 was so helpful to us -- tried to think through some of
21 the issues when we might make a recommendation that
22 this is how we think that the stockpile ought to be
23 used, and this is who we think ought to be receiving
24 the medications. At the local level there may be
25 completely different concerns or considerations and, in

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1 particular, there may be political pressures to give it
2 to people who we don't necessarily think ought to be
3 getting it, and how you reconcile some of these
4 problems, or we may say we're only going to give three
5 days of ciprofloxacin and then switch over to
6 doxycycline, and somebody else may say, no, we don't
7 want to do it that way. And these are circumstances
8 where many of these issues have to be resolved over a
9 period of a couple of hours. It's not like you have
10 days to discuss many of these potential differences of
11 opinion. That's why I say, you know, thinking about
12 trying to collect meticulous information in a setting
13 like that I think would be really quite challenging.

14 DR. LaFORCE: Ron.

15 DR. WALDMAN: I don't really know how to
16 ask the question really well, Stephen. I'm not asking
17 for a very in-depth answer, the people who are
18 interested can get it somewhere else, but I'm just
19 curious about sort of the layering of the thinking
20 that's occurred. I mean, this can't just be a one --
21 there needs to be a lot of contingencies and a lot of
22 conditioning to plans like this because something
23 always goes wrong, I guess. You know, you talked about
24 the bubble. I assume there's plans to verify the
25 manufacturers actually are up-to-snuff with it, you

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1 know, and that they're not cutting corners here and
2 there. I'm sure that there's thinking that goes beyond
3 just calling FedEx on the phone. Could you paint that
4 in a little bit just for a minute or two?

5 DR. OSTROFF: Right. A couple of things
6 that I'll say about that is that, one, we require --
7 and part of this is in response to many of the
8 deficiencies the GAO identified with the maintenance of
9 some of the other stockpiles -- is that we will have
10 total access to the inventory management systems, the
11 computerizing of inventory management systems, so that
12 we can verify anytime that we want to basically that
13 the materials are actually there and that the bubble
14 actually exists.

15 In addition to that, we will make
16 unannounced inspections and we will also exercise the
17 stockpile a minimum of three times per year to assure
18 that what's supposed to be there is actually there.
19 So, you know, we have thought through many of those
20 issues, and if there's one thing that the GAO was very
21 helpful for in this particular report, it was to focus
22 us on where the potential vulnerabilities and problems
23 are. There are all kinds of issues related to security
24 and making sure that the bubble is the bubble that you
25 contracted for, and so there will be particular

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1 inventory numbers which will be our -- I mean, we
2 thought through many of those issues, without going
3 into too much detail.

4 DR. LaFORCE: Pierce?

5 DR. GARDNER: I have a question for each
6 of our last two speakers. To LtCol. Christopher, first
7 of all, it's a wonderful document you've created here,
8 and I appreciate it very much.

9 I was looking at the quinolone data with
10 regard to Q fever, glanders and Brucella, and I don't
11 think that you cover those in the February 29th. Is
12 there additional data that makes you feel more
13 comfortable in using quinolones for those three
14 situations, but I don't think they are covered in your
15 February document.

16 LtCOL. CHRISTOPHER: (Inaudible.) Those
17 were not included. (Inaudible.)

18 DR. GARDNER: But you're comfortable with
19 them?

20 LtCOL. CHRISTOPHER: Actually, those
21 recommendations for quinolones for the additional
22 agents were not included in the Field Manual. They are
23 basically based on the very limited in vitro data --
24 for example, coxiella burnetii, to my knowledge,
25 there's no good clinical experience for those. I would

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1 feel less comfortable with those.

2 DR. GARDNER: It seems to me a lot of the
3 time you're not going to know what the aerosolized
4 agent was immediately. You may have to make some
5 decisions beforehand.

6 LtCOL. CHRISTOPHER: Correct.

7 DR. GARDNER: And each of these --
8 doxycycline gets somewhere in the hit parade, cipro
9 shows up higher on the hit parade for anthrax, but in
10 the others it's sort of lost. And I guess I still
11 coming back, are we grabbing onto the newer agent and
12 forgetting our tried-and-true old friends?

13 LtCOL. CHRISTOPHER: I would not recommend
14 these newer ciprofloxacin for the other indications --
15 Brucella --

16 DR. GARDNER: So if you didn't know what
17 the aerosolized -- if you just knew people were
18 wheezing and coughing but you haven't made a diagnosis
19 yet, what would you use?

20 LtCOL. CHRISTOPHER: Either doxycycline or
21 cipro.

22 DR. GARDNER: Well, I know that.

23 (Laughter.)

24 LtCOL. CHRISTOPHER: Whichever one we have
25 available to us in the stockpile.

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1 DR. GARDNER: I'll let you get away with
2 that.

3 LtCOL. GARDNER: We need more in vivo
4 data, more animal data, clearly. That's why the in vivo
5 studies are clearly important. In fact, a series of in
6 vivo experiments will be started here at USAMRIID this
7 August, testing some of these newer antibiotics against
8 these specific agents, using animal models.

9 DR. OSTROFF: And as far as the civilian -
10 - I mean, you notice in the Push Packages that both of
11 them are included. It's my guess that probably both of
12 them are going to get distributed.

13 DR. GARDNER: My sympathies to Dr. Ostroff
14 because you're going to have lots of kids and pregnant
15 women and other people there who are not going to be
16 candidates for either of your major drugs.

17 DR. OSTROFF: Right.

18 DR. GARDNER: Ergo, you've got to consider
19 some other things in your package, I think, and I was
20 wondering --

21 DR. OSTROFF: We have grappled with that
22 issue about defining potentially in some of those
23 populations having criteria that are somewhat more
24 stringent in terms of assuring that people were in the
25 risk group that was exposed. Part of the problem is

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1 that you know you may not necessarily have that type of
2 information right off the bat.

3 DR. GARDNER: Again, going back to some of
4 LtCol. Christopher's data, and a little drug in that
5 situation, chloranphenocol, looks actually pretty good.

6 It's considered certainly safe for children, and
7 except at term women, it's safe in pregnancy, and
8 except for the 1:100,000 enterological problems, which
9 might not look too bad in the face of an aerosolized
10 anthrax or plague, probably deserves some
11 consideration.

12 LtCOL. CHRISTOPHER: Well, you know,
13 everything has its pluses and minuses. You know,
14 availability as far as chloranphenocol is certainly an
15 issue.

16 DR. LaFORCE: Yes, you can't find it. You
17 can't buy it.

18 DR. GARDNER: If you decided to stockpile
19 a lot of it, you probably could get somebody to rev it
20 up again.

21 DR. LaFORCE: I want to close this a
22 little -- we're just about back on time, but I want to
23 close it by reading the charge to the Committee, the
24 charge posed, or the question posed, by Adm. Clinton.

25 I read, in light of the need for the

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1 Department of Defense to maintain a high level of
2 readiness and to maintain adequate stockpiles of
3 specific antibiotics, I request that the Armed Forces
4 Epidemiological Board conduct a review of antibiotics
5 approved by the Food and Drug Administration that may
6 prove useful against certain infectious biologic
7 warfare agents. This review should involve appropriate
8 consultation with the Centers for Disease Control and
9 Prevention staff, as they will have very similar
10 concerns regarding what is needed for the domestically
11 oriented National Pharmaceutical Stockpile for Medical
12 Response to Terrorism. I ask the AFEB to provide
13 recommendations to this office on the most appropriate
14 antibiotics that would be indicated for the treatment
15 of primary bacterial and rickettsial agents on the Bio
16 Warfare Threat List. Of greatest concerns are the
17 infectious agents causing anthrax, plague, tularemia,
18 brucellosis, glanders and Q fever. The recommendation
19 should describe any precautions and contraindications
20 associated with the administration of these
21 antibiotics.

22 I think that's the task to wrestle with,
23 and I think Pierce has brought out very important --
24 there are exceptions with certain antimicrobials in
25 terms of individuals that can't be used.

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1 COL. DINIEGA: Just to add on No. 1 is we
2 have in forward deployed areas, we do have family
3 members, so the age does become an issue for DoD. No.
4 2 is, Dr. Lisa Ross from the CDC, is willing to work
5 with the subcommittee on this issue. Steve stepped in
6 because Dr. Ross couldn't be here today, but he's also
7 very capable and has been handling a lot of the issues.

8 And LtCol. George Christopher, the good person that he
9 is, will be PCSing the end of July, but is willing to
10 work with the subcommittee on this issue until he
11 leaves.

12 DR. OSTROFF: Maybe we won't let him go.
13 And let me just make one quick comment, is that you
14 will notice in some of the things that I distributed,
15 it's stamped "Draft", so please don't share them
16 outside of this room.

17 DR. LaFORCE: Admiral.

18 RADM. CLINTON: I think for the purpose of
19 this, it might be useful to explicitly exclude
20 antivirals. It isn't entirely clear that the word
21 "microbials" is used, but we're not wanting to suggest
22 that this is enough to do, we will deal with the
23 antivirals at some other time.

24 DR. LaFORCE: Super okay. Thank you very
25 much. This is really a great set of presentations.

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1 Let's go ahead with the review of the Squalene
2 manuscript and the question that has been distributed
3 that has to do with objective analysis of article
4 entitled Antibodies to Squalene in Gulf War Syndrome.
5 Stan Music, please.

6 DR. MUSIC: Unless you have serious
7 objections, I think I can be heard from here, and I've
8 got some things I'd like to --

9 DR. LaFORCE: Your call, Stan.

10 DR. MUSIC: Okay, great. I worked on this
11 issue with Elizabeth Barrett-Connor and Phil Landrigan,
12 and I learned a lot about this paper and about this
13 issue.

14 One of the first things that I learned is
15 that the article was originally submitted to a rather
16 prestigious medical journal, and that the reviewers had
17 had a fair number of questions and criticisms and
18 comments about it, and these had been communicated back
19 to the authors. What happened is that the authors
20 published the article, unchanged, in another journal
21 and, therefore, tit-for-tat, the paper was rejected and
22 they rejected the rejection.

23 There was also something that I learned
24 existed an article in Vanity Fair titled The Pentagon's
25 Toxic Secret, the subheadlines stating "Veterans Suffer

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1 From Debilitating Gulf War Related Illnesses, But The
2 Origins Have Remained A Mystery. A crusading molecular
3 biologist and internal military documents now suggest a
4 shocking scenario. Pentagon's possible use on its own
5 soldiers of an illicit and secret anthrax vaccine".

6 I also became aware of a GAO report to
7 Congressman Jack Metcalf and a clear record that there
8 was no squalene containing vaccines that were given to
9 military personnel in or around the Gulf War. And
10 there has also been a fair amount of what I would call
11 much heat and little light, with a fair amount of
12 discussion that I referred to in my own head as The
13 Squalene Squabbles, and that is probably one of the few
14 amusing things about this whole issue. It is also
15 amusing that the author's name, Asa, is, in fact, a
16 mnemonic for the Anti-Squalene Antibody or the Anti-
17 Squalene Assay, the ASA test that we're supposed to do
18 or think about here.

19 DR. OSTROFF: I mean, there is no Pamela
20 Asa?

21 DR. MUSIC: There is, but her name itself
22 is also a mnemonic for the ASA. It's very interesting.

23 Anyway, the committee has been given the charge -- and
24 everybody else in the room -- but only the Board itself
25 has been given a very rough draft of what Elizabeth and

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1 Phil and I wrote as a review of the paper.

2 We talked about dose response, and we said
3 that none is apparent. In the figures of the Asa, et.
4 al., paper, there is no obvious dose response in
5 relation to the amount of antigen (squalene) deposited
6 on the nitrocellulose membrane. And dose-response
7 should be seen with respect to antigen and antibody
8 concentration, neither is shown.

9 With regard to the subject of controls:
10 Despite assertions and disclaimers in the paper, there
11 are no valid controls. For a valid positive control,
12 one needs serum previously proven to contain antibodies
13 to squalene, only this can validate that the assay can
14 detect antibodies to squalene. What the authors use as
15 and assert is a positive control are two sera from
16 individuals reportedly vaccinated (either once or three
17 times) with an NIH trial vaccine containing squalene.
18 The authors provide no pre-vaccination data to
19 demonstrate that the activity detected in their assay
20 was not present before vaccination with a squalene
21 adjuvant.

22 Negative controls are essential to prove
23 that the assay is not detecting something other than
24 anti-squalene antibodies. Missing are controls which
25 omit serum containing the presumed antibodies or which

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1 omit the avidin-conjugated horse radish peroxidase.
2 Also missing is a negative specificity control to rule
3 out non-specific binding of normal IgG molecules to
4 squalene.

5 With regard to blinding: It is unclear if
6 the immune researchers were blind as to
7 illness/wellness status. The paper does assert at
8 several points that this is a blinded study, but it
9 remains possible that the critical element of knowing
10 the illness/wellness status or category may have been
11 known even if "...the identities or exact number of
12 samples from each category was not made available...",
13 as the paper itself states.

14 With regard to specificity: The question
15 is, does the ASA Assay specifically measure antibodies
16 to squalene? In this type of blotting experiment, one
17 normally demonstrates specificity of the reaction by
18 blocking (or absorbing) the antibody with the antigen
19 (in solution). This is not demonstrated. Hence, it is
20 not possible to know what the ASA Assay detects. It is
21 a Western-blot type assay, and is either positive or
22 negative. Since the paper describes it being used in
23 only one dilution of patient serum (1:400), it seems
24 the assay can determine only whether "something" was
25 detectable or not, and this "something", whatever it is

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1 that it is detecting, is not presently definable.

2 Antibodies to squalene, or to any other
3 substance for that matter, should be detectable across
4 a range of concentrations, so antibody assays are
5 normally constructed otherwise, the most common form
6 today being an enzyme-linked immunoassay (ELISA). The
7 actual level or concentration of antibody, ranging from
8 undetectable to just detectable through high
9 concentration, should also have medical/biological
10 correlations and implications, with some threshold
11 point that correlates with the development of symptoms
12 or disease.

13 Nitrocellulose is a highly reactive
14 substance that binds lots of things. The paper does
15 not show that the squalene deposited on the membrane is
16 actually still there at the end of the assay. For
17 example, one could imagine that squalene could block
18 the nitrocellulose membrane long enough to protect the
19 dot from the milk treatment and then be washed out, as
20 polyoxyethylene sorbitan laurate is a detergent that
21 could remove a lipid like squalene. This could leave a
22 naked spot of nitrocellulose to react with some other
23 protein.

24 If this were a valid assay it should work
25 with another substrate (other nylon membranes, like

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1 Immobilon).

2 Given the relationship between squalene and
3 cholesterol, do these sera react with cholesterol? The
4 authors raise the question but don't answer it.

5 Can one actually raise antibodies,
6 deliberately, to squalene? It is a common component of
7 cells and should be present in amounts that would swamp
8 out any squalene-specific antibodies.

9 Well, as you can see from what I've said,
10 I'm not a real fan of this paper, and the committee
11 felt similarly. And we confined ourselves to the big
12 things. When you first read the paper, you are
13 impressed with the numbers, and the results, when
14 displayed in a graph, are pretty dramatic -- it's
15 basically either all or none. I've never seen a test
16 that does everything all or none. The deployed sick,
17 the vaccinated illness onset a few weeks later to years
18 after the war, 95 percent were ASA-reacted, and that's
19 the only deviation from either zero or 100 percent.
20 Zero percent of the deployed well, none out of 12
21 reacted, but 100 percent of the not-deployed sick, 8
22 out of 8 reacted, 100 percent of the UK deployed but the
23 vaccination status was not discussed, that's 3 out of 3
24 reacted. None of the 34 breast plants, both of the so-
25 called positive controls, none of the 70 autoimmune

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1 disease, and none of the 48 general public reacted.

2 Well, we felt very strongly that we should
3 go beyond our mandate, which is to provide a critical
4 review of the paper, and we moved on to try and cut
5 through all of the Squalene Squabbles about what this
6 test measures and what it doesn't measure and whether
7 it's done right or not in this patent-pending antibody
8 assay, and decided that there really was only one
9 question that was critically important: Does the ASA
10 Assay test clearly, reliably, and unequivocally
11 distinguish people who are ill with Gulf War Syndrome
12 from people who are not ill with Gulf War Syndrome?

13 It seems clear that a definitive study
14 could be useful in answering this question. Let us be
15 clear that we are not discussing a study to validate
16 whether the ASA Assay can detect antibodies to
17 squalene. Rather, we are trying to leap over this
18 intermediate obstacle and get quickly to the bottom
19 line -- does the ASA Assay distinguish people with GWS
20 from all others, and, if so, with what specificity and
21 sensitivity? Many caveats and qualifiers would have to
22 be in place to assure meaningfulness, and the following
23 bulleted list can (and probably should) be usefully
24 expanded and further refined to help assure that any
25 ensuing study would be definitive. However, the main

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1 points of a definitive study would include the
2 following:

3 Establishing a clear a priori selection
4 and exclusion criteria for cases and for controls;
5 selection of participants, cases and control subjects,
6 by an independent ad hoc body or committee, chaired by
7 a tenured academic from a well known medical research
8 institution, such as but not to be restricted to,
9 Harvard or the Mayo Clinic; serological testing done in
10 a secure and absolutely blind manner with strict chain
11 of custody rules and documentation; and a sufficient
12 number of subjects to have statistical power for
13 specificity and sensitivity at the 95 percent
14 confidence level or greater; and a study design with at
15 least two arms -- testing done as in the paper by the
16 people who have licensed this patent-pending technique
17 versus testing done by one or more lipid laboratories
18 using standard antibody techniques such as enzyme-
19 linked immunoassay to detect anti-lipid antigens, such
20 as Carl Alving's laboratory. And Col. Alving is in the
21 audience today.

22 There are problems with the paper, and
23 it's amusing, the more you get into this, the more
24 niggling you can get. Look at Table 3, and look at the
25 column labeled Deployed Sick, the first column, D-S,

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1 and it says percent who have the symptoms. Well, go
2 down to photosensitive rashes, which is the fifth one
3 down. Now, how do you get 25 percent of 38 people? I
4 don't know how you do that. Fifty percent I can
5 handle, that's 19, but 25 percent? It's either 9 or 10
6 --

7 DR. BARRETT-CONNOR: They rounded up.

8 DR. MUSIC: Well, they didn't round up
9 because 9 is 23.7 which rounded is 24, or 10 is 25.8
10 which rounded is 26.

11 COL. DINIEGA: They could have excluded
12 people who said "don't know".

13 DR. MUSIC: The point is that there are
14 lots and lots and lots of problems in the paper, and
15 every time I re-read it I find something else. But we
16 tried to take the high ground, tried to offer the
17 critique that was asked for, and tried to get around
18 the impasse that -- and the heat -- that has surrounded
19 this to take us to the other side with the study
20 recommendations which the group may or may not accept,
21 that would tell us definitively whether this test is
22 worth the squeeze. That's all I really wanted to say,
23 and I'm happy to take any questions.

24 DR. LaFORCE: Elizabeth?

25 DR. BARRETT-CONNOR: Well, it's a really

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1 nice review. I'm not sure that it's clear to everybody
2 that these are the only people who had the test, so
3 it's another Catch-22 is that you're either going to
4 have to get them to sell you their test, in which case
5 they will argue that you didn't use it right if you
6 don't find what they found, or get them to do it
7 themselves with completely blinded samples that they
8 don't know the identity, the Gulf Warness or
9 Deploymentness of the samples, but I certainly think
10 you did a very good job of criticizing the main points.

11 (Inaudible.) The only thing I would change in the
12 written document is I wouldn't mention potential
13 investigators or universities by name. I think that's
14 appropriate and we shouldn't niggle over which would be
15 the best people or place but, otherwise, I agree with
16 it all.

17 DR. LaFORCE: I had a question when I went
18 over this. What happens, Stan or Elizabeth, if you
19 take squalene -- you have a rabbit and you simply
20 inject squalene with either Freund's adjuvant, complete
21 or incomplete, or squalene? Can you raise an IgM/IgG
22 response to squalene, and can you measure it?

23 DR. MUSIC: I'd like to ask Col. Alving to
24 definitively answer that question.

25 COL. ALVING: We've done it. Injection of

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1 squalene does not induce antibodies to squalene.

2 DR. LaFORCE: Because it is not antigenic?

3 COL. ALVING: That's correct, just by
4 itself. Just injecting squalene oil into a mouse will
5 not induce antibodies to squalene under conditions
6 where -- I should point out that my laboratory has
7 developed an alternative enzyme-linked immunoabsorbent
8 assay for squalene using -- and we have actually
9 succeeded in creating monoclonal antibodies to squalene
10 as positive controls. So we have an assay where we
11 believe we can actually detect antibodies to squalene,
12 and we have found methods for immunizing animals so
13 that we can induce antibodies to squalene. We looked
14 at eight different methods for immunization, one of
15 which was injection of squalene, and it does nothing at
16 all -- flat zero.

17 DR. LaFORCE: Because it's normally
18 present in sera. That means that you must either
19 change an epitope on the squalene itself that's
20 recognized by a T-cell, or what changes? What do you
21 have to alter on the squalene?

22 COL. ALVING: We put potent adjuvants in
23 together with the squalene. Lipid-A, for example --
24 but Lipid-A plus squalene also did not do anything. So
25 what we did was we used liposomes containing Lipid-A

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1 with squalene, and you have to have a huge amount of
2 squalene, and there you can get antibodies that will
3 react with squalene. There are, to a much lesser
4 extent, certain kinds of emulsions if you put Lipid-A
5 as an adjuvant in the emulsions where you can get
6 antibodies to squalene. But most emulsions themselves
7 also will not induce antibodies to squalene. It's not
8 easy. It's not very immunogenic.

9 DR. LaFORCE: Steve?

10 DR. OSTROFF: Does anyone know anything
11 about this supposed NIH trial that used squalene when
12 these two individuals came from, and whether or not
13 there actually was such a trial, and did these people
14 have some side effects?

15 COL. ALVING: I could definitely answer
16 that. The trial was using the so-called MF59 adjuvant
17 that's manufactured by Otyron (phonetic), and I believe
18 it was in the herpes simplex Phase 3 trial that they
19 were looking at where they were using the squalene-
20 containing adjuvant, and there was -- out of some many,
21 many thousands of people, there were a couple of people
22 who had illnesses and they selected those two people.
23 Actually I believe there were two people, maybe one
24 person, who had a problem. But that adjuvant now has
25 been approved -- that contains MF59 that has squalene

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1 in it has been approved and licensed in Europe with an
2 influenza vaccine called Fluad (phonetic). In the
3 current influenza season, there have been 500,000 doses
4 of Fluad that have been distributed, and it's estimated
5 that about 2-300,000 of those doses have been
6 administered in Europe, particularly in Italy, I guess,
7 although it is now licensed in France, too, I
8 understand.

9 DR. OSTROFF: The second question I would
10 have is -- I don't know what the potential working
11 relationship is with these individuals, but has there
12 been an offer to provide blinded specimens to them to
13 see whether or not the results would be reproducible
14 with some other specimens?

15 DR. LaFORCE: I don't know. Anybody?

16 CAPT. TRUMP: This is Dave Trump. Not
17 that I'm aware of, not from the Health Affairs level.
18 Dr. Alving?

19 DR. ALVING: I had a conversation with Dr.
20 Garry about a year ago by telephone, and I offered to
21 come down to his laboratory and to bring a colleague
22 from my laboratory, to learn how to use the technique,
23 and they seemed very agreeable to that, to having us
24 come down and learn the technique if we wanted to do
25 that. So, from that standpoint, they seem agreeable to

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1 collaborations. Whether they would agree to a blinded
2 study or not, I don't know.

3 DR. LaFORCE: David.

4 CAPT. TRUMP: Yes, the Gulf War issues are
5 within our office at the Assistant Secretary for Health
6 Affairs come under Dr. Mazzuchi. Dr. Rick Riddle is
7 the point of contact on this request to the Board for
8 this review. He was not able to be here today and just
9 asked me to pass on his main concern, which was that
10 the request was one of four, and a review and an
11 objective analysis of the article, which he felt was in
12 the draft that Dr. Diniega provided earlier, was
13 addressed in the first part, does express some concerns
14 which I echo regarding the step to making a
15 recommendation for additional studies, especially in
16 the context of the ten years worth of work with Gulf
17 War illnesses, sort of a more structured approach to
18 requesting research to help enlighten us along the
19 issue of illnesses among Gulf War veterans which has
20 been coordinated by the Research Working Group, an
21 interagency group under the Persian Gulf Veterans
22 Coordinating Board.

23 I'm not going to say it's not helpful, but
24 it really has to be -- I think the Board needs to weigh
25 with care making a recommendation, a specific

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1 recommendation for a specific study of this test or any
2 other test, and it basically has to be in light of the
3 science that we are aware of that's been presented
4 here, whether this is something that is worth the
5 investment of DoD's time and dollars to do. And I
6 think what is in that second section is of value. What
7 I might ask is a consideration of listing what the
8 requirements would be for doing such a study like
9 you've done, and the challenges.

10 One of the very first questions is, define
11 for us what is the case definition for Gulf War
12 Syndrome. I don't think DoD, VA, or Health and Human
13 Services has a case definition yet for Gulf War
14 Syndrome. We have in various studies looked at chronic
15 multiple symptom illnesses among Gulf War veterans,
16 that is a symptom-based determination. It would really
17 have to be very carefully thought out about which
18 populations were studied as cases and controls in such
19 an effort. So that was just a concern, and one
20 possible consideration being is to answer the direct
21 charge, and then as a second report or a second -- a
22 follow-up or a second report about recommendations for
23 what could or could not be done to further look at this
24 issue.

25 DR. LaFORCE: But it would come down to,

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1 one, on the basis of the review, and looking at the
2 paper, none of us would have any confidence that this
3 is measuring anti-squalene antibodies. That's point
4 one. So I think that would address very clearly one of
5 the questions that's being posed.

6 I do think, though, that the suggestion
7 that was provided by the review group was, wait a
8 second, even if we're not even talking about anti-
9 squalene antibodies, if there's some mystery compound
10 that seems to be sorting disease versus nondisease,
11 well, for heaven's sake, let's not miss something that
12 might be there, and if there is a serum bank or a bank
13 of these particular individuals that properly coded
14 could be sent, that you could answer that particular
15 question quite easily. And if that's jumping ahead,
16 then, okay.

17 CAPT. TRUMP: I think the question is
18 quite easily -- we preclude this with issues like
19 mycoplasma and the ability of a test to detect
20 mycoplasma as being the objective marker of Gulf War
21 illnesses. It is not easy, and we still don't, after
22 several years worth of effort pursuing that effort, I'm
23 not sure we have an answer, that the test that was
24 being proposed to look at mycoplasma has gotten us
25 anywhere.

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1 So, I think the issue is one of what
2 you're proposing I don't think is easy, especially with
3 all the caveats with doing the study.

4 DR. BARRETT-CONNOR: I feel that this is
5 not a difficult thing to do. If they will either do
6 the test themselves on blinded samples, that's the
7 easiest way to say whether this test, whatever it
8 measures, is associated with the people who say they
9 are sick. And that's where we are with all the other
10 studies, and it seems to me that it would be relatively
11 cheap to put a stake through the heart of this idea, or
12 it will be true, in which case it will be extremely
13 interesting whether it's squalene or not.

14 I think that the military is in a very
15 funny position, if you find a paper which to the naive
16 reader looks as impressive as this, without the
17 headlines, just look at the graphs, and then nothing is
18 done about it because we can't decide who's got
19 disease. And it seems to me they couldn't decide
20 either. I don't see any harm in giving them a small
21 number of samples and seeing if they can replicate.
22 This isn't a huge study, to see if you can get the same
23 results twice.

24 CAPT. TRUMP: I just want to clarify that
25 we've not done nothing, there has been through requests

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1 for proposals, funding has been --

2 DR. BARRETT-CONNOR: Well, I understand
3 where you're coming from, but I guess we felt that
4 after all we are only an advisory committee, so we
5 should be able to recommend something. You are not
6 forced to do it. And we just thought that the way to
7 get around the question, not whether it's squalene
8 antibodies, not whether it was associated with an
9 experimental vaccine, but whether they are really
10 measuring something that picks up people who are sick
11 compared to people who say they are not sick. If they
12 can't replicate that, that would give, I think, people
13 a lot of pause about pursuing this in some more
14 elaborate way. So it was a recommendation. I must say
15 that I find the -- we did separate -- and this was your
16 idea -- Stan's idea was to separate the review from the
17 recommendation part so that you can ignore that second
18 half if you like, but I feel as a member of an advisory
19 committee who spent a long time reading that paper,
20 that it's appropriate to make a recommendation as a
21 member of an advisory board, and I find the
22 recommendation that we don't make a recommendation a
23 bit strange.

24 DR. LaFORCE: Adm. Clinton.

25 RADM. CLINTON: I'm also new to this

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1 subject, but I'm reminded in looking at Dr. Mazzuchi's
2 letter that this was a request which generated in part
3 because Congressman Metcalf requested this objective
4 analysis. So that means everything that's stated about
5 this is going to go back to the Hill. Now, if the
6 research could be undertaken, there are various ways to
7 develop it, (Inaudible) but certainly if we put it into
8 Congress' hands it will be explored even further, which
9 makes it far more complicated. (Inaudible.) So I must
10 admit to some reservation to putting additional
11 requirements in this other than meeting the
12 Congressman's most immediate requirement.

13 DR. OSTROFF: Well, all I can say is, that
14 as a long-term veteran chronic fatigue syndrome, I
15 mean, we've had many similar circumstances where people
16 have proposed various causes of chronic fatigue
17 syndrome, and generally when they do them, then that's
18 the way that we pursue it, which is that we try to
19 independently reproduce the findings, and if we can't,
20 we try to work with the laboratory. I realize the long
21 history of mycoplasma but, I mean quite frankly, I'm in
22 agreement with Elizabeth in that I would be somewhat
23 uncomfortable with the Board basically simply saying
24 that we really seriously question the science that went
25 behind this article without making some sort of a

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1 suggestion about how to potentially see your way
2 through getting through those issues. I mean, I think
3 as a Board member I would be a little bit uncomfortable
4 with that.

5 DR. LaFORCE: May I ask the people, does
6 anyone have any experience with this Journal,
7 Experimental and Molecular Pathology? I personally
8 didn't have any experience with it at all. Have we got
9 some basic biologists in the room?

10 DR. MUSIC: The chemists that I consulted
11 read this journal. It is not at the highest level in
12 their regard --

13 DR. LaFORCE: But it's also not --

14 DR. MUSIC: -- but it's also interesting
15 that when the authors published the paper in that
16 journal, it was as an invited paper. Yes.

17 DR. LaFORCE: What? This wasn't peer
18 reviewed?

19 DR. MUSIC: I was not -- well, I think it
20 was peer reviewed, but it was not peer reviewed perhaps
21 with the same --

22 DR. LaFORCE: I want to know, because an
23 invited paper is all together different --

24 DR. BARRETT-CONNOR: Not necessarily.

25 DR. LaFORCE: Now, those of us who have

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1 done editing in journals know that that's entirely
2 different.

3 DR. MUSIC: That's the information I was
4 told.

5 DR. WALDMAN: I wish that were the case.
6 Some of the journals to which I submit invited papers
7 and then don't get --

8 (Laughter and simultaneous discussion.)

9 DR. LaFORCE: We've got some hands here.
10 I'm sorry, Colonel?

11 COL. ALVING: Yes, I -- first of all, with
12 respect to that, I believe it's a peer reviewed paper,
13 but I believe it was also an invited paper. I've heard
14 that same thing. So they invited it and then peer
15 reviewed it.

16 I'd just like to give some aspect of this.
17 I've been working in lipid-immunology for more than 30
18 years now, and when I went into this, I went in with
19 the idea of is it possible that squalene itself, that
20 you could induce antibodies to squalene. And the
21 results of our work -- and we have sent this off for
22 peer review, incidentally to a scientific journal --
23 but we actually have created monoclonal antibodies to
24 squalene, and so that tells us that it is possible to
25 induce antibodies to squalene.

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1 I agree with all of the comments and
2 criticisms that the committee made with respect to
3 this, but I would like to add one additional thing, and
4 that is that the question arises as to whether these
5 antibodies, if they are antibodies to squalene, if
6 these things, whatever they are seeing -- whatever this
7 nonspecific stuff or specific stuff, whatever it is --
8 if this occurs in normal humans who are not sick? And
9 the answer to that is yes, it does. They simply --
10 they admit that. They simply deleted it out so that it
11 says in the paper so that they could optimize the thing
12 so that they could only look at illnesses. It does
13 occur in normals where you can see this kind of
14 reaction, and they admit that.

15 So, in my view, it is possible that they
16 just have, for whatever reason, they've inadvertently
17 or through some brilliant insight or whatever, have
18 latched onto a phenomenon that can distinguish illness
19 of a certain sort versus lack of illness. So, the --
20 it is -- it's possible that if you were to give a
21 sample of people who have "Gulf War Syndrome", who
22 have, let's say, some particular kind of autoimmune
23 diseases, that in fact it may give positive results,
24 which would pour fuel on the fire in addition to that.
25 So, the, it is, I think it is equally useful to get

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1 people who have these kinds of illnesses but who have
2 not been in the Gulf and who don't have any Gulf War
3 connections, to see whether or not this is something
4 that simply happens in the normal population and that
5 this is a marker that could be done.

6 DR. BARRETT-CONNOR: It could, in fact, be
7 a marker for stress. I just heard a really interesting
8 report by somebody -- some National Academy of Science
9 person whose name escapes me that's working with Jack
10 Rose data, looking at various types of stressors and
11 showing this huge number of changes in immunologic
12 reactivity to a lot of things, including lipids, in
13 people who self-reported themselves as being stressed
14 compared to people who didn't. So they may have found
15 something, and I think if they found something and it
16 takes ten years to show it and we didn't say at this
17 meeting that we think that it should be looked into,
18 look pretty stupid. We just look sort of like the RAND
19 paper we looked at last week -- not that bad -- but I
20 mean, I really do think that we have to make some kind
21 of a commitment about what we think they should do.

22 DR. LaFORCE: Ben is a very wise man and
23 has suggested, I think, an appropriate compromise, one
24 that I think could address the issue that is going to
25 flow back to Congress by simply proposing two responses

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1 -- one response that frankly is more the Congressional
2 response, and then a second response back to Adm.
3 Clinton that addresses the more cerebral aspect, the
4 more investigative aspect of what the AFEB wants. I
5 just sort of toss that out.

6 The second thing, though, if there is a
7 marker in terms of autoimmune disease, I think they
8 thought of that, too. And one of their tables is --
9 they were pretty careful in looking at SLE patients,
10 chronic fatigue patients, and they've got a --

11 DR. MUSIC: None out of seventy.

12 DR. LaFORCE: Yeah. They had a fair
13 number of individuals. And at the dilution that was
14 used as the cutoff point -- Lord knows what happens to
15 the data at 1-200, but at 1-400 there appears to be
16 some sort of sorting, or something that's present in
17 some sera that's not present in others.

18 The problem again that I have is, I have
19 no faith at all that this has anything to do with
20 squalene.

21 DR. MUSIC: So what?

22 DR. LaFORCE: Well, if you go back to the
23 congressional -- that letter from that Congressman in
24 that packet of stuff, I mean, he was absolutely fixated
25 on some sort of coverup against anti-squalene antibody.

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1 So I would say for sure the response that we would
2 send back from the AFEB is, number one, the AFEB has no
3 confidence that we're talking about anti-squalene
4 antibodies in this particular paper, period, for the
5 following reasons. Again, there is no gold standard
6 anywhere in this. The gold standard of these two
7 individuals who received these doses of squalene-
8 adjuvants in NIH trials done years and years before. I
9 have no way of knowing what that means.

10 COL. ALVING: I would like to point out
11 again that the Kyron Corporation has now, in their
12 Phase 3 trials prior to introducing the MF59 that
13 contains a huge amount of squalene in humans, they
14 conducted trials in 18,000 people. And in the current
15 influenza trial, they have administered more than
16 200,000 doses. The Kyron Corporation has huge amounts
17 of sera in their freezers that could be examined for
18 immunization and post-immunization, to see whether, in
19 fact, injection of squalene per se induces antibodies
20 to squalene and, number two, as to whether or not it
21 does induce antibodies to squalene, is there any
22 correlation with illness.

23 DR. MUSIC: And I think, just for the
24 record, Marc, I think it is accurate to say that we
25 don't know what this test measures. I would be

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1 uncomfortable saying that we have no confidence that
2 this measures is anti-squalene antibodies. I don't
3 know what it measures. I end up with a question mark
4 rather than a certainty of what it does or does not do.

5 DR. BARRETT-CONNOR: I don't think it
6 matters very much because the carpet rolls up tight
7 around it.

8 COL. DINIEGA: I'd like to make a couple
9 comments. One is there is no -- I don't think anybody
10 has defined Gulf War Syndrome as a syndrome. That's
11 one. Two is, I think the general question is, is there
12 a marker for Gulf War Syndrome?

13 DR. WALDMAN: There may or may not be, and
14 it may or may not be squalene, although it doesn't look
15 like it. But Marc has said, Dr. Barrett-Connor has
16 said, and we've heard from others that the one thing we
17 can say from this paper, at least on a first -- I
18 haven't read it as many times as -- I will never read
19 it as many times --

20 (Laughter.)

21 DR. BARRETT-CONNOR: Good thinking.

22 DR. WALDMAN: -- but at least on a first
23 reading, it seems to sort something from something else
24 at particular dilution. We don't know exactly on what
25 basis it's doing that, but it seems to be doing that,

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1 and I think that we, one, would be reasonably
2 comfortable in making that positive assertion, and it
3 doesn't sound like it's unreasonable -- to me, it
4 doesn't sound as if it would be unreasonable to go back
5 to these investigators in a blinded fashion with sera
6 representative of different things, some people who
7 perceive themselves as having something relatively
8 undefined that they call Gulf War Syndrome, other
9 things, other healthy people, and seeing if in more
10 formal fashion that satisfies our criteria these
11 investigators can continue to show that sorting
12 phenomenon. I think that would be a really positive
13 contribution with a very fuzzy science surrounding this
14 whole thing if they could. It wouldn't answer any
15 questions, we would still have to go beyond that and
16 find out why they are able to sort these illnesses from
17 these nonillnesses. We still wouldn't be closer to
18 knowing that. But I don't see the difficulty in posing
19 it in a more positive light on the basis of their
20 current findings that they haven't taken far enough.

21 Now, I'm not totally naive to the
22 sentiments regarding whether or not it needs to go back
23 to the Congressman and so on and so forth, but I do
24 lean somewhat in favor of presenting our findings and
25 our recommendations in a positive fashion rather than

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1 giving even a hint of a notion that we've read this
2 paper and we think it's sort of kind of all right, but
3 we don't really want to say that.

4 DR. LaFORCE: David?

5 CAPT. TRUMP: I guess one question would
6 be is, if we do that, if you find something that does
7 sort, what is the next step? What does that mean?

8 DR. LaFORCE: No, no, that's incredibly
9 important. Until that avenue, when followed, leads you
10 nowhere, I think that's a whole new -- I mean, that's
11 why people do research. Come on. If you follow that
12 into a whole new toxin, that's very exciting. That's
13 worth a grant, or at least a grant proposal.

14 DR. ANDERSON: I just want to weigh in on
15 it. I think if we're going to do the two parts, they
16 ought to be together. I could see nothing worse than
17 sending one report to a Congressman and then not send
18 another report that's also been -- he's going to say,
19 "What did the AFEB say", and you say, "This is what
20 they said", when, in fact -- so, you can't -- I think
21 the decision has to be to just go with a review of the
22 paper, which is not traditionally what this group has
23 really done, it's to provide advice. So, I think if we
24 want to refine what the recommendation is, I don't
25 think to do it separate and then try to bury it. I

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1 mean, that's been done enough.

2 DR. LaFORCE: The reason why I was
3 smiling, I think that's pretty wise advice because if
4 you followed the nature of the correspondence that come
5 back from that Congressman -- I don't know who the
6 Congressman is, but, boy -- one word that leaps to mind
7 is "pugnacious". I've never seen anybody who was so
8 broiling for a fight.

9 DR. ANDERSON: They're all like that.

10 (Laughter.)

11 DR. ATKINS: I wonder if our -- I'm
12 sensitive to Dave's concerns about committing them to
13 something. I wonder if our recommendation couldn't be
14 sort of a two-step recommendation, the first one being
15 what I would hope would not be so resource-intensive,
16 just to see is it really 95 percent of a sample of
17 however you define them, positive for something. I
18 think some of us have suspicions about were these even
19 blinded, you know, at that level.

20 DR. LaFORCE: You've got a list of
21 symptoms.

22 DR. ATKINS: If it failed at that level,
23 then you can say this isn't even worth pursuing, and
24 then -- but then to say at least there's some
25 confirmation of -- independent confirmation of this

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1 kind of sorting, and then leave it up to groups who are
2 trying to decide what really should be high priority
3 for research.

4 DR. BARRETT-CONNOR: But that actually is
5 all -- I mean, perhaps too many details on the
6 replication, but the recommendation is -- the first
7 recommendation you make for any oddball finding, see if
8 you can replicate it. That's all the recommendation
9 is. We don't need to spell out all that other stuff. I
10 think it's a cheap, quick study, and I bet they can't
11 do it. But if they can, then we've got a whole new
12 ballgame.

13 DR. BERG: Bill Berg. The tenor of
14 Congressman Metcalf's correspondence is that he thinks
15 this is a great study and why isn't DoD climbing
16 onboard. And I don't think he's going to buy an
17 analysis, no matter how objective we think it is, that
18 says this is not a -- that there are a lot of flaws in
19 the study. I think the only way to move forward on
20 this is to do as the panel has recommended, and if, by
21 who knows what reason, it turns out that they can
22 reproduce the findings, then it can be pursued and, if
23 not, that may end it or it may not.

24 DR. LaFORCE: It's after 3:00 o'clock, and
25 I'd like to propose a couple of things. Number one, I

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1 think the Board owes a huge debt to the group that
2 reviewed this. I reviewed this paper. I read it the
3 first time. I said, "What the hell am I reading?"
4 This is one where you go through a couple of times, you
5 have to sort of underline it. It's not that well
6 written, this one. And so for the group and the
7 subcommittee on the part of AFEB, this was hard work.

8 (Applause.)

9 Secondly, I do think the -- what's slowly
10 percolating through my head is we do have an advisory
11 responsibility, and I think the subcommittee, perhaps
12 with some massaging in terms of what's been put there,
13 perhaps taking some things out about universities and
14 specific investigators, that kind of stuff, but I think
15 you all have provided us a splendid nucleus of
16 something that can be massaged, and I think a
17 recommendation, to go on a bit further -- David, as
18 much as I know you're not going to like this -- I
19 honestly think, from a scientific standpoint and from
20 an epidemiologic one, is the quickest way of sorting --
21 of answering the question, does this sort for disease
22 or does it not? And then if it does sort for disease,
23 then, boy, this could be the most wonderful advance,
24 and if it doesn't, than it's finished, let's move on,
25 and let's put this one to bed.

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1 So, with those thoughts in mind, let's
2 take a break -- I'm sorry -- Ben?

3 COL. DINIEGA: Just a couple of
4 announcements. We're going to take a break and then --

5 DR. LaFORCE: Oh, wait a second. Those of
6 you who ate and didn't put any money in, put some money
7 in.

8 COL. DINIEGA: For the breakout for the
9 subcommittees, which is the last thing on the agenda
10 for the day, and then there's people that wanted the
11 tour, we can do that at the end of the day.

12 I guess what I heard Dr. LaForce say is
13 that the issues are going to be the ergonomics issue,
14 which will be -- two subcommittees will work on that,
15 the Health Promotion and Maintenance and Environmental
16 Occupational Health, and that's in the Doctor's
17 Conference Room on the second floor -- who works here
18 at RIID? You know where that is, George?

19 VOICE: You're talking about on the second
20 floor?

21 COL. DINIEGA: Yes, that's what he said
22 was the breakout room.

23 VOICE: The Toxicology Conference Room?

24 COL. DINIEGA: All I know is the
25 conference room on the second floor, holds about 25

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1 people. And so the ergonomics issue will be with that
2 group, and then I guess the whole Board has to,
3 tonight, review the draft from Dr. Music and come up
4 with recommendations for changing it, and we have to
5 approve this thing as best we can tomorrow, and the
6 final message can be done through e-mail.

7 And then the Disease Control Subcommittee
8 will stay here, and they will handle the BW Agents and
9 Antibiotics Issue. And if we can meet back here at
10 5:15 --

11 DR. BARRETT-CONNOR: Health Promotion is
12 going with ergonomics?

13 DR. LaFORCE: I thought that there was
14 enough there. If you don't think so --

15 DR. BARRETT-CONNOR: It's all right with
16 me. I don't know anything about ergonomics, I'm happy
17 to go along.

18 (Simultaneous discussion.)

19 DR. LaFORCE: If you look over that
20 document, what's being suggested in terms of that
21 action plan, I think that's pretty comprehensive and
22 pretty important.

23 DR. BARRETT-CONNOR: But it seems to me
24 that it's an artifice at this point to have Health
25 Promotion and Ergonomics separately, so I'm happy --

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1 DR. LaFORCE: Put it together, and then
2 we'll talk about the BW antibiotic -- Disease Control
3 will be here, and then let's meet back here at 5:15.
4 So if you take your break, that would give an hour and
5 ten, hour and 15 minutes. So, let's meet back here at
6 5:15 to close out.

7 DR. BARRETT-CONNOR: Do you think we'll
8 need that much time? It's very long. It's already a
9 long day.

10 COL. DINIEGA: We could do it at 5:00.

11 DR. LaFORCE: You want to do it at 5:00?
12 I know it's long for you, you've been up since 2:00.

13 COL. DINIEGA: 5:00?

14 DR. LaFORCE: Let's meet back here at
15 5:00.

16 DR. ALEXANDER: Could you explain what's
17 happening with dinner and meeting again tonight, just
18 so it's clear.

19 DR. LaFORCE: I think if the homework is
20 done at the meeting sessions themselves, I don't think
21 there's going to be any need for any meeting, any
22 formal meeting this evening. Usually what does happen
23 is, when we do get together, there is business that
24 ends up getting transacted through most of the evening
25 as it relates to AFEB. In terms of dining stuff, when

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1 I drove in the other night, there must be 20 places --

2 COL. DINIEGA: I do have some
3 recommendations, and what happened in the past is that
4 people would congregate in groups and go out to dinner,
5 but Dr. Alexander used to live around the area, so she
6 knows a lot of good restaurants, too. But there's
7 Dutch's Daughter, Francesco's, Red Horse Steak House,
8 Ledo's Pizza, and a whole slew of other things. So
9 when we form back at 5:15, we can find out who wants to
10 get together for dinner.

11 DR. LaFORCE: Okay. Why don't we do that
12 at 5:00 o'clock.

13 COL. DINIEGA: And anybody who wants to go
14 with the issue and help the group discuss the issues
15 and draft up some recommendations, please do so. Any
16 questions?

17 (No response.)

18 So we'll meet back at 5:00 after the
19 subcommittee meetings.

20 (Whereupon, at 3:25 p.m., the meeting was
21 recessed, to reconvene at 5:00 p.m.)

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MEETING OF THE DISEASE CONTROL SUBCOMMITTEE

(3:40 p.m.)

DR. LaFORCE: Steve, I'm chairing your meeting as a poor substitute.

DR. OSTROFF: Well, I don't want to take Ben's chair.

DR. LaFORCE: No, no, no. We were talking about -- what's his first name -- Fukuda?

DR. OSTROFF: Kaji.

DR. LaFORCE: Where is he now?

DR. OSTROFF: He's at CDC, he runs --

DR. TSAI: Who is the woman who helped him organize the study -- the serologic study to look for specimens?

DR. OSTROFF: Serologic study?

DR. TSAI: Yes. There was a panel of specimen --

DR. LaFORCE: Not Nancy Cox.

CAPT. TRUMP: The JAMA publication.

DR. OSTROFF: That was a study that grew out of a specific -- this is a person in Pennsylvania, if I remember correctly, and it was done as an EPI aid. So this was an extended EPI aid where there was a lot of assistance from the Air Force because the major complaints basically came from a unit that was an Air

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1 Force unit in Pennsylvania, and so they went through
2 fairly extensive activities to evaluate these
3 individuals, do standardized examinations, collect
4 specimens, et cetera. And I think, if I remember
5 correctly, they had three different control groups
6 because this was a fairly unique group of individuals,
7 and so they had one control group from another location
8 in Pennsylvania, and then because of the particular
9 role that these individuals had in the Gulf War -- they
10 were a tactical -- I forget what the term is -- but
11 they did counter -- I think they dropped like leaflets
12 and things like that behind the lines -- there were two
13 control units that they got in Florida as well.

14 DR. TSAI: Do you know whether there were
15 remainders?

16 DR. OSTROFF: Oh, yes, there are certainly
17 specimens that remain.

18 DR. LaFORCE: Because one of the questions
19 we came up with is that his particular study was one of
20 a few studies where actually they've defined using a
21 case definition, who is what within those categories.
22 If those sera are still available and if he would be
23 amenable to becoming involved in this -- boy, you're
24 talking about cutting through a lot of stuff fairly
25 quickly if that serum set along with all the

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1 information he's collected, then becomes the sort of
2 test for the Asa bunch.

3 DR. OSTROFF: If I remember correctly --
4 because the initial part of the investigation was done
5 as an EPI aid and the subsequent parts of the
6 investigation were done as basically an IRB approved
7 research -- and if memory serves me correctly, we
8 actually got large amounts of specimens from these
9 individuals, and I'm pretty sure that those materials
10 are still in existence.

11 DR. LaFORCE: Could you find out from
12 Kaji?

13 DR. OSTROFF: Yes.

14 DR. BRADSHAW: This is the same study that
15 they did looking at the antibodies for BOT-TOX?

16 DR. LaFORCE: Yes. And wouldn't it be
17 neat now, just because you have all that other data,
18 you're just sort of adding the one test.

19 DR. BRADSHAW: What would be particularly
20 interesting, since anthrax is the big question, is
21 whether there is any correlate at all between so-called
22 antibodies and --

23 LtCOL. GRABENSTEIN: There were only ten
24 or 15 people who tested positive for anthrax antibodies
25 in that group in his study, as I recall. So the

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1 vaccine exposure would be small among that group, for
2 what that's worth.

3 DR. OSTROFF: Well, when you read this
4 article -- and I sort of had the same response that
5 everybody else had in terms of reading this article --
6 I mean, there was the suggestion sort of built into it
7 that it was somehow related to getting all of these
8 vaccines, but again I think we ought to look at it as a
9 potential assay that in some way, shape or form can
10 distinguish people with whatever the syndrome happens
11 to be versus people that don't. And, again, these
12 individuals were relatively well characterized. They
13 are not sort of a random sample from the Gulf War
14 Syndrome Registry or something like that, but they are
15 probably among the best defined individuals that have
16 been evaluated.

17 LCDR. JOHNS: I do have one observation on
18 this paper. They did imply the vaccine in the early
19 parts of the paper, but on the last page, the last
20 column midway down, saying there was no evidence that
21 squalene was in any of the vaccines given to service
22 members which, in my honest opinion, puts them in the
23 same category as used car salesmen.

24 (Laughter.)

25 DR. LaFORCE: Put it this way -- how about

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1 successful used car salesmen because they've gotten us
2 to talk about their data. Okay. What I would suggest
3 is look at this draft -- I think the idea of Fukuda, as
4 we're looking at this section here in terms of
5 suggestions, sort of considering making a suggestion
6 about an already defined set of sera, and perhaps not
7 mentioning any names, but at least suggesting that a
8 defined set of sera, rather than having to go back and
9 then going through a very, very complex process to
10 identify something, that might have merit.

11 Okay. I've finished my poor substitution.
12 Now it's up to you.

13 DR. OSTROFF: Sorry, I was on the
14 telephone, but --

15 CAPT. TRUMP: The other potential set of
16 sera is from a CB study that Greg Gray at Naval Health
17 Research Center did. I don't know if they have any --

18 DR. LaFORCE: When was that study?

19 CAPT. TRUMP: It's the same time frame.
20 The data collection was '94-'95.

21 DR. LaFORCE: If you know of a set of
22 sera, I really think that might -- that thing is going
23 to drive me crazy.

24 DR. OSTROFF: Okay. It seems like the
25 major task, at least for this meeting, is to try to

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1 deal with the issue that was posed to us concerning the
2 selection of antibiotics for use in the field for BW-
3 related issues, and I can -- I'm looking through these
4 -- try to specifically find the request from Adm.
5 Clinton -- I have it here.

6 Basically, it says "Request a review and
7 prioritization of biological" -- it says "The AFEB has
8 been very helpful in reviewing and prioritizing threat
9 agents facing our Armed Forces, though we require a
10 review of the antimicrobial drugs.

11 "In light of this need, there's a request
12 that the AFEB conduct a review of antibiotics approved
13 by the Food and Drug Administration that may prove
14 useful against certain infectious biological warfare
15 agents", and I note the very specific language approved
16 by the Food and Drug Administration, but that doesn't
17 necessarily mean approved for that specific indication.

18 And they "ask AFEB to provide recommendations on the
19 most appropriate antibiotics that would be indicated
20 for the treatment of the primary bacterial and
21 rickettsial agents on the Biowarfare Threat List. Of
22 greatest concerns are the infectious agents causing
23 anthrax, plague, tularemia, brucellosis, glanders and Q
24 fever".

25 Now, one thing I do think is relevant to

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1 point out is that tomorrow we are going to have several
2 presentations about sort of an update on the Threat
3 List, and that conceivably may alter some of the
4 potential agents that we may want to look at. But I'm
5 going to presume, unless somebody has other
6 information, that there probably isn't a tremendous
7 change in some of the list of prioritized agents based
8 on what we may hear tomorrow. I'd be interested in
9 hearing tomorrow whether or not there's some updated
10 information concerning the issues of antibiotic
11 resistance, which I think obviously would have some
12 impact on what some of the recommendations may be.

13 Fortunately, as was mentioned just before
14 the break, there are a couple of people, including Col.
15 Christopher at least for the next month or so, as well
16 as Lisa Ross in my office -- for those who don't know,
17 the way things are structured at CDC is that the NCEH,
18 the National Center for Environmental Health, basically
19 does the administration and the technical issues
20 regarding the stockpile, but the scientific input into
21 what goes into the stockpile comes from my Center,
22 which is where the Bioterrorism Preparedness and
23 Response Activity is located, and Lisa has been
24 basically the point person in that activity. And so
25 when Ben approached me, she was the person that I

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1 recommended would probably be most helpful to the Board
2 in terms of how the deliberations were done for us to
3 come up with the recommendations that we have up to
4 this point in terms of the materials that are in the
5 stockpile. So I think Lisa will be quite helpful.

6 And it specifically says here they would
7 like to have our evaluation within 60 days of this
8 meeting, so it does give us some time to put that
9 assessment together.

10 So, I think with that, let me just --

11 COL. DINIEGA: I have a comment first.
12 The 60 days, if the subcommittee feels that they need a
13 face-to-face, we can do that; otherwise, it can all be
14 done via e-mail or teleconference. But if there is a
15 need for a face-to-face at least once before it goes
16 out and we've finished up via e-mail, then I need to
17 know so we can arrange the time and place.

18 DR. GARDNER: Does the shelf-life of these
19 differ, since essentially we're looking at quinolones
20 versus doxycycline. I know there's a 25-fold
21 difference in cost. What about the shelf life?

22 DR. OSTROFF: Well, somebody from DoD may
23 want to comment on this, but the shelf life issue isn't
24 as big of an issue for Dod as it would be for us
25 because we don't have people that we, on a day-in and

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1 day-out basis, prescribe ciprofloxacin and prescribe
2 doxycycline for, which DoD does. So my assumption
3 would be that they would rotate.

4 LtCOL. GRABENSTEIN: As a pharmacist, I
5 would say -- I don't know the specific for these drugs,
6 but the standard would be three or four years.

7 DR. BERG: Bill Berg. There was recently
8 a study, though -- at least I read in the paper of the
9 I think it was the DoD Shelf Life Committee that looked
10 at some of the drugs, and that shelf life is actually
11 years longer. In fact, for some reason, cipro sticks
12 in my mind as being incredibly long.

13 LtCOL. GRABENSTEIN: It was in the Wall
14 Street Journal, actually, as a good story of the
15 Government saving money, and what I know is from what
16 was in that study, but there's folks at the U.S. Army
17 Medical Materiel Agency here in Detrick who coordinate
18 those testing programs.

19 DR. BERG: If we can piggyback onto that
20 information, the shelf life might not be as much of an
21 issue.

22 DR. OSTROFF: Ted.

23 DR. TSAI: Are there other prophylactics
24 for chemical warfare, other medications soldiers are
25 likely to take that might interact either as inducers

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1 of P450 enzymes or other kinds of interactions that
2 need to be considered?

3 DR. WALDMAN: In regard to your comment
4 about cost, I was wondering when cipro -- I think it's
5 coming up real soon now, in fact, that the price is
6 likely to drop precipitously in the very near future.

7 DR. OSTROFF: For those who may not have
8 heard, he was talking about when cipro goes off-patent,
9 and once that happens, clearly the price will decrease
10 significantly, as it has with many other drugs, and as
11 we were talking this morning with hepatitis-B, when
12 many of the cost-benefit analyses were done, they were
13 done at a time when the vaccine was much more expensive
14 than it is now. I don't know the answer to that.

15 DR. LaFORCE: That's a good point, though,
16 because it's not like this is going to go away, and --
17 it's a bit silly to make a very important decision when
18 the end of patent is going to be over in a year or year
19 and a half or a couple of years because that just
20 disappears as an issue, you know, in terms of making a
21 decision about a stockpile.

22 DR. WALDMAN: I know it's available fairly
23 cheaply in some places now that don't have quite the
24 same respect or patent that we do. I think it's a very
25 desirable drug for dysentery control.

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1 DR. GARDNER: Steve, I have a couple of
2 questions. I divided sort of three considerations.
3 What about the efficacy of the doxycycline versus
4 quinolone, and I got the sense from Col. Christopher
5 and from his document here that they look pretty
6 comparable. There's more data with regard to
7 doxycycline than there is for quinolones, and at least
8 for three of the ones that the Senator's worried about
9 -- glanders, brucellosis and Q fever -- there were no
10 quinolone data. So, that was -- and it will be a long
11 time before cipro gets down to doxycycline, which is
12 pretty dirt cheap.

13 So, in that sense, I kind said, why aren't
14 we using doxycycline? Well, the answers, I think, may
15 be two. One is the concern about they're going to make
16 resistant -- it's easier to make a doxycycline
17 resistant anthrax bioterrorism weapon than it is to
18 make a quinolone, although there was some mention of
19 some quinolone resistance, I guess, being reported at
20 some point.

21 The other part, I guess, the issues of
22 photosensitivity, and I guess vaginal yeast and some
23 things like that, would make doxycycline a little less
24 accepted, so there may be a reactogenicity or adverse
25 reaction that comes out slightly in favor of the

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1 quinolones. But I thought it was a pretty even draw.

2 Then there is the issue of the military
3 looking to treat with either/or and the civilians
4 getting a 5-day packet of quinolone, and then figuring
5 out whether you really need it or go forward with
6 something else. That was an interesting -- very
7 interesting idea economically, but as you point out, it
8 sounds like a logistical nightmare to get people to
9 actually do that. I thought we ended up with sort of a
10 -- I wasn't sure we were all on the same page.

11 CAPT. TRUMP: One of the other concerns --
12 it hasn't come up here, but it certainly came up in the
13 ACIP Working Group discussion about the anthrax
14 recommendation -- is one of the concerns for an adult,
15 18 -- healthy, young adult population versus the
16 pediatric population, not much data, you know, general
17 avoidance of the tetracycline and the ciprofloxacin for
18 pediatric use. And actually they are talking about
19 starting with cipro or doxy but switching to
20 amoxicillin or penicillin.

21 DR. OSTROFF: In terms of cipro versus
22 doxy, I mean, you know, it's sort of another issue
23 which is a therapeutic issue rather than a prophylactic
24 issue that we've gone round and round and round, is
25 gentamicin versus streptomycin, and it's a similar type

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1 of a problem, which is that all of the work on plague
2 and tularemia was done when streptomycin was around and
3 gentamicin wasn't, and so streptomycin is the licensed
4 product. But when streptomycin was unavailable and
5 people used gentamicin instead, it worked quite well,
6 but the problem is that nobody has done the definitive
7 study to show its equivalency to streptomycin, and so
8 streptomycin remains sort of the licensed product for
9 use in plague and gentamicin is considered off-label.
10 But in practical terms, people aren't going to want to
11 use it. Streptomycin is so inefficient to administer,
12 and having to give all these IM injections and many
13 other issues related to streptomycin that -- I mean,
14 you know, most of the recommendations that have been
15 developed preferentially go towards gentamicin. The
16 problem is it's an off-label indication and, once
17 again, you get into all these FDA issues about needing
18 an IND to be able to use it.

19 DR. GARDNER: Well, just as we accept
20 doxycycline as -- we accept tetracycline data as
21 doxycycline equivalents, it's a little more of a
22 stretch to use the immunoglycocides interchangeably,
23 but for the organisms we're talking about, it's
24 probably true, isn't it?

25 DR. OSTROFF: Yes. But I mean in terms of

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1 doxy versus cipro. I mean a lot of the work was done
2 when doxy was available and cipro wasn't.

3 DR. GARDNER: Well, I think doxy versus
4 cipro is a different -- I mean, those are different
5 drugs, clearly. These other ones are modifications of
6 a class, and if you can show in vitro MICs, I would
7 think you could get those extensions pretty -- it would
8 make more sense to do that.

9 DR. OSTROFF: Ted.

10 DR. TSAI: The point I was trying to make
11 earlier was that is it possible to have a team of
12 people look at (inaudible) this intervention, so you
13 will have to accumulate those data. Think of it as an
14 EPI aid kind of an outbreak of drug administration or
15 whatever, but it would seem to me that you could have a
16 protocol already written up, ready to go, so that when
17 this emergency strikes you would be able to -- it
18 wouldn't have to be real-time, it could be after the
19 emergency, it could be a retrospective study, but you'd
20 have some means of getting some information on
21 efficacy, and probably less for side effects, but
22 efficacy, I think -- it would be part of an evaluation
23 of the exercise and intervention. I would guess that
24 if this were to -- if we had a terrorist kind of
25 incident, there would be some attempt to evaluate the

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1 response. This would be part of the evaluation.

2 DR. OSTROFF: There would be absolute
3 efficacy, which is that if somebody was to say cipro
4 was what we're going to be using versus relative
5 efficacy --

6 DR. TSAI: Not everyone is going to get
7 treated probably -- you know, or treated in the same
8 time frame. I mean, there would be ways to look at it.

9 And it seems to me even you could begin to think about
10 a protocol now.

11 DR. LaFORCE: I'd like to explore the idea
12 about whether the subcommittee would be comfortable
13 with making a recommendation to Adm. Clinton about a
14 single agent, whether it's doxy or cipro. That, to me
15 -- you know, in terms of -- we talked about one versus
16 the other, and the question that always came to my mind
17 -- that's why I was asking about this antimicrobial
18 susceptibility on some of those four isolates that came
19 out of Sverdlosk. I would be a little bit concerned
20 about the issue of putting all one's antibiotic eggs in
21 one basket, as it were, and that's just me.

22 DR. GARDNER: Well, Carl Curling -- he
23 isn't here now -- that was what he had done in his
24 analysis, and basically he says instead of spending --
25 you put it all in the cipro basket, you're going to

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1 spend 25 times more than if you put it all in the doxy
2 basket. And he suggested some weighting. He has, I
3 think, three-quarters cipro and a quarter of doxy. One
4 could consider --

5 VOICE: Half and half.

6 DR. GARDNER: -- or going three-quarters
7 doxy.

8 DR. WALDMAN: These are clearly
9 exceptional circumstances that we're talking about.
10 We're talking about reacting toward a public -- even if
11 we're talking about the military -- it's the population
12 affected by -- it depends on how much people are
13 willing to spend to guard against that. I know in my
14 mind it doesn't seem that the cost necessarily needs to
15 be the important issue. I think it's one of many
16 issues, but I would sort of -- imagine you got the heat
17 on other things, imagine the heat you would take for
18 saving some pennies in the case of a terrorist attack,
19 I'd be uncomfortable not -- if there were a clear
20 choice, I'm be uncomfortable not going --

21 DR. GARDNER: But we don't know about
22 glanders and --

23 (Simultaneous discussion.)

24 DR. WALDMAN: Okay, fine. But in terms of
25 glanders, then one could say that it might be more --

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1 and that's all I want to get to, that it might be more
2 clearcut for some things.

3 (Simultaneous discussion.)

4 DR. GARDNER: But there is a tetracycline
5 resistant anthrax.

6 DR. WALDMAN: So both need to be available
7 then.

8 DR. GARDNER: We need enough cipro to get
9 us through some of --

10 DR. BRADSHAW: But all the last three or
11 four were doxy. Brucellosis, tularemia and Q fever,
12 they all recommended doxy.

13 DR. GARDNER: So for three, doxy looks
14 better and the other really look the same unless these
15 folks are smart enough to get a resistant spore.

16 DR. WALDMAN: If I had my druthers, I'd
17 want to have both around.

18 DR. OSTROFF: Well, one question that I
19 have is --

20 DR. WALDMAN: I wanted to say, if I could
21 -- I'm not really challenging it to say that, but in
22 addition to efficacy, there are other considerations
23 also. In a circumstance like this, you want to be
24 absolutely sure that whatever you give is going to be
25 most effective to the people who are taking it. And in

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1 terms of what I would call, for want of a better term,
2 "bioavailabiity" of differences, potential differences,
3 isn't there a lot of findings that tetracycline is
4 resistant to dairy products and the like that have an
5 impact on absorpction and things like -- you know, you
6 have to go through some hoops to make sure that people
7 are getting maximum benefit from the tetracycline that
8 you wouldn't necessarily have to do with quinolones,
9 those kinds of considerations.

10 Now, I had another question also. When
11 we're talking about casualties on the military side,
12 did that include dependents also, or just soldiers
13 because if it includes dependents, then you're talking
14 about pregnant women and you're talking about children
15 again, and --

16 DR. OSTROFF: Well, this was the question
17 that I was going to ask, is that what's not entirely
18 clear to me is how these materials are actually going
19 to be deployed. I mean, are we actually talking about
20 soldiers on the battlefield that are going to have a
21 packet of drugs with them that they are going to start
22 using when somebody gives them the signal to say start
23 taking your antibiotics, or are we talking about
24 putting these things on bases in various places and
25 using them in those circumstances because I think

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1 clearly some of the recommendations would be quite
2 different if we are talking about a packet of drugs
3 that are going to be on the front line with the soldier
4 versus something for one of the bases in Saudi Arabia.

5 CAPT. TRUMP: I think the answer is yes to
6 both of those. It probably is prepositioned in Saudi
7 Arabia now. Depending on the threat level and how much
8 the concern is, at some point you're going to say the
9 threat is high enough that we don't want to have it
10 sitting 100 miles behind the line, we want to move it
11 forward, we actually want to dispense it in the blister
12 packs to the individual soldiers. So, it's usage will
13 be -- some of this is making a decision about what we,
14 as an organization, will stockpile and have ready to
15 go, but it will be something that at some point will be
16 handed to the individual.

17 DR. OSTROFF: My feeling is that if it's
18 going to get handed to the individual and they are
19 going to carry it out into the field with them, I'd
20 like to make it as simple as possible so that they
21 don't potentially make a mistake and pull the wrong one
22 out of their packet. If it was a more controlled
23 situation, then I think having more options is
24 preferable.

25 DR. LaFORCE: Except if you're talking

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1 about profoundly safe antibiotics, and you're talking
2 about either of these two agents. You could screw this
3 up royally and nothing bad would happen. I mean, maybe
4 they would have a little diarrhea. I mean, this is
5 really a no-brainer. If you're talking about either of
6 these two agents, I'd even trust those with my
7 daughter.

8 And I would propose that if we're talking
9 about those two -- amoxicillin in Peds, and gentamicin.
10 We're not talking about four agents.

11 DR. OSTROFF: If I'm not mistaken, they've
12 been mostly talking about issues of prophylaxis rather
13 than therapeutics.

14 DR. LaFORCE: So you don't need
15 gentamicin.

16 DR. OSTROFF: Unless I misunderstand, I
17 thought that the task here was to look at prophylactic
18 agents.

19 CAPT. TRUMP: I think it's inclusive of
20 both preventive and treatment.

21 DR. LaFORCE: I think it's treatment as
22 well.

23 CAPT. TRUMP: If it's treatment as well,
24 then the array of agents gets a little bit more
25 complicated because there is the issue of oral versus

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1 intravenous therapy for individuals who are sick that
2 might not be able to take oral agents.

3 DR. WALDMAN: The letter, in fact, says
4 only treatment (inaudible).

5 DR. LaFORCE: And I think that that would
6 be fine in the prophylactic regimen oral ciprofloxacin
7 or oral tetracycline -- doxycycline, and from the
8 parenteral standpoint, parenteral gentamicin, and I
9 would suspect you're talking about oral in parenteral -
10 - or certainly amoxicillin as an oral compound. Are we
11 talking about a parenteral compound as well for kids,
12 because amoxicillin is not given, that's ampicillin.

13 CAPT. SCHOR: Just one other caution.
14 It's one thing to talk about prepositioning things in a
15 fixed setting, like you would in a local county health
16 department, that sort of thing. It's another thing
17 when you're looking at expeditionary operations. The
18 more things you have to worry about carrying -- there's
19 only so many little boxes you can carry for medical
20 supplies. Ships, sure, they have a lot more space in
21 their holds and you can airlift those things ashore or
22 whatever. But as the Air Force and the Army looks at
23 getting lighter, more mobile, that's an issue that
24 they'll have to confront. So, as much as we would like
25 to have a bigger formulary available, the practicality

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1 of that -- there's a limit -- and I'm not so sure I can
2 draw the line, and it varies from unit to unit.

3 DR. LaFORCE: Don't get me wrong. For the
4 fighting, for the recruit or for the soldier, it's
5 really pretty simple. We're talking about only two
6 agents that -- if it's chemoprophylaxis that are
7 available orally -- and they probably take up about the
8 same amount of space, don't they? There isn't a huge
9 advantage, one over the other.

10 DR. WALDMAN: They're administered on the
11 same schedule.

12 DR. LaFORCE: Same schedule, every 12
13 hours or something like that. So I don't think that
14 that would be a big limiting factor. The problem would
15 be for dependents. If you've got dependents in harm's
16 way, then there has to be some sort of proviso for at
17 least amoxicillin and penicillin or ampicillin.

18 DR. OSTROFF: But the question would be in
19 many of the higher risk areas are there that large a
20 number of dependents that it becomes an issue?

21 DR. LaFORCE: In Korea? Oh, yes, there
22 are dependents all over Korea, aren't there?

23 MAJ. PAVLIN: Lots in Korea.

24 DR. LaFORCE: Yes, because that's
25 considered harm's way, isn't it?

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1 DR. OSTROFF: But in the Middle East, it's
2 not.

3 DR. LaFORCE: Who's in the Middle East?

4 DR. OSTROFF: There are some in Turkey.

5 DR. LaFORCE: Well, the only question is,
6 every time someone says there are some, you think, what
7 if they were mine?

8 DR. OSTROFF: And then the same issue with
9 dependents, there's also pregnant women, is the other
10 potential group.

11 DR. LaFORCE: Okay, what's the list going
12 to consist of?

13 DR. OSTROFF: The other issue is in terms
14 of treatment. I mean, if you look at what we developed
15 for the Push Packages, it's a rather lengthy list of
16 materials, but most of them are sort of the nonspecific
17 support materials, and I would imagine that a lot of
18 this is forward deployed the types of battlefield
19 situation, et cetera --

20 CAPT. TRUMP: You don't have to worry
21 about that part, just focus on the antibiotics.

22 DR. OSTROFF: The only thing in terms of
23 the therapeutic component of it, when I read through
24 the document itself, there is a lot of information at
25 the beginning about policies regarding moving large

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1 numbers of individuals with potential exposure or that
2 are ill from one of these agents, and you get into all
3 of these issues regarding the international health
4 regulations and whether you could move somebody with
5 plague from one country to another, since it's a
6 quarantinable disease, et cetera.

7 DR. LaFORCE: That could be like one of
8 those FDA questions.

9 DR. OSTROFF: I know. But they say to try
10 to do as much as possible in-theater.

11 DR. BRADSHAW: I think the AIREVAC system
12 has addressed those problems, as far as transport and
13 who can be transferred and -- I think they have all
14 that stuff.

15 DR. OSTROFF: I must confess, when I read
16 through the document I was a little surprised by some
17 of the issues about decontamination and requirements to
18 decontaminate people before they can be put on a plane,
19 and things of that nature which I think really, I
20 think, is very questionable, about the necessity to do
21 something like that. I'm not quite sure why that's
22 still a policy because most of these are not -- you
23 know, from somebody who was exposed to plague or
24 anthrax. They don't pose a tremendous risk of
25 contaminating their environment as they are moved. And

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1 this is an issue that we constantly are confronted with
2 in the civilian sector when anybody opens one of these
3 anthrax envelopes or whatever. The next thing you know
4 there are hundreds of people being decontaminated out
5 on the street because we simply can't get it out of
6 people's sort of array of experiences that that's an
7 appropriate thing to do. So, I think it's unfortunate
8 that it continues to show up in these documents, but
9 apparently there's some sort of policy in the Air Force
10 about requirements to decontaminate individuals before
11 they can be put on the planes.

12 CAPT. TRUMP: I didn't look at the
13 specifics, it may be related to just responding to a BW
14 or a CW event.

15 DR. OSTROFF: But I hope somebody that's
16 sick it wouldn't require that they be hosed down before
17 you can put them on an airplane.

18 DR. GARDNER: Steve, in your list of the
19 12-hour package, you have erythromycin.

20 DR. OSTROFF: I never quite understood
21 that.

22 DR. GARDNER: That hasn't come up at all
23 for this.

24 DR. OSTROFF: It's an alternative for
25 anthrax. It's amongst the list of alternatives for

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1 anthrax. It's among the list of alternatives for
2 anthrax.

3 DR. LaFORCE: If you want to simplify your
4 list, get rid of it.

5 DR. GARDNER: Why not a penicillin?

6 CAPT. TRUMP: I know for anthrax it's
7 there because of the pediatric issues -- I'll have to
8 pull up the draft of the ACIP recommendations.

9 DR. GARDNER: Is it better than
10 penicillin?

11 DR. OSTROFF: Because of other issues, the
12 sensitivity issue.

13 CAPT. TRUMP: Actually -- that was some of
14 the interest -- Dr. Christopher talked about pursuing
15 things like a zithromicin and whether or not it's
16 effective in vivo.

17 DR. OSTROFF: I don't pretend to
18 understand the logic behind having erythromycin.

19 DR. LaFORCE: I've up to six agents,
20 folks. I've got three PO agents -- doxy, cipro, and
21 amoxicillin for kids, and then three parenterals --
22 ampi, genta -- oh, erythro -- that's PO and IV.

23 DR. OSTROFF: Actually, I'm with you,
24 Marc. I think that the list of antibiotics that are
25 really needed in a situation like this is really pretty

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1 limited, and you only get into problems with some of
2 these agents like brucellosis and glanders as far as
3 some of the recommendations, but the recommendations
4 that are in this text are very much in concert with
5 what Henderson's group at Hopkins has been developing
6 for the last year, at least for the ones that they've
7 gotten through so far. So there's nothing radically
8 different here than what everybody else is proposing.
9 And I actually think that the document that Col.
10 Christopher has put together is really a great
11 document.

12 DR. LaFORCE: Does the military currently
13 stockpile something, David? Do you have already
14 stockpiles that are set aside for BW?

15 CAPT. SCHOR: Well, I think we're sort of
16 heading, to some degree, in the same direction that the
17 civilian stockpile is. There's vendor-managed
18 inventory.

19 DR. LaFORCE: So it will be the bubble
20 stuff? It will be the bubble inventory, rotating
21 stocks, but held at the manufacturer's?

22 DR. OSTROFF: DoD already has contracts
23 for vendor-managed inventory. They had it before we
24 did.

25 LtCOL. GRABENSTEIN: Burn creams, as an

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1 example.

2 DR. WALDMAN: So we do have stockpiles of
3 antibiotics.

4 DR. OSTROFF: Yes. In fact, one of the
5 issues that came up from Congress was whether or not
6 these companies were double-dipping in terms of vendor-
7 managed inventory purchased by DoD and vendor-managed
8 inventory purchases by CDC and, in point of fact, we've
9 got different inventory numbers between the two of
10 them, so there really isn't duplication. But,
11 basically, they are getting paid twice to hold
12 materials in abeyance.

13 And the other question that's come up
14 repeatedly is, well, who goes first? There's only a
15 certain bubble sitting there, who gets it first? And I
16 imagine it's whoever calls first probably gets it
17 first. They are roughly equivalent in terms of what
18 they're asking for to maintain the VMI for the DoD and
19 for the CDC.

20 DR. LaFORCE: But theoretically that
21 shouldn't make a difference, right -- because the
22 bubble, if it has to assume a large enough volume to
23 account for both, right -- I mean, that's what they're
24 getting paid for.

25 DR. OSTROFF: Assumedly, right.

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1 Mobilizing and getting it there --

2 DR. LaFORCE: Oh, I love the suspicion.

3 DR. OSTROFF: Well, it's natural that
4 Congress would ask such questions.

5 DR. LaFORCE: There is experience, though
6 -- Ron remembers -- and it's a bubble that continues to
7 be done now for all the vaccines for all of Central and
8 South America, through a revolving fund. There is no
9 depot. It's all stocks. And it's a system that has
10 worked flawlessly, absolutely flawlessly. No one runs
11 short, and this bubble is always available because they
12 have a common purchasing pot, and these bubble of
13 vaccines that are located at different manufacturers --

14 DR. WALDMAN: Like a bank that people
15 withdraw from whenever they want.

16 DR. LaFORCE: Yes. And it sounds terribly
17 -- I thought it was very complex when it was first set
18 up a long time ago. It turned out it was very, very
19 simple.

20 DR. OSTROFF: One other question that I
21 would pose is that while we're specifically looking at
22 treatment and prophylaxis for these agents, one
23 potential problem is if you have many people exposed
24 and being treated, that they could well have
25 complications which may require other types of

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1 antibiotics, such as for secondary pneumonias and
2 things like that. Is it sort of beyond the scope of
3 our group to make recommendations about potential other
4 materials that may need to be there?

5 DR. LaFORCE: I would say that's beyond.
6 You know, if you had some octogenarian that now has
7 gotten over and has developed a nosocomial pneumonia,
8 they are probably going to be triaged to death, or
9 treated with whatever is around. I'm not sure.

10 DR. BERG: There is a question that was
11 sort of addressed in there about people who are
12 allergic to certain medicines, or what do we do if they
13 take prophylactic medicine and get infected anyway? Do
14 we want to address that or do we want to keep it just
15 simple?

16 Part of the implication was if cipro is
17 the drug of choice, then there ought to be doxycycline
18 readily available as a backup for those cases, or vice-
19 versa.

20 DR. OSTROFF: Yes. I can tell you, for
21 instance, in the TOP-OFF Exercise which -- you know,
22 the agent -- as Adm. Clinton mentioned, the agent was
23 plague -- was ultimately found to be a genetically
24 manipulated organism that was multi-drug resistant,
25 however, in terms of whoever put the exercise together,

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1 people who were prophylaxed with something that the
2 organism was resistant to didn't get sick.

3 (Laughter.)

4 We were quite fortunate that we didn't
5 have to deal with that situation.

6 LCDR. JOHNS: I can comment on that. I
7 was sitting in a Denver control cell. We don't know
8 where that inject came from because it was not part of
9 the original plan.

10 DR. OSTROFF: That it was manipulated?

11 LCDR. JOHNS: That it was manipulated.

12 DR. OSTROFF: Well, there were all these
13 suggestions at the beginning that had had funny
14 plasmids and sort of was an atypical plague strain, so
15 I don't know who did that either, but one of the pieces
16 of information that was available very early on was
17 that people who were being prophylaxed weren't getting
18 sick. So that was a nice wrinkle, but your point is
19 well taken. The problem is that there are infinite
20 varieties of resistance that can occur, and I'm not
21 sure that we could necessarily anticipate every
22 potential resistance pattern and have an alternative
23 available.

24 DR. LaFORCE: Was the exercise a success
25 or a failure?

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1 DR. OSTROFF: I think the exercise was a
2 success in terms of really --

3 DR. LaFORCE: In other words, how do we
4 feel?

5 DR. OSTROFF: Well, in terms of helping
6 people understand what potential issues may or may not
7 necessarily have been adequately addressed. I mean,
8 for us at CDC it was the quarantine issues that came up
9 as a real big problem. The difficulty that we had was
10 that as far as the way it played out, it was a little
11 bit unrealistic. I mean, I think we at CDC probably
12 would have figured out what was going on within a
13 matter of hours based on what the exposure was, which
14 was that it was a concert at a particular location, but
15 the problem was the way the exercise played out, they
16 would only give you certain pieces of information and
17 then they said you had to wait a couple more hours
18 until we could give you some additional piece of
19 information and, by the way, you can't interview any of
20 the patients until tomorrow. And so there we were sort
21 of left holding the bag, saying we would have known
22 already that it was this or this, or that this was the
23 population that needed to be prophylaxed, but they
24 wouldn't do that in the exercise.

25 LCDR. JOHNS: That was deliberate for a

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1 reason.

2 DR. LaFORCE: Like taking Board exams.

3 DR. OSTROFF: What was the reason?

4 LCDR. JOHNS: The reason was basically
5 because they wanted the TOP officials to focus on Fort
6 Smith and then hit them with Denver from behind.

7 DR. OSTROFF: But the problem was it was
8 unrealistic in terms of how rapidly some things could -
9 - I mean, I think that --

10 LCDR. JOHNS: And it's been accepted that
11 with the astute positions and the local hospitals and
12 with the CDC support, that the handle would have been
13 had on the problem a lot sooner in the exercise. That
14 was openly acknowledged.

15 DR. OSTROFF: I mean, as one example, the
16 sick people started coming in on a Friday evening, but
17 the health department didn't call us until 2:00 o'clock
18 the following afternoon when there had already been
19 hundreds of people that had come into 16 or 18
20 emergency departments.

21 DR. LaFORCE: And it's over a weekend.
22 Don't put too much confidence in these astute
23 diagnosticians in the emergency rooms.

24 DR. OSTROFF: This wasn't that subtle,
25 though, because people were flooding --

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1 (Simultaneous discussion.)

2 DR. OSTROFF: -- these people were
3 flooding in and by the following morning there had been
4 many of them that had shown up -- and many of them were
5 dead. I mean, that's the type of thing that they
6 probably would have called us on the telephone very
7 quickly -- anyway.

8 It sounds like we've identified a number
9 of critical issues that the group has to consider as
10 they move forward with the recommendations, and it
11 sounds like the issue isn't going to be that there are
12 some antibiotics that aren't on the list that ought to
13 be on the list, the issue is selecting amongst
14 reasonable alternatives and what criteria that might be
15 helpful in terms of sorting through the alternatives.
16 And I've heard a number of them discussed, including
17 shelf life, potential drug interactions -- and I think
18 that potential drug interactions is actually an
19 important one because there are a whole array of
20 different things that may be happening at the time that
21 a decision is made to take antibiotics. So that's an
22 important one.

23 Obviously, there's cost issues which, as I
24 think Ron rightly pointed out, might not be as much of
25 an issue in a couple of years. There's the efficacy

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1 question. There are the drug resistance questions, and
2 there are the side effect questions. Are there other
3 considerations?

4 LtCOL. GRABENSTEIN: What's the
5 expectation on how fast a diagnosis can we make? So
6 what's the importance of broad spectrum antibiotics
7 early? Is that a major criterion, to have a broad
8 spectrum antibiotic available, or is it a minor
9 criterion?

10 DR. OSTROFF: I don't know, let me open
11 that up to the group. Obviously, forward diagnostics
12 has been an area that DoD's been working a lot on, so -
13 - I mean, my presumption would be that you would be
14 faster than we would in terms of trying to determine
15 what the agent is.

16 DR. BRADSHAW: I notice that this actually
17 says treatment, but was that intended to include
18 prophylaxis? I mean, the issue, I guess, would be you
19 may not have the luxury of, depending on how widely
20 things are disseminated, of knowing what antibiotic
21 sensitivities are to drive your thing and say, gosh, I
22 wish we had more Bactrim, et cetera, instead of cipro
23 or something like that. And the other issue is if you
24 would get the detections ahead of time and start
25 everybody pending confirmation. So the issue is,

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1 again, if you're going to have to stockpile stuff, you
2 have to stockpile something that would have the
3 broadest application, I would think, instead of the
4 "silver bullet" idea.

5 DR. BERG: But as it turns out, the two
6 primary drugs, doxycycline and ciprofloxacin, do have
7 broad spectrum for the leading agents. I think what
8 may turn out to be of greater concern that we're
9 probably not going to be able to deal with, is
10 resistant strains. That means we either try to come up
11 with some cocktail that will cover every resistant
12 strain, which is impossible, or we keep life simple and
13 hope that the microbiology lab comes through quickly
14 with the resistants.

15 DR. OSTROFF: I think I would agree with
16 that. Clearly, if you find out that it's got certain
17 features which tell you that the only drug that you
18 could use is Imipenum (phonetic) or something like
19 that, there's going to be some problem, but I don't
20 think that we would want to recommend forward deploying
21 some of these other agents.

22 DR. LaFORCE: No.

23 DR. BRADSHAW: I think the other point is
24 well taken about maybe not putting all your eggs in one
25 basket, too, because if we came out and said this is

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1 it, then the question would be then does everybody
2 start working on a strain that's resistant to that one
3 hit.

4 DR. OSTROFF: That's a good point.

5 LCDR. GRABENSTEIN: It's two or three
6 years ago and others may know the story better than I,
7 but the Israelis were prepositioning antibiotics when
8 they thought they were under threat of Iraqi attack,
9 and they kept the name of the antibiotic classified. I
10 don't know for how long, but -- under the theory that
11 you could dial the antibiotic up.

12 DR. LaFORCE: If you are a focused
13 terrorist, this is not going to be a secret when this
14 stuff goes out. If you're a focused terrorist, they'd
15 say, "Oh, thank you very much", and I'm back in the lab
16 for a while, that's not very hard. So that's why the
17 efforts that we go through while they are necessary --
18 but, boy, if you're a serious, committed terrorist,
19 you've got to be kidding me. This is a roadmap for
20 making sure that I'm going to choose something you
21 can't do anything about, particularly an anthrax strain
22 or a plague strain that's resistant to both cipro and
23 doxycycline.

24 DR. WALDMAN: Maybe we could write two
25 reports.

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1 (Laughter and simultaneous discussion.)

2 DR. LaFORCE: That's right, maybe we could
3 fool them.

4 DR. OSTROFF: I think that's part of the
5 reason -- I mean, the list of what's in our Push
6 Packages we are trying to keep as circumscribed as
7 possible so that individuals don't have access to what
8 exactly is going to be in there, and part of the
9 difficulty is while Hopkins is publishing all of these
10 articles with recommendations concerning plague,
11 anthrax, et cetera, anyone has access to them, and they
12 would have to presume that we're not foolish enough to
13 go off on some completely other direction in terms of
14 any choices that we may make either in the civilian
15 sector or in the military.

16 DR. LaFORCE: Vaccines are the answer.
17 Vaccines are the answer.

18 DR. OSTROFF: But then the problem is the
19 same thing, that they'll just manipulate the strain --

20 DR. LaFORCE: No, no. Actually, it's
21 extraordinarily difficult. It is extraordinarily --
22 you could take the most resistance anthrax -- as long
23 as that IgG recognizes whatever epitope it's going to
24 recognize, adios. It's gone. It doesn't make any
25 difference whether it's sensitive, resistant, or

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1 whatever. Same thing for plague. Same thing for any
2 of these. This is why the issue of identifying these
3 presumptive ways of delaying things are really only
4 delaying tactics -- particularly with anthrax, or
5 inhalation anthrax -- until you can get real vaccine
6 into them because you never cure an aerosol exposure.

7 DR. OSTROFF: Well, fortunately, most of
8 these individuals would already have gotten their
9 vaccine, so then it's only a problem for the
10 dependents.

11 DR. LaFORCE: And in point of fact,
12 there's probably a good argument that you don't need to
13 do anything for those that have received vaccine.
14 You've got good animal data that suggests that 900
15 times above the LD50, at least here at Ft. Detrick,
16 they don't have any problem. They just sail right
17 through that challenge.

18 DR. OSTROFF: I doubt that anyone would
19 recommend, though, that they not receive antibiotic
20 prophylaxis --

21 LCDR. GRABENSTEIN: And the analogy is we
22 don't give antibiotics for every skin wound on the
23 basis they've been vaccinated against tetanus, but we
24 don't -- I mean, in my own mind, we don't know to the
25 nth degree how well the vaccine -- I believe the

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1 vaccine works in the unscintillational anthrax, but if
2 we can do something to save the extra X-percent --

3 DR. LaFORCE: Actually, you do have data.
4 You do have data from the goathair workers in that
5 there has never been a case, to my knowledge --

6 LCDR. GRABENSTEIN: Then it's 100-percent
7 effective.

8 DR. LaFORCE: Pardon me?

9 LCDR. GRABENSTEIN: Then it's 100-percent
10 effective.

11 DR. LaFORCE: 100 percent effective. And
12 in point of fact, when we were in those goat mills
13 doing the anthrax surveillance during all of these
14 aerosols, et cetera, the CDC in its wisdom, didn't give
15 us any prophylactic antibiotics at all. I mean, we had
16 anthrax vaccine, period.

17 DR. OSTROFF: It's a different era.

18 (Laughter.)

19 DR. LaFORCE: Well, I feel relieved. I
20 feel relieved.

21 (Simultaneous discussion and laughter.)

22 DR. LaFORCE: No, no, no, I'm serious. If
23 you go back, I don't think there's ever been a vaccine
24 failure even for inhalation -- despite the fact that --
25 you know, you've got pretty documented exposures.

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1 DR. OSTROFF: For people who have gotten
2 at least three doses.

3 DR. LaFORCE: Yes, for people who have
4 gotten at least three doses of anthrax vaccine. So I
5 might modestly disagree with that statement. Now, who
6 knows what it's like if you get, you know, spores that
7 you're inhaling -- I mean, I don't know, but at that
8 concentration, that would actually be very hard to do,
9 from an aerobiologic standpoint.

10 DR. OSTROFF: So I think that's another
11 consideration in terms of some of the antibiotics, but
12 not necessarily in terms of what antibiotic but in
13 terms of how much antibiotic, as whether or not the
14 individual has been vaccinated against some of the
15 agents.

16 DR. BERG: Are we going to have that
17 information and be able to act on it? My concept of
18 this is this has got to be kept as simple as possible,
19 and we're going to have to ask ourselves do we really
20 care about some sensitivity with doxycycline and --
21 considering the consequences, and we're probably going
22 to have to accept that some people are not going to
23 work -- it's not going to work, and we may not be in a
24 position of saying, did you get vaccine? Let me look
25 through your record here. We're talking about doing

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1 this in a public health forum, we're talking about
2 things like firemen with gallon jars of ciprofloxacin,
3 walking up and down and knocking on doors.

4 DR. OSTROFF: But I assume some
5 sensitivity in some place like the Persian Gulf would
6 be a pretty legitimate issue for forward deployed
7 soldiers.

8 DR. BERG: Considering the alternative?

9 (Simultaneous discussion.)

10 DR. OSTROFF: Well, if you had cipro
11 available.

12 DR. LaFORCE: Cipro would be fine. In that
13 situation, cipro may be fine. And in the cloudy
14 Northwest, we could do the --

15 DR. OSTROFF: A risk profile, right?

16 DR. BERG: But can we come up with
17 recommendations that say doxycycline are for Fort
18 Madigan and ciprofloxacin is for Saudi Arabia?

19 DR. OSTROFF: That would be complicated.
20 We'd have to keep it as simple as possible. I guess
21 one of the questions that I would ask, since we seem to
22 be in agreement about what the major issues are and
23 what the potential agents are, is to discuss how we
24 ought to sort of move the process forward, and what
25 would be the most efficient in terms of putting

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1 together our recommendations.

2 DR. BERG: Before we go into that, are we
3 going to address the off-label issue -- that is, are we
4 going to come up with some recommendation to ignore the
5 labeling and use it, or is that part of our charge?

6 DR. OSTROFF: Well, they very specifically
7 asked us to consider the issue of off-label use, and in
8 the specific request it's not mentioned, it only uses
9 the term "licensed products", so they're not talking
10 about experimental antibiotics or antibiotics that
11 haven't been approved. But I think as Ed pointed out,
12 I don't think you can ignore that particular issue, and
13 any material that's off-label, I think it would have to
14 be done under some sort of an IND. I don't think it
15 would be acceptable after the pyrostigmine experience
16 to do it in any other way. And it's going to be a
17 problem regardless of which one of these we recommend
18 because they both are off-label in certain
19 circumstances.

20 DR. LaFORCE: And I think having two or
21 three sentences explaining the dilemma is a dilemma in
22 that you're never going to have enough controlled
23 experience for these awful infections to be able to say
24 -- to be able to show FDA that you've got enough data
25 to show that these are efficacious, and that a lot of

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1 this is clinical guess -- I'm not sure I'd put that
2 down -- but I certainly would put a paragraph or two.

3 LCDR. GRABENSTEIN: The leap from multiple
4 uses of prytostigmine and multiple uses of antibiotics
5 within other kinds of bacterial infections is a lot
6 smaller chasm than it is with prytostigmine. Millions
7 of people have experienced the safety. I understand
8 the FDA's need for evidence before they'll render a
9 judgment.

10 DR. LaFORCE: I don't.

11 DR. WALDMAN: I'm having difficulty, as
12 Marc did before, imagining a situation where a fireman
13 comes and knocks on your door and says, "Excuse me, but
14 we have determined that you are potentially exposed to
15 a life-threatening agent from this terrorist attack
16 we've had in your city, and we've got this medicine for
17 you, but we can't give it to you unless you sign this
18 consent form." I just can't see that really happening
19 in real life. And I can understand why you feel that
20 that needs to be done, but it doesn't work like that.
21 It seems to me it might even be easier to go back to
22 the FDA and tell them we're having this problem, and
23 would you putting on your label that in case of a
24 terrorist attack it would be okay to use this drug.
25 It's easier to do.

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1 DR. OSTROFF: I guess you haven't dealt
2 with the FDA.

3 (Laughter.)

4 I mean, it's not that we haven't advanced
5 these arguments.

6 DR. LaFORCE: I can easily see this
7 fireman in the South Bronx getting mugged, then this
8 guy going down selling this stuff.

9 LtCOL. JOHNS: My prediction after talking
10 to some of the firefighters is, they will take the
11 clipboard from you, they'll hit the first house, that
12 clipboard will hit the garbage can because they don't
13 care, they are going to distribute and use the drug.

14 DR. OSTROFF: That's possible, but it
15 doesn't circumvent the need for DoD as a policy to get
16 INDs and have informed consent documents available in
17 circumstances where they may actually have to
18 distribute this stuff in a circumstance where it's off-
19 label. I mean, the difference is -- and, again, we've
20 been through this issue -- we've gone round and round
21 and round and round and round with FDA in that if
22 you're a clinician and you decide you want to give your
23 patients ciprofloxacin, as long as it's a licensed
24 product, you've more than welcome to do that and nobody
25 is going to question your individual decision to give

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1 them ciprofloxacin. But if you, as an agency, are
2 making recommendations to use a product for an off-
3 label use, then you must do it under the auspices of an
4 IND and recognize that this is not an approved
5 indication for that product.

6 So as soon as we, CDC, are telling the
7 State of Colorado, "We recommend that you use
8 ciprofloxacin in this situation," that's not the same
9 as the individual physician at Denver General Hospital
10 making a decision that they want to give individual X,
11 Y or Z a particular drug. And we can't get around
12 that, and I don't think DoD can get around that either.

13 DR. WALDMAN: Because people don't have
14 confidence in the Government.

15 DR. OSTROFF: Well, I think the
16 alternative -- and just playing devil's advocate -- is
17 that I think if someone finds out that this isn't an
18 approved indication for a product and that nobody told
19 them about it, they may well lose confidence in their
20 Government as well, and that's been the situation
21 repetitively and why we have to go the extra mile to
22 take that into account. I mean, at least one has to
23 make the effort to offer them the information.

24 DR. BERG: I think having lived through
25 part of the Persian Gulf experience and the anthrax and

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1 so on, as I recall, the biggest hue and cry was that
2 nobody told us this was an investigational drug, or an
3 investigational vaccine, even if they weren't -- you
4 know, in hindsight, everything looks a like clearer but
5 -- making an effort may pay dividends even if down the
6 road there will be people who say "I never signed it"
7 and there's no way to produce it and so on, but at
8 least that's a different approach than going out and
9 saying, "Look, this is technically an investigational
10 use of this."

11 DR. OSTROFF: To me, it's the equivalent -
12 - I mean, I recognize the extraordinary circumstances
13 of a bioterrorism attack, but when you go to a pharmacy
14 and they give you a prescription, they usually give you
15 a single sheet of paper that tells you what the drug is
16 about, and tells you what the side effects are, et
17 cetera, and you usually have to sign something before
18 you walk out the door, to indicate that you received
19 that.

20 DR. LaFORCE: Not in a pharmacy.

21 DR. OSTROFF: Sure you do. You received
22 that piece of information, and usually what they do is
23 they tell you you sign in one place if you don't have
24 any questions for the pharmacist, and you sign in a
25 different place if you do have questions of the

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1 pharmacist.

2 LCDR. GRABENSTEIN: It's a Medicaid
3 requirement which typically spills over to a standard
4 of practice.

5 DR. OSTROFF: And, quite frankly, what FDA
6 has agreed to is they are not asking us to do basically
7 anything more than that in this situation. They just
8 want some signature that the individual acknowledges
9 that they received some piece of information that tells
10 them this. And I think that we would feel obligated,
11 just like with those one-pagers that I passed around,
12 to give them the same type of information that you
13 would when you go to a pharmacy.

14 DR. LaFORCE: Actually, those one-pagers
15 were good. Did you happen to see those, the one-page
16 sheets?

17 LCDR. GRABENSTEIN: On the back of your
18 medical tag sheet, you have the signature.

19 DR. TSAI: That's essentially for therapy.

20 LCDR. GRABENSTEIN: Exactly. I agree to
21 take this medicine.

22 DR. BERG: I think doing something like
23 that shifts it from "you never told us anything" to
24 being able to say "Well, we did try to get the word
25 out," even if there were some individuals who didn't

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1 get it or didn't understand it.

2 DR. OSTROFF: And I think in this
3 situation you would have to do something like that.

4 DR. WALDMAN: I think part of the
5 organizational aspect of dealing with a situation like
6 this is to make sure, if there are requirements like
7 that, that they don't impede the rate at which you can
8 get everybody covered. If you have to do that, fine,
9 but then I think you need to augment it.

10 DR. OSTROFF: Well, I can tell you that
11 I've asked our bioterrorism group to actually go back
12 and make a determination for us as how much extra
13 manpower and how much extra cost it would be if we
14 actually had to get real informed consent from
15 individuals that we would be distributing the
16 medication for, to be able to demonstrate to FDA the
17 sort of logistical impossibility of having a three-page
18 informed consent form that people have to read through
19 and then have a number where they can ask questions.

20 DR. WALDMAN: I think you'd have to
21 question whether you could get real informed consent
22 under those circumstances.

23 DR. OSTROFF: Right. I mean, I think it
24 would be viewed as being coarse -- "if you don't take
25 this, you're going to die" -- I mean, somebody is going

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1 to say something like that to someone.

2 DR. WALDMAN: And the person is going to
3 say, "If you don't give it to me, you're going to die."

4 (Laughter.)

5 DR. OSTROFF: I think that the off-label
6 use is an issue, but I don't think it's an
7 insurmountable issue, and I would say that we clearly
8 feel that there is a preference for one over the other,
9 that we ought to convey that regardless of the issue of
10 whether it's off-label or on-label. I think if they're
11 relatively close to each other, it's probably something
12 that ought to be considered, but if there's clear
13 preferences, then we ought to go with that clear
14 preference.

15 DR. TSAI: The media will make the public
16 aware of all of these issues, at least I would assume
17 so.

18 DR. BERG: Do you know if these informed
19 consents -- are they going to have like a bar code on
20 them and then have a label that could be put on the
21 pill bottle and stuff like that, I mean, just for
22 tracking purposes?

23 DR. OSTROFF: I don't know the answer to
24 that. I mean, we haven't, as of today, still haven't
25 gotten anything back in writing from FDA as to what

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1 their requirements would potentially be so that we
2 could then negotiate with them.

3 I mean, I guess they're talking about
4 doing it almost as if it were some kind of research
5 thing, but certainly I think the tracking mechanisms
6 are important to talk about, and the simpler we can
7 make them, probably the better. But I do think if
8 you've got to do retrospective post-hoc studies on this
9 stuff, like for efficacy or effectiveness, then the
10 more that we have built in that we can go back and do
11 that, the better.

12 DR. BERG: Do we want to get into a
13 tracking -- if by tracking you mean somebody collects
14 all the informed consents and saves them.

15 DR. BRADSHAW: In the Gulf War we really
16 got into this issue, which is why we've gone to all the
17 effort to have the immunization tracking system that we
18 have with anthrax vaccine now, and, yes, it's a lot of
19 work, but, boy, I'll tell you, we have found the need
20 for it in trying to address all these claims and
21 concerns about adverse events and diseases and whatnot.

22 And even if it's rudimentary, I think -- if they're
23 going to require us to do the paperwork anyway, then we
24 might as well do it right, is all I'm thinking about.

25 LCDR. GRABENSTEIN: Taking it from the

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1 CDC's angle, if you go back to the Swine Flu vaccine of
2 '76, I think you need at least a registry of exposure.

3 DR. OSTROFF: Well, again, what we would
4 probably be doing is having -- I mean, you know, it's
5 anticipated, again, what goes on in the civilian sector
6 may bear little similarity to what you would do in a
7 military setting where you have much easier ability to
8 track people than we would have in a civilian sector,
9 but we would probably have central points of
10 distribution where people would come to, we wouldn't
11 likely have firemen going door-to-door.

12 We would likely have certain depots where
13 the stuff would be and people would come to those
14 depots and pick it up. And what we would do is have a
15 sign-up sheet where people are given a piece of paper
16 and they then signed along with their identifying
17 information as to how we could follow up with them
18 because with the example of anthrax where we would want
19 to switch over antibiotics after a five days. We have
20 to have some way to get back to these people.

21 DR. BRADSHAW: But I'm wondering if you
22 had that -- because you would have that so you could
23 follow up with them. I mean, wouldn't it be easy
24 enough if whatever that sheet of paper was, they come
25 to get their prescription, that the bar code is two

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1 things, peel-and-stick --

2 DR. OSTROFF: I think it would sound nice
3 if we could forward deploy the bar coding machines and
4 do all the other things, but in the emergency of
5 actually getting the drug out where you have 12 hours
6 or so, I'm not sure --

7 DR. BERG: You're going to reach a point
8 when people will just storm the barricades and say,
9 "The hell with your informed consent, I want the
10 medicine."

11 DR. OSTROFF: That's right. We anticipate
12 the problem of the media starts saying cipro is what's
13 going to be used and people are going to start breaking
14 into pharmacies all over the metropolitan area and
15 stealing whatever they can find and not bothering to
16 stand in line for several hours to wait to get their
17 medication. So I think it's going to be relatively
18 chaotic, not to mention everybody who is going to want
19 to disappear.

20 But getting back to this issue, it sounds
21 like we've identified the relevant issues that need to
22 be considered, and I guess the question would be, how
23 should we move forward in terms of responding to the
24 request. We will have the assistance of George
25 Christopher, and we will have the assistance of Lisa

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1 Ross.

2 DR. LaFORCE: You want to just draft
3 something, either dictate something or have Jean Ward
4 put something that's dictated -- I'm trying to keep the
5 work to an absolute minimum.

6 DR. OSTROFF: Well, what I was going to
7 suggest -- I doubt that we could do it between now and
8 the morning, but I think since we have -- what I would
9 suggest is working -- I would be happy to work with
10 Lisa and George and put together a strawman, and then
11 disseminate the strawman to the subcommittee, and then
12 I would think that we should be able -- instead of
13 needing to have a face-to-face meeting, I would think
14 that we should be able to do it by a conference call.

15 DR. LaFORCE: Super. And this is one I
16 really would not want to miss the deadline. We've got
17 60 days. Adm. Clinton -- I met with him about a month
18 ago, he explained all of this to me, I looked it over,
19 and that's when I called you. And then I thought this
20 really wouldn't -- I didn't think, was going to be
21 very, very overly complicated, and it seemed important
22 to Adm. Clinton --

23 DR. OSTROFF: Yes. I mean, I really --
24 once again, would work with George Christopher and the
25 rest of the group because Don pretty much set out all

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1 of the issues. I don't see anything in there that's
2 particularly controversial. So it should be relatively
3 straightforward.

4 I think we'll need some help in terms of
5 quantities and those sorts of things, but I would
6 imagine as long as we indicate the agents themselves,
7 that it would be up to the logisticians within DoD to
8 make decisions about how much they need to procure --
9 you know, what their planning notions are for.

10 DR. TSAI: Steve, an issue of civilian
11 preparedness -- do you remember a while back when we
12 were talking about distributing -- asiniodine
13 (phonetic) -- is it appropriate for everybody to have
14 it in their medicine cabinet? If these drugs are
15 indeed stable for five or six years, is there any
16 consideration to sort of make a recommendation like
17 that?

18 DR. OSTROFF: For the military or for the
19 civilian sector?

20 DR. TSAI: Everyone.

21 DR. OSTROFF: Not in the civilian sector.

22 I mean, everything would be antibiotic-resistant
23 because the problem that we always have even after you
24 give people a prescription for a medication is they
25 take whatever they didn't take and they leave it up on

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1 their medicine shelf, and the next time they're sick
2 they start taking it again. So, my guess is that if we
3 distributed ciprofloxacin, to everyone in the country,
4 when it was really needed, most of it would no longer
5 be there because they will have used it.

6 DR. GARDNER: Can I make a request that
7 you get a DoD document about what immunizations were
8 given -- that's this committee, right? I was surprised
9 this morning to learn that we're not using hepatitis-B
10 routinely and that we are using other things. Should
11 we be looking at questions such as smoking is
12 responsible for half of the pneumococcal invasive
13 disease in younger adults, should we be coupling
14 pneumococcal immunization in with our smoking program
15 somehow?

16 DR. OSTROFF: It was actually -- if I
17 remember correctly, in the last couple of months there
18 was an article in Clinical Infectious Diseases about
19 the cost-benefit of pneumococcal vaccination in the
20 military.

21 DR. GARDNER: Is it positive?

22 DR. BERG: Oh, very positive. It's
23 minuscule for any individual, but for the group as a
24 whole, if I recall, it was something like a couple
25 million dollars in ten years.

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1 DR. OSTROFF: I think it was in the Navy
2 that they did the analysis, right?

3 DR. GARDNER: That's a big ticket item
4 that we might -- this is the committee that would
5 consider that, right?

6 DR. WALDMAN: In the last few years,
7 there's been a lot of discussion about all of the
8 issues of immunizing --

9 (Simultaneous discussion.)

10 DR. LaFORCE: The AFEB just published last
11 year the compilation in terms of vaccines in the
12 military, plus all the AFEB recommendations on vaccines
13 for the last ten, 15 years. They are all there. And
14 so we'll send you a copy of the Red Book.

15 DR. OSTROFF: One question that I have in
16 terms of some of the presentations this morning is, can
17 somebody elaborate on where things stand with the
18 adenovirus vaccine in light of that outbreak?

19 DR. LaFORCE: There is no adenovirus
20 vaccine, and it's one of the key areas that the IOM is
21 now talking about in terms of the -- IOM Subcommittee
22 on Military Vaccines. And one of the challenges is
23 that this is a scandal, you know, to have a very
24 effective vaccine that all of a sudden has disappeared
25 and you see that blip that was up there. I've actually

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1 gotten two pieces of conflicting information. That's
2 why I was asking about whether there was any
3 reprogramming of recruits because what I've learned
4 after the meetings at the IOM was that the base
5 commanders, even with outbreaks of 4 in 7, to have been
6 able to sort of wire around these outbreaks such that
7 there hasn't been reprogramming, because the problem is
8 that if a recruit is sick for a week or five days and
9 then falls out of their training, they have to then be
10 either retrained or recycled -- that's the term -- they
11 have to be recycled, and that is very disruptive, from
12 everything that I've been able to find out. It turns
13 out that 15 or 20 years ago -- or longer than that, 20
14 to 25 years ago, prior to the 4:7 vaccine, recycling
15 was extremely common as well as hospitalizing all of
16 these recruits with 4 in 7. Now apparently there are
17 fewer hospitalizations and they put them through their
18 courses even if they're moderately or mildly ill, which
19 wasn't the case 20 years ago. Now, Ben, do I have that
20 right?

21 COL. DINIEGA: Yes, the impact of
22 recycling is less today. They still will graduate with
23 -- correct me if I'm wrong -- however, the case
24 definition, URI (phonetic) symptoms with fever, still
25 stands. And they do get admitted, although sometimes

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1 they don't get admitted to the hospital, they have a
2 special ARD ward, but they don't leave them in the
3 barracks. So, a lot of the admission reasons are for
4 nursing and supportive care so that the -- but there is
5 money in there, and I think Charlie Hoke had mentioned
6 that they put out the Request for Proposals and so on.

7 But we're going to hear about this in September more.

8 Some people wanted it to be on the agenda this time,
9 but it was just too full, and the IOM has taken up the
10 issue and is going to use adenovirus as a case example.

11 DR. LaFORCE: Case study. It's a case
12 study for military vaccines.

13 DR. OSTROFF: Did anybody type this strain
14 that caused the outbreak at Ft. Benning?

15 COL. DINIEGA: At Benning? I'm not so
16 sure that they know what caused --

17 MAJ. PAVLIN: They don't know yet. They
18 did have a lot of adeno -- and actually, just to
19 comment on that outbreak, it appeared that four people
20 -- I wasn't there, but I talked to some people that
21 worked on the -- four people (inaudible), about 50 to
22 60 developed fevers. They really think that most of
23 the rest of them was kind of a hysteria. They just
24 kind of admitted everyone to the ward and, you know,
25 sit tight because there were so many people coming

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1 forward that they just kind of put them into these new
2 ARD wards and let's sort it out as we can. I think it
3 was a very, very short hospitalization time, which
4 means that's another reason they want --

5 DR. LaFORCE: I would suggest that is the
6 definition of disruption. I mean, that's pretty
7 disruptive. Be that as it may -- okay.

8 (Whereupon, at 5:05 p.m., the subcommittee
9 was adjourned and the meeting of the full Board was
10 reconvened.)

11 DR. LaFORCE: Let's finish things off for
12 today. I have a couple of announcements. The next
13 AFEB meeting is going to take place here in Washington
14 at WRAIR. And I was going to try to get a hold of Ted
15 Woodward to have dinner with us. Ted was President of
16 the AFEB for how many years, Ben? Must have been ten,
17 15 years. He really has an enormous history as far as
18 the AFEB. And Stan Music was after me in terms of
19 saying, "Gee, you know, could we have a chance to sort
20 of chat with Ted" -- Stan, of course, studied with Ted
21 years and years ago -- and so I thought if our next
22 meeting was going to be in Washington, what I'd do is
23 try to set something up -- because it's going to be in
24 September, the weather is still pretty good -- and I've
25 got a place that I'm staying at, a small townhouse in

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1 Georgetown, and maybe have a reception at my place, and
2 then just have dinner up the street somewhere in
3 Georgetown.

4 COL. DINIEGA: The dates are 12 and 13
5 September. They are locked in. WRAIR knows that we're
6 coming.

7 DR. LaFORCE: So, if we come in September,
8 as I say, it would be nice to have some sort of
9 reception and some sort of chance to meet Dr. Woodard.

10 Two, we have two persons that are leaving
11 the AFEB --

12 COL. DINIEGA: Well, we have actually
13 seven, but two are here.

14 DR. LaFORCE: Two are here, Andy Anderson
15 and Ron Waldman, and in honor of their being here and
16 leaving the Board, we have a plaque. Here you are,
17 Andy, in appreciation of your contributions as a member
18 of the AFEB.

19 (Applause.)

20 COL. DINIEGA: We also have a certificate.

21 (Simultaneous discussion.)

22 COL. DINIEGA: Capt. Trump has those.

23 DR. LaFORCE: Oh, yes, before Capt. Trump
24 leaves and the institutional memory is gone.

25 CAPT. TRUMP: It's a Certificate of

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1 Appreciation to Henry Anderson for exceptionally
2 meritorious service as a member of the Armed Forces
3 Epidemiological Board from July 1996 to July 2000, for
4 his contributions and expertise and his leadership on
5 the Board, and his service especially as Chair of the
6 Environmental and Occupational Health Subcommittee.
7 Dr. Anderson significantly enhanced the health and well
8 being of Soldiers, Sailors, Airmen and Marines, DoD
9 civilians and family members, and it's signed by Dr.
10 Sue Bailey, Assistant Secretary of Defense for Health
11 Affairs.

12 (Applause.)

13 DR. ANDERSON: Thank you.

14 DR. LaFORCE: To Ron Waldman, deepest
15 appreciation for contribution to the Armed Forces
16 Epidemiological Board.

17 (Applause.)

18 CAPT. TRUMP: A Certificate of
19 Appreciation for his service, which happens to be from
20 July 1996 to July 2000 also, and for his outstanding
21 leadership in infectious disease and for health issues,
22 even though he couldn't continue to do as much as he
23 would have liked to, that's for Board activities and
24 for policy recommendations and program reviews. And,
25 again, signed by Dr. Bailey.

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1 DR. WALDMAN: Thank you.

2 (Applause.)

3 COL. DINIEGA: We will mail out -- to the
4 other members who are departing, we will mail out their
5 plaques and certificates.

6 I have some announcements. Just a few
7 reminders. Don't forget to turn in your badges,
8 otherwise, they'll come looking for you. Tomorrow -- I
9 have schedules here -- tomorrow is a closed session for
10 the members, and we start at 7:30. And I have
11 clearances on everybody except -- and it's just some of
12 them go through easy, some of them don't. There's a lot
13 of paperwork, we all know that, and it just takes a lot
14 of time. So the ones that would have to step out --
15 Mr. Plasse's presentation is one, and then actually
16 LtCol. Schnelle has one classified, so I told her to
17 show it at the very end of Mr. Plasse's presentation so
18 the others can come back in and join the group, and
19 we'll get the guideline just to the discussion, what
20 can be said and what can't, but the following cannot be
21 here during the classified presentation -- Dr.
22 Alexander, Dr. Atkins, Dr. Gardner, Dr. Sokas -- is she
23 coming tomorrow?

24 DR. ALEXANDER: Yes, she's coming with me,
25 but we're going to be come a little late.

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1 COL. DINIEGA: Yes, but be here for --
2 once Mr. Plasse is done, you can be in here. Dr. Tsai,
3 you can come a little bit late. And Col. Graham -- I
4 guess he knows he can't be here during the classified
5 brief. The rest of it is going to be open and -- the
6 rest of the presentations and the discussions, so we
7 need all the members of the Board to address it. I
8 will hand out tomorrow previous recommendations from
9 previous deliberations.

10 In addition, tomorrow we do want to try to
11 get done with making recommendations on the threats and
12 try to finish up the business, and in the Executive
13 Session during the rest of the morning, we will try to
14 give conceptual approval for the initial draft
15 recommendations or thoughts, and then we will try to
16 finalize it by e-mail.

17 We will be having a working lunch from
18 Heavenly Ham. It's going to be a box lunch and will
19 cost essentially \$7 a person, so if you can come with
20 \$7, and I'll pass out the order forms in the morning
21 and then we'll have to call it in, but essentially you
22 create your own box lunch with sandwiches, choice of
23 bread, condiments, side dishes, cookies and beverage.
24 And then they'll deliver it. I'll pass the forms out
25 tomorrow morning and then collect them up with the

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1 money.

2 For dinner tonight, do we want to set a
3 time for those interested to just meet in the lobby?

4 DR. LaFORCE: Yes. What time, 7:15 or
5 7:00, or what's your pleasure?

6 (Simultaneous discussion.)

7 DR. LaFORCE: We'll meet at 7:00 o'clock
8 in the lobby.

9 (Whereupon, at 5:15 p.m., the meeting was
10 adjourned, to reconvene at 7:30 a.m., on Wednesday, May
11 31, 2000, in the same room.)

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