

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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WEDNESDAY, MAY 31, 2000

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P R O C E E D I N G S

(7:45 a.m.)

DR. LaFORCE: This is the second day's session of the AFEB. I don't have very many welcoming remarks. I do want to make sure that we start off on time at 7:45, in a few minutes.

First of all, I want to thank Ben for sort of serving like a chaperon last night while we wandered around the countryside assaulting all crabs that were edible. It was actually a great deal of fun.

The scope for today's activities are pretty well lined up on the agenda. The Board has got some work in terms of the recommendations that were drafted. I know that Stan has already started a redraft on one of the recommendations, and hopefully we will get to that as we work through lunch.

Without further ado, I need to introduce Admiral Johnson who is a newcomer today. Admiral Johnson, welcome.

RADM. JOHNSON: Thank you.

DR. LaFORCE: Any other newcomers that we have today?

(No response.)

Okay. Ben, do you have something?

COL. DINIEGA: I always have something. A

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1 reminder to the Board members, when you get back fill
2 out your travel settlement form and when you get paid
3 with a receipt, please send us a copy of that so we can
4 keep the books balanced.

5 As you saw the agenda, this day is filled,
6 too, and we should be done before 2:00 o'clock. Are
7 there any members who need a ride to the airport or
8 shuttle or taxi -- it would be a shuttle -- is
9 everybody taken care of? Okay.

10 A reminder again, the meeting is being
11 transcribed. You need a security clearance to be in
12 here. I passed out the working lunch forms. We are
13 not breaking for lunch. Anybody going to be staying
14 for lunch who didn't get a lunch form, let me know.

15 Everybody who is invited to today's
16 session and is cleared, can stay for the working lunch
17 and, if you want, you can stay for the Executive
18 Session, too. The briefings are going to be going on
19 until 10:15. The people who didn't have the clearances
20 will join us after the two classified briefings. We
21 will try to do all the BW discussions and
22 countermeasures for the threat through the working
23 lunch, and then the Executive Session we will try to
24 get the other draft recommendations approved by the
25 rest of the Board. So when we send the final over to

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1 Health Affairs and SGs, we can say that the full Board
2 approved all the recommendations.

3 A status on the last meeting's
4 recommendations, there are only two that are left for
5 signature, and that is Dr. LaForce and my signature,
6 and that is on TB recommendations to the services, and
7 also the Military Public Health recommendations, and
8 Dr. LaForce will sign it before he leaves today.

9 The main goal for today is to get our
10 information background on BW threats for this year,
11 listen to what happened to the recommendations from
12 last year, and then draft up any new recommendations
13 for the threat list this year.

14 In front of you are a whole bunch of
15 handouts from previous efforts this Board has done on
16 BW issues, and those are given to you as background and
17 a way to take a look at what we've done before.

18 There is a DoD instruction, I think, on BW
19 and bio/chem issues and what our role is, and our
20 primary role is to provide advice to the Assistant
21 Secretary of Defense for Health Affairs, review the BW
22 threat list and make recommendations on it. Any
23 questions?

24 (No response.)

25 I guess we are ready to go.

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1 (The classified portion of the meeting is
2 transcribed under separate cover.)

3 (Whereupon at 9:00 a.m., the open session
4 of the Board resumed.)

5 DR. LaFORCE: Okay, I guess we can resume
6 now. Col. Takafuji.

7 COL. TAKAFUJI: Members of the Board, I am
8 Col. Takafuji, and right now I work at the Office of
9 the Assistant Secretary of Defense for Health Affairs.
10 My boss is Adm. Clinton, and my ultimate boss is Dr.
11 Bailey. It's an honor for me to be here today. I have
12 had a long relationship with the AFEB going over many
13 years. At one time, I had Col. Withers' position, but
14 I also, having been Commander of this Institute here as
15 well as the Walter Reed Army Institute of Research,
16 I've had the opportunity and pleasure of hosting the
17 AFEB on numerous occasions. So it's really a pleasure
18 for me to be here in a different capacity representing
19 OASD Health Affairs.

20 As you know, the Board made some
21 recommendations to the Department of Defense last year
22 pertaining to the Threat List. Some of that
23 information, of course, is in front of you, and I won't
24 go over all the details of that.

25 Today, I will discuss some of the actions

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1 that have been taken in regards to the recommendations.
2 Col. Kimm will address some things pertaining to the
3 DoD Directive and where we are with that, as well as
4 things that directly relate to the JCS Threat List. Col
5 Schnelle will talk about some of the things that we're
6 doing in terms of the medical threat assessment. So I
7 will defer those issues to these individuals.

8 Let me just, first of all, say that in the
9 recommendations that were made in May of 1999, the
10 Board had recommended that DoD aggressively pursue
11 clinical investigations that were necessary to revise
12 and/or accelerate the current anthrax vaccination
13 schedule. We have done that and we have done that
14 through the anthrax vaccination/immunization program,
15 or the AVIP as it is also known, and that is in regards
16 to looking at the current vaccine that's FDA approved.

17 There is a research effort that perhaps
18 will be discussed later that involves the next-
19 generation anthrax vaccine, a recombinant vaccine.
20 That was not part of the Board's recommendations, but
21 that may be of some interest to the Board.

22 Regarding the recommendations pertaining
23 to DoD Directive 6205.3, which is the regulation that
24 governs immunizations, that regulation is dated 1993,
25 and obviously in need of some relook. That process is

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1 taking place, and Col. Kimm will comment on that more.

2 In regards to recommendation that the
3 Board made pertaining to medical surveillance as an
4 early detector for exposure to biological warfare,
5 that's something that we certainly are very keenly
6 aware of, as was mentioned before. There is a fine
7 line between endemic disease and deliberately generated
8 outbreaks of disease that are manmade in nature, and
9 sometimes it's very confusing, especially in the early
10 days of an outbreak in terms of what exactly is
11 happening, and we are concerned about this and we
12 understand the importance of surveillance. This is an
13 effort that is a tri-service effort, primarily led by
14 the services and the CINCs, to look at surveillance in
15 an entirety, realizing that unusual events should ask
16 questions pertaining to whether this is indeed a
17 biological warfare or biological event of some sort.

18 The Board also recommended that there be
19 some effort in terms of software programs that would be
20 directed at the reporting and recording of the
21 administration of doses of any vaccine, and we are
22 doing that. It is being done in the context of the
23 computerized health care system. Some people know it
24 as CHCS2, and so forth. It is all part of a tri-
25 service wide approach in terms of computerizing so that

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1 the health record would be readily accessible to health
2 care providers both in the field as well as in-
3 garrison. And that is part of the whole process, and
4 immunizations represent one part of that whole effort.

5 So that is ongoing. As that evolves, certainly DoD
6 Health Affairs would be glad to update the report on
7 the status of that.

8 And, finally, on the issue of education
9 and marketing programs for each of the vaccines, we
10 have learned quite a few lessons from our recent
11 adventure with the anthrax vaccine and the importance
12 of good marketing is of paramount importance. And that
13 clearly is part of the changing attitude that is
14 reflected in this country where people demand to know
15 all they can find out about a vaccine before they
16 receive a vaccine. And we are dealing in a different
17 military setting where people are much more informed
18 and feel that they have many more rights to make
19 decisions even on things that may seem to many of the
20 old timers to be rather straightforward in terms of
21 policies and procedures. This is part of the changing
22 military environment in which we operate, but the need
23 for marketing and information is very clearly evident.

24 So we are very much aware of that and we plan to do
25 that with every vaccine.

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1 With that in mind, I'd like to turn the
2 discussion over to LtCol. Kimm and to LtCol. Schnelle
3 because I really think the thrust of this discussion
4 this morning should refocus on what we are doing with
5 the Threat List. Let me just preface the comments by
6 saying that we met yesterday to go over a few things,
7 and we welcome the comments, additions, recommendations
8 of the Board's we are taking the processes forward in
9 terms of working with the JCS validated threat list.

10 LtCol. Kimm.

11 LtCOL. KIMM: Thank you, sir. Good
12 morning. I'd like to take just a few minutes to
13 address a couple of your recommendations before we get
14 into what we hope is the meat of the discussion, and
15 that is where do we go from here with regard to
16 creating a medical threat assessment. First slide,
17 please.

18 (Slide.)

19 I'll be addressing very shortly an update
20 on the DoD Directive that really is the driver here for
21 the threat list, and introduce to you our initial
22 approach on the medical threat assessment, and then
23 LtCol. Schnelle will follow me there.

24 Other recommendations, I think Col.
25 Takafuji has already addressed those. I don't think

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1 there are any others, but perhaps some others will come
2 out towards the end of the discussion. Next slide,
3 please.

4 (Slide.)

5 You have in front of you a copy of the DoD
6 Directive on DoD Immunization Program for Biological
7 Warfare Defense. This is the driver for what we are
8 talking about here today and, as you note at the top,
9 As Col. Takafuji mentioned, it is somewhat dated, dated
10 1993, and I think as a result of the passing of time
11 but probably more importantly your careful review of
12 the threat list and comments, have certainly given us
13 some significant food for thought about things we might
14 like to incorporate in a future revision of this
15 document.

16 For those of you who are new to this
17 process, new to the Board, this policy essentially does
18 several things primarily in its purpose, it establishes
19 responsibilities among a variety of players including
20 the Chairman of the Joint Chiefs, and I'll address that
21 briefly; provides vaccination guidance related to
22 biological warfare defense -- and I think that's an
23 important point to make. Col. Takafuji brought up the
24 point about counter-crop and potential other uses of
25 biological warfare agents. Since this directive is

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1 solely focused on immunization, I think that has, for
2 the right or wrong reason, somewhat limited our scope.

3 So as we go back and readdress the revision of this
4 directive, perhaps it may be appropriate to broaden the
5 scope to other uses, or perhaps create another
6 directive specific to these other uses.

7 Also, it applies in peacetime and wartime
8 and, very importantly, designates the Army as the DoD
9 Executive Agent in this area.

10 As I mentioned, some of the
11 responsibilities that are outlined are responsibilities
12 of the Chairman. And, in brief, the responsibility of
13 the Chairman of the Joint Chiefs, with the assistance
14 of DIA, is to validate and prioritize the biological
15 warfare threats.

16 I am in J-4, the Medical Readiness
17 Division. We are not the lead, we collaborate with the
18 J-2 on the intelligence side, but this is staffed, as
19 was mentioned earlier, throughout the Joint Staff as
20 well as with the CINCs and services. But I think it's
21 important, if you look at Enclosure 2 to the DoD
22 Directive, and look at what the perhaps somewhat dated
23 definition of "biological warfare threat" is, No. 2.
24 Listed there is a definition -- I can read it -- "A
25 biological material planned to be deployed to produce

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1 casualties in humans", and I think this definition that
2 has somewhat limited our scope because that statement,
3 "planned to be deployed", leads to decisions based upon
4 intelligence and based upon calls about weaponization,
5 proliferation and intent to use. Next slide, please.

6 (Slide.)

7 Based upon that thought, I think we'll get
8 into the next portion of the briefing -- but as was
9 mentioned, the proponent for this directive is the ASD
10 strategy and threat reduction. We are going to work
11 together through our partners at OSD to get the ball
12 rolling to update this and really go back and think
13 about it. Next slide, please.

14 (Slide.)

15 We were tasked -- we have another package
16 in front of you, and the cover of it is a letter from
17 Dr. Bailey, the ASD Health Affairs, a letter to the
18 Chairman of the Joint Chiefs that requested that the
19 Chairman, through his staff, conduct a medical risk
20 analysis and incorporate this into the Chairman's
21 threat list. I got together with my colleagues in J-2,
22 and the initial intent was to come up with some sort of
23 consolidated list, to use the existing list and
24 incorporate a medical threat assessment.

25 I think it was pretty evident from the

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1 last discussion that the list is fairly complicated as
2 it is, and so I guess at least for the interim that was
3 put in the "too hard to do" box, but I think we did
4 make some great strides, and if you follow through the
5 package, the response back to Dr. Bailey from the
6 Director of the Joint Staff for his office, which is
7 the office that commonly replies to letters to the
8 Chairman. It mentions several significant things.

9 In the first paragraph, it mentions in the
10 second sentence that "This reply has been staffed with
11 the Joint Staff, the services and the combatant
12 commands" meaning that they are all onboard,
13 recognizing the significance and the need for a medical
14 threat assessment, and that's a very significant point
15 in and of itself.

16 In our role, the Joint Staff do several
17 things. We integrate between the CINCs and the
18 services in this manner, but also we are the interface,
19 if you will, between OSD and those organizations.

20 And also toward the end of the first
21 paragraph, it mentions that at least for this year,
22 once it comes out, "As an interim measure, the cover
23 memo to the Chairman's threat list is a memo signed by
24 the Chairman of the Joint Chiefs, another very
25 significant matter in and of itself, that will refer

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1 users of the threat matrix to your tier ranking as
2 additional information for those making decisions about
3 programming and resource allocation decisions.

4 I think this is another important fact in
5 that we already mentioned that the DoD directive was
6 specific to immunizations. I think this fact
7 recognizes that there are other users of this threat
8 matrix, to include those in the vaccine community.

9 And then in the second paragraph it
10 mentions that the Director for Logistics, my boss, Gen.
11 McDuffy, has requested that the Office of the Army
12 Surgeon General, in conjunction with the services,
13 perform this medical risk assessment, and this is for a
14 variety of reasons. One, in our view, recognizing the
15 fact that the Secretary of the Army is the Executive
16 Agent and has the responsibility to do so, but also we
17 are a very small staff, and are not properly staffed to
18 conduct this assessment.

19 So the final letter in the back is a copy
20 of Gen. McDuffy's letter to the Army Surgeon General.
21 The last point I'd like to make is in the third
22 paragraph that "we'd like this medical threat
23 assessment to be done in conjunction with the service
24 not only medical but also research and development
25 experts as well as users. This is to be a multi-

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1 disciplinary approach, a coordinated effort that occurs
2 on a recurring basis. This could be an annual
3 validation, some assessment could be made about whether
4 or not perhaps agents were added to the threat list
5 from one year to another, or perhaps recent
6 developments and countermeasures might somehow impact
7 the threat. So it could be just an annual review and
8 validation, or perhaps this medical threat assessment
9 would be totally revised based upon additional
10 information.

11 So I'd now like to, unless there are any
12 questions, introduce LtCol. Schnelle, and she is going
13 to present to you our initial concept of what this
14 medical threat assessment might look like, the approach
15 that we suggest, and then hopefully generate some
16 discussion and feedback from members of the Board and
17 others in the audience.

18 LtCOL. SCHNELLE: Thank you, LtCol. Kimm.

19 LtCol. Kimm set the stage very well in
20 stressing that the goal of the medical threat
21 assessment is to integrate the DIA intelligence threat
22 assessment with the medical aspects so that we can use
23 that combined product to guide us in our prioritization
24 of medical resources. Next slide, please.

25 (Slide.)

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1 So this is essentially the goal of this
2 medical risk assessment, and it does explicitly state
3 in one of those three memoranda that the goal is to
4 prioritize for the purpose of making more effective
5 resource decisions in acquisitions, stockpile, medical
6 research, and so forth. Next slide, please.

7 (Slide.)

8 Before I go into our approach, I just want
9 to review the methodology that has been traditional
10 with the Armed Forces Epidemiological Board for the
11 last several years. We received the validated threat
12 list from the Chairman of the Joint Chiefs of Staff.
13 It comes through Health Affairs at the DoD level and
14 then at the Army Secretariat level, comes to the DoD
15 Executive Agent, which is in my office, and then in
16 consultation with the services and through presentation
17 to this Board and taking back your recommendations --
18 the arrow that's missing here -- that they take back to
19 Health Affairs for their execution of policy
20 appropriately through the DoD directive or other policy
21 mechanisms. So this is the procedure, just to refresh
22 our minds on this, that we use in examining the
23 intelligence threat and asking ourselves what are the
24 medical implications of that threat assessment to the
25 medical community. Next slide, please.

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1 (Slide.)

2 So it is essentially a four-step process
3 that we've come up that we want to share with you today
4 and take back your thoughts and initial concerns about
5 this approach. So, Step 1 is fairly straightforward.
6 We get the threat list but, most importantly, we
7 convene a Joint Service Medical Panel to oversee the
8 contract. This is to ensure that this is not just the
9 work of one contractor or one office, but is truly an
10 integration of the user community, the research
11 community and, of course, all the services. So we
12 would convene this panel. They would actually review
13 the draft Scope of Work, and then review the various
14 project IPRs throughout the course of the project.
15 Yes, sir?

16 COL. DINIEGA: I have a question on this,
17 LtCol. Schnelle. Who chooses the members of this
18 panel?

19 LtCOL. SCHNELLE: This panel?

20 COL. DINIEGA: Right.

21 LtCOL. SCHNELLE: I'm open to your
22 guidance on that. I was essentially going to consult
23 the various members here and staff the panel, but it
24 has not been prechosen at this point, no. So if anyone
25 has any particular guidance or recommendations, I'd be

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1 happy to take that back to initiate that process.

2 In Step 2, we'd actually convene the
3 Medical Risk Analysis Panel. Essentially, we'd be
4 letting a contract in order to do the analytical and
5 report capabilities, but that does not exclude the fact
6 that many members in the military community will be
7 involved in the work, it just means that we're going to
8 pay someone to do all the dog work that lies behind the
9 actual contributions of the expertise. And I strongly
10 recommend that in the Scope of Work we explicitly
11 require the contractors to consider the AFEB
12 recommendations in May '99, to consider the CDC risk
13 analysis product that I saw for the first time
14 yesterday, and to review FM 8-9 which addresses
15 prioritization of biowarfare agents, and any other
16 relevant document. There's no point in reinventing the
17 wheel here, a lot of this information is out there in
18 one form or another, so we shall ask them to consider
19 that information. Next slide, please.

20 (Slide.)

21 Then in Step 3, we would develop medical
22 risk conclusions for each bioagent. It's very
23 important at this point that we define our criteria
24 very carefully, and I'll talk about the criteria in
25 more depth later; that we evaluate the impact of each

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1 criteria for each bioagent and then, if necessary, we
2 weight those criteria appropriately. And I harken back
3 to a long time ago, the decision matrix that many of us
4 learned about in the Command and General Staff Course.

5 And then for each bioagent, using these criteria in a
6 very consistent methodology, we come up with a
7 conclusion as to the medical risk impact of the agent.

8 And I have an example slide to show you what this
9 might look like. Next slide, please.

10 (Slide.)

11 Now, I hasten to add, this is just an
12 example, not in any way limiting the work of the
13 Medical Risk Analysis Panel to use our categories of
14 High, Medium, Low -- they might prefer Category 1, 2,
15 3, wherever the data analysis takes them, but just as
16 an example this is a typical decision matrix with
17 criteria along the left side and then Agent 1, Agent 2,
18 and Agent 3 along the top. So, for each agent that you
19 would consider the impact of the particular criteria,
20 and then you would come up with some sort of assessment
21 using a weighting mechanism -- High, Medium, Low. Then
22 at the end of the chart, or the end of the analysis,
23 you'd be able to make some crisp, firm conclusion that
24 for this agent the ultimate risk is whatever it is.
25 And I've shown as an example the tier levels that you

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1 came up with in your last set of recommendations. I
2 believe you divided your agents by tier levels 1, 2 and
3 3, for example. So this is just a model of what this
4 analytical process might look like. Are there any
5 questions? Yes?

6 DR. BERG: I can't read the yellow color.

7 LtCOL. SCHNELLE: I'm sorry. I did that
8 just to challenge you, but it says "Medium".

9 DR. LaFORCE: Where's mortality?

10 LtCOL. SCHNELLE: Thank you, that's a good
11 point. I couldn't fit all the criteria we talked about
12 yesterday on the chart, so I just put in the ones that
13 fit. And I list them in more detail in a later slide.

14 But there are many more criteria than this. I lack
15 the PowerPoint ranger skills to produce a slide as
16 complicated as Mr. Plasse's, I'm afraid. Next slide,
17 please.

18 (Slide.)

19 COL. TAKAFUJI: Could you go back to that
20 slide? Okay. This is where I would welcome the advice
21 of the AFEB because that listing on the left side are
22 the criteria that we would determine the medical impact
23 of each of these agents. So I ask you to spend some
24 time on that -- morbidity, mortality, communicability,
25 infectivity -- the personal protection refers to the

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1 fact that we may or may not have troops that are
2 vaccinated, for example, or we may or may not have
3 antibiotics that would be available, and so forth. So,
4 under Personal Protection, that can be divided out a
5 little bit more, too.

6 Incubation Period refers to the fact that
7 many agents are going to have explosive impact early --
8 for example, the toxins as the best example, are going
9 to have entirely different kind of impact on the
10 military unit than something that would be incubating
11 in the body for a period of time. So I ask for your
12 comments in regard to those categories.

13 COL. DINIEGA: Ernie, on the Personal
14 Protection, it might be better to -- in my mind, to
15 divide that into medical and nonmedical because then
16 you have the issues of masks and overgarments, et
17 cetera, et cetera. And I think just as a reminder to
18 the Board, I was called by J-4 -- not today, but J-4
19 called me -- but the question to me was, when we made
20 our recommendations last year, what were our criteria
21 for putting diseases into the different tiers. And
22 there has to be a way to go back and look at how we
23 quantitated or what criteria we used, et cetera, et
24 cetera. So I think this is a very important thing, and
25 the Board should really take a good look at what

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1 criteria they should take a look at in order to arrive
2 at a medical risk conclusion.

3 LCDR. JOHNS: Malcolm Johns, with HHS. My
4 immediate thought is that you need to also categorize
5 for each agent what kind of medical resources to care
6 for your casualties are gong to get tied up, and for
7 how long. TOP-OFF Denver taught the lesson that you
8 can very quickly overwhelm a medical capability with
9 mass casualties that require intensive care.

10 LtCOL. SCHNELLE: That's a good
11 suggestion, and let me just -- and it's also important
12 to understand that the criteria we're talking about, as
13 you just identified yourself, would not only include
14 the medical -- the strictly medical aspects of the
15 disease, but also the medical operational aspects of
16 the disease as well. So that's why we -- this is not
17 meant to be an all-inclusive list in any way
18 whatsoever. In researching FM 8-9 and the CDC work,
19 the Medical Risk Analysis Panel may well discover even
20 more criteria than we're going to discuss here today.
21 As Col. Takafuji suggested, though, we are most
22 interested in taking your thoughts of what are the most
23 significant criteria to ensure that we keep a focus on
24 those issues as well as broadening our focus to
25 anything else that might have emerged in these

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1 documents. Any other thoughts? These are good ones.
2 Yes, sir?

3 DR. ANDERSON: Anderson. Do you have a
4 definition of what High and Medium and Low means?

5 LtCOL. SCHNELLE: No, sir, I'm just
6 showing this as a model of what it could look like.
7 Certainly, in the product there must be careful
8 definitions of High, Medium and Low. I'm just kind of
9 modeling a way this might look. I found that when I
10 tried to describe it verbally with hand-waving, it
11 didn't work very well. Any other thoughts or
12 suggestions?

13 (No response.)

14 Next slide, please.

15 (Slide.)

16 So, having come to this analysis agent-by-
17 agent, the final product would be essentially the
18 medical risk conclusions integrated with our
19 intelligence threat estimate. Next slide, please.

20 (Slide.)

21 And, not surprisingly, that would look a
22 lot like the previous matrix. Since essentially this
23 decision matrix technology, or technique, is a way of
24 taking a multi-variable problem and condensing it into
25 a two-dimensional form. I mean, that's essentially

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1 what the process is. So, again, using the language
2 form the previous AFEB recommendations, along the left
3 column you would have the biowarfare agents categorized
4 in accordance with the medical risk conclusions arrived
5 at in Step 3. Along the top, you would have the agents
6 categorized in accordance with the intelligence
7 assessment provided by the Chairman of the Joint Chiefs
8 of Staff from the Intelligence community. And then the
9 combination of those two assessments would then allow
10 you to make a defined -- it would have to be carefully
11 defined, as the gentleman there pointed out -- a
12 defined statement of the ultimate risk that we would
13 use in prioritizing medical resource decisions and
14 efforts. Next slide, please.

15 (Slide.)

16 Once that is done, once that model, that
17 analysis, is completed, it would not have to be
18 extensively repeated every year. All we would need to
19 do is allow us to examine if any criteria changed since
20 the last year. If an agent was weighted as Low because
21 a vaccine was not available and a vaccine has since
22 become available, then we would re-evaluate the medical
23 risk conclusion for that agent using the defined model
24 developed by the contractors. So, the good news is
25 here we don't have to hire contractors every single

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1 year. They are not necessarily being paid for the
2 explicit conclusions they will reach, they are being
3 paid for developing the methodology that the medical
4 community will use to maintain and sustain those
5 conclusions. Did I state that clearly? I've worked on
6 that a lot.

7 And then, also, the importance about this
8 model is that it allowed a consistent analysis of the
9 agents across a multiple variety of aspects, criteria
10 and variables. So, instead of getting into these rather
11 bizarre discussions where two people are discussing the
12 relative availability of vaccine and three other people
13 are saying, "Well, you don't understand, the mortality
14 is so much higher", and no real conclusion can be
15 drawn, we now have a framework for having our
16 discussions in a very focused and logical manner.

17 And the nice thing about this is it can
18 then be customized for an operational or specific
19 threat. Next slide, please.

20 (Slide.)

21 So, you could take the same matrix, but at
22 the top instead of taking the global DIA threat list,
23 all agents all over the world, suppose you were only
24 interested in the threat list for a particular country,
25 or a particular operation, or a particular CINC area,

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1 then you would simply take the Intelligence assessment
2 for that country, operation and area, and apply it in
3 this matrix, work the calculations, the algebraic
4 rules, and you would have a medical risk analysis for
5 that operation, CINCDom or area. So it could be very
6 easily customized to whatever the specific intelligence
7 threat estimate is for that operation. Are there any
8 thoughts or questions?

9 (No response.)

10 Well, I actually got through the hardest
11 part of the brief, so after this it's all downhill.
12 Next slide, please.

13 (Slide.)

14 So, how would this change, if it would
15 change at all, the process that I shared with you
16 earlier? Another good news is it doesn't change the
17 process all that much. Each year, the DoD Executive
18 Agent would receive the validated Chairman, Joint
19 Chiefs of Staff Threat List. We would then talk to the
20 medical community and ask if any of the criteria had
21 changed in a significant way since the last review of
22 the threat list. If the criteria have changed in some
23 way, we would then update, using the defined
24 methodology already approved by the AFEB, we would then
25 update the risk assessment matrix and present it to the

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1 AFEB for your approval, review, validation.

2 If some criteria had changed so
3 substantially that a new assessment of that particular
4 impact of that criteria was necessary, then the AFEB
5 would ideally have the expertise available to focus on
6 that particular issue and make appropriate
7 recommendations concerning that new variable. And then
8 we would return the product back up to Health Affairs
9 through the Army Secretariat channels. Yes, sir?

10 COL. DINIEGA: I have a question on the
11 AFEB role in this. I think the determination of
12 criteria is something that the Board probably should be
13 able to review the criteria every year to see if it
14 needs changing.

15 Your third bullet on there says "reviews
16 and approves". Does that mean you are looking to the
17 Board to review the results of the risk assessment and
18 bless the result?

19 LtCOL. SCHNELLE: I think so because no
20 model is perfect. So we might do this model once.
21 Some small changes over time might have some unforeseen
22 circumstances where the results, the decisions reached
23 might not pass the common sense test. I'm using an
24 extreme example, but I think that's relevant. So, I
25 think we do need the AFEB review of the results each

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1 year just to make sure that the model that is developed
2 makes sense, and continues to make sense in ensuing
3 years. I don't think it needs to be a complete review
4 of the methodology, just of the results to make sure,
5 gosh, that does make sense. Yes, I agree with that.

6 COL. DINIEGA: Well, I think we're talking
7 -- the methodology is what I'm talking about that the
8 Board probably should review to make sure that it's up-
9 to-date and the right criteria is being used.

10 The application of the methodology and the
11 results, I'm not so sure if it should come back to the
12 AFEB. I mean, if the methodology works, unless it's
13 just a "does it make sense" check sort of thing --

14 DR. LaFORCE: Yes, that does make sense.
15 I mean, if the AFEB helps in establishing the criteria
16 and those are used in terms of this particular
17 exercise, I think a -- I won't say a validation step --
18 but I think a common sense step, does this sort of make
19 sense as it comes back to AFEB is reasonable. That's
20 reasonable.

21 LtCOL. SCHNELLE: It's not my expectation
22 that this would be a deep, involved, time-consuming
23 process, it would just be sort of a brief presentation,
24 as has been traditional with the threat list anyway.
25 And my understanding is every year the threat list has

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1 been presented to the AFEB for your review and
2 discussion?

3 COL. DINIEGA: Right, that is a tasking
4 that we have.

5 LtCOL. SCHNELLE: Sort of in that sense,
6 continuing that particular activity, that was my
7 thought.

8 COL. TAKAFUJI: What I would recommend is
9 that -- I think what is catching everyone is the word
10 "approve", and the AFEB is a recommending body, we all
11 understand that. And I do think that an annual AFEB
12 review is clearly indicated. If you go back to the old
13 guidelines that had been provided in 1993, really,
14 things have not changed substantially in regard to the
15 AFEB's role, and that is to recommend to ASD Health
16 Affairs anything that may be new, whether it's new
17 vaccines or whether it's new approaches, new
18 antibiotics, whatever the issue may be. I think that
19 would be very appropriate. So, if I could just make
20 the suggestion that we leave that as "AFEB reviews and
21 recommends", is that acceptable?

22 DR. LaFORCE: Yes.

23 LtCOL. SCHNELLE: Another thought, sir?

24 COL. DINIEGA: Yes. Just a reminder. I
25 think the AFEB's responsibility right now is to review

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1 the BW threat list and to make recommendations on
2 medical countermeasures. But the other question I had,
3 in a previous life, I was involved with trying to look
4 at methodology and quantification of a methodology for
5 determining prioritization of diseases, and at that
6 time we looked at a way to quantify -- not only looked
7 at the criteria, but a way to quantify it so that
8 essentially you have a ready-made formula that you can
9 plug in variables every year, and the intent was that
10 once you have the formula and an initial prioritization
11 list, then it would go to an expert panel for review
12 and validation, and then the expert panel could then
13 shift the formula-derived results as they saw fit. Is
14 that something you have in mind, is to quantify not
15 only the criteria, but quantify the methodology?

16 LtCOL. SCHNELLE: Ideally, yes. I'm open
17 to the fact that we might not reach that ideal. The
18 decisions, the complexities, might not allow such
19 crispness in the methodology, but that would be the
20 ideal end state, yes.

21 DR. LaFORCE: Those of us who have
22 experiences in trying to sort of quantitate things that
23 are in point of fact a bit difficult to quantitate, I
24 just worry a little bit because "quantitate", to me,
25 means put numbers to things and then adding them up and

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1 if it's 1.562 it means something versus something else,
2 and I'm not sure that the -- well, before I -- my bias
3 is I'm not sure that the precision that we have is so
4 precise that it's going to allow anyone to do something
5 more than just set up criteria, evaluate them, and give
6 a common sense judgment where these things should fall,
7 rather than a number.

8 LtCOL. SCHNELLE: My hope is that the
9 quantitative analysis will certainly allow the agents
10 to be categorized in bins that are sufficiently
11 discrete from each other that we have some confidence
12 in the separation, that we are not caught in saying
13 "Agent 1 goes into this bin because it's 1.562, and
14 Agent 2 goes in this bin because it's 1.563". My hope
15 is not so much to arrive at an ultimate number because
16 I think you're right, but the process of getting to
17 that number is going to be a little iffy, but we
18 certainly want a reliable methodology, to the extent
19 that it's quantitative, that we arrive at discrete bins
20 that we have confidence in, and that will take a
21 certain amount of quantitative analysis to get there.
22 If it's totally subjective, it will have to be redone
23 every time it's rediscussed. So, a happy medium
24 between the totally quantitative analysis and the
25 totally subjective analysis is my personal goal.

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1 DR. LaFORCE: I'm excited to wait for your
2 presentation.

3 LtCOL. SCHNELLE: You're seeing me three
4 weeks on the job, and I'm excited by the common sense
5 applications of this technology. So a year from now
6 you'll see me the bitter, cynical staff officer who
7 says, "Hey, listen, this is the best we've got, move
8 out".

9 (Laughter.)

10 DR. LaFORCE: There's several of us who
11 have said "been there, done that".

12 COL. DINIEGA: The criticism in
13 prioritization that I'm familiar with has been that it
14 has been so personality-dependent that you cannot
15 reproduce the results. It all depends on who is in the
16 room. And so I think it's going to be a happy medium
17 because you have to take that criticism off the table.

18 So it can't be all or one, that's why this thing about
19 having a formula to come up with an initial list of
20 prioritization and then having an expert panel go over
21 it to make sure it meets the common sense test might be
22 a way to do it, but there has to be, I think, some
23 quantification.

24 COL. BRADSHAW: I think we need to
25 certainly define our methodology and make sure it's

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1 reasonably reproducible, but I also agree with Dr.
2 LaForce that the -- I don't know that we have that
3 degree of precision on everything, and where we have
4 the precision I think we should use it, but then we
5 should define what's High, Medium or Low, and at best
6 this is fuzzy logic. I think you end up having to come
7 down to some categorization and matrix to do it even if
8 you use numbers in the early stage. I know with a
9 Partnership for Prevention, when they prioritized their
10 things to focus on for prevention, they used a formula
11 -- they had a formula and they plugged numbers into it,
12 but when they got down to the actual prioritization,
13 they grouped it into five categories because they
14 acknowledge that there is some fuzzy logic to it, and I
15 think that's what we have to do with this.

16 COL. DINIEGA: And the difficulty not
17 knowing previous methodology is that you get stuck with
18 a priority list from five years back and you have no
19 idea how they arrived at it. And we definitely have to
20 get away from that.

21 LtCOL. SCHNELLE: Clearly, there are going
22 to be some challenges in this process. Next slide,
23 please.

24 (Slide.)

25 What I would like to do in the time we

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1 have remaining in this briefing is to ask you for your
2 off-the-cuff opinions on what are the criteria you
3 consider most relevant and important, and are there any
4 criteria you consider of such overwhelming significance
5 you would recommend weighting of some kind, that this
6 not be treated as equal among all other equal criteria.

7 And subject to your questions, I will retreat to take
8 good notes of your discussion, if that's acceptable.

9 DR. LaFORCE: David?

10 DR. ATKINS: This is David Atkins. Again,
11 the criteria that are most critical are going to depend
12 on what the purpose is. I mean, if it's to give some
13 ranking on prioritization of vaccine development,
14 obviously one of the most important criteria are do you
15 have an effective treatment whereas if the aim is to
16 give some prioritization to other types of preparedness
17 in terms of stockpiles and things like that, then that
18 is a different set of criteria. So, I think the right
19 criteria really depend on the actual question that's
20 being asked.

21 COL. DINIEGA: Let me give a little bit of
22 background to what Dr. Atkins is asking. In the past,
23 the only prioritized list that has been available and
24 that has been the "Golden Rule" or the "benchmark" for
25 any activities in this arena, in the N/B/C threat

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1 arena, has been the prioritized DIA list, and that has
2 been a concern to the medical community for quite a
3 while. And I think, if I'm not mistaken, the intent of
4 the medical risk analysis initially was to provide
5 input into the development of the overall threat list,
6 and what it's going to end up evolving into, which is
7 okay, too, is that the Chairman's list will continue to
8 be based on intelligence information, and when that
9 list goes out people should be using that list along
10 with a medical risk analysis result, conclusions,
11 before applying the threats they are going to be using.

12 So what I'm saying is that the threat list
13 is used for both research and development activities
14 and prioritization. It's used for operational
15 activities prioritization and development. And so this
16 will give them another way to look at the threats in
17 making decisions on what threats they are going to
18 address. So I'm not so sure if you're asking for
19 several risk analyses depending on what the purpose of
20 the threat list --

21 DR. ATKINS: I guess I'm comfortable with
22 the sort of matrix you applied and I'm also comfortable
23 with the comments I've heard of trying to be
24 quantitative within those boxes but not thinking we can
25 come up with a formula to add up all the different

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1 Highs and Mediums in those boxes into one number. I'm
2 just saying that depending on the decision you're
3 making, how you weight the information in those boxes
4 may change. I mean, if the decision is where should
5 we prioritize our vaccine development, then we might
6 give more weight to a couple of those boxes. If the
7 question being asked is what should we be doing in
8 terms of other elements of preparedness, then we might
9 have to be giving more weight to other boxes. And I'm
10 not suggesting coming up with a new mechanism, just
11 that people think about that -- that be explicitly on
12 the table when they are looking at a matrix and coming
13 up with some global, subjective conclusions.

14 DR. LaFORCE: Yes, because on the one hand
15 you do have a suggested list of criteria that are
16 listed here in terms -- and what I was struck with is
17 the criteria, mainly medical criteria, and I would have
18 thought that all of that is modified by a judgment on
19 whether there's any evidence that this particular agent
20 has been weaponized because if the answer is yes, that
21 moves it -- that is a weighting factor that so
22 outstrips everything else. If it's been weaponized, I
23 would think that this is then an item that's a major
24 threat to any serviceman anywhere.

25 DR. ATKINS: Well, she had that matrix

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1 that put the two together.

2 DR. LaFORCE: Yes, that we can have
3 medical criteria and the medical criteria, in fact,
4 pale a bit in terms of what the threat is. Have I made
5 myself clear?

6 LtCOL. SCHNELLE: Yes, sir, but the risk
7 assessment matrix -- you consider the medical risk
8 conclusions separate from the intelligence estimate
9 precisely because you're going to use them later in a
10 very concrete, physical way.

11 DR. LaFORCE: Okay.

12 LtCOL. SCHNELLE: Col. Parker?

13 COL. PARKER: Col. Parker. Let me kind of
14 use an example that's always been a pet peeve of mine.

15 We have our intelligence list based upon weapons
16 systems, R&D programs in an attempt to recognize a
17 number of countries that may be working on it. And
18 that kind of gets sorted and ranked and so forth, and
19 so you may have an example of ricin that kind of floats
20 to the top, or near the top, of the list because we
21 think X-number of countries might be working on it --
22 in fact, maybe somebody has weaponized it in some form.

23 But when you then look at things like some
24 medical criteria and some of the physical
25 characteristics of ricin, it's toxicity, which when you

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1 do some math there is going to require some quantities
2 of ricin to be an effective open-air battlefield type
3 weapon, so is that conceivable even if somebody did
4 weaponize it? Well, maybe it's conceivable, but how
5 practical is it?

6 DR. LaFORCE: Right, and one of the
7 criteria is practicability of threat.

8 COL. PARKER: The practicability, so
9 you've got to factor that in, but with something like
10 smallpox, the probability of us seeing smallpox, I
11 hope, is real low, but the consequences are very high.

12 So, really, the matrix is trying to help us better
13 bracket something, you know, like smallpox, is probably
14 going to be lower on that threat list because with
15 others it's only suspected. But if you see it and all
16 of its characteristics, it's going to be an extremely -
17 -

18 (Simultaneous discussion.)

19 COL. TAKAFUJI: There are several ways of
20 looking at threats. One is, of course -- and what
21 we're trying to do is keep pure the intelligence
22 country-based threat assessment that comes with pure
23 intelligence and so forth. There's a community that
24 needs that kind of information and we've decided not to
25 touch it. So we're leaving that part pure.

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1 This part, which is the medical risk
2 assessment, looks at these different agents from the
3 standpoint of medical impact, and the focus is
4 primarily on operational medicine -- in other words,
5 units moving out and whether they can function and
6 whether they are truly protected or not.

7 It goes without saying that when these
8 things come to the AFEB, the AFEB does have a
9 responsibility and role to recommend whether there is a
10 need for a new vaccine, a better vaccine, other
11 antibiotics, other countermeasures, whatever they may
12 be. And I think that when you look at these types of
13 lists, therefore, that option is always open. It's not
14 that the AFEB needs to integrate with the threat
15 assessment so much, but look at everything and make
16 recommendations back to us. Those things will be taken
17 very seriously and they will carry a lot of weight, I
18 can assure you, when the ASRAM meet to look at
19 priorities and so forth.

20 DR. LaFORCE: Wayne?

21 CDR. McBRIDE: A couple of comments. Who
22 is the intended recipient of this analysis, who are we
23 doing this for? Would this be for the warfighters,
24 would it be for the medical folks to determine what is
25 a need for vaccines, or to develop new medical

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1 responses, or is it for everyone? Who is our intended
2 audience, for everyone? So, I think it's important to
3 keep that clear and go in that direction.

4 With regard to some additional criteria,
5 I've had some thoughts just for our consideration that
6 may be helpful as we develop a risk analysis tool, and
7 among these additional criteria would be perhaps the
8 persistence or stability of the agent in the
9 environment after it's released, ease of detection if
10 it's been released, and perhaps ease of diagnosis once
11 one has been infected or exposed to it, and those would
12 be additional considerations on a list of criteria.

13 DR. LaFORCE: Other comments?

14 CAPT. SCHOR: I would make two comments.
15 One is that I have difficulty understanding that this
16 has any impact on operating forces. A medical matrix,
17 all I need is the list from Intel to go in and tell the
18 General that Country X has this, this and this, and can
19 do this, this and this, and I say I need to do this,
20 this and this to counteract that. I don't need any
21 other medical matrix list to tell me any of that. So,
22 I think -- you know, as this discussion went on, my
23 sense is this is only looking at the acquisition and
24 product development side of the house. And that's an
25 important thing, but I think that it needs to be looked

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1 at in that. I don't see it as an operational thing per
2 se, Col. Takafuji, I just don't see it that way.

3 And the other thing is, the more variables
4 you put on your list, the less impact each of those
5 variables might have in the overall semi-quantitative
6 ranking that they would contribute to the model.

7 COL. TAKAFUJI: One thing that we have to
8 remember is that when we speak of the operational
9 applications, I agree with you, Capt. Schor, that needs
10 to certainly be kept in focus in terms of what the real
11 threats are to fighting forces. But having a threat
12 and having a countermeasure is very important for the
13 war fighter to understand. If you have, for example, a
14 force that is totally immunized against anthrax, I
15 would think that that threat drops farther down on the
16 threat list in terms of potential impact of that
17 disease. So somewhere in there there has to be that
18 medical sort. In other words, if you went to war with
19 a certain country and that country had weaponized
20 anthrax, pretty good Intel on that but your forces were
21 totally protected through vaccination, it may not be as
22 high on the threat list from the standpoint of
23 operational medicine.

24 The other part to remember is these threat
25 lists are looked at by a whole variety of operational

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1 forces. They include Special Ops and so forth. So
2 there's all kinds of sorts that each unit would place
3 on this depending on their mission and so forth. So we
4 need to keep that in mind, too.

5 We're trying to do a lot, but yet keep it
6 simple but applicable to as many different potential
7 customers out there, and it's not an easy sort to do.

8 DR. LaFORCE: Let's finish this round of
9 comments and then we'll break. LtCol. Curling.

10 LtCOL. CURLING: This is LtCol. Curling.
11 I have two comments, one to address the application of
12 this list and one to address the operational
13 implications, and they sort of go together. If you
14 look at the criteria suggested including the detection
15 and diagnosis and other things that have been added to
16 it, the top portion of the list -- morbidity,
17 mortality, communicability, infectivity, incubation
18 periods -- are characteristics inherent in the agent,
19 and the detection, protection, vaccination,
20 immunization and so forth are responses to the agent.

21 And what you are doing is you are adding to the
22 characteristics of the agent what you can do about it.

23 And, therefore, the application of the matrix can be
24 to identify vulnerabilities that you can address in
25 your response in research and development or

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1 procurement of physical protection or medical
2 protection that's not currently available in the
3 stockpiles of the operational forces, and this comes to
4 the operational response.

5 If there is a threat in the AO, area of
6 operations, that a commander is concerned with, that
7 turns out to have a very low medical impact, then
8 operationally that threat is probably minimal. And
9 examples could be ricin or aflatoxin or other agents
10 which will have either impractical application on the
11 battlefield, or no medical effect. And an example of
12 that may also be anthrax against a protected force, and
13 that will certainly have an operational implication in
14 the planning for that theater.

15 So, those considerations have got to be
16 considered other than do they have it and can they use
17 it. The third part of that is, what will it do to my
18 force? Will it decrement my forces? And if we can
19 medically say no, it won't, or medically say yes, it
20 will, that's a piece of information the operational
21 commander is really going to be interested in.

22 COL. PARKER: And I'll butt in real quick,
23 too, and use the other example of smallpox. There's
24 tertiary effects with that also. And if it's not an
25 immunized force, have we thought about what's going to

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1 happen if we see one case of smallpox and quarantine is
2 going to be imposed, and now the additional requirement
3 for taking care of everybody in that theater of
4 operations, nobody is coming home. So, I mean, this
5 medical analysis I think will be useful from an
6 operational and medical perspective.

7 DR. LaFORCE: Dana?

8 COL. BRADSHAW: I usually agree with Ken,
9 but I would agree with these other folks in this case.
10 And I think why commanders are definitely going to be
11 interested in the mission impact and the medical
12 information is going to be definitely useful for them
13 to look at mission impact of a certain agent, and case
14 fatality ratios, lost duty days, morbidity -- all that
15 is going to affect the mission, and they are going to
16 be interested in that, and that's information we'll
17 need to communicate to them, and we can use a matrix to
18 do that or we can -- but I think that will still be of
19 interest.

20 DR. LaFORCE: Rosemary.

21 DR. SOKAS: I think, establishing the
22 criteria, there should be as precise and as many as
23 possible, but then you have to weight them because they
24 are not all going to be equal.

25 I have a question to raise, and I don't

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1 know how important it is to consider this, but for
2 personal protection equipment, either equipment or
3 vaccines or whatever, the potential adverse effects of
4 the personal protection itself has to be weighted --
5 heat stress from different kinds of outfits, breathing
6 resistance, adverse effects from the vaccines, all of
7 that kind of stuff. And the question -- the weighting
8 of that varies depending on the other parts of the
9 matrix. If it's a low-yield threat, you're going to
10 wind up with -- I mean, 99.999 percent of the time
11 you're protecting against something that's never going
12 to happen, it seems, and so if that's the case then
13 you've got to be a little more careful about the
14 potential adverse effects of the protection itself.
15 And I don't know how you figure that in, but that's
16 just a thought.

17 DR. LaFORCE: Why don't let's break --

18 COL. DINIEGA: I have a comment before we
19 take a break. One is a reminder if you can donate a
20 little bit for the snacks. And then two is, if there's
21 anybody who's going to be here at lunch and wants to
22 order a working lunch, you need to see me and fill out
23 a form so that we can get that ordered.

24 DR. LaFORCE: Okay. Let's break until
25 five after 10:00, if we could.

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1 (Whereupon, a short recess was taken.)

2 DR. LaFORCE: The next speaker this
3 morning is Dr. Linden, the Research Area Manager in
4 Med/Chem/Bio Defense.

5 DR. LINDEN: Good morning. Those of you
6 who know me from my very recently previous life, or in
7 the process of becoming previous life -- I've been at
8 USAMRIID for 20 years as the most recently the Chief of
9 Research Programs, but now I'm in the process of moving
10 to the Research Area Director of Medical, Chemical and
11 Biological Defense Research Program, which is a joint
12 program managed by Medical Research and Material
13 Command, and I'm sure you're familiar with that. Next
14 slide, please.

15 (Slide.)

16 Our mission is to protect service members
17 on the chemical and biological battlefields, and I was
18 asked today specifically to focus this briefing on
19 biological defense, so some of the slides will mention
20 chemical and biological, part of the RAD 4 briefing
21 set, but I will just try to focus on the bio for you
22 today. Next slide, please.

23 (Slide.)

24 The program became joint and was removed
25 from the services in 1996 under the Public Law as shown

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1 here. One of the important features of this slide is
2 the Army remains the Executive Agent for the program,
3 but now since FY96 we've developed an integrated and
4 joint budget that goes forward for funding across the
5 entire spectrum of acquisition, the RDTE, acquisition,
6 procurement, and so forth. Next slide, please.

7 (Slide.)

8 This is a simplified version of all of the
9 complex interactions that take place in terms of
10 directing, managing and executing this joint program.
11 The program is overseen -- I guess is the correct verb
12 -- by the Joint NBC Defense Board in coordination with
13 a Medical Subgroup of the ASBREM -- do you all know
14 what that acronym means, or do I need to dredge out --

15 DR. LaFORCE: Please.

16 DR. LINDEN: Armed Services Biomedical
17 Research Evaluation and Management, and I forget
18 whether it's Group or Committee there at the end.

19 The Joint NBC Defense Board has two
20 functional entities under it, Joint Service Integration
21 Group which develops the requirements -- and LtCol.
22 Bryant Scott I saw in here earlier, I don't now if he's
23 in the room at this moment -- he is from the AMED
24 Center and School, and that's where they work on
25 developing the requirements for the Medical Defense

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1 Material, which also includes all the vaccines and so
2 forth. The Joint Service Material Group is the
3 material development entity of the NBC Defense Board,
4 and we have representatives -- we, out of MRMC, have
5 representatives at the General Officer level as well as
6 the Action Officer level, and serve both of these
7 groups. The JSMG group here develops the budget and
8 basically develops the research plan, the joint
9 Chem/Bio Defense RDA -- Research, Development and
10 Acquisition Plan.

11 In order to complicate things even
12 further, let me point out that the person who sits in
13 this position, which is now me, also serves, in
14 addition to being the Action Officer to this group and
15 wearing a couple different hats and titles, serves on a
16 Joint Technology Coordinating Group for medical
17 chemical and medical biological defense, and that
18 supports the ASBREM. There will be a quiz at the end.

19 Next slide, please.

20 (Slide.)

21 The main locations where we carry out or
22 execute/conduct the research for the Medical Biological
23 Defense Program are all located here in Maryland. You
24 are here at Ft. Detrick where we have USAMRIID, where
25 we're having this meeting, as well as our own

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1 headquarters, as well as the offices of the Joint
2 Vaccine Acquisition Program, where Richard Paul is and
3 he's our next speaker who will talk about the advanced
4 development aspects of the vaccines, Walter Reed Army
5 Institute of Research at their new facility in Forest
6 Glen, as well as the Navy Medical Research Center which
7 is co-located with Water Reed, also participate in the
8 program as does the Armed Forces Institute of
9 Pathology, and the Army Medical Research Institute of
10 Chemical Defense, our sister laboratory located up in
11 Edgewood. Next slide, please.

12 (Slide.)

13 Some of what's on this slide goes back to
14 previous discussion this morning and some of the
15 briefings that you heard from the Intelligence
16 community. Protecting warfighters is a multi-faceted
17 effort and requires the participation of the entire
18 spectrum of the Defense community. Our focus is on the
19 medical countermeasures here, the development of
20 vaccines, drugs and therapeutics, as well as on the
21 education and training, and I'll talk about those
22 things throughout this briefing. Next slide, please.

23 (Slide.)

24 For those of you who aren't familiar with
25 the product development program for the acquisition

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1 rules and regulations in the Department of Defense,
2 this is the very barest of minimal introductions. Our
3 funding is divided up by buckets or these numbers --
4 6.1, 6.2, 6.3 -- and the definitions, the very
5 abbreviated definitions are here -- the most basic
6 research, applied research, and concept exploration.
7 This grouping down here essentially constitutes what we
8 refer to as the technology base, or the tech base, and
9 there are a couple different subdivisions of this that
10 are more subtle where things are either grouped 6.2 and
11 6.3 together or 6.1 and 6.2 together, depending on who
12 you are talking to and what rule book they are looking
13 at. But regardless of that, basically, at this point,
14 as a boundary between this funding, 6.3 concept
15 exploration, and higher levels of funding is what we
16 term a Milestone I transition. This is where, for
17 example, for a vaccine, you go from the point where
18 you've done all the laboratory work and produced
19 material that you believe you could get approval from
20 the FDA for putting in people, and submit an IND and go
21 into Phase I clinical trial, and the advanced
22 development part of this program where you do all those
23 clinical studies and the further manufacture and
24 development of a product, it's under the purview of the
25 Joint Program Office for Biological Defense, and the

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1 people who carry that out, that program out, is the
2 Joint Vaccine Acquisition Program, and like I said, you
3 will hear from Richard Paul on that. So, the Joint
4 Program Office for Biological Defense has the decision
5 authority over the advanced development of these
6 products for biological defense, and is called the
7 Milestone Decision Authority.

8 To complete the explanation of this side,
9 Gen. Parker, the Commanding General of the Army Medical
10 Research and Material Command, is the Milestone
11 Decision Authority for the products for the chemical
12 defense. Next slide, please.

13 (Slide.)

14 You'll see this slide in the next briefing
15 also. And it's intended to give you a sense of how our
16 lifecycle of product development in our world here fits
17 into the outside world, specifically into the FDA
18 process or the process that the pharmaceutical industry
19 would use, to conduct research and development and
20 actually produce a drug or a vaccine and get it
21 licensed. And so the top part of this, just a little
22 bit different terminology for the funding -- the 6.1,
23 6.2, 6.3 funding, the basic research, applied research,
24 concept exploration -- these are the kinds of things
25 that go on in the tech base here -- for example, in

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1 this laboratory where the research is being conducted
2 on biological defense vaccines.

3 It's very difficult to divide science up
4 into neat boxes with solid boundaries, and so right
5 here between the labs doing this development is where
6 things get kind of fuzzy many times. And we've spoken
7 to people in the drug industry, and even they say
8 absolutely, this is the hardest part of the whole
9 thing, right here where you're taking something from
10 the researchers at the bench and trying to turn it over
11 to people who have a more applied or more pragmatic
12 mindset -- like, okay, tell me how to make this stuff,
13 tell me how much to make, and let me get it into
14 bottles for you -- and it's very hard for people who do
15 research at the bench to think that way, but there are
16 certain criteria that need to be met in order to do
17 this successfully, and we have to work very closely
18 across these two areas with the scientists and the
19 managers and so forth in order to get a successful
20 transition from this domain into that domain.

21 I wanted to point out one critical thing
22 here, which is that for biological defense vaccines we
23 have a very difficult time meeting one of the FDA
24 requirements, which is demonstration of efficacy in
25 humans. We don't have the luxury, when we're

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1 developing a new vaccine for plague, for example,
2 specifically a vaccine to protect against an aerosol
3 delivery of plague. There are no natural outbreaks of
4 aerosol plague, that we're aware of anyway, in the
5 world. So there are no populations in which we could
6 go and test a new plague vaccine. Unlike the case, for
7 example -- I'll use cholera just because it was on some
8 of the previous slides that you saw earlier this
9 morning, and also there are in the infectious disease
10 community vaccine efforts for that.

11 If you want to develop a vaccine for
12 cholera, you can go to several places in the world
13 where you can predict that at some point there's going
14 to be a cholera outbreak, and you could immunize a
15 portion of the population and you could do a double-
16 blind controlled clinical study to demonstrate that
17 your vaccine protected against cholera. We can't do
18 that with biological defense vaccines, and so we have
19 to rely on animal models.

20 In previous presentations, you may have
21 heard this issue discussed at length. Last year, the
22 FDA published a proposed new rule which describes
23 criteria under which they might consider accepting
24 animal efficacy data as demonstration of efficacy in
25 support of licensure of a vaccine. I don't know what

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1 the time line is on that rule, I'm sure there have been
2 many comments on it, and the process is that the FDA
3 will review all those comments and then publish either
4 a revised rule or their assessment of the comments in a
5 final rule. Does anybody else know what kind or time
6 line that's on?

7 (No response.)

8 Okay. I don't. But that's out there, and
9 the intent was not just to try and help the Defense
10 community, but there are other examples in the Public
11 Health community where it would be very desirable to be
12 able to use animal efficacy data in support of
13 licensure of a vaccine. As it is, of course, we still
14 have the same requirements as always for demonstrating
15 safety both in animal models and in humans. Next slide,
16 please.

17 (Slide.)

18 This is just a wiring diagram of how the
19 Medical Biological Defense Research Program is
20 structured, to kind of give you some sense of how we're
21 put together.

22 Down here on the lower portion of the
23 slide, about two years ago we reorganized the program
24 into the tech base, the basic research parts of the
25 program into the domains of Vaccines, Therapeutics and

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1 Diagnostics. We did this in part because previously
2 the program had basically been stovepiped by agent, and
3 we divided up all the funding into little boxes -- you
4 know, this much money for this agent, this much for
5 that agent, and so forth -- and it became very
6 cumbersome and didn't allow for a lot of flexibility
7 for us to address new and emerging -- not only new and
8 emerging threats, but new and emerging scientific
9 approaches to solving and addressing some of these
10 problems.

11 So, within each of these domains we then,
12 of course, subdivided into Viruses, Bacteria and
13 Toxins, and the Diagnostics is a singular effort in and
14 of itself, which I will describe in a moment.

15 The more mature research efforts -- and,
16 by and large, this means those things that are really
17 mature in the concept exploration phase, the 6.3
18 funding -- get identified and written up and submitted
19 for review and approval as Defense Technology
20 Objectives. These are descriptions of a problem or a
21 project that has a specific time line of about three to
22 no more than five years, with a very defined end point
23 to it. And in the case of developing new vaccines,
24 that end point is usually, I would say, generically to
25 have accomplished sufficient research so that we have

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1 the necessary data to present for a Milestone I
2 transition, or an FDA read-ahead package, or something
3 like that, something that basically indicates that
4 we've got a vaccine candidate to a point where it's
5 mature enough in the research phase to consider
6 evaluating that for moving forward into the next phase
7 of development.

8 So, the four things that we have Defense
9 Technology Objectives written for at the moment are the
10 staph-enterotoxins, encephalitis viruses, multi-agent
11 vaccines, and the common diagnostic systems, and I'll
12 talk about each of these specifically in a few moments.

13 These were preceded historically over the
14 past several years by Science and Technology
15 Objectives, which is the Army version of the Defense
16 Technology Objectives, and this basically reflects the
17 transition in the FY96 or so time frame from a program
18 managed by the Army to a program managed jointly. Next
19 slide, please.

20 (Slide.)

21 Throughout all of our research efforts, we
22 share some fairly common technical approaches
23 regardless of what the type of threat agent is. At the
24 very basic research effort, we want to identify the
25 mechanisms involved in the disease process, whether

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1 we're talking about an infectious agent or a toxin. We
2 want to identify candidate medical countermeasures,
3 whether they are vaccines or drugs, to either prevent
4 the effects of these agents or to treat them if a
5 person were ultimately to be exposed to them, and as I
6 discussed in some length just a few moments ago, we
7 need ways to evaluate the effectiveness of these
8 countermeasures that we're developing so we invest a
9 fair amount of effort actually in the development of
10 animal models for these various biological threat
11 agents. You may or may not be able to go to the
12 library and pull out scientific literature that
13 describes for you a good animal model that mimics the
14 human disease for a biological threat agent. Actually,
15 you could do the same thing for the infectious disease
16 agents, too. There are not necessarily four-legged
17 critters or other life forms that give you good models
18 for human disease in many cases, so we need to develop
19 those here in our own laboratories with our own
20 researchers, or within our own program at least.

21 And last, but not least, we need the
22 capability to identify these agents and the ability to
23 diagnose their presence or their effects in clinical
24 specimens. Next slide, please.

25 (Slide.)

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1 I just have a series of slides here on the
2 Defense Technology Objectives that I just identified
3 for you, and I divided these up -- I think you all, at
4 least at the table, should all have the hard copies
5 which will be a little bit easier to read -- into the
6 Objectives which actually kind of look very similar
7 from DTO-to-DTO, but I also put some of the recent
8 accomplishments on here -- I'm not going to read those
9 to you, but you can get a pretty good sense of what a
10 Defense Technology Objective is in the content vaccine
11 development -- for example, by looking at the
12 accomplishments that we included here on this slide for
13 the staph-enterotoxins.

14 We've prepared a pilot batch of material
15 using good manufacturing practices, developed and
16 validated assays that will support doing pivotal
17 studies in animals as well hopefully, we believe,
18 ultimately in humans. First, we developed the vaccine
19 candidate and also did some of the critical animal
20 studies that need to be done in order to consider
21 moving forward with this kind of a vaccine. Next
22 slide, please.

23 (Slide.)

24 For the medical countermeasures for the
25 encephalitis viruses, we recently had a Milestone I

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1 with the Joint Vaccine Acquisition Program, meaning
2 that they now have taken over this candidate, this
3 vaccine candidate product, for further development.

4 It's being produced under good manufacturing practices.

5 We had to do a prescribed series of safety tests in
6 animals, to include neurovirulent studies because this
7 is a live viral clone, and because it's live and it's a
8 virus and it was derived from a virus that causes
9 encephalitis and is neurotropic, the FDA requires that
10 neurovirulence testing be done.

11 It has shown -- this vaccine candidate has
12 shown excellent safety profiles in the animal studies
13 that have been done, as well as excellent efficacy,
14 again, against an aerosol challenge. Within the
15 Biological Defense Program, that's one of the
16 challenges that researchers generally do that the
17 Public Health community don't have to deal with, and
18 that is that we believe the threat to the military
19 force on battlefields from biological agents is going
20 to be via an aerosol, and that's not -- in most cases,
21 that's not the normal route of transmission for either
22 the disease in its endemic form, it's naturally
23 occurring form, or for other infectious diseases. Next
24 slide, please.

25 (Slide.)

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1 Multi-agent vaccines is one of our newer
2 DTOs, and we formulated this because, as we all know,
3 logistically it's not realistic to believe that we can
4 line up the force and immunize people against the top
5 ten threat agents. That's in addition to all the other
6 vaccines that they receive because they are members of
7 the Armed Forces, and we've seen now from experiencing
8 the anthrax vaccine immunization program, how difficult
9 it is logistically to immunize people repeatedly with
10 one vaccine, or just to immunize them at all with a
11 special -- essentially a special vaccine.

12 So, within our tech base we started a
13 number of years ago to explore the concept of multi-
14 agent vaccines, and not just simply taking three
15 different vaccines and mixing them together in the same
16 vial and calling it a "trivalent" vaccine, but actually
17 looking at molecular biological techniques and
18 approaches to accomplishing a truly multivalent vaccine
19 -- you know, one thing that you can inject that will
20 protect you against multiple threat agents.

21 The two technologies that are being
22 pursued for this are to use the viral replicon
23 platforms, which we're using one derived from the
24 Venezuelan Equine Encephalitis vaccine, the VEE 3526,
25 and then naked DNA vaccines. Those technologies appear

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1 to be very promising in terms of their ability to
2 string together the genes for the antigen's interest
3 that you want to use as you immunogens to elicit
4 protection, and the VEE replicon, the viral vaccine
5 vector for the multi-agent vaccines looks extremely
6 promising. Our folks have demonstrated the proof of
7 principle in animals of putting in two or three genes
8 for the antigens for different agents, as described on
9 the slide. I think what's on the slide here, we've
10 shown that the replicon vector is capable of expressing
11 the genes for the heavy chain of BOT neurotoxin-A,
12 which in and of itself is one of the vaccine candidate
13 components for a multivalent new BOT vaccine -- that
14 the heavy chain of BOT-A, plus SEB for which we have a
15 genetically engineered candidate, a trivalent version
16 with BOT, SEB and the PA gene from anthrax, and then
17 another version of the replicon that expresses the
18 glycoproteins from two different hemorrhagic fever
19 viruses, Ebola and Lassa.

20 In animal models, these have been shown to
21 be protective against challenge with the respective
22 agents. It's a very promising technology that is due
23 for a transition -- or due for us, I think in this
24 case, to achieve a proof of concept and identify
25 candidate antigens to go into a multivalent vaccine. I

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1 don't have the date written down here, but I think it's
2 in 03, 04, something like that, within the next couple
3 years. Next slide, please.

4 (Slide.)

5 The last DTO that I want to talk about
6 that we have is the common diagnostic systems. This is
7 an effort where we have been very successful in
8 partnering with other research laboratories within the
9 Department of Defense as well as within the civilian
10 sector of the Government as well as industry. Some of
11 our Government partners include DARPA, the Navy, Walter
12 Reed, the Armed Forces Institute of Pathology, the Air
13 Force, the nonmedical community, the Soldier Biological
14 Chemical Command up at Edgewood -- some of you might be
15 familiar with that -- as well as the Canadians. And we
16 have a number of commercial partners in the development
17 of these devices, as you might imagine because our
18 folks aren't the engineers,, but there is a big effort
19 out there in the biotechnology industry to develop
20 hand-held portable devices capable of doing the
21 clinical diagnostic work for application throughout the
22 entire health care universe.

23 So the focus of the common diagnostic
24 systems is to develop the state-of-the-art technology
25 and the reagents of the protocols and so forth that go

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1 along with that for the rapid identification of not
2 only biological threat agents, but also the endemic
3 infectious disease agents. This is very important. It
4 passes the "make sense" test for a change because, as
5 you all know, there's only going to be one health care
6 system deployed on a battlefield. You're not going to
7 send a medic out there with one device to diagnose
8 endemic infectious diseases, and another device to
9 diagnose biological warfare agents, and another device
10 to diagnose something else, whatever that might be.
11 There's going to be one piece of equipment. The
12 clinical laboratory and the technicians and the medics
13 have to have one lab, one device, one whatever, to be
14 able to take that clinical specimen, whatever it is,
15 and get an answer.

16 And so a couple years ago we actually got
17 the Program Management entities for the Biological
18 Defense and Infectious Disease Research Program
19 together, and even though I will say that the bulk of
20 this is funded from the Biological Defense Research
21 Program, we got buy-in from the Infectious Disease
22 community to go forward with a joint effort where we're
23 going to focus on developing the technologies and then
24 making sure that what's built into the capability is
25 the ability to diagnose all the relevant disease

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1 threats that soldiers might face on the battlefield.

2 Yes?

3 DR. SOKAS: I'm wondering if you do
4 sampling for nonbiological specimen so that -- air
5 sampling, for example, for biological exposures?

6 DR. LINDEN: Air sampling does not fall
7 within our mission, but the -- we work very closely
8 with the detection community because where the Venn
9 diagrams come together is on the agent identification
10 is on the agent identification. The folks who are doing
11 the detectors with the point stand-off detectors want
12 to be able to -- you know, the point detectors will be
13 the ones doing the air sampling. They are going to end
14 up with a sample within those systems, for example, the
15 biological identification and detection system. They
16 have the little filtration, the ticket technologies,
17 built into that system, but they quickly realized, once
18 they deployed those devices in various areas of the
19 world, that they got a lot of positives or a lot of
20 false-positives out of those, and they needed the
21 capability to confirm and get better data on those
22 samples. And so the way that is done now is through
23 the theater Army Medical Laboratory -- which is a
24 little bit of a diversion from this briefing -- but
25 those people have technicians assigned here at USAMRIID

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1 that work with the Diagnostics Group, and they are
2 equipped to be able to do some higher order laboratory
3 tests to do the confirmation on those samples that come
4 out of the detectors. In fact, for the Advanced
5 Development Program -- which you are not going to hear
6 about this particular thing today -- there is an effort
7 to develop -- the Common Diagnostic System for
8 biological threats and endemic infectious diseases is
9 the DTO, the Defense Technology Objective. It has as
10 its objective a transition soon -- it would be within
11 this calendar year, I believe, for FY01 -- transition
12 to advanced development of what is going to be called
13 the Joint Biological Agent Identification System. Now,
14 that being said, an important distinction is in the
15 nonmedical community for the people who are doing
16 sampling from battlefield detectors, they don't need
17 FDA approval of that test that they're using for agent
18 identification, but we do need FDA approval for that
19 test that we're going to use for agent identification
20 in a clinical sample in order to use as a basis of a
21 diagnosis. And that's the part that requires a whole
22 lot more effort and a whole lot more money. So,
23 really, the focus on that Joint Biological Agent
24 Identification System is going to be on the clinical
25 aspect of it, at least initially, because that's the

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1 part that's the hardest part.

2 LtCOL. KIMM: LtCol. Kimm. If I could
3 just make one quick point. That is a very important
4 point. The fact is that there is only one TAML
5 (phonetic), and in many cases there are going to be
6 Preventive Medicine personnel, medics, collecting
7 environmental samples. So this close coordination
8 can't be overemphasized.

9 DR. LINDEN: Next slide, please.

10 (Slide.)

11 The next couple of slides are focused more
12 on the bottom half of that wiring diagram that I showed
13 you earlier, talking about the tech base, the things
14 that are not mature enough to be formulated as DTOs at
15 this point in time, but these are the areas where we
16 are focusing our efforts, looking to the future.

17 Genetically engineered microorganisms and
18 the emerging threats -- big, big issue. A lot of
19 people are real spun-up about this. Actually, they've
20 been spun-up about genetically engineered threats ever
21 since about the mid-'80s.

22 I keep telling people that Mother Nature
23 did a real good job of making bad bugs, but I don't
24 know if they believe me or not. Anyway, we along with
25 a number of other agencies, to include DARPA and

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1 Department of Energy, and I guess -- Steve, I see you
2 sitting there -- CDC, Health and Human Services, have a
3 considerable amount of money now invested in sequencing
4 of threat agents to identify the things that we think
5 are the most significant and will be the focus of any
6 kind of illicit or offensive activity which would be
7 the virulence factors, toxins -- production of toxins -
8 - and also antibiotic resistance genes.

9 We feel if we develop the capability to
10 focus in on those things, whether from a diagnostic
11 perspective or even a vaccine or a therapeutic
12 perspective, that we'll be able to deal with these
13 kinds of threats in the future. And I guess that's
14 what I just said, looking at broad-spectrum drugs,
15 advanced diagnostics, and so forth.

16 And sort of along the same concept of the
17 multi-agent vaccine, you know, improving the medical
18 logistics and so forth, is the concept of, dare I say,
19 nonspecific immunity -- something will probably fall
20 off of me for saying that -- that's another area that's
21 been of high interest for a number of years, and not
22 terribly successful at least to this point in time, but
23 this also has some political attention, this whole area
24 of nonspecific immunity and immunomodulators, the
25 possibility of giving people the magic pill or the

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1 magic shot right before they go into the threat area
2 that will turn on their immune system, or if not turn
3 it on, stimulate it in such a fashion that it would
4 respond with a faster and more robust response to
5 various threats. I don't know if this is going to be
6 possible, but it's certainly an area that we're paying
7 attention to and looking into. Next slide, please.

8 (Slide.)

9 In the tech base of the Diagnostic
10 Technologies, we want to move beyond the PCR base
11 things that we're looking at right now. In other
12 words, the focus right now and the things that are
13 going far forward and the devices that are being
14 developed is on the nucleic acid analysis. Toxins,
15 protein toxins, in my definition, don't have nucleic
16 acid in them, although I've heard people make the
17 argument that crude preparations of toxins would be
18 contaminated with nucleic acid, but I personally don't
19 think that's a real vigorous approach to the problem.
20 But we want to expand the capability to include
21 immunological approaches, and very sensitive
22 immunological approaches to agent identification. We
23 want to identify new agent targets -- you know, you've
24 nucleic acid, you've got proteins, and maybe we can do
25 some other kinds of analyses to help us with

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1 identifying some of these agents.

2 And then last but not least, the animal
3 models and the validation of "gold standards", an this
4 is going to support our whole program ultimately in
5 terms of what we're able to do in identifying surrogate
6 markers of protection and so forth for not only the
7 diagnostic technologies employing those, but also the
8 vaccine development. Next slide, please.

9 (Slide.)

10 And in the tech base for the medical
11 countermeasures for the bacteria, viruses and toxins --
12 the next three slides are going to look very similar.
13 For the bacterial agents, we are looking at either next
14 generation vaccines for in the case of anthrax and
15 plague where both of those are based on recombinant
16 proteins, as well as vaccines for agents for which
17 there is no vaccine, such as glanders and melioidosis.
18 Again, we want to understand sort of the more
19 fundamentals of the bacterial threats, the nature of
20 the virulent factors and so forth, and we want to be
21 prepared to be able to address the issues of antibiotic
22 resistance.

23 With respect to therapeutics for the
24 bacterial agents, we have a number of cooperative
25 agreements with industry to look at the newest

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1 antibiotics as well as things that they have in their
2 development pipeline so that we can make intelligent
3 recommendations on what to treat some of these diseases
4 with. As you all know, for example, there aren't very
5 many cases of glanders that occur in the United States,
6 and if you go and look at a textbook, some of the
7 recommendations for treatment of that disease are
8 pretty outdated. But we can do the animal studies here
9 in the lab and make the appropriate recommendations.

10 Another one was, well, during the Gulf
11 War, what do you treat anthrax with? Well, if you look
12 at the textbooks, it says you can treat it with
13 penicillin or you can treat it with doxycycline. So,
14 that's great. Those are good things in the logistics
15 chain for deployment with troops and so forth, but so
16 is ciprofloxacin. So there is the question, does that
17 work? We have to do the studies. There aren't going
18 to be any human studies on that, but we have to do the
19 animal studies in the lab. So that's where we're
20 headed with the therapeutics for bacterial agents, as
21 well as, again, the immunomodulators, looking at the
22 potential for those to be used in treatment of some of
23 these infections. Next slide, please.

24 (Slide.)

25 For viruses, again, vaccines, looking at

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1 expanding the multi-agent platforms and again looking
2 at the emerging viral threats. For the therapeutics,
3 the same kind of approach. We have a number of
4 cooperative agreements with industry where we've
5 identified molecular targets of the viruses that we're
6 interested in -- the pox viruses and tula viruses and
7 so forth. And we can go to industry with a list and
8 say, "If you have drugs that look like they inhibit
9 this enzyme or this step in viral replication or
10 whatever, that's a drug we'd be interested in testing
11 against pox viruses and tula viruses, would you share
12 some with us?" And that's what they do, and there are
13 a number of promising leads that have been discovered
14 using that approach. Next slide, please.

15 (Slide.)

16 Toxins, again, mostly recombinant vaccines
17 for the various BOT-sera types that are of interest.
18 We've already mentioned the vaccine for the staph
19 enterotoxins, and we're working on redefining a
20 technological approach for a ricin vaccine. Initially,
21 several years ago, the approach was basically a ricin
22 toxilate inactivated material, chemically inactivated,
23 very much a standard old approach to making a vaccine.
24 That got basically up to the FDA and they were not
25 real happy with it, and so that particular approach

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1 didn't look like it was going to be a success with them
2 and so we dropped it. We then pursued a chemically
3 modified ricin material that was not toxic, and that
4 has since run into some stumbling blocks, so now we're
5 going back to the drawing board one more time, probably
6 to look at using a genetic engineering approach to
7 making a piece of protein that looks like ricin but is
8 nontoxic and immunogenic. We think that's probably the
9 one that's going to be the payoff.

10 In the area of therapeutics for the
11 toxins, in the entirety of the research community and
12 the scientific community, this area lags way, way
13 behind even antiviral drugs. There essentially are no
14 drugs that I'm aware of that we can use to treat the
15 protein toxin kinds of diseases, but we have used
16 molecular modeling and structure activity relationships
17 to explore the possibility of drugs as inhibitors of
18 the activity of some of these toxins, and with the
19 discovery -- especially for the botulinum toxins over
20 the past ten years of the enzymatic activity of the A-
21 chain of the botulinum toxins -- that's opened up a
22 whole new area of research for looking at inhibitors of
23 botulinum toxin activity. And I, when I was still in
24 the lab, had done some research in that area, and I was
25 just flabbergasted when those discoveries were made

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1 because people had been working with botulinum toxin,
2 looking at its neurophysiological effects and doing all
3 those things, wanting to figure out the mechanism of
4 action for a good 50 years, a solid 50 years before
5 those discoveries were made. So I was personally very
6 excited about that. But now we have the tools with
7 which we can approach therapeutics for some of these
8 toxin agents. Next slide, please.

9 (Slide.)

10 Last, but not least, by any stretch of the
11 imagination, education and training. If the knowledge
12 that we develop in our research community isn't
13 distributed and available, then we haven't maximized
14 our investment. The health care providers of all the
15 services, and now health care providers domestically
16 with the rise in incidents of domestic terrorism,
17 really need to know and understand the issues
18 associated with what the biological threats are, what
19 the properties of the agents are, what the diseases
20 are, how you go about managing and treating them. And
21 to that end, for a number of years we've been putting
22 on a course initially taught right here in this room
23 and now by satellite broadcast -- and several of the
24 people who are involved in that are sitting in the back
25 row there, and they've really put a huge amount of work

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1 into making this a success -- satellite broadcasts of
2 12 hours worth of course work on medical management of
3 biological casualties, and for the past two years
4 that's been done in partnership with the CDC, and one-
5 third of that whole program has been focused more on
6 the counterterrorism piece of it. Next slide, please.

7 (Slide.)

8 I think this just summarizes what I just
9 said, and it does give you the web sites there for the
10 satellite distance learning courses for the biological
11 course as well as for the chemical course. Next slide,
12 please.

13 (Slide.)

14 This is the "doo-wa" slide. Our
15 capabilities, our lab, as well as our researchers, are
16 a unique national resource, and I'd be happy to answer
17 any questions that I can for you about the program.
18 Thank you. Yes?

19 DR. OSTROFF: A couple of questions. I
20 was curious in terms of the group that does a lot of
21 the planning, how do you interface with groups like
22 DARPA and DTRA that are sort of more long-term in terms
23 of helping to influence some of the priority-setting
24 that is done?

25 DR. LINDEN: DTRA is one of the components

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1 of the Joint NBC Defense Board, so we essentially --
2 the Joint Program reports both to the office in OSD
3 responsible for chem/bio defense as well as to DTRA, so
4 that's kind of a given. That's part of our hierarchy
5 and our food chain. The way we interact with DARPA is
6 two ways. As you know, they have fairly large
7 programs, and they've come to us over the years
8 basically asking that we help support their programs by
9 working in collaboration with some of their
10 investigators -- as you know, their programs are
11 entirely contractual programs -- and done what we would
12 call extramural, DARPA -- doesn't have their own
13 research labs. So we have worked very closely with
14 those folks over the several years now that their
15 programs have been in existence.

16 And then a couple of years ago in a
17 Program Decision Memorandum, which is a document that
18 comes out of the Department of Defense and various
19 analysis groups, added money to the Chem/Bio Defense
20 Programs, and there was a specific chunks of money
21 added in there identified for what's called DARPA
22 Transition in shorthand, and what that is is money that
23 was identified so that the DoD could work -- well,
24 DARPA is DoD -- so that the military, the more military
25 parts of the community -- in this case, MRMP as well as

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1 the JPO -- would have money on the spreadsheet, on the
2 books, to work more closely with DARPA to bring some of
3 those DARPA programs into the development cycle. And in
4 the medical arena -- I think in the nonmedical arena
5 that happened starting this past year -- is that right,
6 does anybody remember -- I don't remember because it's
7 not my problem -- but starting in FY01 we will be doing
8 exactly that. We're meeting on a continual basis with
9 the DARPA Program Managers right now to identify the
10 most promising projects that they have. There was a
11 lot of collaboration, a lot of interest in some of
12 their projects in diagnostics as well as in
13 therapeutics. Those are the two areas that we sat down
14 and kind of have gone through all the projects with
15 them right now and said, okay, we think we might be
16 interested in the following ones, and we're working
17 with them right now to further refine that, identify
18 the most promising work, bring it in -- it will be at
19 the top end of the basic research chart there in the
20 6.3 funding -- and then kind of work those research
21 projects kind of into the pipeline so that the things
22 that look like they are going to pay off can be
23 evaluated head-to-head with everything else that's
24 going on, and then go forward to the next phase.

25 DR. LaFORCE: We need to move on. Mr.

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1 Paul will finish the presentations on vaccine
2 acquisition, if he would, please. Thank you.

3 MR. PAUL: Good morning. I'm Richard
4 Paul. I'm the Acting Project Manager for the Joint
5 Vaccine Acquisition Program. It's the Department of
6 Defense program to acquire the capability to produce
7 and stockpile BD vaccines. Next slide, please.

8 (Slide.)

9 I'm going to be talking to you today about
10 our organization and mission, some of the program
11 direction and requirements we have, our products and
12 processes, our prime systems contract approach to
13 getting these capabilities for acquiring and
14 stockpiling products, as well as some of the
15 collaborative BD vaccine development efforts that we're
16 in discussions about. Next slide, please.

17 (Slide.)

18 The Joint Vaccine Program reports to the
19 Joint Program Office for Biological Defense at Falls
20 Church, Virginia. The Joint Program Manager there is
21 the Milestone Decision Authority for biological
22 defense. And he coordinates programmatic issues with
23 DTRA and medical coordination is through the Office of
24 the Surgeon General with MRMC as the Surgeon General's
25 research organization, and the AMED Center and School

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1 for the requirements generation, then interface to the
2 Joint Service Integration Group that deals with our
3 operational requirements document. The Joint Program
4 Manager reports through the Assistant Secretary of the
5 Army for Acquisition, Logistics and Technology to OSD
6 A&T, Acquisition and Technology. Next slide, please.

7 (Slide.)

8 The mission of the JVAP is to identify and
9 transition viable candidates for biological defense
10 vaccines to the Advanced Development Program where our
11 prime systems contractor will continue with the
12 advanced development of these products, represent these
13 products to the FDA and become the license holder upon
14 the successful completion of that development effort.
15 Thereafter, the prime systems contractor will act as
16 our prime vendor in storing and replenishing stockpiles
17 of these vaccines and making them available to DoD upon
18 request. Next slide, please.

19 (Slide.)

20 The direction for the JVAP comes from a
21 Secretary of the Army memo from 25 April '95 that
22 identified the agents for which we needed vaccines, as
23 well as the baseline stockpile requirements for those
24 vaccines. These baseline stockpile requirements were
25 also identified in a Program Budget Decision of January

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1 '96, as 1.2 million Troop Equivalent Doses for the
2 high-threat weaponized agents, the two high-threat
3 weaponized agents, and 300,000 Troop Equivalent Doses
4 for all other agents. We were also given directions to
5 use the prime systems contract approach in that Program
6 Budget Decision.

7 Now, that baseline stockpile quantity was
8 qualified pending a Deputy Secretary of Defense
9 decision on implementing the immunization policy, and
10 so the policy that you speak about, the immunization
11 policy for biological defense vaccines calls for a
12 capability to acquire and stockpile vaccine sufficient
13 to immunize the program force which we estimate in the
14 neighborhood of 2.4 million Troop Equivalent Doses.
15 That term, Troop Equivalent Doses, refers to the number
16 of injections in the primary series. So a one-dose
17 vaccine is one Troop Equivalent Dose, a six-dose
18 vaccine is still a one Troop Equivalent Dose. Next
19 slide, please.

20 (Slide.)

21 In determining what products we need to
22 have options for as we were putting together our prime
23 systems contract approach, we looked at the threat list
24 as well as the vaccines that are maturing in the tech
25 base and would be available for continued advanced

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1 development during the period of performance of our
2 contract, and we looked at the operational
3 requirements. We are not going to bring a candidate
4 vaccine to advanced development unless it has a promise
5 of meeting the user's requirements as they are defined
6 in the Operation Requirements document. Next slide,
7 please.

8 (Slide.)

9 This is some of the typical operation
10 requirements in the OR, and FDA licensure is right at
11 the top of the requirements. Efficacy is defined, and
12 for the most part is minimally 80 percent of the people
13 receiving the vaccine against a battlefield exposure to
14 the biological warfare agent. A quick immune response,
15 a low primary series, and a long shelf life are also
16 what we are aiming for with our advanced development
17 program. Other systems characteristics call for us to
18 speak to the interference of these vaccines with other
19 medical products and nonmedical products that the
20 soldier might be exposed to that could create problems,
21 as well as providing some educational material in terms
22 of risk-benefit analysis that will help our
23 decisionmakers with decisions on implementing
24 immunization policies, and educational materials that
25 will help present that decision to the troops who are

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1 going to be immunized with these products. Next slide,
2 please.

3 (Slide.)

4 When the JVAP was awarded, we had three
5 products that were in advanced development -- a vaccine
6 for Q-fever, smallpox, and tularemia. Since the JVAP
7 has been awarded and established, we've transitioned
8 the Venezuelan Equine Encephalitis to advanced
9 development, as well as the multivalent recombinant
10 botulism vaccines. Other products that we have planned
11 to transition to advanced development include ricin,
12 plague, and a next generation anthrax vaccine, as well
13 as a multivalent equine encephalitis product, over the
14 next couple of years.

15 During this recent budget cycle, we
16 identified other products for which we have no funding
17 and requested funding to bring an SE product, a
18 brucellosis, a Marburg, Ebola, and a multi-agent
19 vaccine platform demonstration to advanced development,
20 and we did not receive funding to accomplish those
21 products. Next slide, please.

22 (Slide.)

23 Here we see the same slide that Carol
24 showed, showing above this line the major decision
25 points for the acquisition process, Milestones 0

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1 through III, the major phases of the DoD acquisition
2 cycle from basic research to procurement. Below this
3 line, we show the events that we have to accomplish in
4 each one of those phases to satisfy the decisionmaker
5 that we are ready to move to the next phase, and
6 ultimately to satisfy the FDA that we have a product
7 that's safe, efficacious, and worthy of granting a
8 license to.

9 This chart also shows a dividing line
10 between the research laboratories and the prime systems
11 contract approach where the program identification
12 occurs with a successful Milestone I decision and we
13 are off to advanced development with our prime systems
14 contract approach. We are working now with MRMC to try
15 to streamline this chart a little bit and work
16 cooperatively between this last phase of the tech base
17 and the beginning phases of advanced development to
18 accomplish some potential schedule savings and shorten
19 this process. Next slide, please.

20 (Slide.)

21 The Milestone 0 permits the beginning of
22 concept exploration of different technologies that
23 might be suitable to satisfying a requirement or
24 addressing a threat. The Milestone I has down-selected
25 some of those concepts for further exploration in a

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1 risk reduction and program definition phase, and if we
2 have an opportunity to streamline this and work this
3 concurrently, we might save a few years. Once we have
4 a Milestone I, the major events that we have to
5 accomplish for the next phase is demonstrate that we
6 can produce this product in a GMP compliant manner,
7 obtain information to support an IND application, and
8 start using the product in human trials to gather
9 safety and immunogenicity data, and begin the studies
10 for efficacy with surrogate animal models. Once we are
11 satisfied that we still have a promising candidate, we
12 will approach the decision authority again for
13 permission to go into the next phase and get into
14 large-scale expenditures with demonstration of
15 consistency in production and pre-production scale-up
16 lots, as well as large-scale clinical trials for
17 safety, then we'll have the information necessary to
18 put together an application to the FDA for licensure
19 and submit that for consideration to the FDA. At the
20 end of that consideration, we'll have the
21 recommendation to go into full-scale production of this
22 product if the application is accepted by the FDA.
23 These are the major events. There are many smaller
24 ones that were not addressed here, and you can see for
25 the most part they are going to be sequential, again,

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1 the large-scale safety trials until you are satisfied
2 that you have a product that you want to take into this
3 trial. This process is estimated to take anywhere from
4 six to many more years. And then I have a slide later
5 on that shows those schedules. Next slide, please.

6 (Slide.)

7 I'll start off by saying the Equine
8 Encephalitis vaccine that we had previously briefed as
9 being close to licensure sometime in the FY07 time
10 frame was impacted recently by some unexpected budget
11 cuts to the program, and I am working with the
12 Integrated Product Team to bring a recommendation to
13 the Milestone Decision Authority about combining this
14 effort and the Multivalent Equine Encephalitis effort
15 into one product that will go forward to licensure.
16 With the budget cut so severely that we cannot continue
17 with an Equine Encephalitis program separately, we
18 might be able to effect some economies to this long PDR
19 phase that would bring that one in a little sooner than
20 what I'm showing here.

21 The symbols on these slides indicate
22 little, white triangles where we are expecting to be
23 having enough information to submit a license to the
24 FDA. The star at the end of the red phase is the
25 acquisition phase for engineering and manufacture and

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1 development, the yellow is the program definition of
2 risk reduction phase, and the green is the production,
3 full-scale production\procurement phase. The stars are
4 where we're expecting after the FDA's review we will
5 have a product to take into production -- the black
6 diamonds. The stars are where we're showing for the
7 most part through the consistency lot production and
8 scale-up of this product we will have sufficient
9 quantity to meet the baseline stockpile requirements in
10 many cases, in most cases, well before that product is
11 ready for licensure. The Multivalent Equine
12 Encephalitis has a particularly long PDR phase because
13 it has five different subtypes of the Equine
14 Encephalitis product that need to be tested
15 individually in humans before they are combined to a
16 single multivalent product, as well as it is stretched
17 to accommodate some funding issues that were not
18 reasonably addressed in the recent POM bill. Next
19 slide, please.

20 (Slide.)

21 The prime systems contract was awarded to
22 DynPort as a joint venture between Porton International
23 and DynCorp, a major defense contract. It is an R&D
24 contract with options for limited production, cost plus
25 award fee.

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1 The basic contract had three products
2 already in advanced development with options for many
3 more products. The options are for predefined products
4 from equine encephalitis, botulinums and some of the
5 other products for which we don't have plan to take
6 candidates into advanced development for the time
7 being, but they are ready to be used in the event that
8 we are able to overcome some of these funding issues.

9 There are options for production for all
10 18 products, limited production, with options for
11 storage and maintenance as well for all of these
12 products.

13 It is a flexible contract vehicle insofar
14 as if we did not identify one of the threat agents for
15 which we needed a vaccine development effort, this is
16 the vehicle that we could modify to accommodate those
17 emerging candidate vaccines. We've used that
18 flexibility once before in adding an effort to acquire
19 a new vaccinia immunoglobulin that works with our
20 smallpox requirement. The previous product that was
21 licensed is no longer available to us and we need to
22 acquire a new capability for procuring more product,
23 and the prime systems contract is going to be
24 responsible for taking that new product to licensure
25 along with the smallpox vaccine that that product will

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1 support. Next slide, please.

2 (Slide.)

3 As the prime, DynPort will be required to
4 get the subcontractors on its team that will be
5 necessary to support all these efforts from Regulatory
6 Affairs, value management product testing, storage,
7 clinical trials, manufacturing, assay development, and
8 these are some of the subcontractors that DynCorp has
9 lined up to be part of the team for the five vaccines
10 that we have in advanced development right now. Next
11 slide, please.

12 (Slide.)

13 The Canadians, the UK and the U.S.,
14 CANUKUS, have entered into some Memorandums of
15 Understanding with the Department of Defense about
16 collaborative research and development, and one of
17 these is going to be signed soon. It's been through
18 Congress for its mandatory 30-day review and it's on
19 the verge of signature. Under this MOU, we will be
20 able to issue stand-alone project arrangements, PAs,
21 for vaccines that all three countries or any two of the
22 countries have an interest in an international
23 cooperative research and development effort for. Our
24 discussions have identified the smallpox vaccine as the
25 first one for those collaborative efforts, and next

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1 week we have some more discussions scheduled with the
2 CANUKUS partners to see where we can go with a national
3 program to provide a single CANUKUS vaccine to the
4 Armed Forces of all three countries. Next slide,
5 please.

6 (Slide.)

7 Some of the prerequisites to collaboration
8 that we've identified are aligning the vaccine
9 requirements for these projects, understanding the
10 regulatory requirements for each of the countries
11 participating, regulatory authorities for each of
12 these; establishing what kind of baseline stockpiles
13 each one of the countries wants to address through this
14 agreement, as well as negotiating equitable
15 contributions to the effort.

16 After smallpox, the next on the line are
17 the plague vaccine and the next generation anthrax
18 vaccine. I think all three countries also have an
19 interest in those two vaccines as well. Next slide,
20 please.

21 (Slide.)

22 Some of the challenges to the program are
23 defining the production capability requirements. I've
24 gone through a prime systems contractor identifying our
25 baseline stockpile requirements, but have been asking

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1 him to keep an eye on a production capability that will
2 satisfy the policy and have us be able to provide
3 adequate stocks of vaccines to immunize the program
4 force, although we can't contract for that, but there
5 are some tweakings that can be done to the process that
6 manufactures these products that would make it more
7 scalable in the event those decisions for immunization
8 policy are announced.

9 Some of those make it more difficult to
10 address, and there are some recommendations you could
11 make about exactly what end point for production do we
12 need to maintain for the DoD that would be useful to
13 the JVAP program. Identifying the battlefield exposure
14 levels for which a vaccine, a BD vaccine, is supposed
15 to provide protection would be -- that has been a
16 challenge and that has caused a lot of uncertainty
17 about whether or not our vaccines -- although we are
18 going to have adequate information to show that they
19 are efficacious against exposure in laboratory, I
20 think, will satisfy the FDA that they'll be licensed,
21 will we have enough information to convince our user
22 that these are the products that we want to take to the
23 field. Until we can identify what battlefield
24 exposures that he is likely to encounter in the field
25 and can demonstrate to him that these vaccines are

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1 going to protect against that exposure, we have a
2 challenge.

3 Some of the emerging requirements from the
4 FDA have been a challenge. Reproductive toxicology
5 studies are something that was unanticipated when this
6 contract was awarded, and gives us a chance to use some
7 of the flexibility of the prime systems approach as
8 well in putting that requirement on the contract.

9 Pediatric rules. We never had anticipated
10 that we would have to gather safety and efficacy data
11 for the use of these products in populations other than
12 the young, healthy service member. And cooperative
13 development are also challenges, aligning requirements
14 and negotiating agreements and avoiding schedule
15 impacts are problems for our CANUKUS partners as well
16 as with the domestic partners and the HHS with next
17 generation anthrax vaccines. There are some
18 discussions of possible cooperative research and
19 development. And we were not able to come to terms
20 with the CDC before they decided that they would have
21 to release their own solicitation for a smallpox
22 vaccine, and they are in source selection now with an
23 award expected sometime this summer for a smallpox
24 vaccine program. Next slide, please.

25 (Slide.)

1 In summary, what we have is a vaccine
2 development program involving a substantial investment
3 of time, effort and resources in the complex regulatory
4 and legal environment. Once we have a product in
5 advanced development, I need to make a commitment to
6 the industrial base and my contractor that the DoD is
7 not so fickle that we're going to walk away from this
8 and tell them to do something else, and these new
9 priority lists that come up, we need to recognize that
10 once we start something we need to maintain that
11 investment with the existing technology base, or
12 industrial base, so that they will continue to be
13 receptive to our requirements and meeting our
14 requirements when we identify them.

15 We have a commitment to cooperative
16 development as well. We have a prime systems contract
17 approach that provides the flexibility to meet the
18 DoD's requirements in obtaining that capability for
19 acquiring and stockpiling BD vaccines. That's all I
20 have to say, and I'll be happy to answer the questions
21 that you might have.

22 DR. LaFORCE: Steve.

23 DR. OSTROFF: I have a couple of comments
24 and questions. Looking at the -- and I realize that
25 this is a very difficult environment and I appreciate

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1 all the work that's been done. I guess the question --
2 obviously, with the experience in procuring anthrax
3 vaccine does not instill tremendous confidence about
4 the ability to effectively maintain stocks of other
5 vaccines. I don't know a lot about DynPort and the
6 capabilities of DynPort. I don't recognize a lot of
7 the subcontractors.

8 One of the questions that's come up
9 repetitively in recent years is, would it be
10 advantageous to potentially have a Federal Production
11 Facility, particularly for vaccines that would have
12 little commercial value outside of certain sectors, and
13 I'm wondering what your thoughts are about that.

14 As far as the decisionmaking about CDC
15 deciding to let their own contract or let out
16 solicitations for their own contract for smallpox
17 vaccine, obviously the volume that we were looking at
18 is orders of magnitude above what DoD is interested in
19 procuring, and the cost associated with the DoD
20 smallpox vaccine was deemed to be quite prohibitive.
21 So the idea was could we go out there and maybe similar
22 to some of the decisionmaking around the antibiotic
23 procurement where cost was a significant consideration
24 for us in terms of smallpox acquisition. And I think
25 that, in large part, plus questions about the DoD

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1 contractor, I think, led to that decisionmaking.

2 MR. PAUL: I think CDC is not getting a
3 completely different group of responders to their
4 solicitation than what we did when we announced the
5 JVAP solicitation. I am not privy to everything that
6 is going on in their source selection, so I can't say
7 anything more than that.

8 Before the prime systems contract approach
9 was decided, there were many analyses done to look at
10 the possibility of Government-owned -- contractor-
11 operated, Government-owned, Government-operated and
12 contractor-operated approaches to fulfilling these
13 requirements. The prime systems contract approach was
14 chosen because it is a variant of the contractor-owned,
15 contractor-operated approach to meeting this
16 requirement, and that has consistently come out on top
17 of previous analyses. There has been a new analysis
18 directed for this summer to be finished by the end of
19 the year, to look at this issue again.

20 DR. OSTROFF: But I guess the question is,
21 what assurances do you have that you won't end up in
22 the same situation that you are currently in with
23 anthrax vaccine?

24 MR. PAUL: Anthrax vaccine is a prime
25 example of a Government-owned, Government-operated

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1 facility. When the State of Michigan owned it, they
2 had the problems, and those problems were not
3 correctable in a regulatory profit-making environment
4 that we're trying to employ. With none of these
5 subcontractors other than DynPort is 100-percent
6 dedicated to the JVAP. We are using their access
7 capabilities and their commercial business to meet our
8 requirements, and if they run into regulatory issues
9 with their facilities, they have to fix them for their
10 own profit-making business as well as what we bring to
11 them. We're not on the dime to fix them 100 percent.
12 Some of them are going to be mostly dedicated to the
13 JVAP, and I expect that we'll be managing that risk as
14 we can. What guarantees are there? Other than the
15 profit motive for the participating subcontractors, I
16 don't think there are any guarantees.

17 DR. LaFORCE: When will we know whether
18 this entire approach is working or not working?

19 MR. PAUL: It's working.

20 DR. LaFORCE: No, no. In terms of having
21 product.

22 MR. PAUL: A licensed product?

23 DR. LaFORCE: Yes.

24 MR. PAUL: You see the schedule, slide No.
25 11.

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1 DR. LaFORCE: Okay, so that's the report
2 card?

3 MR. PAUL: The progress that we're making
4 toward that schedule is something that we brief
5 regularly to our DoD leadership as well as our Joint
6 Program Managers.

7 DR. LaFORCE: No, no, no. The reason for
8 asking is, I am always so impressed at how complicated
9 this stuff is. Every time this is sort of laid out to
10 me, it just seems so daunting that it -- I'm sort of
11 looking at when the box of vials are going to come out
12 for use, but one requires a lot of faith and patience.

13 MR. PAUL: An IND is scheduled to be filed
14 in the next few weeks for the new vaccinia
15 immunoglobulin product. That product has been
16 manufactured. We have information about the testing of
17 that product that will support that IND, and that's one
18 of the first that's likely to be a success, but that's
19 not a separate, stand-alone BD product. I don't read
20 that separately, but we acquired cell banks, working
21 cell banks, master cell banks, for smallpox. That is
22 expected to go into production scale-up later this
23 fall. Tularemia is in small-scale process definition.
24 There were some backward steps we had to take to
25 address some of the regulatory and manufacturing issues

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1 that were previously accomplished that -- in the new
2 FDA regulatory environment we no longer can use that
3 information to support a licensure of these products,
4 and we have to position ourselves to gather that
5 information again in a way that will support licensure.

6

7 Col. Takafuji, do you have a comment?

8 COL. TAKAFUJI: Yes. Let me sort of help
9 you with that one because it's a politically difficult
10 issue to address, but it's also one that I think has to
11 be put in the right context. In reference to a
12 national facility to make vaccines, there has been a
13 lot of discussion over quite a few years in terms of
14 whether we can justify or not. There was a time when
15 the Department of Defense really went at it by
16 themselves, looking at that very issue, realizing that
17 many pharmaceutical firms, frankly, did not see it as a
18 cost -- more cost-prohibitive to get involved with
19 making vaccines in small numbers only for one customer,
20 namely, DoD. And as a result, we had a problem where
21 we were then forced to go into something along the
22 lines of a prime systems contract approach to find a
23 partner in terms of producing a vaccine, or taking it
24 to the next step in terms of advanced development.

25 But things have changed since then,

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1 changed in several regards, certainly in terms of the
2 biotreat, but also in terms of a national strategy in
3 terms of vaccines for this nation, vaccines that not
4 only would have a DoD use, but also would have civilian
5 applications. And whether we're talking about
6 pertussis, or whether we're talking about adenovirus,
7 or whether we're talking about an anthrax vaccine,
8 there clearly is a need for vaccines that have wide-
9 range applicability beyond just the DoD community. So,
10 I think these discussions and revisiting of the issue
11 of a national vaccine production facility that are
12 going to be taking place in the future is something
13 that the AFEB should be monitoring very carefully
14 because sooner or later I think the AFEB is going to be
15 addressing that in terms of some recommendations
16 whether there is that need.

17 Bill Robb, in Health and Human Services,
18 has been deeply involved in developing a national
19 vaccine strategy for this nation that will be going to
20 the President in terms of recommendations, and
21 certainly DoD is a partner in that, Health and Human
22 Services is a partner, the other departments are
23 partners in that whole effort, and I think that needs
24 to be addressed.

25 DR. OSTROFF: They already did, and they

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1 are also very interested in the issue.

2 COL. TAKAFUJI: The other thing that I
3 want to make sure that CDC understood, though, is that
4 we're in a difficult dilemma because although we
5 recognize that we would love to see a national effort
6 in terms of a vaccine being developed jointly with
7 Health and Human Services, we are being pressured from
8 another end, and that is from the standpoint of our
9 Allies because we operate in joint environments where
10 there is a need for interoperability with certain
11 vaccines and, as a result, whether it's dealing with
12 the United Kingdom or France or whatever nation, there
13 is a pressure on us to go into co-development and
14 certainly co-development in terms of research towards
15 some type of vaccine that would be applicable across
16 all forces, regardless of what country you are a part
17 of but still part of a coalition force.

18 So, hence, some of the interest -- for
19 example, the smallpox vaccine -- this is a cell-culture
20 derived vaccine. CDC, on the other hand, is still
21 looking at different options with the old vaccine.
22 There are some disconnects there, that's readily
23 apparent, but it does make sense that sooner or later
24 we do need to come together and someone does need to
25 make a decision at a high level -- certainly many

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1 grades above me and you -- saying that we need to work
2 together, and it's departments working together in
3 terms of a national strategy to co-develop a vaccine
4 that would be of use to all U.S. citizens whether at
5 home or abroad.

6 DR. LaFORCE: Okay. Thank you. It's now
7 11:23. We've got until 1:00 o'clock, since we've got a
8 working lunch planned, and there's a couple of
9 questions that need to be wrestled with. From my
10 standpoint, it's really important that we be very
11 focused to finish these activities, because from 12:00
12 to 1:00, in Closed Session, we have to review -- we've
13 got a fair amount of work to do. We have to review the
14 recommendations that are being massaged. There are a
15 couple of administrative issues that I would like to
16 discuss again with the Board alone, and lastly, a topic
17 that needs to be aired a bit about varicella vaccine.
18 And so there's plenty of work for that closed session,
19 plus all the other details that have to be ironed out.

20 What I very much would like to do is spend
21 some time over the next hour, hour and a half, focused
22 on the memorandum from the Secretary of Defense -- the
23 threat list. We have two tasks, as I recall --

24 COL. DINIEGA: For the Board questions?

25 DR. LaFORCE: Right.

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1 COL. DINIEGA: We have three Board
2 questions -- squalene, DoD ergonomics, and antibiotic
3 and BW agents -- and that was addressed yesterday at
4 the subcommittee, and then today the task is
5 countermeasures -- we heard what the BW Threat List for
6 2000 is, and are there any recommendations pertaining
7 to the 2000 List. And then part of that now is --
8 there was a question asked for the medical risk
9 analysis as a follow-on to the 1999 BW recommendations.

10 DR. LaFORCE: And I would read that as
11 follows from Dr. Bailey. "The AFEB has recommended
12 that the DoD staff proponent initiates a review of the
13 DoD Directive 6205.3 and that a medical risk analysis
14 be conducted for all validated threats to supplement
15 intelligence-based determinations. Since it is the
16 role of the Chairman of the Joint Chiefs of Staff to
17 validate and prioritize the biological warfare threats
18 to DoD personnel and forward that list to the DoD
19 Executive Agent, the Secretary of the Army, through the
20 ASD, I request that you conduct a medical risk analysis
21 as soon as possible and incorporate this analysis in
22 your prioritization of threats. Consideration should
23 be given to the debilitating or lethal effects of the
24 specific agents, the risk of contracting and spreading
25 infection to others, and the potential impact on

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1 mission accomplishment."

2 I don't know what's your take on this, but
3 this is a pretty broad mandate, and I think is an item
4 that is going to require some discussion and
5 deliberation.

6 COL. DINIEGA: Just a correction on some
7 of this. This was the letter from Dr. Bailey to the
8 Chairman of the Joint Chiefs of Staff, to have the risk
9 analysis incorporated as part of the prioritization
10 process. And as we heard in the follow-up of last
11 year's recommendations, the track now has changed a
12 little bit, and the medical input is to come after the
13 prioritization of the Chairman's threat list and to be
14 used in conjunction with the intelligence-based threat
15 list.

16 But before we go on, I'd like to just
17 clarify one thing -- and, Mr. Plasse, the question is
18 to you -- this year's threat list compared to last
19 year's threat list, what are the specific changes?

20 MR. PLASSE: Specific changes -- India was
21 added on -- and, again, this is --

22 COL. DINIEGA: You need to come up to the
23 table. We are in an unclassified mode.

24 MR. PLASSE: India -- in an unclassified
25 way, I can say India has been added to the list, and

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1 there have been some changes in the agents but, overall
2 -- as far as the overall amount of agents on the list,
3 they really haven't changed. There's no new organism,
4 toxin or agent that has come along that has been added
5 to the list. So, bottom line to the Board, it's
6 probably minimal.

7 DR. HAYWOOD: Has there been any change in
8 the ranking?

9 MR. PLASSE: No.

10 DR. HAYWOOD: And who has the ability to
11 do the ranking?

12 MR. PLASSE: Well, the threat, as you saw
13 before, is ranked by us, by DIA, by the number of
14 countries that have the agent. So that really hasn't
15 changed.

16 COL. DINIEGA: So, the bottom line is,
17 there is no change in the threat list. So the question
18 is, do we want to make any new recommendations to the
19 current list, which is pretty much the same as last
20 year's?

21 DR. LaFORCE: I don't see any reason to,
22 at least in terms of what I've heard this morning, but
23 I'm anxious to hear what other member of the -- Steve,
24 you've followed this pretty closely.

25 DR. OSTROFF: I don't think the list is

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1 that much different from the list that's been developed
2 by anybody else. There's certainly nothing on there
3 that I think we wouldn't say needs to be on there based
4 on what I saw this morning.

5 DR. LaFORCE: Ted?

6 DR. TSAI: I know that there are 50 other
7 viruses -- you know, that are numerous -- Omsk
8 hemorrhagic fever, Kajmafors (phonetic) disease -- that
9 have not appeared on the various lists, I'm not sure
10 why. A number of years ago there was a report in
11 Russian, translated by Virology Journal, on an outbreak
12 of Dory (phonetic) viral infection occurring somewhere
13 in Russia. I always wondered why they were studying
14 Dory virus -- this is an orthomix (phonetic) virus
15 that's translated by ticks. It's related to influenza-
16 C that caused CNS infections in lab workers that were
17 involved in a lab accident. There are a number of
18 obscure agents that I think one could point to as
19 potential agents that could be weaponized. It's sort
20 of limited by the imaginations of the terrorists and
21 the accessibility of these agents. And I guess I'm a
22 little uncertain of the process by which these agents
23 appear on lists.

24 MR. PLASSE: And, again, we're talking in
25 an unclassified setting here, but the directive for the

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1 JCS matrix for the threat list, it's an intelligence
2 document, therefore, it is based on intelligence
3 reporting. If there is no intelligence reporting to
4 support Omnsk or the other tick-borne hemorrhagic
5 fevers to be used as a BW agent, it doesn't appear on
6 the list. That is not saying that they are not
7 potentially good agents -- Hanta viruses are out there
8 and people are very concerned about them, they just
9 haven't been -- there is no reporting on them to verify
10 them as a threat agent, based on intelligence.

11 DR. TSAI: I don't know if you can comment
12 on that Dory virus report because it clearly was an odd
13 agent that doesn't -- it's not a great public health
14 concern anyplace, there's just a handful of clinical
15 case reports on ten illnesses --

16 MR. PLASSE: No.

17 DR. TSAI: -- but it is an influenza-
18 related virus, and potentially one could imagine it
19 could be engineered to be spread in a respiratory
20 fashion.

21 MR. PLASSE: Don't disagree with that.
22 The Russians have played with pretty much every
23 pathogen we know of at one point or another. Whether
24 they get through their system to be a BW agent is
25 another question. And as far as reporting on it, there

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1 really isn't anything to base that on as being a threat
2 agent.

3 DR. LaFORCE: Ben, you wanted to bring
4 something up.

5 COL. DINIEGA: Yes. Dr. Linden, before
6 you leave -- I think the gist is that the list hasn't
7 changed, and really I don't hear anybody saying that we
8 need to make any new recommendations, but one of the
9 issues, if you look at the time lines -- Mr. Paul also
10 -- if you look at the time lines, there are some
11 vaccines that are not going to be available for five to
12 ten years. And we saw and heard about the research
13 efforts, and we talked about BW agents and antibiotics
14 yesterday, and antibiotics for treatment and
15 antibiotics for potential chemoprophylaxis use. If
16 there is a gap between that long, what is the interim
17 solution for an attack using an agent that we don't
18 expect a vaccine for eight years? Is anybody
19 addressing temporary solutions or gap solutions?

20 MR. PAUL: I indicate on the chart that I
21 presented a star where those products would be
22 available in sufficient quantities as IND products to
23 meet our baseline stockpile requirements.

24 COL. DINIEGA: Which will take a
25 Presidential Directive to employ as a policy --

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1 MR. PAUL: To waive the policy for the use
2 of those without informed consent. Otherwise, they're
3 available, or would be available for use under informed
4 consent as soon as the IND is filed early in the PDRR
5 phase.

6 DR. LaFORCE: To be very specific,
7 according to this chart you would envision -- and this,
8 again, is where the stars are -- a vaccine that would
9 be available for use, assuming Presidential clearance
10 that it could be used, for Q-fever in 05?

11 MR. PAUL: That particular product is a
12 product that's licensed for use in Australia right now,
13 and we're gathering information for the licensure of
14 that product in this country, but the product exists
15 already in smaller quantities. To renovate their
16 facility and make it capable of producing in quantity -
17 -

18 CDR. McBRIDE: Dr. LaForce, may I make a
19 comment to clarify -- I don't know if this is well
20 understood. As soon as a product is available as an
21 IND agent, it can be administered freely, but it
22 requires an informed consent. The Presidential matter
23 only waives that requirement. So as soon as it's
24 available as an IND vaccine, it can be used freely, but
25 it requires informed consent for the service person.

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1 DR. LaFORCE: Which is voluntary.

2 CDR. McBRIDE: And it's voluntary, and
3 they can't be compelled to take it.

4 MR. PAUL: That's not really true. It
5 needs to be used under that development effort. And
6 the circumstances under which it can be used is
7 logistically burdensome, but it can be used.

8 COL. DINIEGA: The only issue I want to
9 bring up is if there's that long of a gap, what are
10 other alternatives in case that agent is used in an
11 attack upon our personnel?

12 CDR. McBRIDE: It can be taken on a case-
13 by-case basis, what's available for that particular
14 infection -- infectious agent.

15 DR. LaFORCE: Ron?

16 DR. WALDMAN: Isn't that part of the
17 medical risk analysis? The only thing, it seems to me,
18 that's going to be brought to bear on the list as it
19 currently exists that would result in changes are going
20 to be the addition of the medical risk analysis, and we
21 had the presentation on that. I guess that I was a
22 little bit confused about the time line for completing
23 the medical risk analysis of those current conditions
24 with which we're dealing. I know that it's only
25 recently been passed, I guess -- we had an overhead

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1 that showed that process -- but the question is, who is
2 responsible for carrying it forward? Is there a time
3 line that's going to enable us to bring recommendations
4 for changes to the existing list? Is there active Board
5 involvement in conducting that analysis, or is that
6 being done all by the groups that we heard from earlier
7 this morning?

8 LtCOL. SCHNELLE: I can address some of
9 that. The draft Scope of Work is in my office now. In
10 tentative discussions with a contractor, we could
11 convene the Medical Risk Analysis Panel as early as
12 September. That might get pushed back a bit, if
13 convening the Joint Service Panel extends that time
14 line. That panel would include not just contractor
15 personnel, but also representatives from AMED Center
16 and School, USAMRIID and other relevant organizations.

17 DR. WALDMAN: Will there be
18 representatives from this group then, as well?

19 LtCOL. SCHNELLE: I would imagine so, yes.

20 DR. WALDMAN: Because the key factor in
21 conducting that, I think, is going to determine the
22 appropriate criteria on which the analysis will be
23 based.

24 LtCOL. SCHNELLE: And if it's feasible in
25 the classified environment or in some limitations, to

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1 refer to Col. Takafuji's point, the NATO countries on
2 the Bio Medical Advisory Committee, on which I also
3 sit, have asked to be represented or also attend
4 certain portions of that so they can learn from that
5 process as well. So, I imagine it will be quite a
6 large panel in many respects.

7 RADM. JOHNSON: In listening to the
8 discussion and kind of putting myself in the
9 perspective of the warfighters that I hear a lot, I
10 think the point about part of the medical risk and gap
11 analysis may be very important. What the warfighting
12 CINC is going to want to know, and needs to know
13 somehow, is -- they identify a threat or a bunch of
14 threats, and that's an intelligence issue -- then from
15 a medical standpoint is going to want to know what in
16 his tool kit is usable. He's going to want to know if
17 it's a vaccine -- if that's the approach, if it's one
18 that's licensed, there's plenty of it, troops immunized
19 -- that's going to put that threat at a certain level.

20 If the only thing that's available, or if
21 there's absolutely nothing available, and nothing is
22 being worked on, then that's a whole order of magnitude
23 difference, which may affect how he does his battle
24 plan. The gap in between is when there is something
25 available but it's in this pipeline that is anywhere

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1 from five to 17 years long, but the threat is here
2 today. It's not at Day 17. And what are the
3 restrictions? Is this really available or not? Is
4 this an IND? Does the CINC need to go and say "I've
5 got to prosecute in this theater, I've got this threat,
6 there is this thing that's out in IND, and I've got to
7 go to the President via the Joint Chiefs of Staff and
8 get this waived". Maybe he needs to have a list of
9 threats for which the solution are these very
10 complicated, very politically (sic) situations, if
11 that's the only thing available. And I would think
12 that would be very useful information, however it is
13 presented, and probably it's something not as
14 complicated as a big matrix decision tree, but
15 something fairly simple. Here are the threats. These
16 are good to go -- plenty of vaccine, easy to do,
17 everybody's got it. Here's another bunch of threats,
18 we've got nothing. We're dead in the water if this one
19 shows up. And in the middle there are some things that
20 are maybes, but here are some very complicated things,
21 and the CINC needs to be aware of that because to get
22 use of these products, he's got to be thinking about
23 that, or somebody early on, because you can't just turn
24 this on and off that easily, both from a political
25 standpoint and from an availability standpoint. That

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1 might be something, however you recommend it, to put
2 into the medical risk analysis.

3 DR. LaFORCE: Other comments?

4 (No response.)

5 Not hearing any disagreement, then I would
6 propose that we assume that as a responsibility in
7 terms of Ron's suggestion and also what Ben suggested,
8 that we sort of look -- if there are interim steps
9 prior to a vaccine, and to actually weigh that within
10 the decision panel in terms of this risk stratification
11 that we're going to be doing. I didn't say that very
12 clearly, but I hope you understand what I mean.

13 DR. ANDERSON: I would think that kind of
14 take as a template what we did last year and say the
15 medical risk analysis, we think, is a good plan, it's
16 well started. And under that we could say "however, it
17 needs to be organized from a field standpoint into,
18 just as we heard, those where we have a well in place
19 risk reduction activity, those which are more
20 problematic and those for which we have not, and that
21 would fit under a recommendation for additions to the
22 risk analysis that we could think about.

23 DR. LaFORCE: Ernie?

24 COL. TAKAFUJI: Yes, sir. I go along with
25 that. I think that would be very useful to back up the

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1 Admiral and his comments, too. The idea here is to
2 have those parameters that you saw presented identified
3 the agent issues, the agent characteristics that make
4 an agent particularly useful as a biological weapon and
5 threat and so forth, and keep that separate from the
6 countermeasures. And on the countermeasures, as LtCol.
7 Curling had recommended, we would include both the
8 prevention, the diagnostics and the treatment as three
9 different categories. If you have prevention, for
10 example, in terms of a vaccine, that needs to be
11 stated. If one is in development, that needs to be
12 stated. The same thing with antibiotics or whatever it
13 may be, which is another issue that this Board is
14 addressing, but also with the idea of rapid diagnostics
15 on the battlefield, which I think is a very important
16 part of the total equation. That would be, I would
17 think, very useful to the warfighter, to the medical
18 planner. It's something that we can, I think,
19 integrate relatively easy as we move forward to the
20 next step, don't you think, LtCol. Schnelle?

21 LtCOL. SCHNELLE: Yes, sir.

22 COL. TAKAFUJI: Okay. And I think we need
23 to then just lock in some time frames and then move
24 ahead with that. But your recommendations would
25 reflect that, I think.

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1 DR. LaFORCE: Ron.

2 DR. WALDMAN: Maybe I could make a
3 specific recommendation -- and I'm not sure exactly
4 what the intent of the Board was in making the
5 recommendation that the medical risk analysis be
6 conducted because I wasn't here for all those meetings.
7 I doubt, though, that it was meant to be a
8 recommendation and then to let it go. I'm sure there
9 was intended to be some ongoing involvement with it.

10 It seems to me that one of the earliest
11 tasks of the people conducting that analysis is going
12 to be to determine what the criteria, what the
13 parameters are, which are going to be applied to each
14 of the conditions. And I know it's just been said that
15 the panel is not going to be formed until September,
16 but I wonder if in order to ensure the ongoing
17 involvement of the Board that there couldn't be --
18 Marc, if you couldn't determine on behalf of the Board,
19 that there be an updating of the activities on a
20 regular basis. Maybe there should be a report at each
21 of the next few Board meetings, at least with the first
22 one specified as a review of the parameters that might
23 be adopted for application.

24 DR. LaFORCE: I think that's a great idea
25 because this is one of those pieces of business that's

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1 going to continue on for a period of time.

2 COL. DINIEGA: It's done.

3 DR. LaFORCE: We thank you. All right,
4 it's done. Other questions, comments about this?

5 (No response.)

6 Hearing none -- I'm sorry. Andy?

7 DR. ANDERSON: If we're moving on to
8 another area, I just see under No. 4, the effectiveness
9 of current medical surveillance as an early detector.
10 I don't know if we want to just reaffirm all of the
11 various recommendations.

12 COL. DINIEGA: I was not here for all the
13 briefings, but I'm assuming you were, and I'll just add
14 to that. I can say a little bit about that. A week
15 ago I went to a meeting sponsored by GEIS, the Global
16 Emerging Infection System, out of WRAIR, Dr. Kelly's
17 group, and the topic was Syndromic Surveillance for
18 Detection of Bioterrorism, and we had -- it was a very
19 well mixed audience. We had Public Health officials
20 from the civilian sector. We have military
21 presentations on initiatives in the arena of using
22 syndromic surveillance to detect the potential exposure
23 to BW agents. And I think when we made the
24 recommendation last year, it was to provide impetus to
25 medical surveillance efforts, and to use those efforts

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1 to identify or detect early warning signs of BW use,
2 and that effort is an ongoing thing. But I think in
3 the military, there hasn't been that big of an emphasis
4 on it. Is Steve here?

5 DR. LaFORCE: Steve's gone.

6 COL. DINIEGA: I was going to ask Steve --
7 there's some dollars available through CDC to do that,
8 but a very limited amount of dollars. And at the end
9 of the meeting, in looking at the strategy for getting
10 the BW surveillance initiative started, there was a lot
11 of talk about the fact that they don't have senior
12 leadership recognition of the need for syndromic
13 surveillance, nor do they have enough funding to assist
14 in that initiative. And so they talked about strategies
15 to obtain funding and personnel to help do this, to
16 include congressional lobbying, et cetera.

17 COL. TAKAFUJI: If I could make a
18 recommendation, it would be appropriate, I think, for
19 the AFEB to get a briefing at its next meeting on the
20 whole issue of surveillance, certainly the syndromic
21 surveillance would be a part of that, as well as an
22 update in terms of what the service initiatives are.

23 Remember that a lot of the surveillance
24 responsibility falls within the CINCDoms themselves,
25 and it's up to the CINC or the task force surgeons to

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1 kind of decide what they want to do and how they want
2 to do it and so forth, but I would think that that's
3 going to require a whole discussion in itself, and we
4 certainly, at DoD Health Affairs, would support that be
5 an issue for the next meeting.

6 COL. DINIEGA: Just my overall impression
7 at the meeting, that there's a lot of initiatives.
8 These things are very -- their sensitivity and
9 specificity are of question. They all said they do a
10 good job, but there's really been no "efficacy" trials
11 of any sort.

12 COL. TAKAFUJI: And, Col. Diniega, there
13 another part to that, too, and it has to do with the
14 laboratory based surveillance. It's one thing to be
15 doing programs for syndromes, whether it's fever,
16 diarrheal disease and so forth, it's another thing for
17 us to have the infrastructure and the laboratory and
18 hospitals to be able to actually take specimens and
19 actually come up with an accurate diagnosis. Many of
20 our hospitals are already pretty cramped in terms of
21 their budget. There is very little budgetary allowance
22 for many lab officers to be able to do epidemic
23 outbreak type situations when some very sophisticated
24 diagnostics may be required. So, one part of that
25 surveillance effort should probably be looking at the

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1 laboratory-based surveillance part of it, too.

2 COL. DINIEGA: Right.

3 COL. TAKAFUJI: I would think the AFEB
4 would be very interested in that.

5 COL. DINIEGA: Yes. At the meeting, they
6 talked about that the syndromic surveillance would be
7 like an early detector, then you would have to go in
8 and do an outbreak investigation, essentially, and have
9 the right diagnostic tools to go along with that
10 investigation.

11 I saw Dr. Eric Henshal (phonetic) in the
12 hallway just yesterday, and I have told him that we
13 probably will be asking him to come and talk about the
14 diagnostic capabilities and the research and
15 development in that arena at our next meeting.

16 DR. ANDERSON: At the conference we went
17 to, there was a number of software packages that allow
18 one to identify when there is an excess and things like
19 that, and it sounded as though some people were in fact
20 using or had put those into play, and it would be
21 interesting to see if there are some results and is it
22 useful and some evaluation of those.

23 I guess what I was just suggesting that
24 maybe in our report this year we just reaffirm what we
25 said last year, say that progress is being made, and

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1 then underscore a few of these other things because
2 gradually over the years these reports have been
3 becoming more and more prescriptive in what our
4 recommendations are. So I don't want to lose something
5 that we have here so that -- I don't want to leave the
6 impression that, well, because we didn't mention it in
7 this report, then we've moved beyond it. So, I just
8 think we want to say we are adopting everything. We
9 didn't find anything that was irrelevant that we
10 recommended the last time, progress is being made.
11 It's a long-term thing, and we need to continue to -- I
12 mean, the surveillance issue is here, then it talked
13 about the tri-service software program advancement, and
14 that maybe some of us need to get updates on at a later
15 date -- or you do.

16 COL. DINIEGA: I think that would be
17 reasonable.

18 DR. LaFORCE: We're going to pass out the
19 lunches and get you started on that, and give us about
20 a ten-minute break while we look at a couple of
21 questions.

22 (Whereupon, a short break was taken.)
23
24
25

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WORKING LUNCH

(12:20 p.m.)

DR. LaFORCE: Let me call the meeting back to order. I want to summarize where we are in terms of the biological warfare issue. First and foremost, we've agreed unless there's some disagreement that the threat list for the year 2000 we're not going to offer any changes. And, secondly, I would very much like to go through the memorandum dated 25 May 1999. This is really the document that we need to give some sort of feedback on, and it's a long enough document that I

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1 just want to go through the paragraphs individually.
2 Julian brought up some points in terms of -- I didn't
3 want any misunderstandings of who was responsible for
4 what, and I thought the easiest way, and the surest
5 way, to do that so that I don't make too many mistakes,
6 is to actually go through the document.

7 COL. DINIEGA: Let me just make sure
8 people understand what document we're talking about.
9 This is last year's AFEB recommendations back to the
10 Assistant Secretary of Defense for Health Affairs
11 concerning the 1999 BW Threat List that was presented.

12 DR. LaFORCE: AFEB (15-1a) 99-5. Okay. I
13 would begin with item No. 2, "After review of the
14 Biologic Threat Matrix and the above directive, the
15 AFEB makes the following comments and recommendations:

16 "a) The AFEB continues to strongly
17 endorse the current DOD anthrax vaccine immunization
18 program. Further, the Board recommends that DOD
19 aggressively pursue clinical investigations necessary
20 to revise or accelerate the current anthrax vaccination
21 schedule."

22 I think that's pretty noncontroversial and
23 it's something that we feel pretty strongly about.

24 COL. DINIEGA: Let me mention, in the
25 interim after last meeting, we did write a Statement of

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1 Support for the anthrax vaccine immunization program,
2 which Dr. Grabenstein and the AVIP agency welcomed with
3 open arms. So that part was done. And on Mr. Paul's
4 slide, the bottom one on the schedule was the next
5 generation anthrax vaccine.

6 DR. LaFORCE: Okay. Second paragraph:
7 "b) Regarding the use of vaccines and biologics to
8 protect against BW agents, the AFEB recommends that the
9 prioritization for vaccine development, and the use of
10 resources be directed in the following manner:"

11 Then we went through Tier I, Tier II, Tier
12 III.

13 "Tier I: Highest priority to rapidly
14 accelerate and immediately establish vaccine production
15 capability. Agents listed under Tier I include
16 smallpox, plague, anthrax and staphylococcal
17 enterotoxin B.

18 "Tier II: High priority candidates for
19 vaccine development as soon as possible. Agents include
20 ricin, botulinum, tularemia, hemorrhagic fever viruses,
21 encephalitis viruses, Q fever, brucellosis, and
22 shigellosis.

23 "Tier III: Warrants further research and
24 close observation for scientific developments or
25 validated new threats that would move it into Tier I or

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1 Tier II, all other biologic agents.

2 "c) The Board strongly felt that a
3 complete response to the validated biological warfare
4 threat matrix involves more than vaccine
5 recommendations per se. Therefore, we recommend a
6 review of DOD Directive 6205.3, and that it be revised
7 with attention to the following issues:

8 "1) The Board recognizes that
9 prioritization of BW threats is currently only
10 intelligence-based, with no consideration of medical
11 risk-based measures. The Board strongly felt that a
12 medical risk analysis is a vital piece of data needed
13 for prioritization of administering and developing new
14 vaccines. Such input will insure that the proper
15 number of doses are recommended for stockpiling, for
16 use in DOD personnel, essential civilians, contractors,
17 et cetera. Formal medical; risk-analyses should be
18 conducted for all validated agents. Priority should be
19 given to a highly transmissible scenario such as
20 smallpox."

21 COL. DINIEGA: Comment?

22 DR. LaFORCE: Yes.

23 COL. DINIEGA: That was the proposal from
24 LtCol. Schnelle. The only difference is that the
25 validated intelligence-based threat list will continue

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1 the way it's been, and we will then add the medical
2 risk analysis for the user community to also take into
3 consideration.

4 On the issue of highly transmissible
5 scenarios, this doesn't pertain really directly to this
6 recommendation, but the Institute of Defense Analysis
7 is working on a model to look at primary, secondary,
8 tertiary transmission rates, and there is a draft
9 that's been completed, and I will be seeing a copy of
10 the draft. Initial discussions say that they may bring
11 that model to the Board for our review and input before
12 making that a formal model.

13 DR. HAYWOOD: But what we were discussing
14 earlier then is Board participation in that process.

15 DR. LaFORCE: Right. What we are going to
16 add, Julian, is a statement -- actually, what I would
17 prefer to do is say that we support and continue to
18 support what was recommended 25 May 1999. Then the
19 second thing was the Board enthusiastically supports
20 the development of -- or the exercise for medical risk
21 analysis, with the additional proviso of ensuring --
22 and then there are some words about treatment gap --
23 you know, the issue that Ron Waldman brought up.
24 Should that be separate, or could that just simply be
25 folded in?

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1 COL. DINIEGA: I think what I heard, the
2 comments were that the medical risk analysis will
3 probably identify gaps.

4 DR. LaFORCE: We'll include that.

5 DR. WALDMAN: If this memo is restricted
6 to vaccines, then there are other factors, I think,
7 that need to be brought into play as well for purposes
8 of treatment -- chemoprophylaxis.

9 DR. GARDNER: I'd like to ask a rookie
10 member's question. When I see the highly transmissible
11 scenario, it surprised me, in all of this discussion,
12 that influenza really never shows up on the radar
13 screen, and it seems to me it's not that big a trick
14 for someone to resort the genes in influenza, and we
15 know that that's one of the most transmissible and one
16 of the most fatal things. Why is not influenza a
17 concern as a biologic warfare -- is it because we
18 haven't gotten an intelligence-based report that
19 somebody is working on it, or is that --

20 COL. DINIEGA: I think the answer Mr.
21 Plasse gave to Dr. Tsai's question holds, but I'll let
22 Dr. Scott also --

23 LtCOL. SCOTT: I'm Brian Scott, I'm from
24 AMED Center and School Combat Development, formerly a
25 Chief of Medical Intelligence at an Army MEDCOM. Col.

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1 Diniega is exactly right. The threat list is an
2 intelligence community product, developed under a
3 charter and a regimen of guidelines, and must devolve
4 only from intelligence information and
5 counterintelligence sources of products.

6 DR. LaFORCE: Questions? Comments? Yes?

7 DR. WALDMAN: Could we go back for just
8 one second to No. 2, paragraph b). I just wanted to
9 ask -- I don't know if it's Mr. Paul, I don't know who
10 the appropriate person to ask is. These tiers that
11 were established by the Board in this memo, with the
12 suggested agents by tier, to what degree does that
13 correspond to the JVAP plan for vaccine development?
14 There's no value attached to my question at all, just
15 does it or doesn't it?

16 MR. PAUL: The program of the JVAP
17 includes the advanced development which partly is
18 involved with establishing a production capability for
19 smallpox, plague and next generation anthrax. I have
20 asked for funding for the SEB product, and not
21 received any funding for that.

22 DR. WALDMAN: So there's a high level of
23 correspondence then between --

24 MR. PAUL: Well, I had a program that
25 included those three before this recommendation was

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1 made.

2 DR. SOKAS: I think the question might be,
3 is it worth -- to follow up on Ron's question -- is it
4 worth it for us to comment on the fact that the SEB was
5 not included? Is it worth it for us to comment on the
6 fact that the availability for the next generation
7 anthrax doesn't look like it's going to be until FY10.

8 So, yes, some of these correlate, but some of them
9 appear not to have, so that's a good follow-up for the
10 Board.

11 COL. DINIEGA: I guess the statement --
12 and we have done this before -- that the statement can
13 be made that efforts to seek funding of agents in the
14 medical tiers that was defined last year, that those
15 efforts continue and be given higher priority. Would
16 that help at all?

17 MR. PAUL: I don't know if it would help
18 or not. I don't think it would hurt.

19 DR. BARRETT-CONNOR: You have no evidence
20 of prior help, anyway.

21 DR. ANDERSON: But I think we ought to say
22 something so that the omission to say something doesn't
23 get interpreted as we agree with the funding decision
24 not to go. So I think we need to point out, especially
25 for Tier I, that they followed our advice because they

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1 already were doing so for smallpox, plague and anthrax.

2 SEB -- and I guess the question would be, do we feel
3 strongly that that ought to be pursued?

4 DR. SOKAS: Well, not only SEB, but also
5 the anthrax, is that a reasonable timetable, or has
6 that been changed lately, or what?

7 MR. PAUL: Are you asking me if that's a
8 reasonable timetable? I identified some areas where
9 that could be accelerated. That was not funded.

10 COL. DINIEGA: I guess the question is, do
11 you want to still endorse accelerating the schedule.

12 DR. LaFORCE: I would say the delay that
13 is set forth in terms of the anthrax vaccine just seems
14 ludicrous, given the fact that it's item No. 1 and
15 they're running out of vaccine. I would propose that
16 at least there be some sort of statement saying that
17 logic would say that we addressed the largest threat
18 and it's a bit disappointing.

19 DR. WALDMAN: Maybe we could use different
20 words.

21 (Laughter.)

22 DR. SOKAS: I think the wonderful thing
23 for the Board is that there was this paper that was
24 generated. There was a response. The response -- and
25 so this is an iterative process and so where the

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1 response was obvious, that's great and that gets
2 mentioned, and where it wasn't so obvious, then that
3 gets mentioned as well, as a kind of "this is not going
4 to go away, this is the gum-on-the-shoe approach."

5 CAPT. SCHOR: A quick question. The tiers
6 that are mentioned here, how were they determined? Was
7 that the basis of a lot of discussion, things like
8 that?

9 DR. LaFORCE: Arbitrarily. No, I think
10 this was pretty arbitrary. I think this was --

11 COL. DINIEGA: It was a bunch of experts -
12 - well, we did the review in a room, and things were
13 suggested --

14 DR. LaFORCE: We said, what's it sound
15 like?

16 COL. DINIEGA: No, they actually looked at
17 morbidity, transmissibility, and all that sort of
18 stuff, but we never wrote down the criteria.

19 MR. PAUL: I guess I have a question about
20 that, too. The second tier says candidates for the
21 development part of it includes establishing a
22 production capability. What's the difference?

23 The first tier is to establish a vaccine
24 production capability. The second tier is to develop,
25 and the third tier is to research. Part of the

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1 development program is the vaccine production
2 capability, so I'm not sure I understand the
3 distinction between the first and second tier anymore.

4 COL. DINIEGA: I think it's just a
5 priority level for getting things into the pipeline,
6 that was the intent. The lowest tier is -- if you have
7 minimal resources, then you can sort of ignore the
8 lowest tier for now -- until later. That was the intent
9 in making the three tiers.

10 LtCOL. SCOTT: Would you comment on the
11 practical impact upon the Joint Program Managers Office
12 and the JVAP of an AFEB recommendation absent a new
13 Program Budget Decision Memorandum?

14 MR. PAUL: Without the funding that you
15 needed to execute the recommendation, there would be no
16 way to respond to it.

17 LtCOL. SCOTT: So an AFEB recommendation
18 that had an order dramatically different than your
19 current schedule cannot supersede or set aside Program
20 Budget Memorandum 724 which governs your schedule, is
21 that right?

22 MR. PAUL: Now I'm not sure I understand.
23 If the Board said "We don't want a vaccine for Q
24 fever", for instance, I could take that information to
25 the decisionmakers. That's unheard of, but if that's

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1 the decision -- the policy is we're going to have
2 vaccines against all these BD threats, and we have
3 valid threats and valid requirements for them, and we
4 have a program in place for them.

5 LtCOL. BOROSKY: I'm LtCol. Bob Borosky.
6 I'm the Medical Deputy at the Joint Program Office for
7 Bio Defense. There's a practical issue for those of us
8 who are on a first-name basis with the GAO, and that is
9 --

10 (Laughter.)

11 LtCOL. BOROSKY: I thought it would take
12 you a while to figure that one out. In fact, the last
13 conversation I had about six months ago, there's a Dr.
14 Sushil Sharma, who some of us have intimately been
15 involved with, and he calls me up and he says, "Bob,
16 this is Sushil, you know me for a long time" -- you
17 know, that's like the IG being here to help you -- but
18 one of the questions I've been asked over and over --
19 and it gets back to Dr. Scott's point -- is how does
20 the DoD arrive at the priority and how do they match up
21 that priority with their actual efforts in research and
22 advanced development, that's really an issue.

23 And I danced faster than that guy --
24 what's his name, on River Dance or whatever -- I mean,
25 my feet were really smoking.

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1 So what's at stake here is doing it right,
2 but also we will be asked a question, which is the real
3 list, and I've been asked that several times. And we
4 have the DoD CINC's list, and then we have the medics
5 that seem to think it needs to be done a different way.

6 My point is, whichever way we come up with, we've got
7 to come up with a common sense, by numbers -- it goes
8 back to what the Admiral said earlier -- we've got have
9 something that's explainable to the people who are
10 giving us money to do this job. So, whatever we come
11 up with, it has to make sense and it has to be
12 explainable and consistent across all the various lists
13 we develop.

14 DR. LaFORCE: And I agree with you in that
15 I think the intelligence-based decision was one
16 component of it, and I think that what's being
17 suggested in response to our initial -- was that a
18 medical risk analysis could further complement this
19 list of agents because, I assure you, a medical risk
20 analysis that's going to talk about tularemia,
21 hemorrhagic fever viruses, botulinum, et cetera, is
22 going to create moderately harrowing picture.

23 LtCOL. BOROSKY: That point I want to
24 make, though, is when someone like myself -- and I've
25 also been through the Army Acquisition for Training, so

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1 I'm both a medic and I'm also Level 3 certified -- is
2 explaining to members of Congress how we do this. And
3 so if we're adding a refinement to the existing list,
4 we've got to be able to explain then how we develop our
5 programmatic, is the point I'm making.

6 DR. LaFORCE: Okay. Yes?

7 DR. BARRETT-CONNOR: It sounds like we
8 weren't so much refining the list as commenting on the
9 fact that they're doing pretty well on two of the
10 priority items and the other one seems to be -- and we
11 would like to have the accelerated anthrax, which I
12 would just count as anthrax since the old one has gone
13 away and we need some, and I don't know how everybody
14 feels about this staph-toxin, but it was heavily
15 debated before and seemed to come up at top of the
16 list. So why has that not surfaced as a priority and a
17 funded priority. I mean, I think one could raise that
18 question that we're curious about that. Why would not
19 we reflect any change of our position, those are our
20 top four things and two of them seem to be moving along
21 and the other two are not.

22 DR. LaFORCE: I think that we're all in
23 agreement with a comment in terms of the Board's
24 concern about the anthrax vaccine. What I don't hear
25 is some unanimity of the opinion in terms of the

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1 strength of the statement in terms of staphylococcal
2 enterotoxin B.

3 DR. BARRETT-CONNOR: My point is that we
4 discussed that long ago and far away, whenever it got
5 to the top of the priority list before. Unless we're
6 going to schedule a meeting to discuss why it should be
7 taken off, I think what I heard is you can't change
8 your mind about what's where on the priority list,
9 either raising something up or lowering it down without
10 some good information or the credibility of the whole
11 operation weakens.

12 DR. LaFORCE: That' why I prefer not to
13 say anything about --

14 DR. BARRETT-CONNOR: Well, we did say it
15 was at the top of the priority list so we could comment
16 on the fact that it does not seem to be receiving any
17 attention now. I don't think that's a very threatening
18 statement, it just notices that those are the things we
19 thought were important before and here's what's
20 happening to them.

21 COL. TAKAFUJI: If I could make a comment,
22 all this discussion be sort of moot in a way because
23 the AFEB is going to be engaging in the medical matrix,
24 the threat matrix. It's going to all come out anyway
25 as we go through these agents and so forth. So whether

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1 you comment on it now or not is not going to make any
2 difference from a very pragmatic standpoint in terms of
3 what we do at this point in time because we are going
4 to be going through the matrix approach anyway, and at
5 that time we would look at those different parameters -
6 - morbidity, mortality and all that. So it may not be
7 worth the effort to comment on that.

8 DR. BARRETT-CONNOR: I must say I find
9 that a bit discouraging. I mean, we spent the whole
10 morning listening to this with the assumption that what
11 we said would have some impact on what's happening. If
12 it doesn't make any difference, we could go do
13 something else.

14 COL. TAKAFUJI: Well, with all due
15 respect, ma'am, the AFEB makes recommendations to the
16 Department of Defense, it doesn't direct the Department
17 of Defense. So the Department of Defense, in its best
18 judgement, has the prerogative to do whatever it
19 chooses to do. And I don't make that statement
20 disrespectfully, I'm saying that the Board can make
21 recommendations -- and I look at the Board, having had
22 a long relationship with the Board -- I look at the
23 Board as really finding the best way that the Board can
24 be effective in terms of getting the DoD to move in
25 certain directions, and I think right now with the

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1 threat risk assessment -- I don't think JCS is here
2 anymore, I think Larry Kimm's already left.

3 COL. DINIEGA: No, Larry's here.

4 COL. TAKAFUJI: But I think that we're
5 going to have to figure out how we can convince the
6 Chairman, JCS and so forth, and the way you do that is
7 by using their system to get to it.

8 DR. SOKAS: I don't disagree that focusing
9 on the -- working on that system is important, I think
10 that is important, but I also, having sat through many
11 discussions saying "adenovirus is going out of stock,
12 adenovirus is going out of stock, adenovirus is out of
13 stock", but the only satisfaction sometimes we have is
14 the somewhat Cassandra-like ability to say "We're
15 pointing out that it would be nice maybe to have
16 anthrax a little sooner than is currently on this
17 agenda," and maybe it won't have a directive impact,
18 but at least we'll feel better for it. I shouldn't say
19 it that way, but I think that it is important to
20 mention these things.

21 DR. BARRETT-CONNOR: Well, we don't think
22 we're directive, none of us think we're directive, we
23 think we're advisory, but if we're advisory and we
24 don't say anything, then it's a waste of our time to
25 listen to all of the information.

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1 COL. TAKAFUJI: Well, a comment was made,
2 for example, about influenza. I happen to agree 100
3 percent with you. I'm worried sick about influenza. I
4 think it's a very powerful biological weapon, but to
5 get me to get JCS to address that as a biological
6 threat is another issue. So what I'm saying is that we
7 must use the mechanisms and the channels that are
8 available to us to get the information through the
9 system, and that's why the matrix was developed,
10 because it's a mechanism for us to do that.

11 That should not preclude the AFEB from
12 making recommendations if it feels strongly that even
13 based on the fact that the treat assessments do not
14 reflect certain biological agents out there that could
15 be potential weapons, the AFEB has the prerogative to
16 make it's recommendations on any agent it desires,
17 whether it's influenza or not. But, again, it's going
18 to be up to the Department of Defense to take those
19 recommendations and to act on them.

20 So all I'm saying is, work within the
21 mechanism you have. I really welcome the AFEB's active
22 participation in the matrix because I think that's the
23 way you get to us, and I say that quite openly and
24 frankly because that's how we're going to get JCS and
25 the services to listen.

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1 DR. LaFORCE: I agree. Super. So what I
2 would propose is to comment on paragraphs -- I guess
3 paragraph 1, and use the questions to the AFEB that
4 were posed to us in terms of the criteria and also the
5 interest on the part of AFEB to work with DoD personnel
6 to develop -- to further develop this matrix.

7 COL. TAKAFUJI: Absolutely.

8 DR. LaFORCE: Okay. I will do that.

9 DR. BARRETT-CONNOR: Excuse me. I'm not
10 sure then -- is your response going to include a
11 comment about the progress on the anthrax vaccine and
12 the no-progress on the other?

13 DR. LaFORCE: What I propose is -- let me
14 be very precise about this -- was a general statement
15 of support for what was sent in a year ago. The Board
16 is concerned about the lack of -- or the slowness
17 particularly in terms of anthrax vaccine.

18 COL. TAKAFUJI: The next generation.

19 DR. LaFORCE: Yes, the next generation
20 anthrax vaccine. And I will circulate also a statement
21 about staphylococcal enterotoxin B as part of that
22 statement. Secondly, the Board supports the effort to
23 develop medical risk-based measures as an effort to
24 standardize selection of vaccine candidates and
25 welcomes participation with DoD personnel. And those

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1 would be the two statements over and above a general
2 statement of support for the document that was sent in
3 a year ago.

4 COL. DINIEGA: I just have one comment. I
5 think what we want to do is support -- and we should
6 use the terminology that was presented by LtCol.
7 Schnelle -- medical --

8 DR. LaFORCE: Risk-based measures.

9 COL. DINIEGA: I don't think she used that
10 -- medical risk assessment.

11 DR. LaFORCE: Medical risk analysis.

12 COL. DINIEGA: Right. So we'll use the
13 same terminology is what I am saying, so there's no
14 confusion.

15 CDR. McBRIDE: I have a comment, please.
16 In making a recommendation or an observation about the
17 next generation anthrax vaccine, we're concerned that
18 it's taking so long -- I just don't know. Maybe this
19 is as long as it can take and they're doing everything
20 to go as fast as they can. Is that what you said?

21 COL. DINIEGA: No funding.

22 CDR. McBRIDE: All right. Then I
23 misunderstood.

24 MR. PAUL: We base it on the substance
25 about what technology would be pure enough to bring

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1 into advanced development at the end of this fiscal
2 year, and that's being defined with an analysis of what
3 (inaudible).

4 COL. DINIEGA: Mr. Paul, can you move up
5 to the mike?

6 MR. PAUL: And presuming that it will
7 follow along a generic development course, there's an
8 opportunity to shave two years off of that schedule,
9 and that was identified -- the funding for that
10 schedule savings was identified, and it was denied when
11 we went through the budget exercise this year, as well
12 as the funding for all of the vaccines that were listed
13 on that chart that I showed you that were expected to
14 be mature enough for advanced development during this
15 POM cycle.

16 CDR. McBRIDE: Thank you for that
17 clarification.

18 MR. PAUL: There's schedule savings
19 opportunities with ricin, next generation anthrax, and
20 a multivalent equine encephalitis, and the next is the
21 vaccines for the multivalent equine encephalitis --
22 excuse me -- SEB, brucellosis, Marburg Ebola, and
23 multi-agent vaccine platform were identified as
24 opportunities for advanced development during this, and
25 none of that was funded. And we have to restructure

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1 the Venezuelan Equine Encephalitis program because not
2 only were we not given funding, funding was removed
3 from the program.

4 CAPT. SCHOR: I would just ask, who
5 determines that funding? Who actually sits on the POM,
6 is that a single service or is that --

7 DR. MUSIC: It's a committee. It starts
8 with the Joint Material Service Group, works its way up
9 to the Joint NBC Defense Board, and those decisions are
10 made there.

11 DR. LaFORCE: I must admit, this should
12 come as no surprise to the Board. If you remember
13 Charlie Hoch's presentation to the Board, it would have
14 been a year ago. Charlie went right through and at the
15 bottom of the funding list, item -- I thought it was
16 No. 10 on his list -- he then said that VEE was at risk
17 of falling off that list this year. And so that
18 generated a comment from the Board, but it's almost
19 deja vu. What Charlie thought was going to happen
20 happened.

21 DR. MUSIC: That was for the tech base
22 funding. That probably did make it to advanced
23 development, and the advanced development funding was
24 cut this year.

25 DR. LaFORCE: That's what got cut.

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1 COL. DINIEGA: Let me just make one
2 comment on this funding issue. When it goes through
3 the Joint Service Material Group and the Joint Service
4 Integration Group and NBC Defense Board, it is a 1-2N
5 integrated list of medical and nonmedical items, so we
6 are competing against a weapon system, et cetera, et
7 cetera. And this austere body, which has a medical
8 representative on it -- and LtCol. Scott could tell us
9 all about -- but there is a medical representative, and
10 you do literally compete against other weapons systems.
11 And they don't fund everything because they can't fund
12 1-2N.

13 DR. LaFORCE: Okay, item three, "3) the
14 issue of countermeasures be performed as taking into
15 account factors such as treatment availability, post-
16 exposure prophylaxis, and stockpiling of currently
17 available pharmaceuticals -- we spent a fair amount of
18 time talking about this yesterday. Was there enough
19 discussion that that would merit a comment on that
20 item?

21 DR. BARRETT-CONNOR: Is there a specific
22 question about that?

23 DR. LaFORCE: No, other than the fact that
24 it was discussed and that the AFEB is strongly in favor
25 of the development of the stockpiling exercise and has

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1 participated in development of recommendations as asked
2 by Secretary Daniel.

3 DR. WALDMAN: The question about
4 antibiotics will cover a lot of what's in here.

5 DR. BARRETT-CONNOR: Can I make one
6 comment about that? I mean, I think my enthusiasm for
7 stockpiling is perhaps irrationally attached to how
8 long the drugs are good after you have stockpiled them.

9 Is that something that --

10 DR. LaFORCE: There's no relevance because
11 you ar talking about the bubble phenomenon in
12 stockpiling, so that you actually don't get them and
13 stockpile them, they are stockpiled in pharmaceutical
14 companies who are responsible for that turnover.

15 DR. BARRETT-CONNOR: So they are selling
16 them form the bottom.

17 DR. LaFORCE: Oh, yeah, and what you're
18 doing is you are paying for the availability of a
19 certain stockpile.

20 DR. BARRETT-CONNOR: That implies that the
21 only things that we will stockpile are the things that
22 the pharmaceutical companies can sell enough of to make
23 the bubble work.

24 DR. WALDMAN: As it were, that's what it
25 is.

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1 DR. LaFORCE: I mean, there isn't a new
2 megamicin that's out there that's not licensed.

3 DR. BARRETT-CONNOR: No, but there might
4 be a new antimalarial, for example, we wouldn't be able
5 to -- I mean, I'm just thinking ahead, but it seems to
6 me that's the problem with that system.

7 COL. TAKAFUJI: The only problem that I
8 see with the stockpiling issue that could create a
9 problem for us is, if we had an incident, a domestic
10 incident, where there was a DoD requirement at the same
11 time, simultaneously there is a civilian requirement,
12 the pharmaceutical industry can only respond so quick,
13 and so you could have some major shortfalls in that
14 regard in terms of being able to --

15 DR. LaFORCE: Steve, would you comment on
16 this. We talked about this last night.

17 DR. OSTROFF: We talked about this
18 yesterday, and in point of fact we have VMI, vendor
19 managed inventory numbers that are HHS-specific
20 numbers, and then there are also numbers that are DoD-
21 specific. So in point of fact, the manufacturers have
22 to guarantee that there is enough of a bubble that they
23 could simultaneously fill both of those orders, or at
24 least that's my understanding of the way that it's
25 supposed to work.

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1 The other thing, just to point out, is
2 that even within the DoD system, there is constant
3 turnover of all of the drugs that would be stockpiled
4 for use in BW situations. So even at the forward
5 deployed areas, they could make sure that they have
6 material that's still within its shelf life. It really
7 shouldn't be a big problem for them to use up the
8 ciprofloxacin as it gets towards the end of its
9 expiration dates.

10 DR. LaFORCE: Item four, "4) The Board
11 recommends a formal review of the effectiveness of
12 current medical surveillance as an early detector for
13 exposure to biologic warfare agents." I don't think
14 anybody would disagree with that, and that's going to
15 be one of the items for the next AFEB meeting?

16 COL. DINIEGA: Yes.

17 DR. LaFORCE: "5) The Board recommends a
18 formal review of the rapid diagnostics available to
19 support medical surveillance as an early detector for
20 exposure to biologic warfare agents." Ditto.

21 "d) The Board endorses and urges rapid
22 deployment of the planned Joint Tri-Service Software
23 programs capable of recording and reporting
24 administration of any dose of vaccine, licensed or IND,
25 administered to DoD personnel." That's not very

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1 controversial. We've discussed this before.

2 "e) Lastly, the Board recommends that
3 high quality education and marketing programs be
4 developed for each vaccine deployed against biologic
5 warfare agents and recommended for use in DoD
6 personnel. Ideally, this would be developed by experts
7 both inside and outside of the DoD."

8 DR. ANDERSON: Has anything happened on
9 these?

10 DR. LaFORCE: The examples that we've had
11 -- we usually -- John Grebensen gives us a follow-up --
12 the best example, of course, the anthrax vaccination
13 program, as the template -- or boilerplate of how you
14 can actually follow a fairly complex vaccination
15 program that is person-specific.

16 COL. TAKAFUJI: The anthrax program is a
17 good example of a well-resourced program that we really
18 -- there has never been a vaccine in this country, in
19 fact, that has been followed as closely as the anthrax
20 program has, as you all know, but it's very resource-
21 intensive. I'm not convinced that we can do it,
22 frankly, for every vaccine, but we're going to give it
23 our best shot. And one of the things that can help us
24 a lot is the computerized approach to a lot of the
25 recordkeeping and so forth. Easier said than done, of

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1 course, mind you, but what we are doing is we are
2 trying to integrate immunizations of all kinds along
3 with all of the other things that are going on as part
4 of the patient health record that needs to be put in
5 some system so it's well documented.

6 DR. ANDERSON: I think it would be helpful
7 if we could say that in reviewing it progress has been
8 made and, if it hasn't, then we don't need to say
9 anything. I guess that was after who made this complex
10 set of recommendations and, in fact, some of it seems
11 to be moving forward and some of it is not. The parts
12 that are, we ought to pat them on the back for moving
13 forward.

14 COL. DINIEGA: Let me make a comment on
15 the immunization tracking system and, Capt. Trump, bail
16 me out if I step out of bounds here. At the last
17 meeting, what we heard and what led to this
18 recommendation, was that in the anthrax immunization
19 tracking, services are utilizing their own software
20 right now. There is not a tri-service software for
21 immunization tracking. But we have three or four
22 immunization tracking -- three out there -- and the
23 intent was to try to put an emphasis on development and
24 moving forward with a tri-service software package.

25 DR. ANDERSON: Integrated.

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1 COL. DINIEGA: Integrated. And, Capt.
2 Trump, I don't know what progress or nonprogress has
3 been made on that.

4 CAPT. TRUMP: They are making progress.
5 You know, it's not as rapid as we would like to see,
6 but there is or will be an immunization tracking
7 component for the CHCS2, which is the next generation
8 of software for medical recordkeeping in DoD. In the
9 component that's called the Theater Medical Information
10 Program, TMIP, there are also -- which is what the
11 deployed platforms will have, immunization tracking
12 will be an element of that, and that will be
13 standardized for all services. How this gets adopted,
14 it's not "this year we have it, next year we won't,"
15 like any other program it's over five to ten years
16 until it will be there for the entire force.

17 DR. LaFORCE: Could we have a follow-up at
18 the next AFEB meeting, David, of that initiative,
19 because we had it -- it was a couple of meetings ago --
20 and I thought that was a fascinating presentation, the
21 tracking system presentation, and this generated a
22 great deal of discussion at that time, and it would be
23 nice to get a follow-up, as brief as it might be.

24 COL. TAKAFUJI: You're not talking about
25 the anthrax, you're talking about --

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1 DR. LaFORCE: No, I'm talking about the
2 more general --

3 CAPT. TRUMP: We'd be glad to do that.

4 DR. SOKAS: I have a clarifying question
5 just to make sure we have this in context because this
6 came up as part of the whole huge Gulf War problem that
7 some service branches couldn't provide any information
8 about immunizations received by certain members of
9 their forces. And my sense is that in follow-up to
10 that, that's no longer true anywhere, that virtually
11 anybody who gets an immunization has it recorded
12 someplace, it's just that this integrated system
13 doesn't exist yet.

14 LtCOL. TRUMP: The only place we're doing
15 it 100 percent is with anthrax vaccine. My
16 understanding -- Ben can correct me -- for Air Force,
17 Air Force is putting all immunizations for active duty,
18 and hopefully I think for family members into a single
19 tracking system. The other services are not doing that
20 uniformly yet, other than for anthrax.

21 DR. SOKAS: But they are moving in the
22 direction --

23 LtCOL. TRUMP: Yes.

24 DR. OSTROFF: I'm sorry that I wasn't here
25 for -- some of these comments maybe already have been

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1 discussed, but one thing that I haven't heard any
2 discussion about is the issue of side effects.
3 Vaccines -- and I know that there has been an enhanced
4 effort to try to do better monitoring of the side
5 effects, particularly from the anthrax vaccine, but I'm
6 not sure it's being done in a standardized way across
7 the services, and I'm not sure it's being done as
8 intensively outside of certain particular centers, like
9 at Tripler (phonetic), et cetera. So, I'm wondering
10 whether or not there should be some sort of a
11 recommendation that we have more systematized side
12 effect monitoring from vaccinations.

13 COL. TAKAFUJI: What I would recommend is
14 you get a briefing next meeting and then bring up these
15 questions that are direct in nature. I happen to agree
16 with you. As I said, you know, our best example is
17 anthrax, but it has just been a monumental effort to do
18 it. I don't think, with the resources we have right
19 now, frankly, I don't think we could do it for every
20 vaccine.

21 CAPT. TRUMP: Right, but I think you're
22 going to have to do it for every vaccine, especially if
23 you're going to be using ones in the future that might
24 be in IND status --

25 COL. TAKAFUJI: What I would recommend is

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1 you get the briefing from the TMA -- or we would have
2 to discuss who would be the most appropriate people to
3 brief you -- but you get that briefing, and you ask
4 these questions of those people who are responsible for
5 that system, and they can tell you accordingly, and
6 then you can make your recommendations based on that.
7 That would be most meaningful to us.

8 CAPT. TRUMP: For anthrax vaccine, we
9 could present what is being done for tracking adverse
10 events for that vaccine in particular because we do
11 have 100 percent --

12 COL. TAKAFUJI: Well, the VAERS system is
13 theoretically applicable to all vaccines, for reporting
14 all adverse reactions, but in reality it's probably not
15 implemented to the same extent as with --

16 DR. OSTROFF: Well, I know there's been a
17 lot of discussion about having the these -- the concept
18 of Vaccine Centers of Excellence where you would have
19 particular locations that would do active monitoring of
20 populations after they receive vaccine. I think that
21 would be a marked improvement over simply relying on
22 VAERS reports, which are basically a passive system.
23 If you really want to know what the levels of side
24 effects are, you have to do something that's a bit more
25 active than simply waiting for passive reporting to

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1 come into play.

2 COL. BRADSHAW: I know of that particular
3 initiative -- this is Col. Bradshaw -- as far as the
4 "Vaccine Centers of Excellence", but I don't know if
5 that type of active monitoring in terms of following
6 cohorts and tough, labor-intensive -- I think the
7 large-link database capability which we do have
8 currently with the Defense Medical Surveillance System
9 and our tracking programs is, I think, the more
10 efficient way to go, and it's certainly one that the
11 CDC has endorsed in terms of what they've done with HMO
12 and childhood vaccines. I think this is a more
13 efficient way of doing it and we are currently doing
14 that, putting in both inpatient and outpatient -- in
15 fact, the reason I wasn't here this morning is I was
16 presenting that data to the Air Force Surgeon General
17 on some focus diseases in relation to anthrax.

18 So I think VAERS, with the known
19 limitations of VAERS and the underreporting has to be
20 complemented by the large-link database capability
21 which we do have. I think this other would be an
22 interesting addition, but I think that's not feasible
23 for the entire force. I think the large-link database
24 capability is the right way to go.

25 And the Immunization Working Group, of

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1 which most of these people are members, we have pretty
2 much all signed off on requiring at least the active
3 duty, and hopefully moving to our dependents as well,
4 all immunizations into the automated tracking systems
5 so that we can link them. And, currently, even though
6 we are using three different systems to put things in,
7 there is a common database, which is the VAERS
8 database, so that that information is able to be
9 shared. So there is a common database, but we just
10 have different front-ends for putting it in, and then
11 CACS2 will have an integrated and common tracking
12 system, including some modules that are stand-alone
13 that you can take out to the field.

14 DR. MUSIC: This is Stan Music. Col.
15 Bradshaw, how big is the large-link database in the
16 military?

17 COL. BRADSHAW: In terms of lines of code,
18 or how many records?

19 DR. MUSIC: What's the population it
20 serves?

21 COL. BRADSHAW: It's the active duty
22 population, and so it includes all inpatient data out
23 of the standard inpatient data record, all outpatient
24 data from the standard ambulatory data record from 1997
25 on, inpatient from about 1990 on, and that's linked now

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1 with the immunization data in the Defense Eligibility
2 Enrollment System, DERS.

3 DR. MUSIC: Well, in the civilian side,
4 vaccine safety is what I do for a living, and we use
5 VAERS or some variation of it -- each manufacturer has
6 it's own database as well -- and then we go to large-
7 link database for hypothesis testing. That's exactly
8 what we do and I would support that concept. I think
9 trying to set up a special study that captures
10 absolutely everything would be a real waste of
11 resources. And you have trouble trying to interpret it
12 anyway.

13 COL. TAKAFUJI: I think these were really
14 set up more as pilot projects with the idea that we
15 would learn from that experience, so I don't want to
16 give you the impression that that would be the standard
17 for the whole system.

18 DR. MUSIC: So VAERS and passive reporting
19 is really for signal generation, and once you get a
20 signal, then you test that hypothesis in a large-link
21 database.

22 COL. TAKAFUJI: There's a big population,
23 too, that we haven't talked about, it's called the
24 Reserves -- nightmare. An absolute nightmare. So
25 there's much more to this equation than just simply

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1 active duty personnel.

2 DR. LaFORCE: Stay tuned, it will be the
3 next meeting.

4 DR. OSTROFF: I also have a couple more
5 comments. One of them is --

6 DR. LaFORCE: No, you can't.

7 (Laughter.)

8 DR. OSTROFF: Oh, I can't? Where do we
9 stand in terms of peer reviewed publication of some of
10 the studies that have already been done vis-a-vis the
11 vaccine? I know that we made an effort to get that one
12 article in the MMWR, but that's not quite the same as
13 peer review publication of the data, and one of the
14 problems with the anthrax situation has always been you
15 are playing catch-up in terms of everybody else getting
16 their stuff out on the Internet really easily, and the
17 real data not sort of being out there in quite the same
18 way. So are we making moves towards getting this into
19 the peer review literature?

20 CAPT. TRUMP: I would say yes, but I don't
21 know the details.

22 COL. TAKAFUJI: Yes. John Grebensen and I
23 and Phil Pittman and all these guys are very much aware
24 of that, and there they're moving. I can't tell you
25 where they are with all the articles, but I know that I

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1 have seen drafts and so forth.

2 DR. LaFORCE: No, because the last session
3 that we had -- I mean, they spent a fair amount of time
4 scolding and discussing and pushing, in terms of saying
5 "get this stuff out."

6 COL. BRADSHAW: I can tell you the DMSS
7 just delivered the hospitalization data study to AVIP,
8 and I'm sure that they will try and follow up with
9 submission of that to a peer review journal, but
10 they've got all the hospitalization data, including the
11 adjustments for confounders and the whole thing.

12 DR. OSTROFF: The third comment that I'll
13 make -- and this may be beyond sort of the scope of the
14 Board, but I continue to really be very concerned the
15 situation with the availability of the anthrax vaccine
16 and knowing that the new generation vaccine is
17 apparently years off -- some sort of a statement about
18 what can be done to correct that situation, especially
19 relying on a single manufacturer for the foreseeable
20 future to produce all of that vaccine, knowing the very
21 jaded history of GNP and stuff like that. Are there
22 some efforts to try to come up with a second
23 manufacturer or do something to try to rectify the
24 situation a little bit better than it is?

25 COL. TAKAFUJI: I'd like to make a comment

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1 off the record.

2 COL. DINIEGA: The recorder is on, you
3 can't do it off the record.

4 COL. TAKAFUJI: I need to make a comment
5 off the record, and the reason I need to make that
6 comment is, I'm going to recommend to the Board that it
7 defer on any recommendations about the AVA until its
8 next meeting because there may be some decisions and so
9 forth that would influence that decision.

10 COL. DINIEGA: And I second that because
11 we've been in discussions about the shortage of
12 vaccines, and there are other avenues that are being
13 looked at to solve this, and other senior policy
14 people.

15 DR. OSTROFF: Anything that we can do to
16 help you --

17 COL. TAKAFUJI: They may be back at the
18 next meeting.

19 DR. LaFORCE: Okay. Let me close this
20 part of the discussion by saying that -- why don't I
21 take a crack at preparing a response and I'll circulate
22 it hopefully within the next two to three weeks to
23 Board members, and then get back to me. I'll probably
24 circulate it by e-mail so that you can make whatever
25 changes -- you could put the lines across or wordsmith

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1 it anyway you want, and then we'll put it back together
2 and then I'll send another version out. I'll try to do
3 that as soon as I possibly can.

4
5
6
7 **EXECUTIVE SESSION**

8 (1:10 p.m.)

9 DR. LaFORCE: We have six items of
10 business that we have to finish fairly quickly. One,
11 could we go to the revised squalene -- either
12 recommendations, or discuss that for the next five or
13 ten minutes, if we could, Stan?

14 DR. MUSIC: I'd be happy to do that. I've
15 got a draft that I have scribbled out, and if I can
16 follow it I'll read it off to you. But I will do the
17 same thing that you just suggested you would do, which
18 is when I get back I will put it all together into a
19 clean document, and I will send it to you for
20 circulation out to everybody, comments, inputs, and
21 then we'll get a final.

22 I'm addressing now the tone that we
23 decided we wanted. We found the paper by ASA, et. al.,
24 very interesting. We find two issues that merit
25 explication.

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1 1) Scientifically, the paper has a large
2 number of flaws, some of which are extremely grave and
3 which invalidate to an almost complete degree its
4 conclusions regarding squalene and the implications
5 which proceed from them. The major flaws include --
6 and then I would go through the Part I, Dose Responses,
7 Controls, Lack of Blinding, Specificity issues.

8 Then -- the net result is that the Board
9 has very little confidence that the patent-pending ASA
10 Assay actually measures antibodies to squalene, though
11 we cannot exclude the possibility.

12 2) Also, whatever the paper's flaws, the
13 Board cannot exclude the possibility that the authors
14 have discovered or somehow stumbled upon a laboratory
15 means of distinguishing persons with possible GWS, Gulf
16 War Syndrome, from all others, so replicability becomes
17 the issue. The Board recognizes the difficulties
18 inherent in defining a "case" of GWS, but feels that
19 the symptom list in the ASA, et. al. paper is a good
20 starting point. Therefore, we recommend that a
21 suitable test of replicability be done in cooperation
22 with the authors and with the following design
23 elements. And then the bullets under Part II,
24 Collection of Participants, Clear A Priori Selection
25 and Exclusion Criteria -- removing Harvard, Mayo and

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1 Carl Alving by name.

2 And then as a final piece I would say --
3 Let us be clear that we are not discussing a study to
4 validate whether the ASA Assay can detect antibodies to
5 squalene, rather, we are trying to leap over this
6 intermediate obstacle and get quickly to the bottom
7 line: Does the ASA Assay clearly, reliably and
8 unequivocally distinguish people with possible GWS from
9 all others and, if so, with what specificity and
10 sensitivity. Many caveats and qualifiers would have to
11 be in place to assure meaningfulness, and the preceding
12 bulleted list can, and probably should, be usefully
13 expanded and further refined to help assure that any
14 ensuing study be definitive.

15 So, that kind of tone gives a lot of
16 flexibility, some general guidance, provides the
17 critical review and trashes it as a scientific piece
18 from which you can draw conclusions, but offers to
19 Congressman Metcalf and others a path to determine
20 whether this is useful or not quickly and with minimum
21 expense.

22 DR. LaFORCE: Great job. Questions?

23 DR. ANDERSON: I think I'd take out the
24 "stumbling."

25 DR. LaFORCE: Oh, well, we'll massage

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1 that, come on now.

2 DR. ANDERSON: I mean, I --

3 DR. LaFORCE: Stumbled upon.

4 DR. MUSIC: The wordsmithing later, just
5 broad ideas.

6 DR. BERG: Bill Berg. I'd like to suggest
7 a consideration of some language to the effect that if
8 they do not attempt to replicate it, we cannot consider
9 the study valid. My concern is that the Congressman
10 Metcalfs of the world and other people are going to say
11 "Aha, they've said this could be true, we're such
12 wonderful people, we don't need to validate it," and
13 they'll pick up on the first half and drop the second
14 half.

15 DR. MUSIC: Can I suggest that you include
16 those suggested phrases in your revision to what I will
17 circulate.

18 DR. BERG: Will do.

19 DR. MUSIC: Thanks.

20 DR. LaFORCE: Okay. Good job. Again,
21 thank you all, the group that worked on this, this was
22 not easy.

23 Steve, in terms of the antibiotics, I
24 assume that you will draft -- you've got two people,
25 one from DoD and one --

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1 DR. OSTROFF: One is behind you.

2 DR. LaFORCE: Okay. Will sort of cobble
3 something together along the lines that we talked about
4 before. There's only one other thing that I would add.

5 You know, last night as I was trying to eliminate the
6 crab smell, I was sort of in a fugue state, and I was
7 thinking about the recommendation in terms of the
8 antibiotics, and then I was thinking of what the
9 Israelis did in terms of when they had stockpiled their
10 antibiotics, they kept it a secret. And the more I
11 thought about this before I fell asleep, I thought that
12 was a good idea. You know what I mean? If we go out
13 and you just tell everybody that you're stockpile for a
14 potential terrorist threat is cipro and doxycycline --

15 DR. OSTROFF: And then they know what not
16 to produce.

17 DR. LaFORCE: That's exactly it. Then
18 they know exactly what to clone or what plasmid to
19 insert in terms of making sure that they would -- and
20 so I was asking myself the question. I said, gee, one,
21 is there merit in terms of this being a secret or
22 something classified and, two, is it possible -- and
23 it's probably not possible, but --

24 DR. SOKAS: Well, the cheaper obverse
25 would be to say you have stockpiled against it and not

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1 have and then obviate the threat that way.

2 (Simultaneous discussion and laughter.)

3 COL. DINIEGA: Let me just make a comment.
4 First, let me ask Nancy -- the publication date is 17
5 July, and so it will be out and it's open literature.

6 No. 2, the age-old debate of vaccines,
7 immunizations, and what do you force the other guy to
8 do is on the table, that's what you're talking about.
9 If they know, what do they do? Well, one of the
10 arguments has been it forces us to think about a new
11 way to do things, which is going to cost people and
12 personnel. And the question then becomes, can we
13 invest in that? So, you can go either way. But I'm
14 saying that debate has been gone through. Do we tell
15 people what we're immunizing against or developing, or
16 not, and there's been arguments both ways. And the way
17 it's done now, it's pretty open.

18 DR. LaFORCE: All right. I should have
19 fallen asleep earlier.

20 COL. DINIEGA: It was the crabs.

21 DR. SOKAS: Too many crabs.

22 DR. BARRETT-CONNOR: The crabs were still
23 putting themselves back together.

24 DR. LaFORCE: All right. How about the
25 ergonomics recommendation in terms of the question that

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1 relates to the ergonomics issue. Who was responsible
2 for that?

3 (Laughter.)

4 The good Dr. Anderson.

5 (Simultaneous discussion.)

6 DR. ANDERSON: I am going to follow the
7 precedent set. One, our group, we were short two of
8 our critical members -- Rosie, who is here today but
9 wasn't here yesterday, and Phil Landrigan. So we had a
10 very good discussion and I got fairly extensive notes
11 which I will then shortly put together as my last
12 official duty before vacating my chairmanship, and I
13 will circulate that shortly, and I think we've got
14 enough to cover it. And the gist of what we said is we
15 need to -- this is a complex area, we're going to
16 maintain a dialogue with the group on the areas where
17 we're going to give some broad, general
18 recommendations, and then say we need to follow up with
19 more in-depth areas, and we'll circulate it.

20 DR. LaFORCE: Do you need more help with
21 that, or did that --

22 DR. MUSIC: Well, he's just got to give us
23 what he has, and then Rosie's going to take the lead
24 with this.

25 DR. ANDERSON: What we're hoping is to get

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1 this done without having to have another meeting or
2 teleconference, and I think I've got enough to do it,
3 or we can wordsmith it over the Internet to get it
4 finished. The fallback would be to say, well, we need
5 more discussion, make it broader as an initial
6 response, and then follow up at the next meeting.

7 DR. LaFORCE: Do you think, Rosemary -- or
8 the group that worked on that -- that a month is enough
9 time to turn this around?

10 DR. SOKAS: I don't think so.

11 DR. LaFORCE: No?

12 COL. DINIEGA: I was just going to talk
13 about recommendation time lines.

14 DR. BARRETT-CONNOR: I think that the
15 question was about cost-effectiveness, and there were
16 so many questions about what went into the model, and
17 we don't have anybody on this committee who is really,
18 to my knowledge -- tell me if I'm wrong -- a cost-
19 effectiveness person. And I really felt that you need
20 to have such a person, either as a new member of the
21 Board or to be brought on as a consultant. I felt like
22 I was in way over my head.

23 DR. SOKAS: And to second that, although I
24 apologize, I wasn't able to be there yesterday. The
25 entire agency that I sit in, which is NIOSH, cost-

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1 effectiveness is never anything that is ever addressed,
2 it's not part of the mandate. So, it's true that to
3 accurately answer these questions, I think we need more
4 resource -- you know, more human resources than we have
5 right now on the Board. But we could give the answers
6 we could give.

7 DR. LaFORCE: Do you need some help?

8 DR. MUSIC: I'm not sure that the question
9 is answerable with the existing knowledge base, period.

10 DR. ANDERSON: Right. I think that was
11 our -- that once we were delving into the question is,
12 what can we provide that will be helpful, and then move
13 on to additional issues -- use this as a springboard.
14 I guess that's kind of a more global framework.

15 DR. LaFORCE: No, no, because what I think
16 I'm hearing is some real discomfort on the part of
17 Board members in terms of answering the question that
18 it was set forth. How do we resolve that? Do we
19 resolve that by finding some more expertise to look at
20 that, or more information --

21 DR. MUSIC: I don't think we can answer
22 that right now, until we see what we can put on paper.

23 DR. LaFORCE: Okay. And then when you
24 come back, you will then suggest what else might be
25 necessary

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1 --

2 DR. MUSIC: We'll talk to each other and
3 come up with something.

4 DR. ANDERSON: The goal is to have some
5 kind of a response relatively quickly. I would like to
6 do it by the end of June.

7 DR. LaFORCE: Okay, fine.

8 DR. ANDERSON: If not, start it by Friday
9 before I leave. If it falls apart and as time passes,
10 our memory of the discussion will also fade, it may be
11 necessary to continue this at the next meeting.

12 COL. DINIEGA: Let me make a comment on
13 the ergonomics question. I approached LtCol. Lopez on
14 the issue to see if they could utilize some assistance,
15 and the initial question was going to be around a
16 surveillance issue and how to identify specifically
17 ergonomic-related injuries. And as you saw from the
18 question that came from her bosses, it grew. And I
19 think the subcommittee did the right thing by pinning
20 her down as to what priorities did she want those
21 questions answered. It is not unreasonable to go back
22 and give a very generic thing and say you need more
23 information or whatever, and give general guidance.

24 If the subcommittee feels they need
25 somebody with special expertise or another meeting, you

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1 need to let me know and I can help with making
2 arrangements. She admittedly says the program,
3 although it gets a lot of press and marketing, is a
4 little on the fledgling side. There's no real action
5 plan like we saw from LtCol. DeFraitess on the
6 injury/occupational illness side, and she acknowledges
7 that. Actually, one of the questions was asking what
8 should be in that action plan.

9 DR. RUNYAN: Could I just say something?
10 My concern about this is that we -- I think what she's
11 trying to do in terms of looking at ergonomic issues is
12 very important and that we ought to endorse that, but I
13 think she's in a bit of a bind, as I understand it,
14 that without a cost-benefit analysis she can't move
15 forward with the program, and yet we don't feel
16 comfortable that the knowledge base is sufficient to do
17 that cost-benefit analysis. And what I don't want to
18 have happen is have the program go down the tubes for
19 the wrong reason. And so I think if we can somehow or
20 other in what we formulate endorse the importance of
21 addressing ergonomics even if we can't endorse the
22 cost-benefit steps to get there.

23 COL. BRADSHAW: Part of the problem is the
24 issue of we're not sure what the knowledge base is, and
25 maybe the first step is to see if Cochran or somebody

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1 has done a systematic review and, if not, then somebody
2 should do that as the first step, and then define what
3 the evidence base is, and then decide if you've got
4 enough information to do a cost-benefit or decision
5 analysis.

6 DR. RUNYAN: That suggestion was made to
7 her yesterday.

8 COL. BRADSHAW: Was it? Okay.

9 DR. BARRETT-CONNOR: I think one of the
10 problems is that there's a lot of kinds of work in the
11 military that are not widely represented in the
12 civilian sector. It would be hard to know what to do
13 with them.

14 DR. MUSIC: You start off with everybody
15 marches, everybody runs, and then people carry 175-
16 pound litters, and other people drive tanks. So it
17 gets a little difficult to separate out what is
18 ergonomic and what is baseline.

19 DR. BARRETT-CONNOR: Anyway, I agree with
20 you completely that I think it's terribly important,
21 and I do think that -- I had the distinct feeling that
22 if there isn't a potential to demonstrate that it's
23 going to be cost-effective, it will die at morning. So
24 I think that's why we're going at it from the opposite
25 end than where one might usually start.

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1 COL. DINIEGA: Let me just make a comment
2 on that. I don't think this is going to die because on
3 the civilian personnel side of the house, the President
4 has directed that they reduce certain things as a goal,
5 and one of them is FICA claims which has some of what
6 you -- you know all about that, I shouldn't be talking
7 about that. And so there is a goal of reducing FICA
8 claims which impacts on this issue, so I don't think
9 it's going to go away. The specific application to the
10 military is probably the issue.

11 DR. ANDERSON: I think as to the final
12 note, part of our issue was one of strategy and -- as
13 opposed to just sheer comment on the science and the
14 issues, and where we kind of got caught up is "can't
15 move forward without cost-benefit analysis," so our
16 recommendation to do additional research or do
17 evaluations and things like that that need money, there
18 isn't money to do that, so it's kind of "what can you
19 do with the available resource" was kind of the bottom
20 line we came to, and I think that's where we had some
21 discomfort -- there just isn't enough there to answer
22 the question to generate the information to really make
23 it a robust, sound analysis when the database, the
24 clinical database, is wrong 50 percent of the time -- I
25 mean, there's all of the data issues wrapped up in it

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1 as well, and I guess where we're sort of headed is,
2 we'll see.

3 COL. DINIEGA: The other importance with
4 this issue is this is a question that's from outside
5 the medical chain. This is under Environmental
6 Security, the Deputy Secretary of Defense for
7 Environmental Security, so they approached Health
8 Affairs to ask the question to the Board. So there's a
9 little bit of a precedence here, so we should try to
10 provide the best assistance we can.

11 DR. LaFORCE: I have three other items.
12 One is a discussion that I've had with Ben several
13 times, and with some of you, and this is the issue of
14 orienting new AFEB members, or lack of orientation of
15 new AFEB members, and this is one of the goals that
16 I've set for myself before I finish. I'm going to try
17 to develop a system so that -- the turnover is such
18 that we usually have, what, three or four --

19 COL. DINIEGA: Five a year.

20 DR. LaFORCE: -- five a year. And what
21 we're trying to develop is a way of actually bringing
22 the five new members into Washington either --
23 hopefully before their first meeting -- so that they
24 could have a session on, one, a history of the Board,
25 the real role of the Board, opportunities, also a

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1 discussion in terms of military medical research
2 activities, vaccinology, how the military funds itself,
3 what the preventive medical officers -- who they are,
4 what they do -- all of the sorts of things that, as
5 members of the AFEB, you sort of pick up after a while.

6 But I must admit, the first couple of meetings, I felt
7 pretty stupid. I didn't quite know what was going on,
8 unless you were talking about a vaccine. If you were
9 talking about a vaccine, I was all right, but I didn't
10 know much of anything else. And I think that that's a
11 mistake because I think it doesn't allow members to
12 sort of get in, hit the ground running, and understand
13 their responsibilities to the Board right from the get-
14 go.

15 And so I'm working with Ben -- I haven't
16 given up. We thought we had some money identified for
17 this, but we haven't given up that process, and I would
18 ask for, if there are questions about this, the support
19 of the Board that this is a good idea.

20 DR. MUSIC: I would second that.

21 DR. ANDERSON: When I came in, it was when
22 they had kind of the retreat out at the Air Force
23 Academy, and there was, in fact, the evening before,
24 the afternoon before the new members came in, and we
25 were briefed at that point in time, and I thought that

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1 was very helpful to get that information, but if
2 there's a travel thing, rather than have it a separate
3 meeting, what you might want to do is have new members
4 all come on at the same time, come in, but come in
5 earlier. A lot of people travel -- unlike me getting
6 in at 11:00 o'clock at night -- you could well have
7 people try to arrive early afternoon, spend three or
8 four hours, and I think you could cover it.

9 Also what was very helpful, we got a copy
10 of the big history of the AFEB, and that's a nice
11 hardbound. Whether you could afford that for
12 everybody, I don't know, but that was very helpful to
13 read the historical perspective on the Board. It has
14 changed some since then, but that gives you some of the
15 history.

16 DR. LaFORCE: We will continue to work
17 with that goal in mind, and it may be the -- the
18 Washington meeting may be the easiest to be able to do
19 that because we were hoping to have it somewhere near
20 the Uniform Medical -- because there are faculty that
21 are there. It's actually easier to find individuals who
22 would be able to do this sort of briefing with. So
23 we're working on that. We don't have it resolved yet,
24 but we are working on that.

25 The second point that I want to make is,

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1 as President of the AFEB, I really rely on AFEB
2 members, and all of you work as hard as I work, and I
3 work very hard. I work a lot of hours during the course
4 of a week, doing what I can, and so everything that is
5 done for AFEB is strictly an add-on because the e-mails
6 don't stop, the mail doesn't stop, the work doesn't
7 stop one iota, but so what? I mean, we accepted this -
8 - no one broke our arms -- when we agreed to be members
9 of the AFEB, and I just make a plea to all the members
10 of the AFEB, please, if I call you, it's not that I
11 have any evil intent to any one of you, it's just that
12 when I look at the vitae and talk it over with Ben,
13 that you've got something that is potentially very
14 valuable as far as discussions -- as far as the work of
15 the AFEB.

16 So I'm going to make a plea, please help
17 me, or help us when we call. And if I can't get
18 volunteers, I'll just simply assign. I would prefer
19 not to do that, but we do have to get some work done.
20 I mean, the group that looked at the squalene issue can
21 fully attest in terms of the amount of time that that
22 took. Those don't happen that often -- or Greg
23 Poland's effort in terms of the "bible." I mean, that
24 was an enormous amount of work that Greg put in and the
25 subcommittee put in, but I think largely Greg. I'm not

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1 suggesting that it is that amount of time that is
2 required by everybody, but I do want to make sure that
3 you understand that I have expectations on your time as
4 well. And I'll try to do it humorously.

5 COL. DINIEGA: And I'd like to chime in.
6 As we staff recommendations around drafts, please
7 respond, otherwise, we kind of get stuck. For example,
8 we don't know if you reviewed it and you agree with it,
9 or you have any misgivings, or thought it was a waste
10 of time, but I do want to try to get the
11 recommendations out in a timely manner, and by that I
12 say four weeks to see the draft that's been staffed,
13 and then we put it into the memorandum format -- and
14 some wordsmithing on my part may be needed -- and then
15 I resend that to whoever authored it, and then it's up
16 to the author to then, if he or she feels it needs to
17 be restaffed, to restaff it.

18 But when I get a draft in, I assume that
19 it's been staffed through the proper subcommittee
20 members and that sort of thing. So, please try to
21 respond to the staffing and the reviewing of things.
22 On several occasions, the authors have said, "Well, I
23 sent it out and didn't hear from anybody." So at least
24 try to do that.

25 And on the issue of orientation, it looks

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1 like it's boiling down where I will try to get the
2 Preventive Medicine Officers to give a service overview
3 and their Preventive Medicine overview, including the
4 research in that arena, because to find faculty at San
5 Antonio at the AMED Center and School is a little bit
6 more difficult to do. The one prohibiting factor would
7 be if we try to get people in the night before or a
8 half a day before and spend four hours, it's not only
9 the new members' time, but the service Preventive
10 Medicine Officers will be involved with that, too. And
11 so we don't want to be doing it for five people five
12 different times.

13 DR. LaFORCE: No, no, no, just once.

14 COL. DINIEGA: We will make all effort to
15 just do it together.

16 DR. RUNYAN: It would be very helpful, if
17 you're going to do that for not only the new members
18 but continuing members I think would benefit from that
19 as well.

20 COL. DINIEGA: Well, at our last meeting,
21 we discussed the need to go to another day, or to fill
22 up the rest of the second day, and there was opposition
23 to that.

24 DR. SOKAS: But it could be optional.

25 COL. DINIEGA: Optional for the --

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1 DR. LaFORCE: Optional, very good point.

2 (Simultaneous discussion.)

3 DR. LaFORCE: Yes.

4 DR. BERG: Bill Berg. Since you're
5 putting together ideas for the orientation, it might be
6 nice to have a one-page briefing sheet, something
7 really short, on ongoing issues the Board is wrestling
8 with.

9 DR. LaFORCE: That's a great idea.

10 COL. DINIEGA: We do have a Web site. For
11 the new members, we do have a Web site.

12 DR. HAYWOOD: In that context, we had
13 previously decided to have a periodic update of the
14 issues that are unresolved and that need to have a
15 periodic updating on.

16 COL. DINIEGA: Right, and that was the
17 intent of the PM updates and some specific follow-up on
18 last year's recommendations.

19 DR. LaFORCE: David?

20 DR. ATKINS: I just wanted to make a
21 comment on behalf of the Health Promotion Subcommittee,
22 since we didn't have any questions to answer, but
23 Julian suggested we could have an answer anyway. So I
24 think that what I'm proposing is that we are going to
25 draft a statement commenting on the Alcohol and Tobacco

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1 Plans, that we found very useful and had some
2 suggestions about standardizing the organization or
3 presentation because that was very helpful for our
4 committee.

5 COL. DINIEGA: What about the Healthy
6 People 2010?

7 DR. ATKINS: Yes. I'm speaking personally
8 since we didn't get a chance to discuss this as a
9 group, but I would like to get involved in that process
10 to get a clearer sense of actually what is being
11 contemplated in terms of narrowing down to a more
12 manageable set of priorities within Healthy People
13 2010. I don't know -- Dana, are you involved in that?

14 COL. BRADSHAW: I haven't been directly
15 involved in the 2010 piece, although this came up at
16 our prevention matrix meeting, which is another PPIP in
17 DoD/VA Clinical Practice Guidelines. The 2010
18 objectives were mentioned in terms of some of the PPIP
19 matrix, so it was only kind of peripherally, but I'm
20 not directly involved in the 2010 group.

21 DR. ATKINS: I guess I'm volunteering
22 myself to make contact with the lead person on that
23 just to get some dialogue going.

24 COL. DINIEGA: Which issue?

25 DR. ATKINS: 2010.

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1 COL. DINIEGA: Lynn Polland and I can help
2 you with that, and I can also -- it's been my intent to
3 bring the PPIP Work Group Chair to the meeting to
4 update the Board on implementation of PPIP.

5 DR. LaFORCE: David, would you do me a
6 favor as you go through this? The other thing I was
7 thinking about is the price of beer. You know, that
8 was a disconnect that I was really --

9 (Simultaneous discussion.)

10 COL. DINIEGA: You raise the price, it
11 hurts my pocket.

12 DR. ALEXANDER: You raise the price, you
13 drop the GC rates, didn't you, for that report?

14 COL. DINIEGA: Like riding a bike.

15 DR. BARRETT-CONNOR: The committee itself
16 is drinking up the difference.

17 DR. LaFORCE: I'm sorry I brought it up.
18 All right. Other comments?

19 DR. HAYWOOD: But we did think that was a
20 great step forward, to have that Joint Group working,
21 and it could help to bring all the services up to
22 speed.

23 COL. DINIEGA: So you're saying you
24 endorse the formation of the PSHPC.

25 DR. LaFORCE: Linda?

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1 DR. ALEXANDER: Do SPDs fall in the Health
2 Promotion Subgroup, or in the ID?

3 COL. DINIEGA: ID, but there is no reason
4 we can't have it in both arenas.

5 DR. LaFORCE: We don't discriminate. I
6 mean, sex is sex.

7 DR. GARDNER: Marc, is it within the
8 purview of our committee to, for instance, respond to
9 this year's flu vaccine production crisis, and to
10 suggest priorities, or if we don't have enough to do
11 what we need to do, what the priorities should be? Is
12 that something that this committee would choose to do,
13 or if there's a national shortage, would we prioritize
14 to elderly versus military, et cetera?

15 COL. DINIEGA: Actually, in our room right
16 now there is -- Dave, are you still the official flue
17 vaccine representative to the committee, or are --
18 remember, they had asked for a DoD representative --

19 CAPT. TRUMP: This was with the VRPAC
20 (phonetic). Charlie was actually, I think, an official
21 member of that committee when they were considering the
22 flue vaccine questions earlier this year.

23 DR. GARDNER: We meet in September next?
24 Is this something we could still cogitate as an agenda
25 item, as a question?

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1 DR. OSTROFF: What I may suggest for the
2 Disease Control Committee is that as more information
3 becomes available about what may happen, then I think
4 that we could conceivably readdress the issue maybe as
5 a subcommittee between meetings because I think by
6 September it will probably be a little bit too late to
7 try to impact some of the decisionmaking.

8 CAPT. SCHOR: Wayne McBride puts out the
9 Navy message that talks about availability and how to
10 order and how to get it out, at least for the Naval
11 services covering the Marine Corps also. And I forget
12 what actual schedule you have for getting that message
13 out, but any guidance, I would think, that this
14 committee could provide balancing availability and
15 recommendations for the field, for the operational
16 forces, would be very critical and very helpful as an
17 objective input to that message.

18 DR. GARDNER: Do we have to wait until
19 we're asked a question, or can we go ahead and --

20 COL. DINIEGA: The norm is to wait for a
21 question and not volunteer to give the answer without a
22 question. That's the normal -- and that way you'll get
23 the best cooperation from the services. Now, the flu
24 season in the military, for vaccination, begins
25 officially 1 October. The general rule is it's

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1 mandatory for all active duty.

2 Secondly, we're supposed to follow ACIP
3 recommendations for nonactive duty personnel, but in
4 the military, if you want the flu vaccine and you are a
5 family member or a beneficiary of nonactive duty, you
6 can get it. I mean, we don't discriminate. The only
7 thing they do is, they will go through the active duty
8 force and make that available to the active duty force
9 first, before opening it up to the rest of the
10 beneficiaries. And we have probably one of the largest
11 segments of outside the range of ACIP recommendations
12 that take the flu vaccine.

13 DR. GARDNER: This year, it may need to be
14 modified. I'm not suggesting that we change the whole
15 show, but if you only get half the vaccine you used to
16 get, what are you going to do with it?

17 COL. DINIEGA: Right. But the priority is
18 always for the active duty first, before they'll
19 release it to the rest of the beneficiary population.

20 DR. LaFORCE: I think also the military --
21 correct me if I'm wrong -- I always thought you had
22 first access than anybody --

23 COL. DINIEGA: I will have to check with -
24 -

25 (Simultaneous discussion.)

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1 CAPT. TRUMP: Before AFEB would be asked
2 for a recommendation, we'd have to know what the impact
3 of the shortage is, and we do contract separately for a
4 relatively large volume of the vaccine to cover DoD
5 needs. That includes the military needs, but also our
6 family members and other beneficiaries. So, it's a
7 matter of what the shortage is. We contract with one
8 manufacturer rather than necessarily with multiple
9 manufacturers -- and, again, I don't know the details
10 of the concerns right now.

11 DR. LaFORCE: I've got one other item. I
12 want to finish promptly at 2:00 o'clock. Stan, could
13 you spend a few minutes describing the sort of
14 varicella issue?

15 DR. MUSIC: Sometime, I think it was in
16 the last spring meeting, we had a presentation that
17 deal with varicella vaccination policy, and there were
18 three presentations -- Army, Navy and Air Force --
19 dealing with the cost-effectiveness of do we screen, do
20 we just shoot everybody, do we use the lab, what should
21 be the vaccination policy.

22 The Army had a presentation which was
23 essentially laissez faire. It basically said we only
24 have a very few cases, and screening and testing and
25 vaccinating is all a waste of resources better spent.

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1 The Navy and the Air Force did recommend screening and
2 vaccinating. The difference seemed to be in the
3 assumption with the Army making policy at the early
4 phase and limiting it to accessions and recruits and
5 basic training whereas the Navy and the Air Force dealt
6 with the longer-range and the rest of the military
7 career.

8 There was also a presentation by CDC with
9 Jane Seward, and another presentation by a MERCK
10 person, Dr. Christina Chan. In the end, the Board made
11 a recommendation and that has been published and it
12 involves screening by history and then vaccinating.

13 The problem is that after all of this was
14 done, the Army published their analysis and their
15 recommendation in a military medical journal which came
16 out very recently, in the last month or so, and they
17 did it without any of the context that I just gave you,
18 and it looks like Army policy. It can be easily
19 misread.

20 It does not talk about what the official
21 policy is or what the AFEB recommendations are, and
22 it's a problem. And I just bring this up to your
23 attention. It came to me as a MERCK employee from, as
24 you can imagine, some people who are not very happy to
25 see this, but it's not a MERCK issue, it's a military

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1 issue, and I think you just need to be aware of it as a
2 Board, and whatever you decide to do with it, do with
3 it, and I will excuse myself from the voting.

4 DR. LaFORCE: Bill?

5 DR. BERG: Bill Berg. Would it be
6 appropriate to send a letter to the editor of the
7 journal outlining the Board's position and history on
8 it?

9 DR. MUSIC: That's a possibility that's
10 always open and is frequently used in situations like
11 this. I don't think this was malicious or that it was
12 their intent to mislead, I just think they had a study,
13 it was publishable, and they published it, and that was
14 the end of it. The context is out of whack, and that's
15 an oversight.

16 DR. LaFORCE: What I was going to propose
17 is that we get a copy of the paper, circulate it to
18 members of the Board, and that I would draft something,
19 along with maybe Ben, or if any other volunteers or if
20 anybody is interested in it, then circulate that to the
21 Board, and if we don't hear from you within two days or
22 three days, we don't have --

23 COL. TAKAFUJI: Question. Is this an AFEB
24 issue, or is this an Army issue?

25 DR. LaFORCE: I think it's a bit of both,

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1 don't you?

2 COL. TAKAFUJI: If it's an Army policy
3 issue, then, Ben, you've got to address it.

4 COL. DINIEGA: There's no Army policy yet.

5 COL. WITHERS: It's just up to the AFEB.
6 The only person who is potentially embarrassed here, if
7 they are embarrassed at all, is the AFEB because they
8 recommended one thing and a group from CHBBM (phonetic)
9 came by a year later and published a study. Their
10 study is not Army policy. I agree that the proper way
11 to approach this is, if AFEB just wants to appear to
12 correct the record or set things straight as to why
13 they made such-and-such -- in fact, Army policy is
14 following AFEB.

15 I'm undaunted by this. I mean, I just see
16 this as, just like Dr. Music said, they had a
17 publishable work and they stated their assumptions up
18 front. There's nothing malicious here.

19 DR. LaFORCE: So if you have no -- if
20 anybody -- we'll circulate that. I don't want to make
21 a big deal about it, but I do think it is important if
22 there was -- as Ben has just pointed out, we did
23 discuss this in detail. There was a recommendation.
24 It is part of policy. And it's just a question of
25 getting it out there clearly, to make sure that there

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1 isn't confusion on the part of individuals who may be
2 looking at this.

3 COL. WITHERS: That's probably the best
4 thing to do because there are probably more than a few
5 people out there wondering when they are going to see
6 my policy memo in a couple of weeks here, you know,
7 they may wonder what's -- they may recognize the
8 disconnect.

9 CAPT. TRUMP: I just wanted to clarify.
10 Subsequent to the AFEB recommendation, there was an ASD
11 Health Affairs policy memorandum to the services that
12 essentially is the AFEB recommendation.

13 COL. BRADSHAW: I think Dr. LaForce's
14 point is the main one, that just in case there's any
15 confusion over the fact that the Air Force went out
16 with a policy letter, Ben's getting ready to go out
17 with one for the Army. The Navy already had theirs in
18 place. And it's not what this cost-analysis came up
19 with which, if I remember, when that was presented and
20 we considered it, it was -- the sensitivity analysis
21 seemed to be totally based on the assumption that they
22 were only looking at disease within the recruit time
23 frame. And if that came out in the article also, then
24 we probably need to point that out. And I would say
25 just a letter back to the editor of Military Medicine

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1 would be the right venue to do that, just to make sure
2 that people aren't confused as to why we discounted the
3 cost-analysis.

4 CDR. McBRIDE: There were some concerns
5 about some other assumptions in the paper that did draw
6 quite a few criticisms, and perhaps elements of that
7 might be mentioned in a careful way, to explain the
8 situation. I think a letter to the editor would be
9 fine.

10 DR. LaFORCE: Okay, super. Ben and I will
11 look at that. I am just about finished -- and we are
12 going to finish on time at 2:00 o'clock -- other than
13 to say that the next meeting is in Washington on
14 September 12 and 13.

15 COL. DINIEGA: It's a Tuesday and
16 Wednesday.

17 DR. LaFORCE: We're going to try to get
18 Ted Woodard, and I've got a townhouse that I'm staying
19 at now in Georgetown, that's right -- it's actually not
20 very far from Dupont Circle, which is the train that
21 you come right down from Bethesda. And so if I'm still
22 at this townhouse, we're going to hold a reception and
23 ask Ted to come. And then probably go find the
24 Ethiopian or the Indian restaurant up near Dupont
25 Circle as a group, which then makes it easy for those

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1 of you who are going back to Bethesda, to get back on
2 the train. So we'll try to get that set up the night
3 of the 12th. Okay, yes.

4 COL. DINIEGA: First off, you heard the
5 comments about the AFEB books. There are two volumes in
6 that set. If you do not have either, or you're missing
7 one, send me an e-mail. We will mail it to you.

8 The Air Force Health Protection Vision
9 2020, or 2010, that LtCol. Kimm passed around, if you
10 would like a copy of that, please send me an e-mail and
11 I will get that out. Don't forget your travel
12 settlements, fill those out as soon as you can.

13 At the start of the fiscal year in
14 October, we all have to fill out the infamous OJE 450,
15 Liabilities and Assets, and we'll send it out when we
16 see the requirement come down to us.

17 The recommendations, if you can send me a
18 draft sooner, or around four weeks is reasonable, the
19 last two recommendations from the last meeting three
20 months ago are here. Dr. LaForce will sign them.
21 We'll send them out next week. The other three have
22 already gone out, and the members all should have
23 received copies of those. We do have a Web site --
24 TRICARE.OSD --

25 CAPT. TRUMP: www.tricare.osd.mil/AFEB.

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1 COL. DINIEGA: And the charter is on
2 there, a little history, and the recent recommendations
3 not to include the last meeting. And then when Capt.
4 Trump leaves, I have to figure out how to do that and
5 get some people to post it.

6 CAPT. TRUMP: The other thing that there
7 was some interest in is copies of the Red Book report
8 on vaccines.

9 COL. DINIEGA: Was that posted to the Web
10 site?

11 CAPT. TRUMP: It is on the Web site, as is
12 the injury report.

13 COL. DINIEGA: That will kill more than
14 one tree, but if you want a copy of the Red Book for
15 the Board members, send me an e-mail and I'll see if I
16 can dig up a copy.

17 CAPT. TRUMP: I have some.

18 COL. DINIEGA: Oh, you have some, too?
19 Okay. And I have some. So send me an e-mail.

20 We're losing seven members this year. We
21 have in the hopper waiting to be considered by the
22 Preventive Medicine Liaison Officers, 18 nominees.
23 Nine of them are year 2000 nominees, the other nine are
24 year 1999 nominees that are carrying over. And the PM
25 officers will probably meet tomorrow and decide on the

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1 new ones. It takes three months minimum to go through
2 the whole system and that doesn't include the security
3 clearances. Those of you who belong to federal
4 agencies other than DoD -- Dr. Atkins, Dr. Sokas, et
5 cetera -- you have to obtain your clearance through
6 your Federal agency. If you're not in a federal
7 agency, federal employee, then you have to fill out the
8 Army form, and I think they are the same forms.

9 Dr. Tsai, you have to fill one out in
10 order to get your security clearance, and pretty much
11 the only time you'll need it is if you get classified
12 briefings like the BW threat or if, for some reason,
13 we're over at AFMIC, to get in the building you need a
14 security clearance, et cetera. So, it should be --
15 like the OG 450, a requirement of being on the Board.

16 DR. ANDERSON: I had a question on the
17 clearance. Is there some paper that you get with that,
18 because I just know that for other DoD activities, such
19 as the -- or DOE activities, when they want clearance,
20 they always say if you've been previously cleared, it's
21 quicker, but -- at least I never got any documentation
22 about the clearance.

23 COL. DINIEGA: They keep it on file.
24 Like, when I need my clearance, I go to my Security
25 Office and ask them for it. However, when you are on

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1 travel as an AFEB member, you're actually an employee
2 of the government, but once you rotate off the Board,
3 you don't keep that security clearance anymore, active.

4 And so once you're off the Board, if you need
5 clearance. You can't come to the Army and ask them for
6 that clearance because you're no longer a member of the
7 Board.

8 DR. ANDERSON: But there will be a record
9 or not?

10 COL. DINIEGA: I don't know how long they
11 keep it. Dr. Alexander retired several years ago, and
12 I'm not so sure they were able to find her record.

13 DR. ALEXANDER: I had to redo the whole
14 thing.

15 COL. DINIEGA: She had to redo the whole
16 thing. I don't know what the rules are. I want to
17 thank all the speakers, and I want to thank again
18 USAMRIID for all the support. I couldn't have done it
19 without their help. And we had a good turnout of the
20 Board members, and I endorse Dr. LaForce's comment
21 about we need teamwork here, and everybody should take
22 a turn in doing some of the writing especially, because
23 that does take up people's time. I review all the
24 recommendations that come in and sort of rewrite them
25 and work with the authors of them. Dr. Ostroff is a

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1 man of a lot of words. He wrote a terrific report.
2 You'll see it when it comes around, but that was a lot
3 of work that he put in. So we do need teamwork, and
4 it's good to see the members attend the meeting.

5 I want to keep the membership at 20,
6 that's our max -- seven Disease Control, six on the
7 other two subcommittees -- because we normally can get
8 three-fourths or two-thirds of the membership here at
9 any one time. I will be sending out calendars again,
10 looking ahead to next year, and what I need is your
11 nonavailability time, and then I will select the dates
12 in the week that we can get the highest attendance. I
13 will try desperately to stay away from Mondays and
14 Fridays as travel dates.

15 DR. BARRETT-CONNOR: And Memorial Day.

16 DR. LaFORCE: Unless there's a holiday on
17 Monday.

18 COL. DINIEGA: Well, actually, we were
19 going to do this last week, but we had people that had
20 all kinds of other meetings, and that turned out to be
21 a not good day. So I'm sorry about this past weekend,
22 but I'm glad you guys could make it.

23 DR. LaFORCE: Okay. Thank you all, safe
24 trip back.

25 (Whereupon, at 2:00 p.m., the Executive

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1 Session was concluded.)