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11 ARMED FORCES EPIDEMIOLOGICAL
12 BOARD MEETING
13 SEPTEMBER 22, 2004
14 12:30 P.M.
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1 DR. OSTROFF: That was a wonderful several
2 hours. And, you know, I'm not from Missouri, but I
3 philosophically share the conviction that it's always good
4 to see things, and this was a great opportunity to see
5 things. And it was exciting, at least for me, having been
6 on the board for some period of time, to see them actually
7 implementing some of the things that we have recommended
8 over the years.
9 As I was just talking with Colonel Gibson, there
10 are some things they haven't implemented yet, particularly
11 the recruit testing pool, that we currently would like to
12 see them using. But overall, I can't say enough about the
13 amount of attention that they're paying to do things to try
14 to reduce the injury and disease burden in the recruit
15 setting, and so they ought to be congratulated for it. And
16 thank you for affording us the opportunity to see that, and
17 we will continue to look forward to opportunities to see
18 other recruit settings, as well. Dr. (inaudible)?
19 UNIDENTIFIED SPEAKER: Yeah. I don't know if
20 it's really appropriate for us to make any comment about
21 this, but one of the things that was raised when (inaudible)
22 and I were sitting at a table with two young women, in fact,
23 one of the honors graduate -- the only honors graduate from
24 this program, and they told us that they were going to stop
25 training women flights at that facility, and they felt that

1 this was a mistake in the sense that they felt training
2 alongside men was good for both the women and the men. For
3 one reason, because the women were motivated to try harder,
4 and there was a bit of a competition between the two, and
5 that the men also appreciated it.
6 And I'm not sure that this has anything to do
7 with the role of the AFEB, but we did say that we would
8 bring this to the attention of those here, if a statement
9 could be made. I don't know whose decision is this or what,
10 but for what it's worth, I think it is a good idea for them
11 to train together, and maybe we could say that to somebody.
12 DR. OSTROFF: Before we get started with the
13 program, I did want to -- a presentation to Colonel
14 Underwood. As is so often unfortunately the case in these
15 meetings, this is going to be her last meeting, and she has
16 certainly made outstanding, significant contributions to the
17 activities of the board over the last couple of years, so we
18 wanted to take an opportunity and provide to you the
19 traditional plaque and certificate for all of your time in
20 service. Thanks so much.
21 COLONEL UNDERWOOD: Thank you.
22 DR. OSTROFF: Would you like to make a
23 comment about where you're going?
24 COLONEL UNDERWOOD: I have big shoes to
25 fill. I'll be following Colonel Robert DeFrades (phonetic),

1 and I don't think anybody in this room wants to follow
2 Colonel DeFrades (inaudible). But I'll be the director of
3 the proponency for preventative medicine for the Army and
4 the surgeon general.
5 And Colonel DeFrades will be going to Fort
6 Detrick, and he'll be working in surveillance under the ACCD
7 (phonetic) umbrella. So I want to -- it's been great to be
8 a -- not a member, but participating as the preventative
9 medicine staff officer. I pass that torch to Colonel
10 (inaudible), and it's been a pleasure, and I hope in the
11 future I'll be able to come to some other meetings in a
12 different capacity.
13 DR. OSTROFF: The good news is that we'll be
14 able to see you at future meetings.
15 COLONEL UNDERWOOD: Thank you.
16 DR. OSTROFF: Thanks so much. Let's go ahead
17 and get started in the schedule here, the presentations
18 before we get to the -- the preventative medicine updates.
19 The first is a subject that's traditionally near and dear to
20 the board, and this is a couple of issues that we discussed
21 earlier in the year, and we thank Mr. Howell for his
22 willingness to return to give us an update on the status of
23 Adenovirus and JE vaccine.
24 UNIDENTIFIED SPEAKER: Just a quick comment
25 before you get started.

1 MR. HOWELL: Sure.

2 UNIDENTIFIED SPEAKER: We have a -- for

3 departure, we send this around, it's got names, "Flight

4 departs at," to try to help coordinate trips to the

5 airport. We've got a rental car, so --

6 MR. HOWELL: Actually, Bob DeFrades is coming

7 to work for me and he can't work for you anymore, damn it.

8 Y'all have seen -- for the most of you, y'all have seen --

9 most of you have probably seen in a couple of meetings back

10 to back that we have come to brief you, so I really just

11 want to give you an update as of where we are based upon

12 what we had planned before, so --

13 And I should also mention, I am the -- I am the

14 management side of the team, I am not the clinical side of

15 the team nor the scientific. But hopefully if there's any

16 questions of that nature, I don't want to deter you from it,

17 we have both Annie Towle (phonetic) from VaccGen and Alan

18 Glist (phonetic) from Barr here today, as well, so if you've

19 got any questions, don't deter to go ahead.

20 So this is what we're going to talk about, and

21 we'll do it fairly quickly. I understand the time frame

22 we've got. I probably don't need to show you this, but it's

23 a nice slide, and our guys love to see it, because it really

24 did show when you had a vaccine, we didn't have Adenovirus.

25 When you didn't have a vaccine, you had Adenovirus; it came

1 back in spades.

2 And that we've been working for a while to get

3 back towards licensure of a product, and we started off,

4 first of all, once we finally were able to convince Wyeth to

5 play with us a bit, then we were able to get Barr on board

6 in 2001 and have been working since on that.

7 Flip one more. This is an eye chart for you.

8 Hopefully you've got the paper in front of you, but

9 basically -- and even that may be an eye chart for you.

10 Basically what it really does show is we've been pretty

11 diligent in trying to get all the different steps we need to

12 final licensure out on a piece of paper and point toward

13 it.

14 We are -- do we have a laser? We are in this part

15 here as we speak today, and I'll talk to you -- which is

16 basically running a Phase I central trial, which is

17 occurring right here in this town at Fort Sam, and I'll talk

18 to you in a little bit more detail about that.

19 The other piece, as you can see, we do believe --

20 obviously we've got some work ahead of us. We're going to

21 have to get to an aptitude trial, and we're going to look

22 for multi-sites. For you who are in uniform, we may be

23 tapping on some of your locations. Obviously to be able to

24 run that trial in big headlights is someplace called Great

25 Lakes, based upon what we've seen in the past. But we'll be

1 willing to listen to any of y'all from an epidemiology
2 standpoint as to where you think is a good place for us to
3 run this trial, so I want to make sure that offer is out on
4 the table.
5 So what have we done so far to get to here? We
6 obviously went out, we had some information that Wyeth
7 provided us, largely how do you manufacture the thing, so we
8 took whatever available manufacturing procedures and records
9 we had, put them out there for people to look at.
10 We got Barr and VaccGen's team together to take on
11 this. They had to overcome, I repeat, had to overcome
12 (inaudible) in those records. This is what Dr. Wolfowitz
13 had my butt many times on, because to overcome it took
14 longer and took more money, which doesn't please him in
15 either case.
16 And finally, as I said before, we had hoped when
17 we first started this thing we might be able to do we a
18 (inaudible) study based upon the data that we had from the
19 old vaccine, but all we had was 40 samples, basically, out
20 of that, and the FDA has kind of poo-pooed that, so we don't
21 believe we're going to get there from here, and we're really
22 planning on doing that an efficacy trial to get it.
23 Just a real picture of what it is. Two tablets, 4
24 and 7, gets down into your gut where it actually takes
25 effect then.

1 Go ahead. So where are we now? In getting toward
2 the Phase I trial -- well, a couple of different things.
3 The Phase I trial, we obviously had to have an IND. It was
4 submitted back on 12 July, and it became active then 30 days
5 later. We got the study site up here and running. We've
6 been doing a whole lot of screening. I'll show you the
7 numbers on that shortly. But we have gotten at this point
8 in time -- Alan just updated me. We believe we've gotten
9 the 70 subjects that we're looking for, so that was very
10 good news.
11 We did have -- just to show you again how much
12 prevalence is out there in the basic training force, you can
13 see here, these are very small numbers that were not in some
14 way, shape or form already exposed to it. And these we're
15 looking at, our 91 Whiskey course here, which is --
16 basically these are kids who have already gone through basic
17 and are now here for an MOS developing skill at Fort Sam, so
18 a good many of them obviously were exposed to it in some
19 way, shape or form.
20 On the other side, the facility here that you see
21 is up and running and FDA approved at this point in time.
22 We've done -- produced the lots, and they've been released
23 at this point in time, as well. They should be here in town
24 next week, Alan? Yeah.
25 Okay. And as I said, poop aside, we'll talk to

1 the screen. So this is what we're doing, a Phase I random,
2 double blind placebo controlled safety trial. I want to
3 make sure everybody understands, this is a safety trial, 70
4 volunteers. We're not looking -- though we always look for
5 efficacy, that is not the intent in the long-term purpose of
6 this particular trial. And I just said that. Okay.
7 This is just the design, how many people we
8 thought we were going to have to go see. The intent is to
9 get 70 subjects, 60 primes, 10 alternates as people fall
10 out, as you all know, for whatever, and then splitting them
11 accordingly, collecting samples thereafter.
12 We have -- the screening itself, as I said, we're
13 pretty much getting close to the close of that particular
14 piece, and so we're getting to where we'll start in the next
15 couple of weeks of actually giving out vaccine, and you see
16 we go out to 180 days thereafter to see what the samples
17 look like.
18 Okay. This is just a picture of the auditorium
19 full of 91 Whiskey perspectives and us on the podium telling
20 them why they wanted to volunteer obviously to do this
21 particular trial. No coercion involved. They all get to
22 raise their hand accordingly and -- but the fact that, of
23 course, this is a medical group that would be more sensitive
24 to it, we should not lose sight of. And as I said, we
25 believe at this point we've got our 70 subjects pretty much

1 locked and cocked, so we're ready to go.

2 So what happens after that? In the meantime, Barr

3 is going back to the manufacturing facility. They're going

4 to put in some lyophilzation equipment for this to have more

5 on site, versus going out to subcontracting to other

6 people.

7 That will, of course, cause us to have to go back

8 to get FDA approval and run another lot to be able to

9 support the Phase II/III trial that we're looking at, but we

10 believe we have plenty of time to be able to do that before

11 we could get to the study's start.

12 We've got a group that's making virus -- they are

13 still in Scotland, if I remember correctly, making virus.

14 That's probably the most tenuous piece in this, but

15 that's -- but we do have a good subcontract through Barr --

16 a subcontractor through Barr for that. And, of course, we

17 plan on after this to go see the FDA again as to our next

18 trial.

19 But we did have a very good meeting with the FDA.

20 And I can't remember where we are in the sequence of y'all's

21 meetings, but we did have a very good meeting with the FDA

22 two months ago that laid out pretty much how we're going

23 to -- in fact, it was right before -- that's right, it was

24 right before this meeting up in Fort Detrick last time, so

25 you heard a little bit of that.

1 So we've got to requalify in the manufacturing
2 facility, and once we make those changes, and in so doing
3 thereafter produce the additional vaccine that will get us
4 into the Phase II/III trial.
5 Report on the Phase I clinical trial, that should
6 be somewhere near the end of this calendar year, we should
7 get the data and then start to assess and put that out in
8 the fall -- excuse me, in the winter time frame. And then
9 what we're look really looking at now is, of course, we've
10 got to know where we're going for our next one. And as I
11 said earlier, you know, besides Great Lakes in headlights
12 and Leonard Wood potentially in headlights, we're looking at
13 other places that we could potentially go where we could get
14 a good dose of people who are exposed to it.
15 So I think in summary that's pretty much it. No,
16 you can go on. And actually this was a risk, but we've -- I
17 think it's kind of off the board, it's worked out well. So
18 at this point, I think we've got a successful piece on
19 schedule from where we last saw you as far as the
20 Adenovirus.
21 One bit of news also -- it's not on a slide. You
22 can kill this. We were able -- we set up with Dr. Wolfowitz
23 a while back. We showed him what the funding was, and as I
24 said, of course, anything takes longer and more money he's
25 not happy with, but he was good. He gave us at least four

1 million dollars -- he gave us four million more this year to
2 go on top of what we've got. We've got another (inaudible)
3 for about two million that are sitting up there on the table
4 now that looks like we may get something out of that, as
5 well. So from a funding standpoint, I think this project is
6 in better shape than it has been in a long time. Any
7 questions on Adenovirus?
8 DR. OSTROFF: Before we move on to JE,
9 Dr. (inaudible) made some comments yesterday, but we didn't
10 have transcripts at that time, so if you would remind --
11 wouldn't mind making some comments now so you could get that
12 for the record.
13 UNIDENTIFIED SPEAKER: This is (inaudible)
14 Savage. Kevin Russell and I yesterday went to -- and met
15 some of the investigators conducting the trial, and it
16 seemed to us that the study design and all the preparations
17 were on track for an excellent safety and immunogenicity
18 trial. And I think we were all pleased with the progress
19 that we saw there, so it seems to be well supported.
20 I think they had at one time 40 different contract
21 personnel in the (inaudible) phase, and they seemed to have
22 all the planning for follow-up to -- it seems to be in
23 order, so congratulations.
24 MR. HOWELL: Thank you. I mean, I think
25 considering when we saw the seroconvergence to start off

1 with, that kind of shocked us a bit as to how much exposure
2 we already had getting here, but it appears we've overcome
3 that, and it looks pretty good right now, so I thank you.
4 DR. OSTROFF: Let me ask if there are any
5 other comments from the board members? I have one
6 question. It's my recollection from our previous meeting
7 was that there was some issues related to females, and what
8 is happening with that issue in terms of the clinical
9 trials?
10 MR. HOWELL: Alan, do you have the repro --
11 MR. TOWLE: Okay. Hi. I'm Alan from Barr
12 Laboratories. And first of all, I want to thank the
13 committee for their input and their encouragement. Keep it
14 coming, we always like to be encouraged. We still are
15 looking for definitive data from the military for previous
16 exposure to females, and anyone and everybody who can give
17 us some real input, we'd love to have that.
18 We are not -- we have separate exclusion and
19 inclusion criteria for females in this trial, but we are
20 letting -- we are admitting them without bias into this
21 current program.
22 The FDA has asked us to present to them a white
23 paper on how we think we should move forward on this, and we
24 are in the process of making that. And again, previous data
25 will be very helpful for that.

1 MR. HOWELL: And I do -- I would add to
2 that. I know that we put some money in to do some
3 historical digging, but I have to tell you, I don't know
4 where that is at the moment. But Charlie did take that back
5 from the last meeting, and we put, I want to say, somewhere
6 between 10, 15 grand to go do a historical look-back in the
7 files to see if there's anything in there we can fuse
8 together, but I don't know if that -- I don't believe that
9 has come together -- let me rephrase. I know that has not
10 come to conclusion yet, but I don't know what results they
11 have had so far.
12 DR. OSTROFF: One other comment. If there
13 are issues related to clinical trial sites, the board would
14 be extremely happy to add their opinion and their weight
15 behind any arm twisting that needs to be done to make sure
16 that -- as we had the prospective from the beginning,
17 anything we can do to overcome speed bumps and barriers, we
18 are more than happy to do, because we would like to see this
19 get through its clinical trials as quickly as possible and
20 get relicensed for use.
21 UNIDENTIFIED SPEAKER: Okay. Yeah, Colonel
22 (inaudible), and I'm with Employer's (inaudible) Education
23 and the office (inaudible). I certainly will take the
24 message back to my boss about places to do clinical trials
25 since we are on Lackland Air Force Base. You know, I

1 certainly am happy to hear that Dr. Wolfowitz is funding
2 this development. Assuming you meet your time line in 2008,
3 perhaps the vaccine will be available. Is the DoD going to
4 procure that vaccine, or will there be another unfunded
5 requirement and there will be a delay in terms of, you know,
6 getting this out to our --
7 MR. HOWELL: At this point it's in our --
8 we've put in the palm -- the DHD palm for the procurement as
9 well, and it is there as I speak. Of course, what happens
10 in the future, we'll see. But at this point, it is not
11 anticipated that -- we're trying to do it from a central
12 standpoint, knowing quite truthfully one of the reasons we
13 lost Wyeth to start off with is because it was disintegrated
14 out -- decentralized out to those, and you didn't have a pot
15 that could really support the industrial base because of the
16 cost -- they weren't -- they basically weren't making money
17 on it, so we've got to be able to have the means that we can
18 at least ensure Barr that they are not going to go bankrupt
19 making this, so we've looked at it from a central pot to be
20 able to do that. The mechanisms of how that money will go
21 out, that's still --
22 DR. OSTROFF: I'm wondering if any of our
23 Navy colleagues would like to comment about Great Lakes?
24 MR. RUSSELL: Kevin Russell, (inaudible)
25 Research Center. Certainly if I had the ability to take

1 over the reins for the new (inaudible) team trial from
2 Dr. Gray. I've had the opportunity in many different
3 recruit training sites to discuss vaccine trials, and I
4 certainly can say when it comes to Adenovirus, you're going
5 to have motivated populations. I don't think there's going
6 to be an issue of being able to get into these populations
7 for trials for Adenovirus. There are issues getting into
8 populations for other trials, and they don't seem as
9 directly pertinent, but I don't think Adenovirus is going to
10 be an issue.
11 MR. HOWELL: I would echo that, as well. I
12 think that's the interpretation we have had in our initial
13 discussions. If we were going in and going for a vaccine
14 that didn't have relevance to the troopies themselves there
15 and didn't take them, then they'd say, "No, you're taking
16 them off the training line, taking them" -- they would fight
17 us instead of help us. I think in this particular case,
18 especially if we target those areas that we know have had
19 high incidents, then we should have a fairly easier training
20 to get in on.
21 UNIDENTIFIED SPEAKER: All of the recruits
22 have had high (inaudible).
23 MR. HOWELL: Well --
24 UNIDENTIFIED SPEAKER: This is Greg Gray.
25 The reasons, at least in my mind, why Great Lakes would be

1 the most attractive site is it has one of the longest
2 durations of training in contrast to the Air Force being
3 rather short. It has had the most recent epidemic of
4 Adenovirus 7, and it brings in people from all across the
5 United States, whereas -- like the Air Force, whereas the
6 Army bases are more regional in their collection of
7 trainees, so those are three good reasons, I think.
8 MR. HOWELL: Clearly, though, when we pick a
9 site, I mean, certainly we want one with a lot of incident,
10 but as you just mentioned, it's not just incident, how long
11 are the troopies there, for example, in the training base?
12 And we'll have to work through those sort of pieces, but
13 there's other considerations, just the fact that you're
14 getting a lot of it there, because we've got to hold onto
15 them for a while for sampling purposes. Okay. Shall we
16 switch?
17 DR. OSTROFF: Yes. Thank you.
18 MR. HOWELL: Japanese Encephalitis. You can
19 put the next -- the problem that we have, for those who --
20 you probably all -- I assume maybe somebody like myself
21 wasn't -- BIKEN is the current manufacturer of the Japanese
22 Encephalitis that is licensed through, and that's just to
23 the services.
24 It is made from a mouse brain derived cell, which
25 is not the best in the world, and Japanese -- basically,

1 their national regulatory authority went back and said,
2 "Okay. Guys, we've got to do better than this." So they
3 have gone to Vero cell culture line to be able to do that.
4 There's other advantages in how you make the vaccine from a
5 buffer and what standpoint to make it actually less
6 reactogenetic, if that's the right word.
7 But where the real problem comes in is to be able
8 to do that, they're going to close their line, they're going
9 to close their current line. Now, they're stockpiling for
10 their own people in Japan and the eastern side of Asia that
11 are customers. And they've come to us. Basically, "Okay.
12 How much do you guys want us to stockpile for you?"
13 Not only that, "Well, when we go back and we
14 manufacture this thing, of course, the first place we're
15 going is we're going to Japan, because that's where our
16 market is, so we're going to do all of our licensing work
17 toward the Japanese folks first, we're not going to touch
18 anything for Americans until after that is done because we
19 don't want anything that can potentially comprise that. And
20 then if you want it, since you're such a small" -- and I'll
21 show you the number -- "small amount, you'll going to pay
22 for it." And we're not going to do it on our own, because
23 we don't have enough sales in the U.S. to warrant that kind
24 of an effort.
25 So the bottom line is, you can see, we've got a

1 gap coming our way of Japanese Encephalitis vaccine. So
2 what are we doing to try to fill that gap and work around
3 it? So that's what the purpose of this little brief is, if
4 you would. Y'all are probably aware that it's used out in
5 the west -- I mean, excuse me, out in Asia. PACOM and U.S.
6 Forces Korea do have wartime contingency requirements. They
7 run somewhere in the range of about 100k of doses.
8 They also -- we are also using somewhere in the
9 range of about 90k worth of doses in a year, on an average.
10 It fluctuates a little. The folks who are -- at least from
11 the Army standpoint who are assigned to Korea are not
12 required in the current conditions, but if in fact we go to
13 war in deterioration of the infrastructure and all that
14 stuff, then they anticipate, of course, there would be a
15 need, and that's why there's a wartime contingency
16 requirement. In the meantime, the Marines are probably the
17 largest user of the particular vaccine today. And you can
18 see wherein the risk of the disease itself.
19 Flip the page. Obviously, you can tell where it's
20 at from the map. A lot of manufacturers, only one that
21 makes U.S. licensed product and only one that has shown at
22 this point any interest to go to the U.S. And you can tell
23 by the number, we are a very small percentage. Only about
24 120k is sold in the states, of which the military is by far
25 the biggest user of it.

1 So at the moment there are three manufacturers,
2 clear manufacturers, who are working on Japanese
3 Encephalitis to fill this particular gap. One is Aventis
4 with BIKEN, obviously. It is willing to continue to work
5 with us, but we've seen the time line sort of already.
6 Intercell, who has been working with VaccGen, who has been
7 working with WRAIR on this particular product, and I'll talk
8 to where they are, and then Acambis, which is the CDC
9 manufacturer of choice, as we know, for small pox and
10 others.
11 We sat down with all the firms, we call them, and
12 DSCP, of course, has been the action agent's defense supply
13 center in Philadelphia -- I'm sorry, has been the point of
14 contact, because they are the ones who do the actual
15 production contracting for vaccines for the services, and
16 they're the ones who were first notified that the product
17 would be coming off the market.
18 So we put it through together and we actually
19 called the manufacturers -- three prospective manufacturers
20 and sat with them for a day and a half to try to assess
21 where they were and what the risks were for us. And you can
22 see there the folks who were playing, at least from a
23 governmental standpoint, on that team.
24 I must note we had the FDA there, and that was
25 very pertinent for us so we could understand what the FDA

1 thought they'd have to do for licensure.

2 Flip the slide. The intent of all of them, and

3 the FDA pretty much agrees, that we probably don't have

4 to -- that we could get by with a non-inferiority study,

5 basically looking at this versus the old vaccine, but they

6 will look at -- because they understand to get to a field

7 trial (inaudible), to start off with it's going to be very,

8 very difficult. And they do believe and everybody believes

9 that there is a corollary protection already established, so

10 if you can show that corollary protection in your new

11 vaccine, then they'll take that across.

12 Bottom bullet talks about the numbers. This is

13 probably not that big a trial note that we're looking at to

14 be able to get there. Okay.

15 So I'm going to walk through -- this is privileged

16 information, lock the doors, you don't get to talk to

17 anybody about it. And I mean that seriously, that's not a

18 joke. This is sensitive information from those individual

19 companies, because they are all in a race. He who gets to

20 the market first win.

21 DR. OSTROFF: Hold on. You're going to go

22 into proprietary information that you do not want on the

23 record? Is that what you're saying?

24 MR. HOWELL: But I thought you all had signed

25 confidentiality statements when you walked in the door.

1 DR. OSTROFF: This is a transcripted meeting,
2 an open meeting, so these transcripts will be on the web
3 site, and I'm required to do that as a federal advisory
4 committee. So if you want to skip a slide --
5 MR. HOWELL: Okay. Let's skip a few slides.
6 MS. BENNETT: Let me know when.
7 MR. HOWELL: Okay. Keep flipping. Keep
8 flipping. Okay. I've leave it at this. This part you can
9 probably get, and I'll talk a little bit to it. When you
10 look at what is out there, BIKEN is basically making the
11 same vaccine, with a few changes. Intercell was making the
12 same vaccine as BIKEN is, for the most part, and they're
13 fairly standard technology. We feel that from a
14 technological standpoint, they'll be able to make it.
15 Therefore the FDA licensure, i.e., it's a known entity, will
16 probably be fairly simple, if one can say FDA licensure is
17 ever simple.
18 The time to approval, well, there's a little
19 bit -- as we talked about before, in the case of BIKEN, they
20 are going to the Japanese folks first, come to us, they're
21 looking at a time period of probably in '09 before they
22 would get the licensure. That's a big gap when they're
23 talking about closing the production plant (inaudible) '05.
24 So you're looking at least four years worth of potential
25 gap.

1 UNIDENTIFIED SPEAKER: Question. When you
2 say same vaccine, it's going to be the same virus, the
3 (inaudible) vaccine, and so basically it's going in a
4 different cell type --
5 MR. HOWELL: Cell -- different cell --
6 UNIDENTIFIED SPEAKER: -- so the virus itself
7 is the same and the concept is the same?
8 MR. HOWELL: Right. Right. Yes, the cell
9 line is different but the concept is the same, the virus is
10 the same. Acambis, on the other hand, has a totally
11 different approach, and so they have a rather novel
12 approach, and so that's why we have given them a little bit
13 higher risk in their technology FDA licensure than the
14 others.
15 In the case of the cost, both Acambis and
16 Intercell said they'll get in there without us, they don't
17 need any money -- they'll take our money, but -- like
18 everybody else will, but they have already got the funding
19 or at least the plan for the funding, unless something
20 dramatic happens along the way, that they would be able to
21 get to licensure with the dollars they have in hand, or plan
22 to. Obviously BIKEN and Aventis has already said right up
23 front, "No, you're going to have to pay."
24 You go the other way, and certainly the
25 manufacturing technology and all the rest and the experience

1 is in BIKEN's favor. They are a -- and Aventis, they've
2 done this for many years, so that's a no-brainer. On the
3 other hand, either of the other two, they are fairly
4 start-up groups, not a great deal of experience there, so
5 you have to take a little bit of grain of salt of how long
6 it would take them to get their manufacturing plan actually
7 up running, scaled properly and through the FDA. And the
8 logistic side of the vaccines are not much different from
9 the vaccine we have today, so it would (inaudible).
10 Some of the assumptions we had going in, I know
11 this is a laundry list, so I'm going to walk through them,
12 if I can, very quickly. Obviously we don't want any
13 shortfalls, both from a contingency of going to war, but as
14 well as our daily use that we see today. We are assuming
15 the requirement will stay about the same as we know it
16 today, and that the contingency requirements, unless
17 something happens, will remain unresourced.
18 Today we have a contingency requirement, but we
19 don't have a stockpile. The rationale for that is we can
20 buy it, and there's so much of it being made by BIKEN that
21 we can get our hands on it in a fairly quick amount of time,
22 but if they close their plants, then we don't have a steady
23 production line, so we would either have to buy that
24 stockpile -- there's a higher risk now than we had before
25 when --

1 UNIDENTIFIED SPEAKER: You don't say what 90K
2 costs. Is there a dollar value?
3 MR. HOWELL: Five mil. Four and a half to
4 five mil. The FDA is in the process of looking at a packet
5 from BIKEN -- from Aventis, technically now, that will
6 extend the shelf life from four years to five, and we feel
7 that that's pretty doable, that they'll accept that.
8 DSCP has already gone ahead and bought 18 months
9 of product. They spent eight million dollars of their own
10 up front. Very unusual. We should all clap and say thank
11 you. The trouble is, the gap is bigger than that, and
12 that's as far as they can go in their own purse, so they're
13 looking for some help.
14 We've already mentioned that BIKEN is going to
15 close production in '05. We assume that the time lines that
16 the manufacturers have shown us are best case, and we don't
17 accept best case, so we figure it's going to take at least
18 one year, maybe as much as 18 months longer, probably,
19 especially in the instance of the start-ups, which we would
20 put Acambis and Intercell in that grouping.
21 They are all looking at a U.S. and European
22 market, but we have sized it, probably still, as less than a
23 million doses out there, so it's not a real big money maker,
24 no matter which way you go for those particular instances.
25 Once the product is available, here's the nuance.

1 If we go and we stockpile too much and the new product
2 becomes available, all of you guys are going to ask for the
3 new product, you're not going to want the old product, and
4 then DSCP or whoever is left holding the bag of whatever
5 they bought because it's now not saleable, so there's a risk
6 that we may invest too much, if in fact they stay on line.
7 We will be asking the FDA to fast track the
8 process in a rolling review with all of them, and we think
9 that will probably happen. And as I mentioned before, the
10 additional stockpile actually brings a financial risk to
11 DSCP, or whomever would pay.
12 Okay. Having said all that, we came up with five
13 courses of action that we're recommending. At this point in
14 time, you are the first ones, outside of my boss, to see
15 these courses of action. My next step up the chain of the
16 force health protection is Ms. Embrey, and helpfully in to
17 see Dr. Wolfowitz shortly thereafter.
18 The first one is, okay, let's take no risks,
19 basically. Let's work with BIKEN and fund them as soon as
20 we possibly can, fund as much stockpile as we can get and
21 keep them on line so that -- I mean, enough stockpile so
22 that that in '09, we'll -- all the way through '09 covered,
23 and then we can pay them to come back on line. But as you
24 can see, that -- which is a great solution if we were to
25 make money. But if we did that, we're talking about 20 or

1 30 million probably to be able to do that, both in stockpile
2 and paying for the licensure part across.
3 All right. Course of Action II, since -- buy the
4 stockpile, but don't fund BIKEN until we know the other ones
5 are unable to make it. So in this particular case, again,
6 we're look at about 13 million, the time difference, about
7 13 million in stockpile. And then depending on what happens
8 with the start-ups, we may have to -- but I should
9 rephrase. We continue to fund -- in this course of action,
10 we continue to fund BIKEN until we know the start-ups have
11 got FDA licensure, so it could go as much as 20 million, or
12 it could cut off somewhere in between if the start-ups
13 actually get to licensure before this particular product.
14 Next. No. 3 is then we buy stockpile through
15 '08, based upon where we see the start-ups. The start-ups,
16 I should have said up front, because that was part of what I
17 took off, they anticipate -- they say they'll be available
18 sometime maybe as early as late '06, maybe early '07. Our
19 estimate, as I said before, puts them more likely in '08.
20 So this one looks at a particular -- a means of extending
21 the stockpile through '08, as well as buying some
22 contingency stocks, so we're probably -- we're up to about
23 13 mil again, if you look at those particular piles. And
24 then we'll watch the start-ups.
25 We will not pay for BIKEN, but if the start-ups

1 start to get in trouble or start to fail along the way, then
2 we'd have to go back to get the dollars to work up with
3 BIKEN. So it's a little less dollars up front, and it's
4 assuming some risk that the start-ups will be successful.
5 No. 4 is not -- the same thing, only not buying
6 any contingency stocks. It's basically saying we'll have
7 enough when we first start in contingency, and once we see
8 the Phase II trials, if we have to, we can always buy IND
9 product and hold it as IND until the final is approved. And
10 not a good situation, I'll readily admit to that. Nobody
11 likes IND products if we can help it, but if we get into
12 financial problems, that's an alternative. This cost is at
13 eight million.
14 Last course of action, of course, the old
15 standard, do nothing, just watch it all happen, and hope if
16 the start-ups get done when they say they will, the
17 stockpile the DSCP has already bought will run out about the
18 same time that the start-ups say and they're planning that
19 they'll show up at the door. So that's where the
20 (inaudible) is.
21 All right. Our recommendation -- I went to
22 General Martinez Lopez -- that he bought off on was No. 3
23 which said basically buy it through '08, buy it -- a
24 stockpile for the contingency and then watch the start-ups.
25 Go ahead. That's where we are today.

1 DR. OSTROFF: I'll open it up to comments
2 here.
3 UNIDENTIFIED SPEAKER: Two questions. First,
4 you said that the Intercell is basically the same vaccine as
5 the AP/BIKEN, but then that the cost of the AP/BIKEN is
6 high, which the Intercell's is low on your chart. Why the
7 difference in cost?
8 MR. HOWELL: The cost that I showed you --
9 there's two segments of the cost. One is the actual get to
10 licensure. It will not cost us anything to get Intercell to
11 licensure. It will cost us somewhere in the range of 10 to
12 20 million to get Aventis to licensure. Now, turn it around
13 the other side, you --
14 UNIDENTIFIED SPEAKER: That's the cost of
15 development, not the cost of the vaccine itself.
16 MR. HOWELL: Right. And the cost of the
17 vaccine would probably be reversed. Aventis will
18 probably -- or BIKEN will probably be cheaper than the
19 Intercell.
20 UNIDENTIFIED SPEAKER: The other question I
21 have, I was on the ACIP committee when we were sort of
22 considering the Japanese Encephalitis, and the thing that
23 was of concern was this relatively bizarre -- it was
24 described as delayed anaphylaxis. I've never even
25 understood the biologic concept, but the idea that up to

1 even nine or ten days there could be an anaphylactic
2 reaction after Japanese Encephalitis. And I don't see
3 anything in any of this presentation that addresses that
4 issue. It is happening in certain travel groups in
5 Australia and Denmark. It was happening one in 6,000, 7,000
6 people. And there was a death in Okinawa, a serviceman that
7 was two days after vaccination that never was -- that always
8 was talked about but never causally related.
9 Anyway, I guess we're talking about looking at
10 immunity response as the licensure, but there is working --
11 has some concern about adverse reactions and whether there
12 be would a differential to (inaudible) these various
13 products.
14 MR. HOWELL: I cannot answer that question on
15 the shock end -- anaphylaxis shock piece, but I know that
16 the whole rationale to move from the current product line is
17 because of the variability of the manufacturing, as well as
18 the reactiveness of it. So the desire is, obviously, to
19 have a product that would be less reactive than the one we
20 have today. The fact that they're moving to the Vero cells
21 and the way they can reconfigure the buffer and the rest
22 does lead, as least notionally, to the belief that it will
23 be a less reactive product. And the studies that they've
24 seen today from both Aventis -- or BIKEN and Intercell have
25 shown almost no reactogenicity. The Acambis product has

1 shown a little --

2 UNIDENTIFIED SPEAKER: Are you suggesting

3 that 2,000 to 3,000 would be enough for the safety studies?

4 MR. HOWELL: Yes.

5 UNIDENTIFIED SPEAKER: That would be not be

6 the case if we're looking at something that happened once in

7 five to 10,000, so I guess I'm -- I -- I think you're going

8 to have that working somewhere in the background as having

9 (inaudible). It's relatively small numbers, but the number

10 of cases when I was at ACIP, I think we had documented 12

11 cases in troops and U.S. travelers over a period of about 12

12 years, one per year, with an estimated end of somewhere in a

13 couple of million, if you take in all the tourists, so this

14 was a low frequency disease and a low frequency

15 complication.

16 MR. HOWELL: I'll currently take that home

17 with me. I will tell you the numbers -- we did not generate

18 those numbers. Those are the numbers that the FDA had

19 pretty much thrown on the table.

20 UNIDENTIFIED SPEAKER: Have there been any

21 discussions with other western militaries about what they

22 are going to do about the situation?

23 MR. HOWELL: To date, no. That's a good

24 question.

25 COLONEL PHILLIPS: This is Colonel Phillips.

1 An update on health affairs and the joint staff have been
2 working in parallel with what's been going on in the
3 research community towards development, and basically in a
4 nutshell, Dr. Wolfowitz's marching orders have been we need
5 to buy enough stockpile to last us until a new vaccine is
6 available and be conservative in your estimate as to when a
7 new vaccine is going to be available, so what that --
8 DR. OSTROFF: A new licensed vaccine.
9 COLONEL PHILLIPS: A new licensed vaccine is
10 available. And so using some information from a white paper
11 that you had written, that worked out to about five years,
12 and Dr. Wolfowitz's orders to his money guy are, you know,
13 "Find some money to buy what we need to get us through to
14 five years." And we've gone to the joint staff to say,
15 "Okay. What's the requirement for five years?"
16 And so I think that if you're able to get onto
17 Dr. Wolfowitz's calendar, which is not easy to do these
18 days, I think he'll look very favorably on the Course of
19 Action No. 3, although defining your requirement in terms of
20 how much is used annually, plus or minus the contingency, I
21 think is being deferred to the PACOM commander to say, "What
22 is it you really need, and we'll take care of getting it
23 stockpiled in the DSCP for you."
24 UNIDENTIFIED SPEAKER: And I'll speak to that
25 whenever we come up. I noticed that whenever you had your

1 group of folks who were working on -- there was five folks
2 and they had OFB (phonetic) policy, but there was no joint
3 staff or PACOM, just the consumer.
4 MR. HOWELL: Right. That's a good point. I
5 did not mention that, of course. We had made contact with
6 PACOM before the meeting to be able to get from them what
7 they thought their requirements were. We could have gone to
8 you to go to PACOM, but we have -- we have no problem
9 bringing you in the loop. And as we go through the briefing
10 cycle, we had every intention of going through General
11 (inaudible) to make him aware of what's going on, as well.
12 COLONEL GIBSON: This is Colonel Gibson. I
13 just wanted to clarify. You'll be able to talk about this
14 issue. In your slide three, you mentioned about
15 contingency. I wanted to be clear. That is operational
16 contingency, not a contingency of failure by BIKEN?
17 MR. HOWELL: No, no, no. That's based upon a
18 work plan.
19 COLONEL GIBSON: I just wanted to be clear,
20 because we'll have some comments about the white page
21 (phonetic), what PACOM is looking for in the event of
22 contingency, operational contingency.
23 DR. OSTROFF: To try to get -- to keep us on
24 schedule, I'll let you know that my comment would be that,
25 you know, in terms of working through these recommendations,

1 this is a critical -- a mission critical vaccine, and it's a
2 totally avoidable risk, as far as I'm concerned, to be able
3 to not run out of this product.
4 My guess is that even if you are to accept this
5 potential option, we're going to find ourselves at some
6 point in having to do something to assist whoever is making
7 this product to get this product to licensure in the United
8 States, and so whether you face up to it now or you face up
9 to it later, I think you're going to end up to facing up to
10 it at some point.
11 And there are a lot of risks that one assumes, but
12 this is one that doesn't necessarily have to be there. So
13 I'll have to think a little bit more about these various
14 options. And I would certainly be happy to provide both
15 mine, as well as the board's perspective, on what the best
16 course of action is. But I just -- I can't see getting to
17 the finish line with this one without some assistance at
18 some point. I don't know if others around the table have
19 thoughts about that, but I do. Yeah?
20 UNIDENTIFIED SPEAKER: You mentioned other
21 western countries. If I can speak, perhaps, for Canada.
22 Historically, we've had not a lot of involvement in
23 southeast Asia, although a few years ago we were quite
24 involved in (inaudible), and before that Cambodia, so we
25 have -- we are purchasing the stockpile for contingency,

1 again.

2 DR. OSTROFF: Thank you very much. The next

3 item on the agenda has to do with an investigation that's

4 been going on for the last several months that I thought it

5 was important to update the board about, and that is a

6 problem with vestibular dysfunction among returnees from OEF

7 and OIF. And this has been a fairly long, complicated,

8 complex issue, and we appreciate Captain Bailey coming to

9 give us a brief on this situation.

10 CAPTAIN BAILEY: All right. Captain,

11 (inaudible) Ostroff, Members of the Board, ladies and

12 gentlemen, I'll go ahead and try -- try and not hold you too

13 far off schedule. Okay. Obviously there's been a lot of

14 both public and media interest in Lariam, mefloquine. It

15 was highlighted for me on the 26th of May, which is really

16 when this outbreak, if you want to call it, came to public

17 attention with reports that a number of servicemen had been

18 diagnosed at Athan Eaton (phonetic) Medical Center in San

19 Diego, which -- with either brain damage or permanent brain

20 stem injury, and the allegation was made that this was all

21 due to the Lariam use, and that's really what kicked off my

22 involvement.

23 Next slide, please. Shortly thereafter at the

24 direction of some of my superiors at Naval Environmental

25 Health Center (phonetic), the interest from Health Affairs

1 and others, certain members of this board, obviously an
2 investigation needed to be done to look into this. I was
3 given very clear direction as to how to do the
4 investigation, but also to collaborate fully with NHRC and
5 CDC, and that was advice that was given, but obviously very
6 excellent advice.
7 What actually do we have? We -- what was
8 reported, again, was a cluster of people who had persistent
9 dizziness long after they had returned from either Operation
10 Iraqi Freedom or Enduring Freedom where they had taken some
11 antimalarial, and it was alleged it was all due to Lariam
12 use.
13 What was -- seemed unique to us about this report,
14 that there were no prior reports of a persistent long-term
15 vestibular disorder after mefloquine use, although certainly
16 we all know that dizziness is a common side effect and
17 reported -- reported in the package insert that's a side
18 effect of mefloquine use.
19 In this case, though, we also -- in addition to
20 the patients' reported symptoms, we had some objective
21 findings, in this case vestibular dysfunction documented on
22 rotational chair testing, which I'll go into further exactly
23 what that is.
24 For those of you who do not know, rotational chair
25 testing is accepted as a gold standard method for --

1 particularly for testing vestibular ototoxicity. Initial
2 reports were that five of the one six-person group of active
3 duty members of a project -- it's called the TDM, which,
4 again, a typical military acronym for the Tactical
5 Dissemination Modular, that suffice it to say that it's a
6 computer system which helps to target enemy-using remote
7 censors.
8 And finally, one other thing is, we really did not
9 have any baseline prevalence data to go on. We really don't
10 know and there's really no literature that says what that
11 prevalence of abnormal rotational chair testing is among our
12 active duty population.
13 Next slide, please. Again, I'm going to go a
14 little bit into this, because this is really the meat of
15 what was reported and really is the sole objective measure
16 that we're going off of. Rotational chair testing, again,
17 is a computer controlled chair. It spins in one axis that
18 provides an objective measure of the vestibular ocular
19 reflex. For those of you who remember back in medical
20 school days and traditional caloric testing by placing hot
21 or cold liquids into the ear canal, this is a much more
22 physiologic method of testing, because it stimulates both
23 vestibular canals at the same time.
24 As far as sensitivity and specificity data, again,
25 this has been accepted as the gold standard, so really --

1 those things don't really exist. However, as we found,
2 although this is a very objective test, it provides great
3 computer graphics and printouts, the interpretation of what
4 those tests mean is very subjective.
5 Next, please. As a sample, this is -- I will tell
6 you, this is probably the thousand foot view of what the --
7 the rotational chair puts out. This is a summary slide in
8 three parts. You can see that there are three subgrafts,
9 Gain, Phase and Symmetry, and I will put to you in this kind
10 of display, it's pretty -- the top group of three charts so
11 you can see that the normal -- the normal range there in
12 white and the two standard deviations of abnormal is in the
13 shaded area.
14 And so you can see, basically, this will be --
15 this would be considered a totally normal test. It's not
16 unusual for any one measurement to be slightly -- slightly
17 out -- out of two standard deviations. What people who have
18 some --
19 UNIDENTIFIED SPEAKER: Do you have the
20 coordinates? Is it on time and --
21 CAPTAIN BAILEY: Okay. Yeah. I'll cover
22 that -- cover that actually in the next slide here. But
23 Gain is on the Y axis here, Gain being the amplitude of the
24 response, and I'll go into what -- the actual thing. Across
25 here is a measure of the rotational speed of the chair, its

1 frequency in revolutions per second -- excuse me,
2 revolutions per minute. This would be -- this is something
3 that you can see an abnormal chart.
4 Let's go to the next slide, please. I think that
5 will help clear it up. These three measures, Gain -- Gain
6 is amplitude of the response, and here, again, we're
7 comparing eye movement, which is tracked by a set of video
8 goggles that are measuring the eye movement. It's a
9 measurement of the amplitude of the eye movement and the
10 head movement stimulus, in other words, the rotational
11 speed.
12 Abnormality with Gain, and usually we're talking
13 about the decrease in Gain, is commonly seen with
14 ototoxicity. Phase, again, you can read that. It's a time
15 lag thing. It's between when the stimulus is applied, how
16 soon the vestibular reflex -- excuse me, the ocular reflex
17 occurs. It's often seen with peripheral vestibular
18 injuries, but usually the changes are not permanent, and
19 most textbooks and experts feel this is a very sensitive but
20 also very non-specific measure.
21 And third, I'll draw your attention mostly to
22 Symmetry, because that ends up being pertinent to our
23 findings, here. Symmetry is a comparison of the slow
24 component nystagmus to both the right side and the left
25 side. Often, this is -- often abnormalities of symmetry are

1 seen with what you might -- with other causes of dizziness,
2 more central causes, often seen with people who have
3 migraines or headache-related problems or anxiety-related
4 dizziness, believe it or not. And even though the symmetry
5 can -- lets go ahead. I think that's enough on that.
6 The next slide, please. Okay. We took a series
7 of cases. First step in any epidemiological investigation,
8 you get a confirmation that we have an epidemic, or have an
9 outbreak. Because all these findings were made by one
10 particular physician at the Naval Medical Center in San
11 Diego, we gained -- we looked for an outside expert, outside
12 recognized civilian expert in the field of vestibular
13 disorders, found one and submitted all the data to him.
14 And he basically agreed with us that seven -- what
15 turned out to be our seven cases all showed evidence of
16 vestibular ocular reflex asymmetry. And you'll see the
17 quote on the bottom is actually from him, as well. He felt
18 that the Gain and Phase components of the rotational chair
19 testing were essentially normal. There was no oscillopsia
20 or basically eye movement complaints, complaints of moving
21 images while they walked, so he thought this all suggested a
22 central vestibular dysfunction.
23 Next, please. Okay. Our study questioned -- as
24 we started the test, we now understood a little bit better
25 about what was actually being reported and the disease

1 process, was to not make any assumption as to the cause,
2 although as I say, one was suggested to us by the reporting
3 physician. Our question was, was there any significant
4 differences in exposure between our cases and a suitable
5 control group. And again, this was more of a
6 hypothesis-generated study.
7 Next, please. Our case definition that we arrived
8 at -- and this took actually quite a while to come up with,
9 this case definition, to be as specific as possible, because
10 dizziness is a very subjective complaint. It means many
11 different things to many, many.
12 We were looking for an active duty member who had
13 deployed, who had new onset of symptoms of persistent
14 vertigo, and after an ENT evaluation had no other
15 identifiable cause for the dizziness, such as head trauma,
16 Meniere's disease. You can read. Labyrinthitis,
17 Neuronitis. On physical exam by the EMT physician had to
18 demonstrate unsteadiness while walking or -- or even worse,
19 while standing still, and then had to have an abnormal
20 symmetry portion of the vestibular -- his VOR had to show an
21 asymmetry on rotational chair testing.
22 Next. We took all the cases that had initially
23 been referred to us from the Naval Medical Center San Diego
24 where they have a spatial orientation laboratory. They
25 initially thought 12 patients met the profile. However, on

1 close review of all of those cases, we basically excluded
2 five. Two were excluded due to a fairly recent history of
3 head trauma, such as one person was medivacced due to a
4 shrapnel injury while in combat. One was excluded because
5 basically the rotational chair data was never recorded and
6 was not available for review. And then two patients,
7 although -- who did have complaints of dizziness had
8 absolutely normal VOR symmetry on rotational chair testing.
9 Now, interestingly, three of the seven cases were
10 from one particular very small -- it's not a command, it's a
11 support team that was sent overseas to Kuwait. That's the
12 location -- the acronym there is Ali Al Salem Air Base in
13 Kuwait. It's about 50 miles outside of Kuwait City. So
14 three members were from one small team. The other four
15 cases really didn't seem to have any apparent
16 epidemiological link, so we decided to focus our attention
17 on this cluster of cases.
18 Next, please. We initiated what should be
19 probably a pretty classic case control study. Looking at
20 the patients from the Navy's TDM project -- and again, this
21 is a group who basically worked with computers and imagery,
22 and their task was to relay this imagery, which was obtained
23 real time from aircraft in the air to special forces on the
24 ground, so really basically working with computers and
25 radios, really no other unusual occupational exposure.

1 We -- after deep thought, we came up with two
2 control groups. One is all the other members of this
3 particular project who deployed, although they may have
4 deployed at different time periods, but were working with
5 the same equipment and in the same location. The other
6 control group we found was members of the Army's air defense
7 artillery, which is a Patriot battery, which was also
8 deployed to the same location at the exact same time in
9 Kuwait. We were able to interview 18 controls on that
10 group.
11 Next, please. You can read this, but we spent
12 quite a bit of time coming up with an appropriate survey
13 instrument to look at not just mefloquine use, although that
14 surely was one of the exposures of unique interest, but all
15 the other occupational, environmental, past medical history,
16 you name it. In addition, we found some -- some of the
17 people we interviewed, actually if they had taken an
18 antimalarial medication, particularly mefloquine, had some
19 tablets remaining from their journey overseas. And because
20 we wanted to look at the possibly that those tablets were
21 either contaminated or the wrong dosage, we obtained those
22 from three individuals and sent those to the FDA for
23 testing.
24 We have obtained post-deployment serum specimens
25 from the -- serum specimens from those who had a specimen on

1 file in the DoD serum repository, and that's undergoing
2 analysis -- will be undergoing analysis actually this week
3 at CDC looking for mefloquine or metabolites. And again,
4 other things obtained in environmental health site
5 assessment that actually the Air Force performed at that
6 location, seeing if they had any reports of any unusual
7 environmental or toxic chemical exposures in that location.
8 Next, please. Okay. This is just some very
9 preliminary findings. We really do not -- the study is not
10 complete. We're not really prepared to discuss the results
11 at this time.
12 Again, we have a total of seven cases, in which
13 three are from the cluster, and they are all -- at this
14 point they are all males, fairly similar ages.
15 Next, please. The clutter group was all
16 reservists who had been activated for specific technical
17 abilities to support this one particular project, but our
18 cases actually come from all -- all over.
19 Next, please. As far as where these patients
20 were, again, the cluster of three here at Ali Al Salem Air
21 Base in Kuwait. We've had -- the other cases occurred among
22 soldiers or Marines inside Iraq proper, and then one in
23 Afghanistan.
24 Next, please. This is a somewhat complicated
25 chart, but it's useful to just plot several things. One is

1 the blue or green line is when a person was deployed, either
2 Operation Iraqi Freedom or Enduring Freedom. Yellow is if
3 they took an antimalarial, and in this case it was all
4 mefloquine for our cases. If they took one, when did they
5 take it. And then the red or orange appearing thing is when
6 they started -- or reported they started developing symptoms
7 of dizziness. And you can see that in some cases the
8 dizziness was related, it started while they were deployed,
9 but in other cases, it could have started as much as a year
10 after they returned.
11 Next, please. As far as symptoms that these cases
12 report, in descending frequency, they all have dizziness,
13 obviously. Quite a few have ringing ears, some have
14 difficulty walking, headache. But we also found a
15 surprisingly high percentage who had sleep disturbances,
16 anxiety, mood changes, down to panic attacks and outright
17 depression.
18 Next, please. As far as initial findings on
19 laboratory testing, they all obviously had VOR
20 abnormalities, part of our case definition. I will just
21 tell you that these are other not -- more subjective as
22 performed by the clinician tests, the bobbing head thrust or
23 a head shake, designed to elicit a response. And they all
24 had gait abnormalities, although none of them had the exact
25 same gait abnormality. And anybody who wants, we can go

1 into those later off line about what those exact tests are.
2 Next, please. Because I mentioned earlier there
3 really -- we looked through pretty thorough literature.
4 There really is no prevalence data for what -- what's the
5 prevalence of rotational chair abnormalities in an active
6 duty asymptomatic population. There is prevalence data, but
7 it's usually related to people who are older. Usually these
8 are in-patients, and commonly there -- it seems to be in
9 some ways more and more prevalent towards people who have
10 vestibular injuries due to some ototoxic (inaudible) due to
11 in-patient hospitalization or IV use, so we thought there
12 was a need to actually define the baseline here in our
13 study.
14 We are doing -- we just got review board approval
15 to start that study, and 150 active duty members in San
16 Diego are going to do that.
17 Next, please. Okay. So where are we now? Well,
18 the data collection is complete. The data analysis is
19 almost complete. Actually, it should probably be done in
20 the next week or two. However, we're now at a point where
21 we're -- okay. We've investigated this cluster of cases,
22 the cluster of three. We have four other cases that
23 occurred outside the cluster, and then we are hearing of
24 anecdotal reports of clusters -- excuse me, of patients who
25 might meet this case definition, although we don't know,

1 coming out of Colorado, of other units.

2 And I will tell you that there is an informal

3 patient network where people who have dizziness symptoms and

4 think it may or may not be related to taking Lariam are

5 reporting this, and then those reports are being relayed

6 both to myself and I think Health Affairs and possibly other

7 members of the board, saying that, "Hey, you need to take a

8 look at this gentleman or this lady and investigate them."

9 So the question is, what do we do? Not all these

10 patients have come through the San Diego spatial orientation

11 lab. Do we need a standardized protocol for evaluating

12 patients with these kind of complaints? We could probably

13 provide that now fairly easily, based on our findings, and

14 then if you do identify somebody who meets the case

15 definition, what do you do with them? You know, is there --

16 do we need to go to a Phase II -- or a Phase II type of

17 study?

18 We have collaborated with an investigation that

19 the NHRC is doing, that was initiated by this board, I

20 believe, looking into health outcomes after mefloquine use.

21 And actually you may want to comment on where they are with

22 that study, but I understand they have actually completed

23 data collection and are in the analysis stage right now of

24 that.

25 Next slide, please. We have come up with two

1 other options as to where we could go, based on if the
2 results of our study and NHRC's study indicate that
3 additional research in this area is needed. A Phase II
4 study would be to expand case finding outside our of cluster
5 of really just three patients. We have looked initially at
6 the data of people who have similar IC-9 codes to those with
7 vestibular disfunction. And I must say vestibular
8 dysfunction could be coded as many different things.
9 There's really no one IC-9 code that you'll find these, as
10 it's highly variable among providers, how they code this
11 diagnosis.
12 But using those IC-9 codes and looking at all
13 patients who come through San Diego since January 2002, we
14 identified approximately 5,000 patients initially, about a
15 third -- excuse me, a quarter of those, 1300 and some,
16 have -- had deployed to either Iraq or Afghanistan. We
17 foresee that we could screen those fairly quickly, and then
18 administer those via telephone, basically the same
19 instrument that we've developed so far to see if we could
20 find any cases in that group.
21 However, because not all the patients have come
22 through San Diego, I don't want to mislead anybody that they
23 are all coming to the west coast. It might make more sense
24 to do that on DoD-wide basis. However, I will tell you, I'm
25 in charge of a Navy's Environmental Preventative Medicine

1 unit in San Diego, it's a 30-person group, and such studies
2 would be certainly outside of my purview to undertake all by
3 myself.
4 Next slide. Okay. But as far as contributors,
5 like I say, I do want to acknowledge the help of the CDC,
6 who was a regular member of our working group, Lieutenant
7 Commander Shaw who is back there, Captain Bollin (phonetic)
8 and Captain Freed (phonetic) as well as the Army and NHRC,
9 as well. So that concludes my brief at this point, subject
10 to your questions.
11 DR. OSTROFF: Let me open it up for comments
12 and questions. Dr. Herble (phonetic).
13 DR. HERBLE: Just an observation: The
14 aerospace medical consultation service at Brooks Air Force
15 base might have some prevalence. It might just be on
16 (inaudible) personnel, but that might be a place to look for
17 this baseline there.
18 DR. OSTROFF: Okay. Thank you. Colonel
19 Gibson?
20 COLONEL GIBSON: I just wanted you, if you
21 could, to expend on the types of data elements and variables
22 that you're using in your survey to reply to your --
23 actually to be both cases and controls.
24 CAPTAIN BAILEY: Yeah. These -- the
25 exposures that we're looking -- things that we're look for

1 in our survey, we certainly are looking at the history of
2 antimalarial use, because that was one of the things alleged
3 to be responsible for this. Initially on we thought that
4 this was purely an ototoxic phenomena, not we're not so
5 sure. We're looking really at any environmental exposure.
6 We're looking at noise, jet fuel exposure, toxic industrial
7 chemicals that might have been in the air, certainly things
8 that we think might cause an ototoxic effect.
9 Medical history, previous trauma, other medication
10 use besides antimalarials, also ask about anxiety,
11 depression, what -- really more of a looking at other scales
12 of -- scales of -- excuse me, PTSD, which seems in some
13 ways -- in some reports there's been some literature saying
14 that anxiety and PTSD can cause or be -- contribute to
15 dizziness complaints, vestibular disorders.
16 COLONEL GIBSON: I just wanted to bring that
17 point up, because this -- using the case control
18 methodology, we can obviously look at lots of exposures. I
19 mean, the real hypotheses is what exposures are associated
20 with this vestibular dysfunction, not focus -- obviously
21 mefloquine is a major question here, but it's not the only
22 question.
23 CAPTAIN BAILEY: Right. And I think that we
24 wanted to keep ourselves as open as possible, so you're
25 right, we did not look at any one particular exposure,

1 although certainly there are probably some folks who wanted
2 us just to look at mefloquine.
3 DR. OSTROFF: First Dr. Gray and then
4 Dr. Brown.
5 DR. GRAY: Greg Gray. I'm just wondering if
6 you have any repeated testing in the same subjects using the
7 chair, or is it just a one-time test?
8 CAPTAIN BAILEY: Oh, no. The cases who come
9 through the center have actually come through multiple
10 times, and then these tests are repeated. Just one -- an
11 interesting point is the physician who initially diagnosed
12 these feels that almost all of these injuries are treatable,
13 and actually they're treatable with physical therapy and
14 that basically that can -- you can recover from these. Even
15 if it seems to be a neurotoxic injury or ototoxic injury to
16 the vestibular system, that these patients can recover. And
17 actually, a number of them have made improvements, though
18 not all. But the chair tests are repeatable and are done --
19 and I'm trying to think right now, but I think we have them
20 come back at six-week intervals and after physical therapy
21 treatments.
22 DR. GRAY: I guess what I'm trying to get it,
23 is independent of treatment, is there any indication that
24 these injuries are getting better or worse or is it sort of
25 a stable -- in other words, could this be induced by some

1 alternative exposure that they have endured since the drug?
2 CAPTAIN BAILEY: Well, as far as the first
3 question, they -- I'll say they are repeating rotational
4 chair testing. Could it be caused by something else?
5 Absolutely. You know, I think, you know, there's -- there's
6 a strong psychologic overlay. As you may or may not know,
7 there's a suit pending against the drug manufacturer. We've
8 been trying to sort and tease that away from what is the
9 scientific data here. But I'll tell you, a lot of the
10 patients have -- you know, they have their own opinions as
11 to what caused their symptoms, and trying to get away from
12 that and concentrating on what symptoms they have and
13 looking at it very objectively with them has been a large
14 part of our investigation.
15 DR. OSTROFF: Dr. Brown?
16 DR. BROWN: First a comment. And I think
17 this has become a big issue for the VA. I think we've been
18 asked by some members of congress and some veterans groups
19 to why we don't test (inaudible) rotational chair tests, why
20 don't we test all veterans returning from -- back from OIF.
21 So far we've declined to do that.
22 But I have two questions. First of all, just
23 trying to sort through this conclusion from your subject
24 matter expert, a couple of slides in, and I don't quite
25 really follow what they're saying. It seems like they're

1 saying some contradictory things, (inaudible) like they're
2 saying, "Overall, therefore, the findings of this
3 population, the subjects do not suggest an ototoxic drug
4 exposure," and then it goes on to say, I guess, "But the
5 findings do suggest an abnormality in the vestibular
6 function, probably central." What did he mean by that? Is
7 he saying there's not ototoxicity but there is CNS damage,
8 cranial nerve damage or something? What exactly is he
9 getting at?
10 CAPTAIN BAILEY: Well, what's written there
11 is exactly what this outside expert believes. He believes
12 it is a central process, he believes it's not a peripheral
13 ototoxicity, and he thought that this was more -- yes, he
14 thought this was more along the line of what he sees in
15 patients who have anxiety or headache, specifically
16 migraine-related dizziness. That was his suggestion, just
17 based on -- we sent him blinded data, copies of the chart
18 and rotational chair testing.
19 DR. BROWN: And then my follow-up question
20 is, clinically, what do these -- just by observation, what
21 do these patients look like -- or these subjects look like?
22 Do they look obviously disabled or do they look -- I'm
23 not --
24 CAPTAIN BAILEY: No, no.
25 DR. BROWN: Why don't you characterize

1 what --

2 CAPTAIN BAILEY: You know, I have a number of

3 the patients both within -- both within the hospital

4 assessing and then are basically -- come by our offices

5 because they have a high interest in what this study -- what

6 the study is showing and where it's going. They look

7 normal. They really do. They have complaints, and I think

8 they -- you know, and most of them will tell you they have

9 good days and they have bad days, and on bad days they can

10 be fairly symptomatic to the point where they don't want to

11 get out of bed or stay home from work.

12 But, you know, when I have seen them, they look

13 normal to me. They are not, you know, leaning to one side,

14 they are not having trouble walking, unless we look with

15 very, you know -- I say, clinically, they look normal. I

16 think what you need here is the rotational chair is a very

17 sensitive instrument, and that's where we're seeing

18 findings.

19 DR. OSTROFF: (Inaudible)

20 UNIDENTIFIED SPEAKER: In the Air Force, we

21 used to have a rotating chair. It was called a Vertigon.

22 It was designed to make you sick, and it works pretty well.

23 But a moment of seriousness here, though, I think somehow

24 here we're getting the technology to assess the prevalence

25 of an abnormal vestibular response somehow confused with

1 whether or not we really have a distinct entity that is
2 different than what we'd see in the underlying population.
3 And probably we need as much effort, rather than refining
4 the case control study, is a diligent effort to ferret out
5 some methodology to determine the true background prevenance
6 of whatever it is we think we're measuring here, because I'm
7 not sure what we are measuring here.
8 We're measuring a self-described syndrome that may
9 or may not have been validated by a methodology that -- if
10 it's a gold standard, at least to my quick read looking
11 here, it's a lot closer to fools gold maybe than gold gold.
12 And I don't know, I'm not a neurologist. But I really think
13 that a stringent, diligent effort to get with the National
14 Health Interview Survey, both what people report when indeed
15 there is a question like that, the background level, to look
16 at other sources of data, maybe even do a chart review of
17 the 5,000 to get into what really is the background
18 prevalence of true vertigo.
19 I go back -- going back to my training, it's
20 incapacitating, it's truly -- the room is spinning, and it
21 doesn't kind of happen every third day for a few minutes.
22 So I think a little diligence here around case definition
23 and some degree of investigation of background prevalence of
24 whatever that is (inaudible).
25 And I'm afraid as I see that what is a relative

1 and broad case definition and a relatively broad diagnostic
2 criteria in terms of the technology of how we define it --
3 maybe, for example, are all of these people given
4 traditional caloric testing, as crude as it was? It was the
5 standard for many years before (inaudible). So I don't have
6 the answer to any of those questions, but I just think that
7 more effort in those veins might be as useful as more
8 questionnaires for bigger populations of people, for what
9 it's worth.
10 CAPTAIN BAILEY: The only thing I would add
11 to that is looking at the literature, trying to understand
12 the basic pathophysiology of how this -- how to be
13 (inaudible) the literature and even the experts in the field
14 will tell you, the literature is very incomplete in this
15 regard, so -- so I -- I -- I fully agree with your comments.
16 DR. CLINE: Dr. Cline (phonetic). I wonder
17 if you could clarify a couple of points. Your next to last
18 slide, the Phase II/Phase III option, you say, "Identify
19 approximately 5,000 active duty patients." I don't
20 understand. Does that mean 5,000 people who have had the
21 test and are identified as having the condition?
22 CAPTAIN BAILEY: No, sir. These were 5,000
23 patients who had come through the Navy Medical Center in San
24 Diego and had been given a diagnosis -- given an ICD-9 code
25 that matched the applicable ones for this syndrome, or for

1 our case definition.

2 DR. CLINE: But they have not been tested?

3 CAPTAIN BAILEY: So they may or may not have

4 come through the ear, nose and throat clinic. They could

5 have been given the diagnosis somewhere else, and probably

6 very few of them have had rotational chair testing, if any.

7 DR. CLINE: Related to that, this technology

8 is new to me, how long does it take to do the exam and how

9 many of these chairs are there? Are there a few in the

10 country or hundreds? What does it involve? If you wanted

11 to screen large numbers of people, what is actually

12 involved?

13 CAPTAIN BAILEY: The chair itself is -- there

14 are quite of few. They are usually at your tertiary medical

15 centers, (inaudible). I know there's one here in town, both

16 at Brook and Wilford Hall, as well as Navy Medical Center in

17 Portsmith, Virginia. And most of your other major medical

18 centers have the chair. The test takes about half an hour

19 to actually do the run. It's usually done by a clinical

20 Ph.D. who works with vestibular disorders. They actually do

21 the performing of the test, and then it's usually

22 interpreted by the ENT physician or balance disorder

23 specialist. But it's not that uncommon. As far as the

24 cost, I really don't know the cost of that.

25 DR. CLINE: One other question. The numbers

1 are small, seven cases, but three of the seven have
2 depression. What is meant there by depression? Is that
3 clinical depression or is that -- are they medicated?
4 CAPTAIN BAILEY: No. The -- well, that was
5 symptoms of depression is actually if they met the D.S.M.
6 criteria for depression. Lieutenant -- Lieutenant Colonel
7 Shaw, do you have anything to add to that?
8 LIEUTENANT COLONEL SHAW: I guess the only
9 thing I --
10 DR. OSTROFF: Come to the mic.
11 CAPTAIN BAILEY: Lieutenant Colonel Shaw is
12 one of the CDC EIS officers who came out and has actually
13 been part of our working group working on this project.
14 LIEUTENANT COLONEL SHAW: I guess a couple of
15 things I would to add, if I can. In response to your
16 question about the -- about the baseline prevalence, we
17 don't know it, and there is a study that we're trying to get
18 approval for, maybe we already have approval, just looking
19 at active duty military personnel who are not symptomatic in
20 any way and if they have abnormal rotational chair
21 function.
22 We don't have that information and it's sort of
23 something that we're trying to get, so these data that we
24 collect, we'll have to look at it in light of what kind of
25 numbers we get from our prevalence study, because that's the

1 problem. We don't know, you know -- what you said is
2 exactly true. These people are reporting dizziness. The
3 only thing that we have is these tests results to really say
4 whether they have common symptoms and signs, and so we
5 really need to work with this test and find out as much as
6 we can about this, and this baseline prevalence study
7 hopefully will help us to do that.
8 The question about depression, we -- in our
9 questionnaire we did ask the question, "Have you ever been
10 diagnosed with" -- "Have you ever been diagnosed with
11 depression," so that's a self-reported question, and then we
12 went through the D.S.M. IV criteria in the questionnaire,
13 and depending on how they responded to the questions to
14 decide if somebody meets the criteria for depression.
15 UNIDENTIFIED SPEAKER: Perhaps you said it,
16 but I missed it. I'm just going back to Dr. Brown's
17 question a little bit and looking again at the -- I don't
18 know who the ENT doctor and neurologist that read that test
19 outside of the military institution, but that basically he's
20 saying that all three of those parameters are normal, so
21 what exactly was abnormal in his --
22 CAPTAIN BAILEY: No, no. He agreed that they
23 all showed signs of VOR asymmetry.
24 UNIDENTIFIED SPEAKER: Well, he said, "Gain
25 is normal, time constant and Phase are normal.

1 CAPTAIN BAILEY: Yeah. And time constant is
2 just a -- other than -- other than the chart there where you
3 saw that shows Phase, the time constant is another phase
4 measurement. It's not symmetry.
5 UNIDENTIFIED SPEAKER: Not symmetry?
6 CAPTAIN BAILEY: Yeah.
7 UNIDENTIFIED SPEAKER: I don't think there's
8 any specific advice we can offer on the study. These
9 studies tend to be very difficult, they're adversarial, they
10 go on and on. And there's a long history of such studies.
11 You know, we could all start to name them. VDT for
12 cataracts, (inaudible) for reproductive abnormalities and
13 many other studies where they just won't go away.
14 So my advice would be that one thing that can work
15 is to essentially, since you're part of the problem, if you
16 will -- you know, you're part of the group that sent the
17 soldiers, now victims, into harm's way, is to externalize
18 this problem, which is either to some group that is
19 independent of the participants, whether that be the ION
20 or -- or some other such group, or at the very least,
21 establish yourself a blue ribbon panel of neurologists,
22 neurovestibularologists [sic], epidemiologists, et cetera,
23 and design a study that from everybody's point of view is a
24 definitive study, because if you do anything less, it won't
25 go away, you'll just be stuck with another result.

1 So it's not the specific issues that we quibble
2 with in how you design, but rather the issue of do you
3 really want to be spending a lot of time on this, where I
4 sense that there is a lot of enthusiasm that this is going
5 to be a real public health problem amongst your constituents
6 for whether you want to bring it to closure. And the only
7 way to bring it to closure is to externalize it to a group
8 that is beyond criticism, a blue ribbon panel beyond
9 criticism, and have them look at the data and make a
10 recommendation as to what kind of study, if any, should be
11 done.
12 UNIDENTIFIED SPEAKER: Mr. Greer (phonetic)
13 made the comment about depression. Actually you've got a
14 number of different disorders, and actually the one that
15 sticks out is panic attacks. This is huge compared to what
16 you normally see. I think you've got a cluster of probably
17 somewhat non-specific psychiatric symptoms. Regardless of
18 how they got diagnosed, I would not really concentrate on
19 one diagnosis versus another.
20 DR. OSTROFF: Other thoughts or comments?
21 Dr. Brown?
22 DR. BROWN: Let -- I just -- I just have
23 to follow up a couple of comments that have been made.
24 First of all, I think that in cases like this, there -- the
25 idea that you can do definitive studies is kind of

1 (inaudible) I'm not sure -- it may be impossible to ever do
2 that definitive study, no matter how careful or how external
3 you make it, although it's probably worth considering.
4 And the second -- my second concern is that I hope
5 that you're going to take a look at -- about this background
6 prevalence issue, because it seems like there's at least a
7 significant possibility of what you'll find is that your
8 case definition will disappear when you've done that and you
9 won't have a case, and, you know, it would save millions of
10 dollars.
11 DR. OSTROFF: In the interest of time, let me
12 ask from your perspective at this point how can the board be
13 most helpful to you in working through this issue?
14 CAPTAIN BAILEY: Well, at this point, we're
15 going -- we'll have the data analyzed and report on this
16 cluster investigation out fairly quickly. I -- you know,
17 because the numbers are so small, the chance that we're
18 going to be able to say anything definite, let's be
19 realistic, is almost nil. However, we may be able to
20 point -- generate some hypotheses or something. At that
21 point what I do is wait for the health outcomes after
22 mefloquine use study that NHRC is doing, which has a much
23 higher end. If that points somewhere with this study, that
24 may generate a direction for further study, you know, at
25 this point.

1 I guess the major question I have is whether or
2 not any additional investigation, short of a definitive
3 prospective study of some sort, whether it's looking just at
4 folks who are from San Diego, if it's a population of 5,000,
5 or if it's to go DoD DY (phonetic), whether or not that is
6 something that's something to be done. And then -- and then
7 this whole other question is what to do with the other
8 anecdotal reports, these case reports we get of other
9 soldiers, sailors, airmen, who have similar symptoms in
10 different locals across the nation who think -- also think
11 that somehow their dizziness was caused by mefloquine, and
12 could we -- is it something we put out to the military
13 medical -- or VA, that, "Hey, here's a standard way to
14 evaluate this," and where should that data go once it's
15 collected.
16 DR. OSTROFF: We would be happy to hear
17 additional information about the outcome of the studies, and
18 I think we'd be very happy to provide some assistance to you
19 in what direction to go, because this is in the face of a
20 series of issues related to this particular drug. And so my
21 perspective is that the issue is certainly not going to go
22 away, and it behooves us all to try to get as valid
23 information as possible about the consequences of the use of
24 this drug so that we can hopefully help you as these
25 continued issues arise.

1 This board has a long-standing interest in making
2 sure that the widest range of malaria and
3 chemoprophylacticoxins (phonetic) remain available. And so
4 we have a -- a great interest in seeing this through,
5 whichever way the information happens to come out. So we --
6 we would be happy to work with you.
7 CAPTAIN BAILEY: Thank you.
8 DR. OSTROFF: Greg?
9 DR. GRAY: This Greg Gray. It seems to me
10 that there's some lack of confidence here in the test
11 itself, in the prevalence of any pathology, and that the
12 alleged exposure might be associated in contrast to multiple
13 exposures. I would say that in addition to what Dr. Ostroff
14 has suggested, you might want to get help with your baseline
15 studies, because if you study people who are not likely to
16 have any of the secondary exposures that some of these
17 individuals may have had, their experience might be quite
18 different, and then you would assume that the -- what you
19 think is a pathology now it truly is, and when really it's a
20 manifestation of something like else alcoholism or
21 underlying disease that (inaudible).
22 DR. OSTROFF: Okay. One quick comment.
23 UNIDENTIFIED SPEAKER: I mentioned this
24 before, and as we've discussed mefloquine in this area, and
25 Dr. Gray bringing up the question of interaction between a

1 specific medication, a specific pharmaceutical and other
2 environmental or intrinsic factors in individuals is
3 something that we really need to keep in our mind as we go
4 forward with this discussion.
5 DR. OSTROFF: Thank you very much. Let's
6 move into the preventative medicine updates. Our first
7 update is from Colonel Phillips from Health Affairs. We
8 will try to get through a couple of these before we take a
9 quick break.
10 COLONEL PHILLIPS: Good afternoon. I'll try
11 to move it along so we can get caught back up. The issue of
12 pandemic Influenza preparedness is one that is occupying the
13 minds and the -- go ahead.
14 UNIDENTIFIED SPEAKER: This is Tab 8.
15 COLONEL PHILLIPS: Is occupying the minds in
16 times of health leaders across America, including in the
17 Department of Defense. The U.S. government -- and part of
18 what I'll say is many of you have already seen HHS has put
19 out onto a web page for public review the National Planning
20 and Response Plan for Pandemic Influenza. DoD has been
21 involved in that process for the last several years, as
22 well.
23 And when the HHS plan came out, the plan that DoD
24 has been working on was matched up against it with the
25 parallel planning that we've done, and last week that went

1 to Dr. Wolfowitz for final approval to go out to the
2 Department of Defense. So the Department of Defense
3 Pandemic Influenza Planning and Response guidance has been
4 issued, and it's essentially parallel with what's in the HHS
5 national response plan.
6 In the HHS National Response Plan, there's an NX7
7 (phonetic) for antiviral use, and in the DoD Pandemic
8 Influenza Plan, the guide is basically that the services and
9 the components need to consider the use of antivirals in the
10 face of Pandemic Influenza.
11 So what I'm going to talk about today is some of
12 the work that we've done in the last several months on one
13 specific feature, and that is the notion of stockpiling
14 antivirals to prepare for a potential pandemic Influenza.
15 Many of you know that the U.S. government -- HHS
16 is purchasing Oseltamivir as an antiviral drug for the
17 strategic national stockpile to have available for a
18 pandemic Influenza potential. A lot of reasons why that
19 particular drug was chosen, mainly that's the one that seems
20 to be effective against what's currently perceived to be the
21 most prominent threat, which is the H5N1 virus.
22 Slide. And one of the key features of the
23 situation both in national planning and DoD planning is the
24 notion that we will use antivirals to try to cover the gap.
25 We all understand that the best way to deal with

1 an Influenza pandemic is through vaccination, but that there
2 will be some gap from the time a pandemic emerges until an
3 effective vaccine is available and widely distributed. And
4 both the HHS plan and DoD planning now calls for trying to
5 use antivirals to cover the gap to reduce morbidity,
6 mortality and for DoD to maintain mission effectiveness
7 during the time that we're waiting for a vaccine to become
8 available.
9 Some of the assumption -- a group, primarily
10 preventative medicine officers, some infectious disease
11 folks and some logistics folks from DoD met several months
12 ago to start brainstorming where we need to go with DoD
13 planning for stockpiling antiviral medicine. These are some
14 of the assumptions that we made in our planning. You can
15 argue with one point or another of them, but they are the
16 ones that we used when we were developing our plan.
17 Particularly that the strain will emerge OCONUS
18 and it will have days to weeks notice, but that it will
19 spread rapidly with modern travel and whatnot. In terms of
20 how the pandemic will spread, the time frame of six weeks
21 was agreed upon. A lot of argument about that, you know,
22 with the -- the pandemics won't spread now like they did in
23 1918 or in 1957, but we had to come up with some time frame
24 to plug into that gap, so six weeks is what we chose.
25 That there would only -- I think most experts

1 agree that there would only be marginal slowing of the
2 spread of pandemic Influenza, even with the aggressive
3 public health measures, and that the availability of an
4 effective antiviral medicine, particularly Oseltamivir, will

5 be severely limited worldwide by virtue of the fact that
6 it's only manufactured by one manufacturer at one point in
7 the world right now. And then another assumption that we
8 made is that by six months, a vaccine would be available for
9 use.
10 Slide. Some of the planning factors in making
11 calculations for DoD. At the DoD level, what we wanted to
12 do was we wanted to say, how much should we put into a DoD
13 stockpile, in addition to what's in the strategic national
14 stockpile to help DoD to be prepared?
15 The way Oseltamivir comes, it comes in a blister
16 pack of 10 pills, a treatment course. This flu season, if
17 you're within the first 12 to 48 hours of having Influenza
18 systems and you go on treatment for Influenza, it's one pill
19 twice a day for five days.
20 Prophylaxis is one pill daily for the duration of
21 the time that you're exposed or at risk for contracting
22 Influenza. The package insert does not actually indicate a
23 limit on the time that you can be on prophylaxis, though it
24 does have that studies have only been done out to six
25 weeks. So again, that -- it's part of what our team used in

1 terms of coming up with six weeks as a planning factor for
2 if we were going to use prophylaxis.
3 Slide. So in a nutshell, the DoD strategy for use
4 of antiviral medicines in a pandemic Influenza is to, one,
5 protect forward deployed operational forces. And since I
6 put these slides together and we've had some discussion, you
7 can possibly substitute the world "actively operational
8 forces," because "forward deployed" or "actively operational
9 forces" in the current war may actually be in North America
10 with the north (inaudible), and depending on what our
11 situation is. So it's those forces who are actually forward
12 in whatever area it is, whether it's in CONUS or OCONUS,
13 that are engaging with the enemy and doing the job that DoD
14 is to do, which is to fight and win our nation's wars.
15 The second aspect of our strategy is to protect
16 critical health care personal in outbreak areas. This is
17 consistent with what HHS -- is the core of the national plan
18 for supporting the health care infrastructure in the United
19 States.
20 The third is treatment for high risk patients.
21 And then fourth, if there's medicine -- depending on the
22 epidemiology of the pandemic as it emerges, if there's
23 medicine available for treatment of other beneficiaries.
24 Slide. So the first part of the strategy, prevent
25 forward deployed or actively operational forces from

1 developing Influenza by providing prophylactic medication
2 during the time that they're at risk. We chose six weeks as
3 a time. Again, there are a lot of arguments why that should
4 be longer, why it shouldn't be so long. That's the number
5 we chose.
6 Slide. So implementing that strategy, we had to
7 make a rough calculation of what's that population at risk,
8 and so for our foreign deployed forces at any one point in
9 time, that's 300,000, give or take several thousand. And
10 that situation changes month by month, depending on where
11 we're engaged in operations. But currently, obviously, the
12 big places are now in southwest Asia. We've got forces also
13 deployed in Korea and a few other spots around the world.
14 Adding to that, per Dr. Wolfowitz's guidance said
15 that we needed to make some rough calculation for who
16 critical headquarters personnel are. There's 23,000 people
17 that work at the Pentagon, there's several thousand more
18 that work at key headquarters around the nation and other
19 parts of the world, so we used a planning figure of 10,000
20 critical headquarters personnel that would need to be
21 prophylaxed so that they wouldn't get sick during a time
22 when Influenza was in the area so that they could continue
23 operations.
24 With the six week planning factor, we did a little
25 math, that came out to 13 million pills, or 1.3 million

1 packages. $41 is the current federal supply schedule price
2 for a 10-pack of Tamiflu. And I'll talk a little bit about
3 that in a moment.
4 Second part of the strategy, in staying in sync
5 with what HHS had in their plan, keeping the military health
6 care system operational, and again, this is with a
7 prophylaxis strategy as opposed to a treatment strategy.
8 Slide. There's roughly 117,000 active duty
9 personnel in the U.S. military health care system, along
10 with 40,000 civilians. In terms of how you determine which
11 ones of those are critical, that's an issue that HHS, the VA
12 and DoD are all wrestling with.
13 We had a meeting last week to try to come to some
14 consensus as to who critical personnel are. The way we came
15 up with the number is we took roughly 25 percent of -- I
16 guess you could call it a snow day model. You know, on a
17 snow day when you have to tell people to stay home and you
18 only need the critical people, you need to be able to keep
19 your place open, how many people is that? Roughly 25
20 percent was the number that we used to make our
21 calculation.
22 Again, part of the thinking that went into this is
23 of the 75 percent of people that don't get prophylaxis --
24 and again that's not a decision we make at Health Affairs
25 level, that would be made hopefully at the lowest possible

1 level as to who is key and critical in maintaining the
2 health care infrastructure at the local command level.
3 The other part of the assumption I was talking
4 about is the 75 percent of the people that aren't getting
5 prophylaxis would have available either a treatment dose, if
6 they started to get sick and they were -- and they needed to
7 get back to work in a timely fashion. And part of the
8 calculation there is we were thinking that based on past
9 history of pandemics, we were thinking of a roughly 30
10 percent attack rate, so the 75 percent of people that are --
11 are not on prophylaxis, only about a third of them would
12 actually get Influenza.
13 So that's how we came up with the number. I tried
14 to give you some of the background on how we did it. We can
15 argue about the numbers, but that's the one we did.
16 Slide, please. And the third part of the strategy
17 is that we did feel that we needed to make sure that we had
18 some antiviral available for treatment. Prophylaxis is the
19 essence and the majority of our strategy, but that some
20 treatment would be required, in particular for high risk
21 beneficiaries, people that would become ill, and in
22 particular for OCONUS.
23 Within the continental United States, the current
24 DoD director for emergency health powers on military
25 facilities indicates that local commanders are supposed to

1 have a public health officer who's coordinating with local
2 health officials in terms of dealing with an emergency. A
3 pandemic Influenza, we think, would certainly fall into that
4 category, so in terms of obtaining antivirals, we wanted to
5 ensure that there was a consistent standard of care
6 throughout a community so that here in San Antonio, Texas,
7 if you worked on Randolph Air Force Base or Brooks Air Force
8 Base or Fort Sam Houston, you are no different than someone
9 who would get care at the public health center or the
10 community hospital, that there's one standard of care in
11 terms of treatment courses available for beneficiaries.
12 Slide. So in summary, protect operational forces,
13 protect our critical health care infrastructure, treat high
14 risk patents. I say OCONUS, because OCONUS, we're not
15 counting on being able to get medicine from the strategic
16 national stockpile to send overseas, it would be here.
17 We came up with a number of roughly one and a half
18 million packages, or 15 million pills required for a DoD
19 stockpile to be prepared for a pandemic Influenza scenario.
20 Slide. This slide has also changed. The
21 acquisition strategy we proposed to Dr. Wolfowitz was to
22 build that stockpile over several years. Actually in
23 meeting with him last week, he wants to advance that and
24 purchase up to a million packages in FY'O5 to get us to
25 about 80 to 90 percent of where we need to be by next

1 December, to push forward with our preparedness.

2 So in summary, what I can tell you is at this

3 point in time, the Department of Defense is going to lay in

4 a DoD stockpile for antiviral medication based on the

5 strategy that I've outlined for you here. We are working

6 with HHS and VA. The federal supply schedule price of

7 $41 -- Roche has worked out some agreements with HHS that if

8 we purchase together with VA and HHS, that price can come

9 down to -- the purchase that HHS made here a month ago or

10 two months ago for the strategic national stockpile, they

11 only paid $34 a pack for the Tamiflu. And if we can get the

12 order big enough between HHS, VA and ourselves, we can get

13 that down to $29 a pack, so there's some significant savings

14 by working together.

15 The other part of working together is outlined in

16 that strategy for guidance to pass down to our components

17 with regard to defining who's critical within your health

18 system in terms of maintaining that. And with that, I'll

19 take any questions you have.

20 DR. OSTROFF: Thank you very much. Let me

21 open it up to questions and comments. My first question is,

22 is that amount of drug purchased in the time frames that

23 you're talking about?

24 COLONEL PHILLIPS: Yes. Roche came and gave

25 a presentation last week to HHS at the meeting that we had

1 last week, and they were significantly ramping up their
2 efforts. If they get an order in before the end of this
3 year big enough, they will actually begin some of their
4 product finishing here in the United States so that there is
5 a strictly U.S. supply chain that doesn't necessarily have
6 to go over to Bad Holtz, Switzerland (phonetic) for
7 production. And by mid FY'05, they will be at least twice
8 the capacity that they've been so far.
9 UNIDENTIFIED SPEAKER: (Inaudible).
10 COLONEL PHILLIPS: The shelf life right now
11 is four years, and there's active work going on with -- with
12 the company and with FDA to look at -- within the strategic
13 national stockpile, the shelf life extension program, to try
14 to take that up to five years or possibly even beyond. But
15 four years right now is the shelf life that we're looking
16 at.
17 DR. OSTROFF: Are there -- Bill?
18 UNIDENTIFIED SPEAKER: You know, you're -- I
19 don't know what the evidence is from 1967 or 1968, but from
20 1918 there's a clear -- at least speculated clear --
21 relationship between training -- a recruit movement, putting
22 people into the kinds of facilities that we saw today and
23 essentially fueling the epidemic, which luckily now we would
24 have something to do, the drugs and possibly the
25 immunization later to come. So tasks -- I presume the

1 obvious question, is part of the strategy if there were to
2 be pandemic flu to suspend or curtail recruitment and
3 training until -- which transported all of these people from
4 all over the country, mixing, et cetera, et cetera, until
5 either the vaccine is close at hand, et cetera, and -- so is
6 it part of the strategy?
7 COLONEL PHILLIPS: That is a potential that
8 is discussed in the DoD plan, that possibly, you know, if
9 the pandemic is in the United States, that the president can
10 say, okay, we're going to suspend activities at this place
11 or that place.
12 DR. OSTROFF: We have, you know, looked at
13 this option extensively, and it's generally thought that
14 that has the potential to slow the spread of Influenza, but
15 certainly wouldn't prevent it from spreading, because
16 there's just so much population movement these days, that if
17 you try to choke it off one way it will just move in a
18 different way, and so it's thought as a temporizing measure
19 and not a very effective preventative measure. So it is
20 addressed, it is mentioned, but I don't think there's any
21 evidence that it would in these days substantially inhibit
22 the spread of this virus.
23 I must say that when you very methodically go
24 through your thinking about how to use and deploy the
25 antiviral, it makes lot of sense to me because it is

1 consistent with what the thinking has been in the civilian
2 pandemic planning. The major issue that we've grappled with
3 fairly consistently is the prophylactic use versus the
4 treatment use of the rather limited stockpile of product
5 that we're going to have available, when you know the far
6 more effective way to use this would probably be
7 prophylactically. The problem is that that requires a lot
8 more product than does the potential therapeutic use, and
9 there simply isn't enough product that can go into the
10 stockpile to make that a large-scale, feasible plan.
11 And then there are, of course, the logistical
12 issues around doing that, which you pointed out. But the
13 military obviously has different requirements and different
14 issues to deal with. And, you know, at least what you're
15 proposing makes some sense to me. I don't know how others
16 feel about it. John?
17 UNIDENTIFIED SPEAKER: Could you walk me
18 through the philosophy or the concept of operations for
19 inside the U.S., beneficiaries of the U.S. military health
20 care system? And the perspective I'm asking this question
21 from is for a public health planner for a 28-county region
22 of South Texas, including San Antonio. And we struggled
23 with, do we in our numbers calculate for the Tri-Care
24 protection area here as -- as civilian public health folks,
25 or are the military medical facility commanders of the

1 Tri-Care region going to plan for that, or is there a
2 concept as to how that's -- how that's going to work?
3 COLONEL PHILLIPS: The concept and the
4 guidance and the answer to your questions are yes, everybody
5 should be planning it, and the guidance to -- in the DoD
6 plan is they shouldn't be planning in a vacuum. We don't
7 want planners like yourself to say, "Oh, well, don't worry
8 about the military beneficiaries because the Army will buy
9 it for them." But we also --
10 UNIDENTIFIED SPEAKER: So it isn't that
11 everybody should be planning, what I'm suggesting is that if
12 I'm planning to stockpile this, to get my piece of the
13 strategic national stockpile for our 28-county area here,
14 then (inaudible) doesn't have to be doing that and the air
15 education and training command preventative medicine officer
16 doesn't need to be worried about that. It can't be
17 everybody, it has to be one -- one person needs to be the
18 belly button. Do you see what I'm trying to say here?
19 COLONEL PHILLIPS: I do. And what I'm saying
20 is that the guidance we're giving is that that should be
21 done together. I was the deputy commander of the health
22 clinic at Fort Drum, New York after -- during 9/11. And
23 after 9/11 when we started preparing for bioterrorism and
24 that sort of thing, I worked with Jefferson County Public
25 Health and Samaritan Medical Center, because we said, you

1 know, we've got -- you know, two-thirds of our population
2 live outside the fence, and we didn't know where a
3 bioterrorism event would be.
4 And that's kind of the model that people are
5 thinking with pandemic flu, only it would be much bigger
6 than any particular bioterrorism, is that the planning has
7 got to be done synchronized, you know, within a community
8 and not, you know, stove piping, you know, military and
9 civilian. And particularly you mentioned, you know, the
10 Tri-Care, which is -- so much of our beneficiary population
11 is taken care of within a civilian sector now with the
12 Tri-Care contract that it's planning that needs to be done
13 together.
14 UNIDENTIFIED SPEAKER: But if --
15 (inaudible).
16 DR. OSTROFF: Just for one minute.
17 UNIDENTIFIED SPEAKER: If I, as a public --
18 as a public employee, public health department local health
19 authority preparing for this, then do I go approach the --
20 the -- the Tri-Care subcontractor and say, "Are you going to
21 do this?" Or do I need to set up a vaccination or a
22 distribution center at the Alamo Dome, do I need to -- just
23 here within Bexar County, then I'd need to negotiate with
24 Randolph Medical Treatment facility, the Lackland base, the
25 Fort Sam Houston base, and then I've got to figure out how

1 (inaudible) Wilford Hall as tertiary medical center, each
2 commander (inaudible). It gets very confusing very quick.
3 COLONEL PHILLIPS: It does, and I'll tell
4 you, I don't have a good answer for you right now, but
5 that's something -- and some of the preventative medicine
6 docs here late last week when we were talking about it have
7 driven down, too. Because I anticipate that each Tri-Care
8 region will be developing plans and pushing it down that
9 way. So I'm sorry, I don't have a good answer for you right
10 now, but I will try to get back with you on where to go with
11 that.
12 UNIDENTIFIED SPEAKER: No, that's okay. I
13 just wanted to put it on the table, because I've been
14 working on this limitation of the DoDI of the emergency
15 public health, trying to get those folks involved in our
16 planning group, and it's not -- it's not there yet.
17 DR. OSTROFF: Pierce?
18 DR. GARDEN: Yeah, two points. When
19 Oseltamivir was introduced, it had the advantage of being
20 effective against both A and B, having a relatively low rate
21 of immunogenicities to resistance, versus the older drugs,
22 and also turned out to have vacctivity (phonetic) against
23 H5N1. There have been recent reports about a surprisingly
24 high rate, I believe, of resistance developing during
25 prophylactic and treatments, so we have to be concerned

1 about that. I think the most recent data tend to tarnish a
2 little bit of the optimism that this is going to be an
3 effective, long-range treatment and we have to worry a
4 little bit more about it.
5 COLONEL PHILLIPS: I'm assuming you're
6 referring specifically to the Lansed (phonetic) article and
7 subsequent -- and company editorial last month. That was
8 discussed by GUDA (phonetic) and some folks from HHS at our
9 meeting last week, and actually there's a neurominadase
10 resistance group that is meeting and working on putting out
11 some additional information.
12 They are not -- when I first saw that, I also was
13 very pessimistic. I remember sitting down with my boss and
14 going, "Okay. Great. The U.S. government is about to spend
15 millions of dollars on a drug that might not work." I can
16 see the headlines in the Post. But their information is
17 that they are not as pessimistic about that because of
18 particulars associated with that study. They are not -- it
19 certainly is a concern. They presented evidence about, you
20 know, development of viral resistance, but it's not nearly
21 as pessimistic as the Lansed editorial would lead us to
22 believe.
23 UNIDENTIFIED SPEAKER: The other interesting
24 conversation I had with one of our illustrious members last
25 evening, if one could reliably predict that the next

1 pandemic is going to relate to the avian virus instead of
2 just being another pervasion on H1, 2 or 3, the issue -- and
3 I'm looking, the cost of this is 29 to $42 a pack, the cost
4 of vaccine certainly would be less than that. Shouldn't we
5 be making a -- I'm giving thought to the discussion of
6 beginning to go background immunity to the avian virus by
7 annual immunization prior to the actual fact of pandemic.
8 COLONEL PHILLIPS: I was part of that
9 conversation last night, as well. And it's a fascinating
10 topic and one that I hope to bring up with the -- as -- as
11 the DoD representative on the VERBAK (phonetic), it's
12 certainly something that I think is worthy of discussion
13 among the decision makers in the country for where we go
14 with the vaccine.
15 DR. OSTROFF: Dr. Cline, last comment. Oh,
16 I'm sorry. Yeah.
17 DR. CLINE: Yes. Could you give me some more
18 information on what is considered to be high risk? Is that
19 from a pre-existing condition or someone who has contact
20 with a known or suspected --
21 COLONEL PHILLIPS: In the planning of the
22 high risk groups as outlined by ACIP for Influenza vaccine.
23 DR. CLINE: Is that adequate or well thought
24 out, because clearly if we're talking --
25 CAPTAIN PHILLIPS: It's well thought out. It

1 may or may not be adequate.

2 DR. CLINE: Well, if the disease is highly

3 virulent and pathogenic, then everyone is at high risk from

4 having an adverse event, so I guess the question is, you

5 know, the 17-year-old Lacrosse captain is as at much risk of

6 being infected and harmed as someone who has some type of

7 pre-existing --

8 CAPTAIN PHILLIPS: What I can tell you is in

9 terms of moving along here, that the devils and the

10 details -- that's one of those details that gets argued at

11 every meeting that happens, and the agreement of the group

12 that met last week, the HHS, DoD and VA, is that certainly

13 the epidemiology of the pandemic will influence decisions

14 that are made at the time with regard to how this drug would

15 be utilized.

16 DR. OSTROFF: And that's the right answer.

17 It depends on what the epidemiology is of who constitutes

18 the high risk group (inaudible). Thank you very much.

19 Let's go ahead and do one more presentation before we take

20 the break. We have an update from joint staff, and that is

21 Major Kilian, who I know will be quick.

22 MAJOR KILIAN: These are the topics that I

23 want to talk to y'all about today that are pertinent there

24 on the joint staff.

25 Next slide. Total Force Vaccination Proposal is

1 our long-term effort to vaccinate the entire force, active
2 reserve component, national guard, against Anthrax, small
3 pox. The other two topics here intertwine, so when we get
4 to sourcing, I'm going to talk about how actually we operate
5 here in a moment, or whenever I get there.
6 But the important take-aways here are this is a
7 significant political decision. It's been up for the -- for
8 a while in the OSD offices trying to get the long-term
9 policy position signed off on. We're not going to get
10 anything done before the election. There's -- this summer,
11 the 28th of June, Dr. Wolfowitz, the deputy secretary of
12 defense, signed into policy an expansion of the small pox
13 Anthrax. We are -- based upon its guidelines, we're asking
14 (inaudible) getting to this, because once you're enrolled
15 into the Anthrax vaccine program, you're in it. And if you
16 were deferred, you're now back in it.
17 I personally am a tweener (phonetic). I've always
18 been between those things. I haven't got the first shot
19 yet, so I know I'm part of that decreasing part of the line
20 in the (inaudible).
21 Next slide, please. Little did I know whenever I
22 sent a tasker out to PACOM the other day that JEV was going
23 to be such a hot topic. The tasker that went out to the
24 commander at PACOM from the director of the joint staff was
25 this: "Please articulate your actual requirements for

1 Japanese Encephalitis vaccine by component, by your -- for
2 the next five years." I got the number back of -- it's
3 still coming back through channel (inaudible), the actual
4 number that they're saying is approximately 400,000. That's
5 a 30 million dollar bill that --
6 And basically how I got involved with this, my
7 previous job was med ops officer for a medical support unit
8 with Tripler (phonetic) supporting deployments and knew what
9 the time for determining specific policy was on JEV. And I
10 went to a meeting and I heard that he's about to change his
11 policy. Well, I just came from there and that just wasn't
12 true, and the number was about 800,000.
13 So I quickly engaged PACOM, got the target out.
14 Talking to the folks there as we went down through the list
15 of things that were pertinent to this was, one, defense
16 intelligence agency doesn't rate JEV as a significant
17 threat, and in fact, they rate the risk to be low.
18 There are other good counter measures that should
19 be being used concurrently already for fighting (inaudible)
20 malaria, mainly DEET, and use Permethrin on the uniforms,
21 doing some other stuff. (Inaudible) obtained the authority
22 to use IND.
23 The vaccine is expensive, it's $75 a dose. That's
24 the DSPC number, that's been validated. I called the NTF to
25 see if we can start shooting people what you charge. $75 is

1 what the service incurs per dose. It takes three shots.
2 There was the misperception amongst the line that this was a
3 shoot and go, meaning one guy, roll up the sleeve, one shot
4 and out the door they went. So we clarified that, that no,
5 you have to notify these guys in advance.
6 There was lots of -- apparently it's quite
7 controversial on how effective this is. There's a large
8 range on how many folks will still get JEV after they've had
9 the series of vaccines. And so if you take the (inaudible)
10 of the second infantry division, my old division, and the
11 attack -- and worse case scenario, you're talking about five
12 folks who are probably going to became fatalities to JEV,
13 worse case scenario. If your choice is to spend that much
14 money to save those five lives, or by a medivac first, you
15 might be able to save more lives.
16 So that was what was going through Major Peacock's
17 (phonetic) decision of his limited resources and where is he
18 going to spend his money best.
19 Next slide, please. And currently the majority of
20 the 400,000 is going to go to the U.S. Marine Corps on
21 Okinawa. Talking to folks in the Navy staff, apparently
22 whenever they routinely go to the north 40, which is where
23 the JEV is on Okinawa, they don't treat their uniforms, so
24 they use liquid Permanol (phonetic), Permethrin, and use of
25 DEET. So I understand their logic behind using the

1 vaccine.

2 So it comes to sourcing. This is where I want to

3 hopefully bring a couple of these important things together.

4 Next slide, please. OIF-3, we're using non-specific combat

5 service support units to support the Army.

6 What do I mean by that? That means that the Army,

7 whenever they rotated out, they left their equipment and

8 everything they owned, except their personnel and their

9 clothes on their back, in theater, and various other units

10 fell in on it. The Air Force took over a couple of the

11 detachments, the Navy had units there, and they are having

12 to adhere to Army doctrine. They are having to act like an

13 Army unit. It goes beyond medical.

14 Air Force folks -- there's quite a few Air Force,

15 airman, that have died as a result of being a truck driver.

16 They were put in to work basically as -- in Army lingo, an

17 88 Mike, a driver as an 18-wheeler, not normally what you

18 think of Air Force guys doing, but due to manning

19 constraints and what have you, we -- (inaudible) has changed

20 how we do things now.

21 There is a buzz word that was in the morning -- or

22 the early bird (phonetic) the other day. It's called global

23 force management. It emphasizes, "I asked for a

24 capability." I -- if you're the co-com commander, do not

25 ask for a combat support hospital, do not ask -- you know,

1 what you need to ask for is, "I need a capability to provide
2 resuscitative surgery and holding -- and beds to hold
3 somebody X amount of time."
4 If you need an infantry battalion, there's few
5 services that provide that, the Army and the Marine Corps.
6 The same for artillery or armor. So as we progress, what
7 we're going to see is that -- that this bottom line of --
8 Dr. Wolfowitz talked about was not only do the medical
9 forces need to be interoperable, but the next logical step
10 is they need to be interchangeable.
11 The three services have done something like this
12 with what in Army lingo would be 91 Alphas; they're the med
13 (phonetic) maintenance tech. It doesn't matter if you're
14 with the FSSG or with the Marine medical support unit or an
15 Army combat support hospital or an Air Force e-meds, that --
16 the X-ray machine is the same amongst us, and we've done
17 some brilliant, wonderful collaborations.
18 In fact, that school that's done up at Wichita
19 Falls at the Air Force base up there, there's -- when
20 preventative medicine -- the best example of this, I could
21 use one Navy PMT. To replace that one Navy PMT, I need two
22 Army preventative medicine type folks, 91 (inaudible) and 91
23 Romeo. One's an environmental health technician, the other
24 one is a food service guy. And to replace those two Army
25 guys, I need four Air Force ones to do the same job that you

1 go back that you only need one Navy PMT to do. And with the
2 Air Force guy, you also have to bring in an engineer,
3 because they have the guy who can identify the sucking mouth
4 parts out of the mosquito, but he can't go apply the
5 pesticide.
6 So in conclusion, I just want to let y'all know
7 that those are the three major objectives that are going on
8 at joint staff. Joint forces command is working on the
9 joint force help protection concept to collaborate these
10 things together.
11 DR. OSTROFF: Thanks very much. Let me open
12 it up to comments and questions. I must confess, I don't
13 necessarily agree with everything that Dr. Wolfowitz says,
14 but sometimes he's right and sometimes --
15 MAJOR KILIAN: He leaves you scratching your
16 head.
17 DR. OSTROFF: Exactly.
18 UNIDENTIFIED SPEAKER: When you go to
19 all-force Anthrax vaccination, when do you expect those in
20 the training cycle to be performed? Would that be in
21 recruit camp training?
22 MAJOR KILIAN: The services would have to
23 operationalize it. How I think they would do it is wait
24 until after basic training, because all the services have
25 folks, for whatever reason, that decide -- in basic training

1 that they wash out, whether it's due to screening --
2 (inaudible) screening -- the Army is unique in the fact that
3 we don't do that categorically. The other services will
4 allow the service member to opt out, or, you know, if
5 they're in week one and they break their leg and they need
6 to recycle. It would probably be more appropriate to -- at
7 Advanced Individual Training or maybe a school, once -- once
8 they get to a school.
9 COMMANDER LUDWIG: Can I make a comment on
10 that? I'm actually in the Coast Guard. This is Sharon
11 Ludwig. In the Coast Guard we are already vaccinating our
12 recruits with small pox vaccination. All of our recruits go
13 directly to deploy -- are deployable, and they do deploy.
14 And we are giving it toward the end of basic training for
15 the reason that we lose track of them.
16 If we send them out to the units, then the units
17 have to get vial vaccines to maybe vaccinate, you one, one
18 or two people who are new to the unit, and that is sometimes
19 problematic, and the units really want to have the people
20 come to them ready.
21 And the other thing is that we don't do it right
22 at the end of basic training, because we don't want them --
23 we don't want to lose track of them during the time when
24 they might have some, first of all, side effects that we
25 would want to keep track of, and second thing is to go home

1 on leave right after recruit training and maybe contact
2 people who are -- or be in contact with people who are at
3 risk from the small pox vaccine. So we've actually already
4 started.
5 DR. OSTROFF: Well, you actually know that
6 the board has repeatedly suggested that the appropriate
7 approach, which is the approach that currently is still in
8 operation in Department of Defense, is to do a threat-based
9 approach, and that's true both for Anthrax and for small
10 pox. And so I guess the query would be what -- what led the
11 Coast Guard to believe that their total force was at a
12 higher risk?
13 COMMANDER LUDWIG: We did not actually make
14 that decision in a vacuum. The argument was that our folks
15 are -- are deployed every single day on a Homeland Security
16 mission, and that if there were any kind of attack, the --
17 the folks in what we call deploy -- the forward units, the
18 units who are actually operational, as opposed to, you know,
19 going out and interdicting migrants or going to foreign
20 ports or protecting the harbors or whatever, those units are
21 in as much danger or at risk as anyone deployed in -- at
22 least as much risk in the sense of it could happen anywhere,
23 anytime.
24 DR. OSTROFF: If it's a natural -- natural
25 extension of that type of logic that every citizen in the

1 United States is at high risk for being exposed to small
2 pox, then --
3 COMMANDER LUDWIG: They are at risk, but they
4 don't have the mission of protecting people of the United
5 States.
6 DR. OSTROFF: Oh, but there are millions and
7 millions and millions of individuals in this country that
8 should have that risk -- they should have --
9 COMMANDER LUDWIG: The argument was made and
10 Ms. Embrey agreed, and that's why we went forward.
11 DR. OSTROFF: Yeah. I mean, we don't
12 continually, you know, recognize all first responders as
13 being (inaudible) so I would argue that is inconsistent with
14 Navy policy. Any other comments? Thank you.
15 CAPTAIN KILIAN: Thank you, sir.
16 DR. OSTROFF: Why don't we take a five-minute
17 break.
18 (Recess from 3:13 to 3:23)
19 COLONEL STANEK: Well, good afternoon. I'm
20 going to give the Army preventative medicine update, and I
21 will endeavor to keep us moving forward and make up for any
22 delays we have on the schedule. I only have two slides to
23 brief, so this should go fairly quickly.
24 First, I know at the last AFEB Colonel Underwood
25 briefed the current situation for the Army on Leishmaniasis,

1 and this is what our slide is as of today, or as of the end
2 of August. We had 659 cutaneous Leishmaniasis cases and
3 three visceral cases.
4 The only reason I really want to put this up, and
5 it's not a significant change from the previous slide she
6 briefed you in May, the point I want to show is towards the
7 end on the right-hand side of the chart for July and August,
8 that these are when the cases become known, these aren't the
9 number of cases that actually occurred in that month.
10 Through a lot of questionnaire and medical history
11 that's obtained based on each of the cases, we've figured
12 out that the exposures to all of the cases that have
13 occurred, and what we can say is for the -- although you see
14 a lot of cases listed as showing up in the year 2004, we can
15 say that only three of those cases have actually occurred
16 due to exposures that occurred in 2004, all the other
17 exposures that occurred are believed to have occurred from
18 exposures that occurred in 2003 and earlier.
19 And a lot of that is felt to be now that we've
20 been in the theater for a while and the (inaudible) have
21 matured and the servicemen are now residing more in more
22 built-up structures and air conditioned structures and less
23 sleeping on the ground and in more of a deployed
24 environment. So that was the message that I wanted to bring
25 forth on that particular slide there.

1 This slide is an update on an issue that's been
2 discussed by the board a couple of times, QuantiFERON lab
3 testing and QuantiFERON testing for tuberculosis. And in
4 May 2003, the board made the statement recognizing the
5 potential benefits for those QuantiFERON testings and
6 recommended that an initial pilot program be done to see how
7 this may work in the military. And then it asked to be
8 informed or kept informed of the progress that was being
9 done on this issue. I think that was actually discussed
10 yesterday. So this is the first iteration of helping meet
11 that requirement, keeping you informed.
12 At this time Magidan Army Medical Center is doing
13 a -- what's being called a Proof of Concept Study in our
14 area. And it started in the summer of '04, it's only been
15 going on couple of months, and it's being done at the
16 hospital itself when they do the monthly annual review of
17 the hospital employees. Some of them need TBC testing and
18 all the required training and things like that. They've
19 been doing the QuantiFERON testing on all those
20 individuals. It's too early to draw a lot of conclusions at
21 this point.
22 Actually as of lunch time today I checked my voice
23 mail, and they actually had test results for 69 people in
24 their program. And they don't have any real conclusions yet
25 in terms of how -- how the cost is breaking out per person

1 and all the other issues, but they have obviously identified
2 an increased burden in the laboratory.
3 They plan to expend this to larger units. There
4 are some units that are going in and out of Iraq from the
5 Fort Lewis area, and they are going to expend this program
6 from the small hospital setting to the larger soldier
7 readiness setting to see if they can do large numbers at one
8 particular time. And hopefully they will be doing that
9 later on in either the November or December time frame, and
10 they'll expand this year to do that.
11 There's also going to be a rather in depth cost
12 benefit analysis study done, and Major Ross, who's here from
13 The Center of Health Promotion and Preventative Medicine
14 will be involved in that. We're really getting a detailed
15 analysis as to how much it's costing to use the QuantiFERON,
16 logistically, time saved, employee time and everything. And
17 we'll get those results and bring that to the board, too.
18 Depending upon how this is working and the
19 feasibility of how well it's working in the one location, we
20 may also try to expand this group of content study to some
21 of the larger areas or larger power projecting platforms in
22 the Army.
23 We're obviously doing this in the method of, you
24 know, you learn to crawl and you learn to walk and then you
25 learn to run. We're kind of just trying to transition now

1 from the fast crawl to the slow walk. And hopefully within
2 the next -- within the next couple of AFEB meetings, they'll
3 be able to give you an update on how well this is -- this is
4 working for larger numbers.
5 I don't know if any of the other services have
6 started doing any QuantiFERON tests, but this is what the
7 Army is doing so far, and I just wanted to bring that to the
8 board. And that's all I have.
9 DR. OSTROFF: Thanks very much. Just in
10 commenting about the QuantiFERON, I did attend a two-day
11 meeting that was put on by CDC where they had the company
12 that makes the QuantiFERON test come and give some updated
13 information. This was in, I believe, July, and I think
14 Colonel Underwood, you were supposed to come, but -- or
15 there was somebody from DoD that was supposed to come, but
16 unfortunately it fell on the day of the funeral for
17 President Reagan and turned out to be a federal holiday, and
18 so that significantly limited attendance.
19 The company has actually made significant progress
20 in coming up with new generations of this assay that have
21 gotten over some of the performance characteristics that
22 were problematic for this test, and that exposed some of the
23 logistical issues, as well as better performance
24 characterizations in terms of specificity and sensitivity.
25 And the newer generations of this assay look absolutely

1 fantastic in terms of its performance, and it's causing CDC
2 to go back and re-examine its statement about how this assay
3 ought to be used. And it's very likely that (inaudible)
4 statement will indicate that this is a preferred screening
5 test. And so that is something to keep in mind. It's
6 really -- I mean, the performance of this test looks
7 absolutely fantastic.
8 And (inaudible) with FDA. FDA was at this
9 meeting, and FDA is certainly on board. And so as you make
10 your small steps forward, it's worth keeping in mind that
11 there will probably be additional information coming from
12 CDC suggesting that this is probably the best way to go.
13 COLONEL STANEK: Yes. I've seen some of the
14 material on that other assay, and that will certainly make
15 the whole logistical and screening process easier once that
16 test finally gets approval.
17 UNIDENTIFIED SPEAKER: Admiral, is there a
18 time line we might see that in our (inaudible)?
19 DR. OSTROFF: Well, it's never as quick as
20 you would like, and some of it is clearly dependent on the
21 progress that the companies are making in terms of getting
22 the newer generation assays licensed for CDC. Those
23 guidelines and recommendations have to go through the
24 advisory committee for the elimination (inaudible). And so
25 given that it has to go through that process, I wouldn't

1 anticipate seeing something until well into next year.

2 UNIDENTIFIED SPEAKER: One of the things that

3 the board brought up at the last meeting was the issue of

4 clamydia screening. And could you update us? I ask each of

5 the services to give a very brief update on the clamydia

6 screening process.

7 COLONEL STANEK: The surgeon general sent out

8 an instruction that the clamydia testing should be done on

9 all females under the age of 25 and all service members

10 under the age 25 with their annual Pap smear, and then also

11 any other time it's indicated with a visit to a clinic, and

12 that guidance went out, I believe, two years ago.

13 I don't have any information at this time on, you

14 know, changes in clamydia testing, volume or anything like

15 that that I can present to the board, but I know the

16 instruction did go out that the health care providers were

17 supposed to start doing that.

18 DR. OSTROFF: One other question that I have

19 is related to the Leishmaniasis issue. That's a fascinating

20 epi-curve in the additional information that most of the

21 2004 cases that have been identified are not due to

22 exposures in 2004.

23 I know there were a fair number of concerns

24 that -- especially given recent activities in Iraq, that

25 possibly we would revert to a situation similar to the

1 initial combat activities, and it kind of surprises me that
2 we're basically not seeing any cases that could be
3 attributed to exposure in 2004. Is the situation that much
4 different than it was last year, or is there some
5 epidemiological change?
6 COLONEL STANEK: I'll -- Colonel Underwood
7 was in the PM office during the time those issues were being
8 discussed, so I'll let her go ahead and talk about it.
9 COLONEL UNDERWOOD: I think really it's a
10 combination of things. I think, one, if you recall, we had
11 some issues with availability of Permethrin-treated uniforms
12 and some (inaudible). That -- that has been -- is on the
13 way to being rectified. We're getting more of those items
14 into theater. Certainly an emphasis on use of personal
15 protective measures.
16 But I can say that they did try to some spraying
17 effects, as well, but even though they tried to -- they did
18 spray for sand flies. The sand fly population very rapidly
19 came up again, even after all of their efforts in doing
20 that. So epidemiologically speaking, it's probably more
21 relating to the type of facilities that people are in now,
22 with more infrastructure in place and more -- and air
23 conditioning, quite frankly, and use of fans. And the type
24 of theater has matured, basically, rather than being in a
25 more primitive state last year.

1 COLONEL STANEK: We're certainly hoping that
2 we continue to see this sort of (inaudible) on this.
3 DR. OSTROFF: It looks like a success story,
4 so it's nice to see a success story. Thanks very much.
5 Our next update is from the Navy.
6 LCDR LUKE: Admiral, ladies and gentlemen,
7 Captain Kilbane was scheduled to present to you this
8 afternoon, but he had a family emergency so I'm presenting
9 in his stead. In response to the questions by the AFEB
10 about what the Navy is doing with clamydia screening, as
11 well as prevalence issues, we've presented the -- we'd like
12 to present the following slides.
13 So screening policy varies by circumstance and
14 where you are in -- in your career. For recruit training in
15 the Navy, the females are -- received GenProbe (phonetic)
16 during their PAP for clamydia, as well as gonorrhea, and the
17 males are being screened, all of them, with an urine
18 leucocyte esterase, which is an indicator of general
19 problems within the urological system of potential
20 infections. But in this age groups, it seems to have a good
21 sensitivity for gonorrhea, as well as clamydia.
22 In the Marine Corps, at least down at Paris
23 Island, only the females are being screened, and they are
24 using the GenProbe during their PAP, as well.
25 Other times that Navy service members are being

1 screened is that generally all females who are pregnant or
2 are being assessed for an IUD will have a clamydia, a GC, as
3 well as during their annual PAP, if they are designated by
4 the M.D., P.A. or nurse practitioner of being high risk for
5 having GC.
6 Now, high risk can be the -- the advice that's
7 been sent out by the AFEB is one guideline. There are
8 others by other boards, as well as professional
9 organizations, but it seems to be a fairly universal
10 practice at the hospitals that we contacted. So the family
11 practitioners, as well as the OBs and GYNs, as well as nurse
12 practitioners, have been using this term of high risk as the
13 indicator for when they would do a screening. And then
14 discharge and retirement physicals, again at high risk.
15 Next slide. So just a snapshot of what we're
16 looking at as far as clamydia prevalence in Naval
17 personnel. At recruit training commands from Great Lakes,
18 females had a prevalence of 5.93 percent, and that was from
19 January to July of 2004. Males with a positive leucocyte
20 esterase were 5.14 percent, and at the Marine Corps recruit
21 training center it was 8.7 percent. That was only
22 calculated for a three-month period, but substantial
23 numbers, so that's probably a good estimate.
24 Next, please. So we'd like to address the
25 following notes, here. Great Lakes is reporting that they

1 may no longer do a PAP at accessioning, and they are
2 considering to screen for clamydia and gonorrhea by an urine
3 DNA amplification probe that reportedly has a very high
4 sensitivity.
5 As far as the males are concerned, this is much
6 more acceptable than the standard urethral probe, for
7 obvious reasons. So the question is essentially this, that
8 when we were talking at U-med (phonetic) to our women's
9 health advocate, as well as some of the other practitioners
10 and preventative medicine specialists, this fact comes out,
11 that 70 percent of unplanned pregnancies result from having
12 relations with an activity duty father, which as a surrogate
13 probably means or indicates that sexual activity amongst our
14 young service is an intramural sport.
15 And if we're spending a tremendous amount of time
16 where females are being screened not only at accessioning,
17 at the recruit depots, during their annual PAPs and so
18 forth, are we actually doing any good if we're not also
19 taking a look at the other half of the problem, which is
20 these high risk males that we have that really only get
21 screened if you're in the Navy, in Marine Corps not at all,
22 or if you come in with obvious signs and symptoms, and since
23 it's a high level of number of asymptomatic cases in males,
24 we may not be addressing this whole issue correctly.
25 So clearly the question that's coming back to us

1 is do we need to put an increased emphasis on high risk
2 active duty males, particularly since this new urine DNA
3 amplification probe is now available, which makes it much
4 more acceptable for the patient, as well as for the
5 practitioner.
6 DR. OSTROFF: Thanks very much. Let me open
7 it up to comments from the board members. It strikes me --
8 and again, this is not an area of my specific expertise, but
9 it strikes me with that type of prevalence and -- as well as
10 this type of information, anything you can do to reduce the
11 prevalence of clamydia makes a lot of sense to me.
12 So while there's good reason to concentrate on
13 females because of the issues related to infertility, et
14 cetera, that it seems that you're only addressing half of
15 the problem if you just concentrate on females and don't try
16 to do something about reducing the reservoir that may well
17 be in the male. It probably is worth doing a cost-benefit
18 analysis for them. You know, certainly from the prevention
19 standpoint it makes perfect sense.
20 UNIDENTIFIED SPEAKER: It seems to me not
21 only can we check for clamydia and -- by less invasive means
22 in males and females, and since our real concern here, one
23 might consider -- you doing annual Pap smears (inaudible).
24 Is that correct?
25 UNIDENTIFIED SPEAKER: That's generally the

1 rule.

2 UNIDENTIFIED SPEAKER: Well, we now have the

3 ability to check for Human Papilloma Virus, and I believe

4 the national OB/GYN organizations are considering doing an

5 every third year PAP smear if you are okay in terms of your

6 Human Papilloma Virus. So I'm thinking of a way where we

7 might increase our surveillance for the (inaudible)

8 clamydia, but diminish the need for annual PAP smears by

9 doing a -- emphasizing Papilloma testing at the time of

10 bringing them on service.

11 But if they're negative, that's not an advantage,

12 I don't think, at least as the rest of the world is moving

13 to do much less than every -- away from the annual PAP smear

14 to every third year, I believe, is what's happening in most

15 OB/GYN practices.

16 UNIDENTIFIED SPEAKER: If I could comment on

17 that. I'm a family practice doctor. My understanding is of

18 ACOG's position on that is that it's risk-based, and so if

19 you've got a young population that's sexually active,

20 unmarried, even if their HPV probe is negative this year,

21 they're still at risk for developing that over the next

22 year, so I don't see that in particular the population that

23 we're targeting here is that changing to an every third-year

24 exam.

25 UNIDENTIFIED SPEAKER: Well, the idea is that

1 once you're Papilloma virus positive, then you need more
2 frequent checks cystologically to see if you've developed a
3 pre-malignancy, but if you're negative, you're not going to
4 develop cancer in the next three years --
5 UNIDENTIFIED SPEAKER: But you might be able
6 to --
7 UNIDENTIFIED SPEAKER: -- if (inaudible) you
8 in the next week.
9 UNIDENTIFIED SPEAKER: But if you're still
10 high -- engaging in high-risk behavior, you can still come
11 back HPV positive or clamydia positive.
12 UNIDENTIFIED SPEAKER: Well, what I'm
13 suggesting is that you check more often for clamydia,
14 because that requires an immediate intervention, but less
15 often for -- at least a histologic aspect, because we're
16 really only investing in the long-term consequences of the
17 Papilloma virus.
18 UNIDENTIFIED SPEAKER: Well, Papilloma virus
19 is not going to make us --
20 DR. OSTROFF: Could you use your microphone,
21 please?
22 UNIDENTIFIED SPEAKER: So I guess the
23 question that we had for AFEB is are we doing enough to
24 screen for males, particularly since the trend is to reduce
25 unit size, reduce, you know, manning aboard ships. And in

1 our case, in many of our vessels, and this is a personal
2 opinion, that -- and a fact, that -- that there aren't
3 positions aboard a lot of vessels, so woman who have, in the
4 instance of pelvic inflammatory disease in the South Pacific
5 or in the middle of some ocean really are in a rock and a
6 hard place.
7 And if we're going to be putting a lot of effort
8 and emphasis on making sure that our females are not
9 positive or infected with GC or clamydia, maybe we should
10 also start taking a look at males to make sure that we don't
11 just reinfect them as soon as they get out of boot camp or
12 into their (inaudible).
13 UNIDENTIFIED SPEAKER: (Inaudible) says that
14 you can do both of the male and female in collecting urine
15 specimens and also do --
16 UNIDENTIFIED SPEAKER: Yes, sir.
17 UNIDENTIFIED SPEAKER: -- the regional swabs
18 and pelvic exams.
19 LCDR LUKE: Well, I think we'd have to take a
20 look at cost effectiveness, as well as combat effectiveness
21 and efficiency, but with a UA before deployment policy -- a
22 urinalysis before deployment for a periodic time -- men are
23 never screened, literally, until they come up with, you
24 know, a specific complaint of having, you know, a burning
25 sensation or actually go to be treated. So, you know, our

1 men never have an opportunity to be screened once they, you
2 know, are initially screened at one of our recruit depots,
3 but never if they are -- you know, never actually show up
4 with a complaint.
5 UNIDENTIFIED SPEAKER: I guess I'm not making
6 myself clear. It sounds to me like the real reason to do
7 pelvic exams on women is not cancer prevention so much as
8 sexually transmitted disease prevention in terms of force
9 availability. I think that's what I hear --
10 UNIDENTIFIED SPEAKER: For recruits, yes,
11 sir, that's probably -- in that age group. Ultimately they
12 will have to have their -- they have PAPs and determine
13 whether or not they have a cervical lesion. But it seems to
14 me what the reason -- the primary focus of force health
15 protection, at least in recruits, is whether or not they
16 have clamydia or gonorrhea.
17 UNIDENTIFIED SPEAKER: So I think right now
18 if you can screen for Papilloma virus, you have -- it's as
19 good as a PAP smear, basically, better than; it's a pre-PAP
20 smear indication of who's at risk of developing cancer. But
21 you don't need to follow that all the time. And what you're
22 suggesting, I think, is that we should be testing both males
23 and females at a much higher frequency than we do now, but
24 you can do that easily through urine specimens, so you might
25 have some protocol of regular examination of urines for both

1 sexes rather than the current, much more invasive and
2 unpleasant methods that are required to test for this.
3 UNIDENTIFIED SPEAKER: That's a fact, sir.
4 DR. OSTROFF: Can I ask, do you have any idea
5 what the cost of the urine assay is?
6 LCDR LUKE: No, sir, but I can get that data
7 for you and send it to you very quickly.
8 DR. OSTROFF: I mean, if at all feasible
9 (inaudible) --
10 LCDR LUKE: Well, a lot of -- one issue is
11 just time. It's a significant investment in time for the
12 clinics to do PAP exams at the recruit depots, so a urine
13 sample is much more efficient, so there's (inaudible).
14 DR. OSTROFF: Right. And as Dr. Kilpatrick
15 pointed out, they're doing annual urine screening for, you
16 know, substances, so there are opportunities to do it at the
17 same time.
18 LCDR LUKE: Yes, sir.
19 DR. OSTROFF: Thanks. Our next update --
20 LCDR LUKE: Sir, we've got one more, here.
21 We were also asked to give some data to the AFEB, and it's
22 general information, about a mumps outbreak we had during
23 joint fleet exercise, a war on Norfolk (phonetic) of this
24 year.
25 Next slide, please. So the background is a major

1 fleet exercise in late May and early June, there were seven
2 nations that were involved. There was a rather large
3 British amphibious task force that comprised of several
4 ships, I have been informed 11, with a total of 6,000
5 Marines and sailors. They were scheduled not only to do
6 operations, but also to have port calls and liberty in
7 Virginia and Florida.
8 They noticed on their way over from England an
9 index case of mumps on the 19th of May on the HMS Ocean,
10 which is an amphibious warfare ship. On board this
11 particular ship, there were approximately 1,000 Marines and
12 sailors, and it was later estimated that 100 of these
13 Marines and sailors were without previous immunization
14 against mumps or previous history of disease.
15 It was also noted that cross decking from ship to
16 ship during transit from England was exceptionally common,
17 and the amphibious task group arrived in Norfolk on the 27th
18 of May.
19 Next, please. So on background on mumps
20 immunization, the epidemiology is actually very interesting
21 between our two nations. In Great Britain, only measles
22 vaccine was offered prior to 1992. Rubella and mumps were
23 added to that vaccine, which is provided by their national
24 health service, in 1994 and 1996, respectively. Their
25 service policy is that service members may refuse force

1 protective vaccines, MMR, Bacinium (phonetic), and they also
2 have the right, apparently, so we've been told, to refuse
3 the use of prophylactic medications, such as mefloquine or
4 other antimalarial medications, should they choose to.
5 The rates that are being reported out of Great
6 Britain, depending upon your socioeconomic status, as well
7 as the region of Great Britain that you were raised in, is a
8 10 to 25 percent of individuals under the age of 25 years
9 old have never been vaccinated with the MMR vaccine, and
10 this is due to a public perception of a link between MMR
11 vaccination and autism. And as a result, there are annual
12 outbreaks of mumps in Great Britain and significant concerns
13 about the ability of a measles epidemic to break out in the
14 island, as well.
15 This compares with the United States, in which MMR
16 has been offered since 1977, and mumps as an individual
17 vaccine since 1967, and that 93 percent coverage in the 19
18 to 35 month of -- age group with additional coverage being
19 effective when the children enter grade school or later on
20 when they go to college.
21 Next. So the outbreak dynamics are actually very
22 interesting and instructive, I think for all of us as
23 preventative medicine officers. The U.S. fleet surgeon
24 arrived on HMS Ocean on the 27th of May for a courtesy call
25 to talk to his British colleagues. As he made his way up

1 the gangplank, he noticed that there was a very festive
2 group of sailors and Marines ready and willing to go on
3 liberty in Norfolk, and he said the departure was imminent.
4 When he got down into the sick bay spaces, the
5 question was, what about our mumps? And having little
6 experience with mumps, the fleet surgeon made what would be
7 called a command decision, and he invoked a quarantine on
8 the spot for the English amphibious task group. He thought
9 that that probably was not going to be taken very well with
10 the junior sailors and Marines, as well as the admiralty and
11 preventative politics involved.
12 So he got himself a bum boat (phonetic) and he
13 sped over to talk to the exercise admiral, who, according to
14 the surgeon, displayed what he would call initial
15 consternation about -- about the quarantine. As cooler
16 heads prevailed, it turned out that he was later was
17 commended really for taking a very difficult decision with a
18 limited amount of information in a tough situation. So it
19 doesn't always turn out badly for -- for our preventative
20 medical or preventative medicine or preventative
21 medicine-minded colleagues.
22 Next, please. So the outbreak dynamics, it really
23 also is very interesting, because there are a host of laws
24 and agencies and -- are involved in something like that,
25 including federal maritime law, the CDC, state health

1 departments, harbor masters, you know, various services, and
2 it took a considerable amount of effort for EPMU2 and NEHAK
3 (phonetic) and CDC and -- to, you know, coordinate exactly,
4 you know, what would be the appropriate response. This is
5 what they came up with.
6 They decided they would have a vaccination
7 campaign in an at-risk -- at-risk ATG personnel from the
8 30th of May through the -- to the 3rd of June. Now, they
9 identified approximately 10 percent of the fleet as being
10 unprotected, and they designated at-risk as being under the
11 age of 25 years old, the idea being that if you were older
12 than that, you were probably already exposed to mumps as you
13 were growing up, and -- or no history of vaccination.
14 And then the bigger issue for the junior enlisted
15 personnel was liberty, and after they were vaccinated,
16 liberty was authorized for those that were older than 25
17 years old and not in a high-risk group, prior history of
18 vaccination, or those who had actually been newly
19 vaccinated. Now, obviously there is a period of time before
20 you seroconvert, but they thought the risk was fairly small
21 for the United States population and went ahead and let
22 those individuals come off -- off the ship.
23 I thought it was very interest that 50 Marines and
24 sailors refused to be vaccinated, and therefore could not go
25 on liberty, which when you think -- you know, if you're an

1 18 year old and the new world is beckoning with Norfolk,
2 Virginia and Florida on tap there, if you would just take
3 the shot, then you would probably get it, but they refused
4 it and were held aboard ship.
5 Now, very interesting, that after that initial
6 case, two more developed, and nine additional cases on HMS
7 Oceana within the predicted date incubation period after
8 this vaccination campaign.
9 If you'd go to the next slide, here. This is just
10 a little schematic, here. This is the HMS Ocean. The
11 estimated population at risk was 100. That's a real number,
12 not something that was fudged. And as you see on 5/19 to
13 5/27, there was one case. From 5/28 to 06/07, they had
14 three cases break out on Oceana, and that was during the
15 period of the mass vaccination campaign. And then following
16 that, from 06/08 to 06/16, there were nine additional
17 cases. And the incubation period for mumps is generally 10
18 to 14 days but it has been reported for as long as 26.
19 And then following up with our British patriots,
20 there have been no additional cases after 06/16. So this
21 vaccine campaign was highly effective.
22 Next slide, please. So the considerations that I
23 think we can all consider here, you know, based upon not
24 only the fact that we deploy worldwide, but also, you know,
25 the English and the Polish and other allies, is that

1 different laws concerning vaccine administration and drug
2 prophylaxis, you know, really kind of drives that policy.
3 And then I think that many of us were quite surprised that
4 the English weren't thinking exactly like we did on this
5 issue, and we just assumed that everybody -- England would
6 be getting MMR vaccines, just as Americans would.
7 We've also asked that (inaudible) epidemics and
8 what effect that would be on joint operations if they were,
9 say, securing a flank operation or responsible for an area
10 of operations for the fleet. And, you know, clearly with
11 biowarfare and so forth, the question is, you know, is it
12 significant enough if 20 percent of an allied force refused
13 to take vaccinia, how does that impact us, and what we
14 really base on a population health issue, of course, hurt
15 immunity, but if we continually have individuals coming into
16 our midst who are infected, you know, what effect will that
17 have on our overall vaccine efficacy.
18 And finally, the force health vaccination policy
19 and procedure should be carefully assessed during planning
20 phases for not only exercises, but more importantly, for
21 exercises in which we may be going into combat. The
22 assumption that, you know, we're doing this and other
23 nations will be doing it is probably not valid, and I think
24 it's a significant enough concern that perhaps the AFEB may
25 want to consider that and make a recommendation about, you

1 know, what our policy should be in the future, you know, for
2 operations like that, but also what we should be
3 considering, should we be doing joint operations with allied
4 nations in various different operations that we may be
5 called on.
6 DR. OSTROFF: Thanks very much. I know we
7 have our British colleague here, I don't know if he wants to
8 make any comments.
9 UNIDENTIFIED SPEAKER: He had some
10 fascinating comments, sir.
11 COLONEL WHITE: Well, I --
12 DR. OSTROFF: Please come to the microphone.
13 COLONEL WHITE: Thomas and I discussed this
14 earlier. I would have to confirm the statements he made
15 about public health vaccines being voluntary. I'm not sure
16 that's quite the case exactly, although I assume anything's
17 possible in the Navy.
18 But I know that for -- I mean, you're certainly
19 right in saying that for biowarfare vaccines are not
20 compulsory, but let me check up on these things.
21 UNIDENTIFIED SPEAKER: I guess as a member of
22 one of the colonies, my understanding is that it -- well, my
23 understanding is that the vaccines for the British forces
24 are voluntary, pretty well, I think most of the vaccines.
25 We -- Canada is struggling with this whole issue regarding

1 mandatory versus voluntary for vaccines, which vaccines
2 should be considered mandatory, which can be voluntary. And
3 it's really important, because there's all kinds of legal
4 questions and we're struggling with this, so it's a very
5 interesting question.
6 Concerning knowledge of what NATO countries are
7 immunized with what, or given what immunizations, there is
8 actually a (inaudible). People seldom look at them, but
9 sometimes they are helpful, and there is a (inaudible) on
10 immunization, I think it's 2037, that has an
11 (inaudible) that actually lists vaccines each NATO member
12 gives its soldiers and under what conditions.
13 It's not always right up to date, but it's usually
14 within a year or two, so that's certainly one starting
15 point. If you're a joint force surgeon who wants to know
16 what's going on with your allies, that's one place to
17 start.
18 But I -- this is fascinating to me, and I'm
19 absolutely -- having been a fleet medical officer for a
20 certain part of my career, I am really amazed that 50 of
21 the -- I think you said 50 of the Marines and sailors still
22 refused to get vaccinated, even though they lost a chance to
23 get shore liberty, it's amazing, speaks to me that there
24 must be real terror of MMR. I thought that was very, very
25 interesting.

1 DR. OSTROFF: The bigger amazement to me was
2 that they knew there were other colleagues on the ship that
3 had this particular disease, that they would recognize that
4 their risk was significantly higher than it was in the
5 general population, you'd think that would be a reason to
6 get it.
7 COLONEL WHITE: I was going to say that -- I
8 mean, you mentioned the time -- the place to bring this
9 issue up, really, is in a NATO group.
10 DR. OSTROFF: I have one question about -- of
11 those nine individuals that subsequently developed disease
12 after you made these decisions about the course of action,
13 how many of them were actually allowed to go ashore?
14 LCDR LUKE: Some of them actually did go
15 ashore, but when they became symptomatic, they were
16 restricted to the ship. So they received their vaccine and
17 went on liberty as allowed, but they then subsequently
18 developed the disease, so they --
19 DR. OSTROFF: So knowing what happened, would
20 you still make the same recommendation?
21 LCDR LUKE: Well, sir, fortunately it wasn't
22 I who made the recommendation. (Inaudible) of the CDC, so
23 how can I be wrong?
24 I guess the situation was that the United States
25 has such high coverage and the likelihood that these sailors

1 would be interacting with very young children or other
2 people who you might expect not to have been vaccinated
3 against mumps or had the disease was relatively small.
4 Obviously, had this been measles or some other, you know,
5 very infectious disease, I think a different course of
6 action would have been taken.
7 I think it was a pretty gutsy decision. Clearly
8 if there had been a mumps outbreak in the Norfolk area, you
9 know, after this had been -- after British sailors had been
10 allowed to come to shore, I think there would have been a
11 lot of displeasure coming from different, you know, areas
12 and organizations. I mean, that's the least we can say, but
13 it didn't happen, so I would probably say in this case it
14 was the right decision, but it was in fact a gutsy decision,
15 and we can't --
16 DR. OSTROFF: And one more question. Were
17 any of those individuals greater than 25?
18 LCDR LUKE: Sir, I don't have the answer to
19 that, either, but I can get that for you.
20 UNIDENTIFIED SPEAKER: I was just curious.
21 The 50 who refused the vaccine, how many of them
22 subsequently developed infection?
23 LCDR LUKE: Sir, I don't know whether any of
24 those 50 subsequently developed infection. But I want to
25 make a note, those 50 were across the -- the eleven ships in

1 the British amphibian task group, it wasn't just 50 on the
2 Oceana, but because of the cross decking, they decided that
3 they would have to vaccinate the entire force, or at least
4 those at risk within the entire force, so --
5 UNIDENTIFIED SPEAKER: Didn't you say there
6 were 10 cases after vaccination?
7 LCDR LUKE: There were three waves of
8 outbreaks, one, and then followed by three cases, and they
9 pulled in on the 27th through the 30th, and then there were
10 nine cases, sir, after the mass vaccination campaign, but
11 none -- none subsequently after that.
12 DR. OSTROFF: Thanks very much.
13 UNIDENTIFIED SPEAKER: A comment about
14 clamydia testing. There was a question about how much
15 clamydia tests cost. According to our laboratory, which
16 receives about one third of -- or roughly 10,000 per month
17 tests from the Navy, it's about approximately 10 to $12 per
18 test.
19 DR. OSTROFF: Thank you. On to the Marines.
20 LCDR LAVENDER: Good afternoon. I'm
21 Lieutenant Commander David Lavender. I'm not a Marine, I'm
22 a Navy medical entomologist, and I'm from the Disease
23 Factory College and Control Center (phonetic) in
24 Jacksonville, Florida. I recently participated in Operation
25 Secure Tomorrow. This was a combined joint task force

1 deployed to Haiti as an interim force to stabilize the
2 country of Haiti until the United Nations could take over.
3 The combined joint task force was made up of not
4 only U.S., but Canadians participated, as well as France and
5 Chile, and all the DoD services were represented, as well.
6 The core of the CJTF was made up of a Marine Corps special
7 MAGTAF (phonetic).
8 Next. I was the team leader for Forward Deployed
9 Preventative Medicine Unit, this is the FDPMU. It's one of
10 the deployable medical platforms that the Navy Environmental
11 Health Center currently provides. It was made up of seven
12 preventative medicine specialists from two units, mine in
13 Jacksonville, the Disease Factory College and Control
14 Center, and Captain Bailey, who presented earlier, who was
15 the officer in charge of the Environmental Preventative
16 Medicine Unit No. 5 in San Diego.
17 In addition to myself being a medical
18 entomologist, I also had an environmental health officer, an
19 advanced laboratory technician and four preventative
20 medicine technicians with me.
21 We had two primary missions. Insect surveillance
22 and control to prevent malaria and dengue in joint task
23 force, and also to conduct environmental health site
24 assessments, or EHSA, to document potential exposures to
25 hazardous substances for our force. Our role also evolved

1 to include general camp sanitation and safety for the
2 primary camp for the headquarters of the CJTF, to include
3 such things as food safety, water tests, WBGT testing for
4 heat exposure and that kind of stuff.
5 We were responsible for six camps throughout the
6 Port-au-Prince area. This included about 3,500
7 multi-national interim forces, as they were called, all in
8 the vicinity of Port-au-Prince. The troops began arriving
9 in mid March, but our preventative medicine team did not
10 arrive until the first of April.
11 Just for a little background, the rainy season in
12 Haiti, or the island of Hispaniola is April and May, and the
13 primary transmission for dengue and malaria occurs in the
14 month of June.
15 The United Nations was supposed to take over this
16 role on 1 June, which meant we would have been out of there
17 before the primary transmission season began, but in fact
18 they delayed 30 days, so we were there -- the force was
19 there until the beginning of July.
20 This is an example of one of the six camps that we
21 were responsible for. They were all combinations of tent
22 facilities and existing local structures. This particular
23 camp was just off the end of the Haiti International Airport
24 runway.
25 Next. We lived and worked out of either tents or

1 warehouses. This particular slide is of a tobacco warehouse
2 that was leased from a cigarette company, and this housed --
3 actually it was two facilities just like this that housed
4 about 600 Marines. As you can imagine, we cleaned them
5 before we went in. Initially they weren't cleaned at all.
6 They had, of course, held cured tobacco, and for quite a
7 while these things reeked of cured tobacco. Of course,
8 eventually sweaty Marines overpowered that smell or we just
9 didn't notice it anymore, one or the other.
10 Next, please. Looking through the barbwire
11 surrounding the headquarters camp, you can see that we were
12 surrounded by the city and its inhabitants. We were
13 literally spitting distance from slums, farm animals, open
14 sewage and filth.
15 Next. And this is an example of what many of the
16 local habitations right around our camps looked like. If
17 you've heard the recent news about the number of deaths in
18 Haiti attributed to Hurricane Jean, you can imagine that
19 these structures do not withstand wind and rain very well.
20 In fact, we were in Haiti when the first tropical storm of
21 this season came through, and there was thousands of deaths
22 in Haiti then due to mud slides and floods, and the combined
23 joint task force spent weeks conducting flood relief and
24 transporting humanitarian assistance and supplies to the
25 flood victims.

1 These living conditions also presented huge public
2 health concerns for us since we were living so close to
3 these areas. From an epidemiological standpoint, my concern
4 was that it brought potential disease reservoirs into the
5 inhabitants of other viruses in close proximity for our
6 troops with little besides their personnel protective
7 measures and our vector control efforts to protect them.
8 Piles of refuse along the roads breed filth flies
9 (phonetic) and fungus in Haiti and provide harborage and
10 food for commensal rodents. We battled filth flies in the
11 dining areas constantly throughout the deployment and caught
12 dozens of roof rats and house mice within the camps.
13 Next. One of huge undertakings of this deployment
14 was the Operation Clean Sweep. The Marines that were there
15 initiated an extremely successful program, very well
16 promoted within the city of cleaning the refuse off of the
17 streets. What they would do is they would go in after the
18 curfew -- there's a curfew set at 2200 every night.
19 The Marines would go into certain areas of the
20 city with bulldozers, backhoes, road graters, dump trucks,
21 that kind of stuff, and literally create piles of refuse,
22 like you see in this slide, pile it into dump trucks, haul
23 it off to a local dump. And locals would come out the next
24 day and their streets would actually be clean. Now,
25 unfortunately, within a week the Marines claimed that they

1 would have just as much garbage back out on the streets, but
2 nevertheless, people really appreciated what they were
3 doing.
4 Unfortunately for my team, this also put the
5 Marines at risk, from our standpoint, anyway, by exposure to
6 vectors of malaria in areas where we could not control. We
7 had no ability or we were prohibited from applying
8 pesticides outside the camp perimeters. And they were also
9 there during the peek fighting times for the (inaudible)
10 vectors that were there, which were generally between about
11 2200 at night and 200.
12 Next. Standing water was everywhere within the
13 city, and these puddles were absolutely full of mosquito
14 larvae in every species. You'd find multiple species in
15 each of these puddles. However, it also was not unusual for
16 us as we were passing through going from camp to camp to see
17 many of the local inhabitants dipping containers into these
18 puddles and either drinking from them or bathing with the
19 water, so there was absolutely no way that even carefully
20 that we could apply pesticides in the form of throwing
21 larvacides or something like that into these puddles for
22 fear of the people drinking them.
23 Even within our own camp sites, of course, we even
24 had mosquito breeding sites. Pools with vegetation like
25 this one are ideal habitat for Cranopolin (phonetic)

1 mosquitos to transmit malaria. This particular site we
2 treated for weeks as we were trying to get the engineers
3 to -- to come in and do something more permanent to control
4 the site. Eventually our Canadian friends were building a
5 mess facility and had a road grader in the camp, and I
6 borrowed it for just a short while. In less than an hour,
7 this was what it looked like. It worked perfectly, drained
8 perfectly. For the rest of the deployment, we never had any
9 more problem with standing water there.
10 We also kind of created our own mosquito breeding
11 sites. This is a clearing barrel, a field expedient
12 clearing barrel, we'll call it. Any time you left the camp
13 perimeter, you had to lock and load your weapon because of
14 the threat of violence there. And then when you would enter
15 another camp site, you had to clear your weapon to ensure
16 that there was not a round in the chamber, and this is what
17 many of the clearing barrels look like. It was just made up
18 of tires with sand bags around them.
19 Unfortunately, these also collected water and
20 became ideal breeding sites for Aedes aegypti, the primary
21 vector of Dengue, and it wasn't long before all these were
22 chock full of Aedes aegypti larvae, so we had to go through
23 and drill holes in all these tires, as well, to prevent them
24 from breeding our own problems within our camps.
25 Eventually, we did get showers built through a

1 contract. Unfortunately, the camp commandant of one of the
2 camps was to eager to get these showers out to the
3 personnel, they didn't follow our recommendations for a
4 drain field or drainage requirements, and in a matter of no
5 time whatsoever, the water coming out of the showers and the
6 trucks coming through on a daily basis refilling the
7 containers made these huge trenches, which, again, were
8 ideal mosquitos breeding sites.
9 And they're in the worse possible place, because
10 in the showers, you've got people without a treated uniform,
11 they're washing the repellent off, they're unprotected
12 completely, and so it was a huge problem for us. We spent,
13 again, weeks getting them on our preventative medicine
14 inspections, talked to the camp commandant. Finally he
15 relented and we were able to bring in simply three
16 truckloads of gravel and completely took care of the
17 problem. It still drains in here, there was still water
18 underneath there, but there was no way for the mosquitos to
19 access the water to breed in it, so it took care of the
20 problem completely. It cost virtually nothing, when you
21 consider the pesticides that we were using the complaints
22 that it was causing, as well.
23 To control the mosquitos, of course, we used every
24 type of equipment and pesticide in our inventory. We
25 sprayed them where they bred, where they rested during the

1 night, at night while they were active. We sprayed early in
2 the morning before people got out and got moving, we sprayed
3 during the day. We could apply residuals that didn't have
4 to worry about the pesticide evaporating. We sprayed them
5 at night during their active season -- or active time for
6 biting. But we sprayed pretty much all day, seven days a
7 week in an effort to try to stem the tide of these
8 mosquitos.
9 The problem was that we could only spray within
10 the camp sites, and outside the camp sites there were all
11 these breeding areas. So if we had to stop spraying for any
12 length of time, then the mosquitos would simply migrate in
13 and we would have problems.
14 This is an example of one of the camps. This is
15 Camp Henderson where the special MAGTAF was primarily
16 located. As you can see, it's, you know -- there's no walls
17 surrounding this, it's simply surrounded by concertina wire
18 to protect us.
19 Anyway, in the top left-hand corner just outside
20 the concertina wire, this facility right here was a sewage
21 treatment facility, if you will -- in the -- in the waters
22 that moved through this sedimentation area, these canals
23 were literally covered, absolutely full of mosquitos
24 larvae. All this black that you see is mosquito larvae.
25 The light colored areas are simply the exuviae of the

1 already hatched or shed skins or the mosquito larvae, so
2 that one dip of a mosquitos dipper looked like this, where
3 this entire layer here is all mosquito larvae and
4 (inaudible).
5 And it was, as you saw it, just outside of the
6 concertina wire from our camp. Now, one thing we did, even
7 though we couldn't apply pesticides, we did do manual
8 control, in that we had a preventative medicine technician
9 that every other day would go out there with a dip net and
10 literally dip pounds, just globs of mosquito larvae out of
11 this facility and dump them on the ground to die.
12 Environmental Health Site Assessments. This is
13 the second half of our primary mission. These are required
14 by joint chiefs of staff memorandum to conduct environmental
15 health site assessments at any location where U.S. forces
16 are deployed for greater than 30 days or more. We were
17 going to these areas and -- all of these areas and conduct
18 soil, water and air samples, as well as doing entomological
19 reports, safety reports for anything that we saw in the
20 area, hazardous plants, venomous animals. All of those
21 things went into our report.
22 So looking at the same camp that we were just a
23 minute ago, this is an example of all the different
24 selecting sites. Most of them were random, but if there
25 were areas of concern, then we did focus on those, as well.

1 We tried to focus also on areas where the Marines or the
2 other forces might have been particularly exposed to
3 hazardous chemicals, either because they were sleeping on
4 the ground, or -- for instance, this was a heli landing pad
5 here, which, of course, stirred up a lot of dust, and so
6 that was one of the sites that we did soil test, as well.
7 Air quality was a concern. At some of the camp
8 sites we did get back some readings. There was vehicle
9 emissions, industrial pollutants, because we had some camps
10 that were right down in the middle of the industrial area.
11 And there was ubiquitous burning trash. Everywhere you
12 went, there were piles of trash that someone was always
13 setting on fire.
14 In fact, one of the most unpleasant parts of this
15 deployment was the stench from these burning piles of
16 trash. It was everywhere you went throughout Haiti.
17 DR. OSTROFF: Commander, can you possibly
18 wrap up?
19 LCDR LAVENDER: I will, sir. This is getting
20 a soil sample. Keep going. Water samples. We took water
21 samples from every existing source that we had. Keep going.
22 This is the tent that we worked out of. It operated at the
23 laboratory storage for all of our hazmat and all of our
24 equipment and office space for seven people. And I'll wrap
25 up with that.

1 DR. OSTROFF: Thank you. I have one quick
2 question. My understanding was that particularly after the
3 experience in Liberia that there was -- I wouldn't say
4 directives, but greater urgency to there not being any
5 retro-borne disease occurrence in this particular
6 operation. Was there any?
7 LCDR LAVENDER: You're certainly right.
8 There was great --
9 DR. OSTROFF: It was preparedness. Let me
10 just say that. Did they succeed?
11 LCDR LAVENDER: We did -- we had one single
12 case of malaria in a Marine that admitted to not taking his
13 malaria chemoprophylaxis. One of the things that we saw was
14 that after we had been there for a very short time, we were
15 able to control very well the mosquitos within the camps,
16 such that people could go out and absolutely have no
17 mosquitos bite them. That wasn't the case when we got
18 there, but after a while it was.
19 And so we had a hard time convincing people to
20 continue wearing their repellent and wearing their sleeves
21 down on their uniform and that kind of thing in that
22 situation. So you'd have that situation going, and then
23 these Marines would go out at night for Operation Clean
24 Sweep to areas where this was not the case, and so there
25 would be problems.

1 But mostly we had very good luck with people
2 taking their malaria chemoprophylaxis. This one individual
3 did not.
4 DR. OSTROFF: And there was no (inaudible)?
5 LCDR LAVENDER: Excuse me?
6 DR. OSTROFF: There was no Dengue?
7 LCDR LAVENDER: We did not have a single case
8 of Dengue.
9 DR. OSTROFF: And do we know where the census
10 of the joint operation -- were the other countries that were
11 involved this successful?
12 LCDR LAVENDER: They were, but you've got to
13 remember, we were supporting them, as well. Now, the
14 Canadians had their own preventative medicine forces. They
15 did not apply any pesticides -- we applied pesticides for
16 them. The Chileans did bring some of their own vector
17 control equipment with them, and they did some. The French
18 did not, but we pretty much did all of the vector control
19 for the entire force.
20 DR. OSTROFF: Thank you. Quick comment?
21 UNIDENTIFIED SPEAKER: Yes. Excuse me. To
22 the best of my knowledge, we -- our troops had neither
23 dengue nor malaria. In our previous deployment there, we
24 did have a number of cases of dengue --
25 DR. OSTROFF: And my recollection is that

1 this was also a problem previously in deployments to Haiti,
2 so somebody did something right. Congratulations.
3 We'll move on to our next presentation. This is
4 the Air Force presentation. I have Colonel Snedacor.
5 COLONEL SNEDACOR: Good afternoon. Should I
6 turn this off now? Next slide. I'm going to give an update
7 on clamydia screening in the Air Force. This is just a
8 summary slide. Our general policy for clamydia screening is
9 to follow USGFDS guideline (phonetic), or (inaudible)
10 guidelines, which I think are generally followed.
11 We also have the same issue of, you know, the PAP
12 smear done, is it done annually, who decides how often it's
13 done. And I think generally it's the providers who decide
14 how often and what's done. But generally clamydia screening
15 is done with PAP smears.
16 And we also portal data that gives information on
17 who needs PAP smears, so that if we do have people that go
18 beyond the three-year point, they do show up on action lists
19 that the providers and their teams can use to identify and
20 contact them.
21 Next. Now I'll move on to accession screening.
22 Lackland Air Force Base, which you just saw, currently does
23 no clamydia screening. However, there are plans to do a
24 pilot test, 1,000 males, 1,000 females, to look at what the
25 logistics are for this. This was discussed at our Air Force

1 Training Health Work Group (phonetic) extensively over what
2 kind of follow-up tracing we would do, understanding that
3 even with the five percent positive rate, we would still see
4 significant numbers who would need contact tracing, and we
5 didn't have the staff to do that.
6 So after some research into Texas law and what the
7 guidelines, recommendations were from the CDC, I think the
8 decision was made to -- to counsel the infected person and
9 put the onus on them to contact anyone they felt might be at
10 risk from their past sexual activity.
11 Next slide. At the Air Force Academy where I just
12 came from, I was successful in getting the female screening
13 this past summer, this past incoming class. We had one
14 positive out of 209 tested for a positive rate of .5
15 percent. There were 18 women who were not tested for
16 various reasons, and they will be followed up and tested,
17 but I don't have that information.
18 Right now there's no plans to test the males.
19 That's, once again, a significant, logistical hurdle.
20 There's 200 or 300 women, there's probably 1250 men, so
21 that's quite a large job. So unless there's change in
22 policy, there's probably no plan to test males as a whole.
23 There was some talk of doing some random selection testing,
24 just to see what the prevalence might be.
25 Next slide. Maxwell Air Force Base where we

1 in-process our officer candidates, and also our commissioned
2 officers, such as docs, nurses and lawyers, chaplains, there
3 is -- there is no testing done and no current plans to start
4 testing, unless policy changes.
5 Next slide. Next I'd like to brief you on a study
6 that was done by one of our major Air Force commands. They
7 did this testing during our annual physical exam, which we
8 call preventive or periodic health assessment. Some of the
9 bases did universal testing, meaning they tested everyone
10 who showed up for their annual, male and female. Others
11 tested all females and only tested males if they showed
12 symptoms. You can see the numbers there, the number sets
13 for each -- each group of those, and the data was collected
14 from April 2002 to January of 2004.
15 I only have limited access to some of the results
16 from this. What I have was in a poster presented to a
17 conference recently, so I don't have all the data associated
18 with this, but I'll give you what I have. At the universal
19 sites, the overall test-positive rate was 5.3 percent. I
20 believe that is the monthly rate, and it varied from a low
21 of 3 to a high of 8.4. And the charts I'll show you in the
22 next couple of slides will be much more informative of what
23 they actually say. As you can see, the overall prevalence
24 was between four and six and a half percent.
25 The focus testing, the overall test-positive rate,

1 of course, was higher, because they were only testing the
2 males who were -- there was predominately more of them, so
3 of course, their test-positive rate was significantly
4 higher.
5 Next slide. These are, I thought, very
6 interesting findings. This is of the bases that did the
7 universal testing. They tested all the males and all the
8 females, and you can see this very interesting trend over
9 time. And before you make any conclusions, look at the next
10 slide which shows the positive rates at the bases -- they
11 just did targeted testing, all females and only males who
12 were -- who had symptoms. And you can see the females in
13 both locations had similar trends down and about the same
14 positive rates, which I thought was very interesting.
15 I do have on -- on the next -- the next briefing
16 the actual poster presentation, but it's going to be very
17 hard to see, I think, if we --
18 DR. OSTROFF: It's in the briefing.
19 COLONEL SNEDACOR: You have it in there?
20 DR. OSTROFF: Yeah.
21 COLONEL SNEDACOR: Great. Can you read it?
22 DR. OSTROFF: Oh, yeah.
23 COLONEL SNEDACOR: That was my concern. I
24 couldn't quite get it to fit on a briefing slide.
25 DR. OSTROFF: Yeah, it's in the middle of Tab

1 8.

2 COLONEL SNEDACOR: Any questions?

3 DR. OSTROFF: Let me open it up for questions

4 or comments. I mean, it looks like the prevalence that was

5 found in the larger survey was fairly similar to what the

6 Navy found. Possibly the reason that there's not more

7 impact by screening the males might be different patterns of

8 intimate interaction amongst Air Force personnel than there

9 are amongst Navy personnel, who are more confined to ships

10 and don't have as many alternative opportunities. I don't

11 know.

12 But is there any thought currently being given to

13 re-evaluation of the current Air Force policy?

14 COLONEL SNEDACOR: I think so. One of the

15 plans is to re-engage this issue at our Air Force Training

16 Health Work Group (phonetic) to look at what data we do have

17 and see if our working group can make a policy

18 recommendation to us at air staff to see if we might

19 reconsider or consider implementing change in policy.

20 When I was at the academy, I was an advocate for

21 putting our in-policy specifically targeted to accession

22 screening, because the plan was to move from giving very

23 specific directions to just follow national guidelines, and

24 as they change, the policy won't need to be updated because

25 you'll just be following policy that gets updated and

1 changed.

2 However, most of those guidelines don't address

3 our specific situation of accessions. And when I tried to

4 implement clamydia training at the academy, I ran into a lot

5 of resistance from people who said, "Well, where's the

6 policy? Why should we be doing this?" You know, "Give me a

7 reason to do this or, you know, if you can't, then I have a

8 lot of good reasons not to do this."

9 So if I had a policy that said you must, then it

10 was very easy to get it done, otherwise it was an uphill

11 fight. So unfortunately, that AFI and another AFI which

12 addresses some screening issues are in final coordination,

13 and I'm not able to impact them at this late date.

14 DR. OSTROFF: And as far as the assays that

15 were being used -- do you know which assays were being

16 used?

17 COLONEL SNEDACOR: I believe they use the

18 urine test, but I'm not positive for all of them.

19 DR. OSTROFF: Colonel Phillips?

20 COLONEL PHILLIPS: Real quick. The downward

21 trend, as you said, is interesting. I'm wondering, can you

22 comment on were there other things going on in addition to

23 increased tests that might count for the downward trend;

24 i.e., was there more risk communication or more preventative

25 medicine efforts towards counseling or educating soldiers

1 about -- or airmen about the risks, that kind of thing?

2 COLONEL SNEDACOR: I don't believe so. This

3 was spread out over quite a few bases, and I don't remember

4 hearing of and I'm not aware of any specific educational

5 campaign or counseling campaign that was done just in that

6 (inaudible) that would have affected those bases.

7 UNIDENTIFIED SPEAKER: But this is what you

8 would expect from any screening test, to identify the

9 prevalent cases first, and then you get them cleaned up, and

10 then what you start seeing is (inaudible) cases. So this is

11 perfectly consistent with any number of screening tests that

12 have been initiated, you know, since the history of

13 screening tests started.

14 UNIDENTIFIED SPEAKER: I would argue to some

15 degree you've got some outlining -- outliner (phonetic)

16 months here that need to be looked out to see whether

17 there's differences in those populations. I'm not convinced

18 that this isn't in fact a trend, and that if you did

19 additional statistical analysis where you would started

20 controlling for outliners (phonetic), this thing may turning

21 into a straight line. At least evaluate the outliners to

22 see if there's anything different. You've got three or four

23 big points (inaudible).

24 UNIDENTIFIED SPEAKER: If you cover up the

25 left-hand side with your hand, I think you'll see a straight

1 line. I mean, the first three months, just get rid of
2 those, and you've potentially got a straight line, so
3 I think (inaudible).
4 DR. OSTROFF: There have been -- over the
5 years there have been several board members who have had
6 strong expertise in this particular area, and the board has
7 on several occasions issued recommendations around clamydia
8 screening. And I must confess, I'll have to go back and
9 look at our previous recommendations, but they strongly
10 advocated the proactive screening policy, to say the least.
11 And it is a little dismaying to hear that those policies are
12 not being universally embraced by the various services.
13 I know that in particular (inaudible), as we
14 talked yesterday, is very interested in coming and giving
15 the board an update on this issue, and I think it sounds
16 like it's an opportune time to do that, since it doesn't
17 look like we've totally reached consensus on this issue.
18 Other comments? Thank you very much. Commander Ludwig?
19 COMMANDER LUDWIG: I actually am going to
20 touch on three topics. I'm sorry you don't have a handout
21 for my presentation, but I'm going to try to make it quick.
22 Next slide, please. I'm going to talk about our
23 immunodeficiency virus policy revision, STDs in Coast Guard
24 recruits and MR assay on a Coast Guard cutter, Polar Star,
25 which is an ice breaker. I won't go into detail on our

1 policy revisions, I just want to say thank you to the board
2 for your recommendation to change to every two year testing,
3 because one of the things that came of that was a real focus
4 on the need -- although we were aware of it, a focus on a
5 need to revise our policy, which was scattered and did not
6 address many of the Coast Guard's unique kinds of situations
7 and hadn't really been revised for many, many years.
8 Next slide, please. As far as STD tracking of new
9 recruits at Cape May, we, for many years, have had testing
10 of females for gonococci and clamydia and, of course, HPV,
11 along with our PAP smear. That has continued. The nice
12 thing that I'd like -- well, I'd like to talk more about it,
13 but I don't have the data with me, is that I have -- there's
14 a new lab director there and she's very interested in
15 providing whatever kind of help she can to medical
16 surveillance and some of the other efforts.
17 So she has started in the year 2004 providing me
18 with the data on clamydia testing. And prior to that there
19 was no surveillance associated with it, it was just -- it
20 was for clinical purposes only.
21 And what I can tell you is in looking at it, the
22 clamydia rates for females is around five percent, which is
23 pretty consistent with what we've seen on the other slides.
24 The unfortunate thing about it is that they don't separate
25 out recruits from people who come in for testing for

1 clinical reasons. However, that's a very, very small
2 number, and I don't think that it affects it much.
3 Also we have talked -- I talked to this new lab
4 chief about possibly doing some work with Dr. Charlotte Vega
5 (phonetic) using the urine test and working on getting
6 specimens from males and females.
7 Next slide, please. The last thing I want to talk
8 about is this outbreak of MRSA -- outbreak, if you will --
9 on the Polar Star. I'm not sure I can say for sure that
10 it's an outbreak in that I don't know what the prevalence
11 is. However, this particular cutter, I got a report in
12 about March -- February, March last -- this year of a case
13 of MRSA on Polar Star.
14 And the reason I got it is because this -- this
15 cutter was on its way from Antarctica back home, actually
16 via Australia, and this particular individual had had
17 several furnacles or skin infections. And the point that
18 they were in Australia, he had a culture taken and they
19 found MRSA and reported it back. Although we never got a
20 hard copy of the lab report, I have no reason to doubt their
21 results.
22 And then rather than going through all the
23 details, I'll just say that there -- so far, the
24 investigation shows that there are five people with
25 laboratory confirmed MRSA from that time -- from that time

1 and forward, and that several of these individuals have --
2 actually, I think I do have another slide. I do.
3 The number of skin infections that each of these
4 people have had, so there are some people who have a
5 problem. Some of these have had nasal swabs and been found
6 to be MRSA positive, in other words, carriers, but they've
7 all had skin infections, too.
8 The main thing -- the main concern -- is there
9 another slide? Okay. Okay. The other thing they are
10 concerned about right now is that they are getting ready to
11 deploy again to go to Antarctica in November, and the crew
12 is understandably a little concerned that when you say
13 something like, you know, (inaudible) you mean (inaudible)
14 or, you know, anything that sounds like methacycline
15 resistant (inaudible) sounds pretty impressive, I think, to
16 a lay person.
17 And I am going out there next week to brief them
18 on MRSA and what it is and what can be done to prevent it.
19 And I've talked to the (inaudible) briefly on the subject,
20 and I'd like to gather a little more information before I go
21 on things that we might do to reassure them that we're doing
22 everything we can to prevent it.
23 Now, what I'm told about the conditions on these
24 cutters is that there's no way to avoid your wet towel from
25 hitting somebody else's wet towel or your clothing -- you

1 know, they are just so tightly packed in there that they are
2 going to have contact. And toward the end of some of these
3 voyages, they have to limit water, depending on when they
4 can take on water and so on, so they may not be able to wash
5 their clothes that often or shower more often.
6 And so I think -- you know, I think we do have a
7 legitimate concern, and I know that some of the other
8 services have experience with MRSA outbreaks under possibly
9 similar conditions, but this is something I'll be looking
10 into.
11 DR. OSTROFF: Thank you very much. Comments
12 from the board? Do you know -- has anybody been able to
13 look at these lab-confirmed cases, as far as both the
14 susceptibility, as well as to know whether or not this is a
15 common (inaudible)?
16 COMMANDER LUDWIG: So far what I've gotten is
17 actually what the -- what the -- the HFC did, chief health
18 services technician, he did a key word search on his local
19 Benacal (phonetic) list, which is his sick call roster,
20 basically, and went back a couple of years and picked up
21 everything that smacked of a skin infection, a boil or, you
22 know, anything that sounded like it could be a staff
23 infection, wound infections and so on. He gave me a
24 spreadsheet with a fair amount of information.
25 But in every case that these cultures were done,

1 as far as I know, there were no sensitivities, and I need to
2 call medical officers at various places, but it once again
3 brings up one of the things that we struggle with all the
4 time in the Coast Guard, and that is that our care is very
5 scattered. It's not centralized at all. We don't have our
6 own hospitals, and in a lot of places we don't even have
7 clinics. You know, the cutters go out with an independent
8 duty corpsman and -- or health services technician, and they
9 don't always get a chance --
10 DR. OSTROFF: I might suggest then that one
11 of the things that you could possibly do to help -- because
12 if these are going to happen somewhere off in the
13 Antarctica, it's going to not be possible in that setting to
14 do susceptibility, and it would be nice -- I mean, these
15 things often are highly sensitive to fairly commonly
16 available antibiotics. But the problem is it's very
17 variable, based on the bug, and you really do need to know
18 what --
19 COMMANDER LUDWIG: Yeah, one of the --
20 DR. OSTROFF: -- and as a potential issue,
21 you know, you could take a couple of mouth cultures and get
22 some bugs and have those bugs looked at, so that if they do
23 have cases, you at least some have data --
24 COMMANDER LUDWIG: And also have the right
25 antibiotic ahead of time.

1 DR. OSTROFF: Right. Make a decision about
2 what antibiotic to use. And the second is keep in mind
3 alcohol-based hand sanitizers which do not involve water are
4 as effective, if not more effective, than -- they are
5 certainly -- they are certainly easy to use in that
6 setting.
7 COMMANDER LUDWIG: Right. Yes. Thank you.
8 Other comments?
9 COLONEL UNDERWOOD: Yes. This is Colonel
10 Underwood. I just wanted to mention that we've noticed this
11 problem in base training sites, in particular at Fort
12 Benning, which they've studied rather recently. And part of
13 the risk factors -- of course, they also talk about close
14 contact, extended contact, poor hygiene, recent antibiotic
15 use and the fear of being recycled. They don't want to come
16 to attention with their furnacles, et cetera.
17 COMMANDER LUDWIG: Thank you.
18 DR. OSTROFF: Thank you very much. Our next
19 presentation is Dr. Brown from the VA.
20 DR. BROWN: Thank you very much. I'm going
21 to try to get through my slides very, very quickly. I guess
22 my time is already over. Except I do feel sort of slowed
23 down a little bit. I made the mistake of trying to keep up
24 with those two Air Force recruits in terms of the amount of
25 food I ate at lunch.

1 I'm going to talk about a project that VA has been
2 doing that we initiated very shortly after Operation Iraqi
3 Freedom began, and it represents an effort to track the
4 health care utilization of veterans who returned from
5 Operations Iraqi Freedom and Enduring Freedom and therefore
6 become -- separate from military service and therefore
7 become eligible for VA health care.
8 And we now have the computerized record system
9 that allows us to track each time that a veteran comes to VA
10 for the health care that they seek and the diagnoses that
11 they receive and other information for every outpatient and
12 inpatient visit that they have.
13 Next slide, please. We've developed a roster of
14 veterans of these two conflicts that's given to us by the
15 Department of Defense from BMBC (phonetic). It's a
16 preliminary file of OIF and OEF troops, and it's really
17 coupled together from a couple of different sources that
18 combine to make this one roster. It's combined from active
19 duty and reserve pay files, combat tax exclusions and
20 imminent danger pay data that DoD keeps on deployed service
21 members.
22 And the latest update that we have of separated
23 war veterans was provided to us as of last June, June 23rd,
24 2004, so that means our data is only as up to date as that
25 date.

1 Next slide. Very quickly, we have -- on our
2 roster now, we have 168,528 OIF veterans. And you can see
3 the breakdown of active duty versus reserve/guard. We have
4 45,880 OEF veterans. And again, you can see there the
5 breakdown by reserve and guard.
6 And a couple of observations I would make is that
7 the reserve and guard component is over-represented compared
8 to what is deployed. We're seeing a higher preponderance of
9 reverse and guard who are coming to VA who have separated --
10 I'm sorry, separated from the military service. And 10
11 percent served in both, so there's some overlap in the two
12 sets.
13 New slide. So just to quickly characterize the
14 kinds of health care that we're providing to these
15 individuals, amongst OIF veterans, 16 percent have come to
16 VA for -- primarily on an outpatient basis since they've
17 separated, and we've had 489 hospitalized, that is they've
18 taken on an inpatient basis. Amongst OEF veterans, a
19 slightly smaller number, 11 percent have sought VA health
20 care of the total who have redeployed, and 127 of those were
21 hospitalized.
22 Next slide. If you combine them, you get the
23 question we get asked a lot, the question -- combined
24 between the two conflicts, OIF and OEF, how much of a load
25 does this represent to the VA? How many patients are we

1 seeing by the two conflicts combined? Congress in
2 particular is interested to find out if we have the
3 resources that we need to provide the health care that these
4 veterans need or deserve.
5 And if you do combine them, there's some overlap
6 between the two sets. But if you combine them, there's
7 almost 200,000 OIF and OEF veterans who have served and then
8 separated and then been eligible for VA health care. And
9 almost 16 percent, 15.6 percent have sought VA health care
10 at least once.
11 Amongst the active duty troops, amongst those
12 whose were just active duty, 22 percent have sought VA
13 health care since deployment.
14 Next slide, please. Continuing this line of
15 reasoning amongst reserve and national guard, 12.7 percent
16 have sought VA health care since deployment.
17 Next. The impact on VA health care. We -- in the
18 fiscal years of '03 and '04, we've evaluated and seen on --
19 primarily on an outpatient basis, but either on an
20 outpatient or inpatient basis, we've seen 27,507. The one
21 OIF veterans -- and that's about -- and the question is, do
22 we have the resources to handle that as a load? Does our
23 hospital system have the resources to handle that as a load,
24 and we argue that we do, because it's actually a fairly tiny
25 percent of the total number of veterans that we see in that

1 year. That's about .6 percent of the four and a half
2 million veterans who have received health care in fiscal
3 2003.
4 So it's a significant number, but in terms of the
5 total number of veterans the VA is seeing, it's quite
6 small.
7 Next. Just as another example on the impact it's
8 had on VA health care, in just the one month of April 2004,
9 we saw 7,916 OIF veterans. It was primarily clinic
10 appointments. And if you average that over all our
11 hospitals, it's about 50 veterans each at our 158 VA centers
12 in the month of April, or fewer than two individuals per day
13 per hospital. So far, OIF veterans are really a tiny
14 proportion of the total number of patients that we see.
15 Next. This is -- I'm not going to go over this,
16 but it describes the demographics of OIF and OEF veterans,
17 and these are in your handouts, so you can see the details
18 of this.
19 Next. Next I'm going to talk about some of the
20 diagnoses that we've seen amongst these two groups of
21 veterans. And the point I'm going to make is that OIF and
22 OEF have presented to VA with a very wide range of medical
23 and psychological conditions. There's more than 38,000
24 discrete ICE diagnostic codes that have been used for this
25 group. The most common diagnosis is primarily

1 musculoskeletal ailments of principally joint and back
2 disorders, as well as dental problems, which I think is what
3 you'd expect for a populace like this.
4 Next. This is frequency of diagnoses for OIF
5 veterans. And again, if you look at this, the diseases of
6 musculo -- are broken down by categories of ICD-9 codes.
7 And if you look at it again, the highest category is
8 musculoskeletal system -- connective system diagnoses.
9 Next. This is the same breakdown of primary
10 diagnoses for OEF veterans, and it shows basically the same
11 point.
12 Next. Comparing diagnoses between OIF and OEF
13 veterans, this breaks it down by the top three -- I'm sorry,
14 top six most ICD common diagnostic categories, ranging from
15 musculoskeletal system, the second is diseases of the
16 digestive system and so forth. And the point is that
17 veterans who served in Afghanistan and veterans who served
18 in Iraq have essentially very similar -- essentially
19 identical frequency in the diagnoses that they receive.
20 They don't appear that different. Even though they're
21 serving in different parts of the world, the types of
22 diagnoses that they're receiving at VA are very similar.
23 Next. There's a lot of attention, as you all
24 know, to mental health issues amongst to OIF and OEF
25 veterans, and so we've looked particularly at diagnostic

1 categories that involve mental health diagnoses. And this
2 slide summarizes that, and you can see there is a wide range
3 of mental health diagnoses, but, of course, the one that
4 people focus on primarily is -- is in the -- an adjustment
5 reaction, that includes the diagnoses of PTSD.
6 And we summarized that data. We found that out of
7 the total number of veterans that we looked at, 1,743 Iraqi
8 and Afghan OEF and OIF veterans, have a diagnosis of PTSD.
9 We have been criticized for this as being underestimated for
10 total prevalence of PTSD in this population.
11 And there's probably some validity to that
12 complaint, because this is kind of an early snapshot of what
13 mental health conditions in general look like in this
14 population, and it's not really necessarily giving us a good
15 indication of what this is going to develop into over time,
16 so we're going to be monitoring that.
17 Next under findings. I've tried to summarize the
18 various findings from this fairly large data base that we
19 put together now. The first major finding is the separated
20 OIF and OEF veterans have experienced similar health
21 problems. The two groups look pretty similar.
22 Second, 16 percent rate of VA health care users
23 among separated OIF veterans is slightly higher when
24 compared to OEF veterans. I don't really know what to make
25 of that. OIF veterans appear to be using our health care

1 services at a slightly higher rate.

2 Next. Higher percentage of separated active duty

3 troops have sought VA health care compared to reserve and

4 national guard. For some reason, active duty service

5 members, amongst those who have separated, are seeking VA

6 health care at a higher rate than reserve and guard. And

7 again, we can't really -- we don't have any particular good

8 explanation for that.

9 The second bullet I think is an important point

10 that the diagnoses -- we've been doing this now -- I think

11 this is probably about the sixth or seventh update we've

12 done for OIF veterans. We get the data from DoD and churn

13 it through our data bases and match it up based on social

14 security number with our inpatient and outpatient data

15 basis. And it looks fairly stable.

16 If you look at this over time, the analysis that

17 we've done over time, the relative frequency of different

18 diagnoses that we see don't really change that much. The

19 total number of individuals that we're looking at is bigger,

20 of course, but the diagnoses don't change.

21 I think -- of course, the obvious point is, you

22 know, are we seeing anything unusual? And the answer is no,

23 we are not seeing anything unusual. Health problems just

24 jump out at us at this point. But, of course, it's

25 important to caution this is not an epidemiological study,

1 there's no control group. I mean, this -- you know, if
2 there was something going on, it's small rate, if it was
3 unusual, this type of analysis would -- of course, wouldn't
4 pick it up. It's not really a substitute for a longitudinal
5 study or some type of other epidemiological study.
6 Next slide. Summarizing, OIF and OEF are
7 presenting to VA with a wide range of both medical and
8 psychological conditions. And the implications of that, as
9 far as clinical care, we really can't make any specific
10 recommendations to our health care providers within VA about
11 what they should look for or what types of tests they
12 should -- they might want to consider for those veterans,
13 and that they should be assessed, therefore, obviously, on
14 an individual basis, looked at -- you know, treated as a
15 unique patient.
16 Next slide. One of the things you have to
17 consider in this is that veterans in these current
18 conflicts, because of legislative changes, changes that --
19 and laws that Congress has given VA, they have quite a bit
20 better access -- quite a bit easier access to VA health care
21 than, say, veterans from the 1991 gulf war didn't have --
22 had.
23 They had -- essentially can get free health care
24 from VA, pretty much no questions asked, for a period of two
25 years after they separate, and so that makes it a little bit

1 hard to compare this data to anything we had in 1991.
2 And then finally, we're going to be doing this --
3 we're going to continue to monitor the health status of
4 these veterans indefinitely as long as this conflict goes on
5 and after that.
6 I think that's my last slide. The other point I
7 would make is that this data base has turned out to have a
8 number of uses that weren't necessarily anticipated when we
9 started this. It's been used -- we're going to start a
10 mortality study soon on OIF veterans and OEF veterans. And
11 this will provide us, of course, our roster of veterans to
12 conduct the -- you know, the mortality study that will go on
13 essentially indefinitely.
14 It's also been used for a significant amount of
15 outreach that I think has been very useful, but it wasn't
16 something we really planned for initially. Our Secretary of
17 Veterans Affairs, Anthony Principi, has mailed out a
18 personalized letter to every single separated veteran
19 thanking them for their service and telling about the
20 benefits the VA can offer them. And we can use this roster
21 because it has addresses, Social Security numbers and so
22 forth as a means for outreach.
23 And we've also given the data base to our
24 individual medical centers, our individual hospitals, so
25 they can identify OIF and OEF veterans who may show up for

1 health care in their particular facility and think about the
2 particulars that they might want to talk about with that
3 group of veterans.
4 I would caution there are some problems -- my
5 final point is that I would say there are some limitations
6 in this data base. We have no denominator. We don't -- we
7 have -- you know, DoD only gives us those who've separated
8 from military service, but we have no denominator, we don't
9 know what the total (inaudible) is here.
10 And secondly, there's some odd effects in this
11 data base. From month to month when DoD gives us updates,
12 some people who were veterans of war suddenly disappear from
13 the list, and they are no longer listed as veterans. And we
14 think what's going on is that they are being -- that they're
15 reserve and guard and they're being reactivated, therefore
16 they're active duty again, but that's just speculation.
17 There could be some other problems. This data base is not
18 quite perfect.
19 With that, I'd be happy to answer any questions.
20 DR. OSTROFF: Thank you very much. Any
21 questions or comments? Dr. (inaudible)
22 UNIDENTIFIED SPEAKER: Is there any
23 difference in between access and care between active duty
24 and your reservists? In other words, do they have to go
25 through more of a paperwork rigamarole, or --

1 DR. BROWN: Oh, the question is, I guess, do
2 we -- from VA's perspective, do we provide benefits
3 differently for reserve and guard than to -- versus active
4 duty, and the answer is no. Legally, they have the same
5 access. There is a problem that reserve and guard have some
6 problem sometimes accessing our -- you know, they aren't as
7 aware of VA's health care services as active duty. But
8 legally, their access is identical.
9 UNIDENTIFIED SPEAKER: But the procedures
10 they have to go through, do they have any additional
11 paperwork?
12 DR. BROWN: No.
13 DR. OSTROFF: Dr. (inaudible)
14 UNIDENTIFIED SPEAKER: Could you clarify for
15 me the definitions of active duty? Does that mean someone
16 who has been like on a four-year active duty tour, like the
17 airmen we saw today, and then they separate from service?
18 Is that what --
19 DR. BROWN: Yeah, that's a good -- that's a
20 good point. That's a term that we -- yeah, that's -- we use
21 the term active duty use in this -- I mean, everyone's
22 active duty when their activated, but we use the term -- in
23 this sense, I'm using it in the sense that -- like the
24 airmen, the people who were going to be joining the Air
25 Force today and become -- are put on active duty

1 permanently, as opposed to somebody who's been activated on
2 the reserve and guard, is how we use it.
3 UNIDENTIFIED SPEAKER: I have a question on
4 the -- just a quick question on the mortality study. That
5 mortality study, is it going to encompass everybody in the
6 data base -- that shows up at least once in your data base,
7 not just those seeking --
8 DR. BROWN: Yeah, correct. Yes. The
9 question is -- so far it's only a minority of those who have
10 separated and theoretically are eligible for VA health care
11 who come in to get health care from VA. But the plan for
12 our mortality study is we'll look at every -- every veteran,
13 living or deceased, that we can identify.
14 DR. OSTROFF: One quick question for you. I
15 noticed that for Enduring Freedom that 80 percent those who
16 sought care from VA are reserves and guards. Is that -- it
17 strikes me as high in comparison to probably those who have
18 participated in OEF.
19 DR. BROWN: I don't really have a good
20 explanation for that. I guess -- but it is an observation.
21 For some reason, reserve and guard, after they separated --
22 you know, we're seeing a much higher utilization from that
23 component.
24 UNIDENTIFIED SPEAKER: I think just maybe to
25 try to answer that, is that when the reserve and guard are

1 called to active duty, it's for a set period of time,
2 anywhere six months to a year, maybe a little longer. And
3 when they are released from active duty, when they come
4 back, they then go onto the VA data list. Those who are on
5 active duty, that are sent to theater, when they come back
6 tend to stay on active duty and continue to serve on active
7 duty, so they are not released. So as the reserve component
8 continues to stay at a set number, whether it was 10, 15, 20
9 percent, 40 percent in theater, there's a higher turnover
10 rate, so that number goes up faster than the active duty
11 people who get out of the service.
12 UNIDENTIFIED SPEAKER: (Inaudible).
13 DR. BROWN: Yeah, that sounds like a pretty
14 logical --
15 UNIDENTIFIED SPEAKER: And I think as we've
16 gone through several turnovers that you're going to have a
17 higher number of people in the reserves and national guard
18 who were in the theater and now are released from active
19 duty, and therefore are on the VA's list.
20 DR. BROWN: That sound like a good
21 explanation.
22 UNIDENTIFIED SPEAKER: (Inaudible) of the
23 AFIP. I'm very glad to hear that the VA is going to do the
24 mortality study. It's been kind of a hit and miss now at
25 AFIP and at the -- Lisa Pearse (phonetic) in the mortality

1 work at the AFIP in that when someone has been active duty
2 and has come down with an illness and then comes to the
3 system, such as Walter Reed, and then is farmed out, or
4 whatever you want to call it, given to the VA, and then they
5 die of the same disease, we don't hear about it unless it
6 happens to be that the pathologist sends us the case for our
7 review as a personal interest. And so then I get a hold of
8 Lisa Pearse and say, "Do you know about this case," and she
9 says, "No." And so I'm very glad to hear that you're doing
10 that, and I hope that your group will contact Lisa Pearse,
11 and --
12 DR. BROWN: Yeah, I had the opportunity to
13 meet Lisa and talk to her about her work. I mean, our sense
14 now at this point, we've had enough experience after the
15 Vietnam war and after the first gulf war, we'll be doing
16 mortality studies and eventually morbidity studies --
17 epidemiological studies within mortality and morbidity on
18 every conflict that we've involved with, because we are
19 going to get questions from Congress and from veterans and
20 veteran service organizations and the media about what's
21 going on with their health, are they suffering any unusual
22 health problems or high rates of cancer or whatever, and
23 we'll have to be prepared to answer those questions.
24 DR. OSTROFF: Thank you. We have one more
25 presentation -- oh, I'm sorry.

1 UNIDENTIFIED SPEAKER: Just to follow on in
2 the mortality -- I don't think you'll have to answer
3 anything, if you're ready to sit down. But on the mortality
4 investigations, there's an ongoing attempt to do more of
5 that in a systematic fashion in the DoD, and at this time,
6 of course, we have AFIP's fine program looking at combat
7 casualties and any active duty casualty, or death, and doing
8 autopsies on all of those.
9 But there's been the retiree portion and there's
10 been those issues and the separations. And there is an Air
11 Force mortality registry which has struggled for years and
12 we need to decide if it should become a DoD mortality
13 registry. It certainly could be participating in something
14 like this, at least from the standpoint of already having
15 agreements with all the states and territories in obtaining
16 death certificates based on the list that they get from the
17 personnel offices. So I don't know how much of that
18 infrastructure you really set up, but that's something that
19 we may want to talk about.
20 And we considered bringing that to the board, as
21 far as what is the feeling of having a DoD mortality
22 registry, and traditionally it was considered a very vital
23 tool for public health practitioners, and yet the military
24 has never established one. The Air Force does have one. It
25 could be expanded capacity wise to accommodate the other

1 services, rather than starting one from scratch. Realigning
2 it under AFIP has been discussed. I've sent some notes to
3 Major Pierce, but I haven't been able to find the right
4 people within AFIP with whom to discuss that proposal yet.
5 So it's something that the group may want to consider.
6 The other interesting thing I wanted to mention
7 was you mentioned how the active duty were seeking care at
8 VA in higher percentages than reserves, and one potential
9 explanation I want to mention is that people who are
10 separating from active duty frequently don't necessarily
11 have a follow-on job, especially in lower levels, don't have
12 access to health care insurance yet, so it would be easier
13 for them to seek that, whereas the reserves and the guard,
14 as least 80 percent of them, as our studies have found, have
15 pre-existing health insurance that they can go back on when
16 they return.
17 DR. OSTROFF: We have one last presentation
18 from Colonel White, who has waited quite patiently. I will
19 say that given the topic that we discussed, you're going to
20 give us a snapshot at this point. And being that this is an
21 issue that's of great interest to us and is particularly
22 pertinent to our next meeting, we'd like to propose, as many
23 of the board members are not any longer here at this
24 meeting, that we give you the opportunity to give us a much
25 more extensive presentation at the next meeting, as well.

1 COLONEL WHITE: You spoiled both my jokes,
2 but never mind. I was going to say that I had already
3 accepted an unspecified inducement from Colonel Gibson not
4 to give the talk at all.
5 I also groomed my joke about (inaudible) the
6 graveyard. I'm talking about suicides, because I'm not even
7 going to talk about it.
8 So I just have a couple of administrative things I
9 wanted to sort of share with you, just first tell you about
10 the liaison officer posted in the office of the Army surgeon
11 general who used to be Colonel Mike Staunton (phonetic).
12 And about the time of the last AFEB meeting his replacement
13 arrived, and unfortunate he couldn't make it to the
14 meeting. And since that meeting he's now left, and he
15 hasn't been replaced. He will be replaced, hopefully,
16 though, in October, by someone called Colonel Phil Guenter,
17 who's a nursing officer, and so hopefully he might be able
18 to attend the next meeting.
19 And I thought you might also be interested know
20 that another British Army veteran has recently arrived in
21 the U.S., and she Major Tiffany Copshal (phonetic), who is
22 the new U.K. integrated officer at the Armed Forces Medical
23 Intelligence Center, and she's particularly interested in
24 comparative aspects of epidemiology. So I hope she'll be
25 able to participate in future meetings of the board.

1 I just want to -- this is what I was going to talk
2 about. Two reports have been published very recently by the
3 MOD (phonetic), one on rates of suicides and one on
4 methods.
5 Next. If you go to this -- go to that web site,
6 download them, they're not too big, and have a read, and
7 that's all I'm going to say. But really -- yes, you're
8 right, we can -- we can maybe deal with this more
9 appropriately in the next meeting.
10 I should do a quick plug, though, which was my --
11 one of the main aims of my talk was to say that we are very
12 keen to collaborate with U.S. and Canadian researchers on
13 certain aspects of following up on some of the findings on
14 this, so we might get some of the investigators, maybe, at
15 the next meeting to kind of present it themselves. Thank
16 you.
17 DR. OSTROFF: Can you possibly just give us
18 the -- the quick note version of what the pertinent findings
19 are?
20 COLONEL WHITE: Yes. Keep going. Keep
21 going. I'll tell you when to -- well, there was -- this is
22 one of the interesting things. There was a lower rate
23 amongst recruits -- people who haven't been trained and the
24 people who have been trained, and the initial point is that
25 this has become an area of public interest, mainly

1 because -- or largely because of death in recruit camps
2 rather than people returning from deployment. So there's a
3 different public perception of this problem, if it indeed is
4 a problem, between the U.K. and the U.S. So that was an
5 interesting finding.
6 Just go on. Yeah. Army in red, with higher rates
7 than the other services in the under 25s. And this
8 wasn't -- this looks like it's higher in the over 40s, but
9 it wasn't specifically significant when it was looked at at
10 aged standardized rates.
11 Go on. That just shows the statistical
12 significance of the difference in the trained -- by the
13 recruits and the trained people.
14 Go on. It seems to be -- suicide rates seem to
15 have peeked now and seem to be falling, and we see open
16 boxes of -- of verdict because we're waiting, so there may
17 be some changes there.
18 Okay. So lower rates than -- than when compared
19 with the U.K. general population, except for young Army
20 males. That's just showing that that is one area where it's
21 greater than the -- using a comparison rate to standardize
22 mortality rates, then that was just the one thing that is
23 greater than the U.K. population.
24 Go on. So I suppose after this discussion, the
25 things that we wanted to follow up on was the deployment

1 effect. I think that was really the -- really the one thing
2 that we're particularly interested in.
3 DR. OSTROFF: So I take that to mean that the
4 news from the report was generally good?
5 COLONEL WHITE: Yes. Well, unless you're in
6 the Army and under 25. And methods -- I mean, I'm not sure
7 that there's much to be taken away from this.
8 Go on. Right. Just the three major methods of --
9 of suicide. Hanging seems to be on the -- again, those open
10 boxes are verdicts that are still pending.
11 Next slide. Firearms peeked in the Army, and it
12 seems to be quite low in all services.
13 Go on. Poisoning by gases, not by solid or liquid
14 poisons, but this is putting the exhaust pipe in the car
15 basically seems to be on the decline, as well.
16 Go on. Really just that the Army, you know, it --
17 there's just such evidence, a lot of studies show if you
18 have access to means, then that's what you'll use, and the
19 Army has more access to firearms. So that's another area
20 that we wanted to follow up as to whether or not other
21 people in sort of occupations with -- with similar access to
22 firearms such as farm workers, whether they have similar
23 rates.
24 That's about it. There was an interesting point
25 here that poisoning with gases has reduced since catalytic

1 converts were installed in cars. And again, there is
2 evidence among the studies that shows when one method of
3 suicide becomes unavailable, other methods are used
4 instead.
5 And another bit which I haven't got on the slide
6 is interesting, from E.U. legislation, which is basically
7 trying to make a bore of car exhaust pipes incompatible with
8 garden hose pipes, so we'll see if there's an increase in
9 some other methods to compensate for that.
10 DR. OSTROFF: Our colleagues in the E.U.
11 always think that.
12 COLONEL WHITE: I think that's about it.
13 DR. OSTROFF: One question for you, because I
14 do think the board would be very interested in hearing more
15 at the next meeting, given the topic. Is this thought to
16 largely emanate from a specific intervention that's being
17 applied to deal with this problem, or --
18 COLONEL WHITE: Is what?
19 DR. OSTROFF: The declining trends that
20 you're seeing.
21 COLONEL WHITE: No. Well, this is just a
22 report. There's no -- there's no analysis that's been done,
23 really, so I'm not sure there's any thought gone into that.
24 I don't know. I couldn't answer. Again, that's something
25 we could deal with in greater detail in the next --

1 DR. OSTROFF: Because it would be nice to
2 know if there are specific interventions that are being
3 applied to --
4 COLONEL WHITE: I mean, there aren't any --
5 there are some programs, but they are not anything worthy of
6 being described as, you know, something big enough to cause
7 that decline.
8 DR. OSTROFF: Thank you very much. Are there
9 any additional comments? We have broken one of my cardinal
10 rules, which is that we're actually overtime. To my
11 knowledge, it's the first time during my tenure as board
12 president, and I apologize for that, and I'll try to make
13 amends at the next meeting. So I think with that, I think
14 what I will do is rap the gavel and call the meeting to a
15 close.
16 (Concluded at 5:14)
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1 REPORTER'S CERTIFICATION

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3 I, DANA MONTGOMERY, Certified Shorthand Reporter

4 in and for the State of Texas, hereby certify that I have

5 transcribed this meeting to the best of my ability.

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