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SPRING MEETING

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DALRYMPLE CONFERENCE ROOM  
1425 PORTER STREET  
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TUESDAY, MAY 20, 2003

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P R O C E E D I N G S

(1:30 p.m.)

(Technical malfunctions prevented adequate recording of discussion.)

DR. OSTROFF: Tab 4.

(Slide)

LTC. SKVORAK: As I said, I did this briefing to you last year, and I know Dr. Linden did it the year before that. I think one thing that you may see in a year is the fact that this briefing may be provided by the Defense Threat Reduction Agency rather than USARMC, and that's because of the first bullet here.

About a month ago the management and execution of this program had been transferred to DTRA. In addition, they established the Joint Program Executive Office which of course LTC. Clayson is a member of.

I think the natural question is what does that mean, and I don't think we really have that answer yet. The fact that execution responsibility has been transferred from ARMC to DTRA which does not have a lead lab as we do will maybe mean some changes for USAMRIID and for the

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1 program, but that's something that will evolve over  
2 the year. As far as the '04 program, that will  
3 still pretty much rest in our hands to accomplish  
4 as they get up to speed and get some hiring actions  
5 completed.

6 (Slide)

7 I always like to start here. We're  
8 going to talk about the medical countermeasures  
9 today, and that's what we like to think of as the  
10 most important part of the program, but obviously  
11 it is not. Chem/Bio defense involves some medical  
12 countermeasures, but also what we sometimes term  
13 the "non-med" or the physical countermeasures, the  
14 detectors, the decon systems, the masks, the suits,  
15 the intelligence assets which I think obviously has  
16 been covered quite well this morning but, again,  
17 our mission is to look at medical solutions to  
18 military requirements and those requirements come  
19 from those threat assessments.

20 And, finally, the education and  
21 training, which I'm not going to talk about, but  
22 the medical community is very much involved in  
23 developing and providing instruction to health care  
24 providers on chem and bio injury.

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1 (Slide)

2 As I've already said, our mission,  
3 military requirements is what we're based on.  
4 We're trying to find those medical solutions, and  
5 our goal is to prevent casualties. Short of that,  
6 to treat casualties, to treat them as soon as  
7 possible to maximize return to duty. And, finally,  
8 hand-in-hand with that is to have the diagnostic  
9 assets that are necessary far forward on the  
10 battlefield to facilitate that.

11 (Slide)

12 I think we've kind of covered this in a  
13 sense this morning, but again based on threat  
14 assessments the requirements are developed for us  
15 and they are communicated to us in a number of  
16 different forms, but based on those requirements  
17 the programs are developed that we execute. And  
18 basically this discussion today will be about our  
19 programs and our progress toward meeting those  
20 requirements.

21 (Slide)

22 Our organization to meet those program  
23 requirements is as follows. We divide ourselves  
24 into bacteriology, virology, and toxinology, and

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1       beneath that we have two subdivisions, vaccines and  
2       therapeutics.

3                       On this chart we've listed the DTO,  
4       which stands for Defense Technology Objective, and  
5       really that's just a management tool for execution.

6       They are really highlighted areas within the  
7       program, and we'll talk about those as we go along.

8       Also, the diagnostic systems and the genetically  
9       engineered threat.       That's a relatively new  
10      program.       We've had some dollars from outside  
11      sources for a few years, but we've now carved out a  
12      portion of our program to address genetically  
13      engineered threat.

14                      Also on this list it shows the DARPA  
15      transition.       That's a finite program which I'll  
16      talk about toward the end of this briefing, but it  
17      does represent dollarwise a very significant  
18      portion of our program.

19                      (Slide)

20                      As far as execution of this program, as  
21      I said, MPMC uses a lead lab, and USAMRIID here is  
22      the lead lab for MedBio defense.       In addition to  
23      USAMRIID there are a number of other Federal labs  
24      involved -- other MPMC labs are involved.       Shown

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1 here are Walter Reed and ICD in Aberdeen Proving  
2 Grounds, Institute for Chemical Defense does a  
3 little bit of work with the BOT agent. In addition  
4 to that, we also do fund the Navy Medical Research  
5 Institute, a little bit AFIP, and some work at  
6 Natick.

7 What this chart doesn't show is about a  
8 third of our program is executed extramurally as  
9 far as the dollars, and then if you include things  
10 like the CRDAs, the Cooperative Research and  
11 Development Agreements, the transfer agreements,  
12 the location for execution of this program is  
13 worldwide.

14 (Slide)

15 This is a pretty involved chart, which  
16 I have no intent of going through. I just wanted  
17 to use it to show you a few things. The dollars we  
18 use, or the tech-base dollars -- the 6-1, 6-2, 6-3  
19 which are listed up here, and then below that are  
20 the kinds of work that we're doing within this  
21 program. All of our efforts, all of our  
22 requirements are to develop FDA licensed products.

23 So, again, there's a lot of studies that need to  
24 be accomplished to meet that requirement.

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1           The other thing I wanted to talk about  
2 to lead into Col. Clayson's talk is the fact that  
3 our goal is to move these potential products to the  
4 development process and then hand them off to our  
5 advanced developer, which is JPEO. And there's a  
6 little period of transition that's kind of shown by  
7 this cross-line where we're both kind of  
8 simultaneously working on these products as the PEO  
9 moves these to IND status and Phase I clinical  
10 trials. At the conclusion, or the successful  
11 conclusion of that, it becomes an acquisition  
12 program.

13           (Slide)

14           And now we'll move into the programs  
15 themselves. I'm going to talk very briefly pretty  
16 much what we're working on and where we're at,  
17 without a lot of scientific detail.

18           (Slide)

19           This is -- we've seen lots of lists  
20 this morning. I just want to use it to show you  
21 what we are indeed working on. As far as bacterial  
22 agents, anthrax, plague, brucella and glanders are  
23 areas of active programs within our research  
24 program.

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1           We're looking at all these viruses, the  
2           encephalomyelitis viruses being the alpha viruses,  
3           the Equine Encephalitis and the top three toxins on  
4           this list here.

5           (Slide)

6           All of the areas will start out with a  
7           slide like this, but I'm not going to spend a lot  
8           of time on them. The objective for all of these  
9           areas mirror that vision and goals slide that I had  
10          before, so basically to develop prophylactic and  
11          therapeutic countermeasures. The JFOC, the Joint  
12          Future Operational Capability, is just one way to  
13          express requirements, and they are the user's input  
14          as far as the prioritization of where we should be  
15          going, and all of the work that we're doing we can  
16          categorize under one or another of the JFOCs. I'll  
17          talk about the DTOs first. After we get through  
18          the DTOs, I'll talk about the non-DTO vaccine areas  
19          and the non-DTO therapeutic areas, which will be a  
20          little different as we get to diagnostics.

21          (Slide)

22          The first DTO is the rPA vaccine.  
23          Actually that's a completed detail, completed in  
24          '02. We have completed all the requirements we

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1 think for transition out of the tech base, and a  
2 little bit differently, but NIAID is actually  
3 acting as the advanced developer for this product.

4 They selected the rPA candidate for Phase I  
5 clinical trials, and those clinical trials have  
6 begun.

7 (Slide)

8 Brucella is another one of our vaccine  
9 products. It says countermeasures, but it is a  
10 vaccine. And we're looking at a live attenuated  
11 deletion mutant candidate. This is orally  
12 administered, and it has demonstrated proof of  
13 concept for protective efficacy in non-human  
14 primates at this point.

15 (Slide)

16 Plague vaccine. Plague has also  
17 transitioned to the advanced developer. We talked  
18 a little bit about this this morning, in a sense.  
19 Both the U.S. candidate and the U.K. candidate have  
20 been transitioned. They are very similar, both use  
21 the F1 and the V antigens. The U.S. candidate is a  
22 fusion protein where the U.K. product is in  
23 combination.

24 (Slide)

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1           Then the non-DTO supporting efforts, we  
2 do obviously have a lead candidate for anthrax and  
3 plague, but we continue to work at more basic  
4 science areas along those lines. Just to know more  
5 about the organism, understand virulence factors,  
6 and possibly new targets for vaccine antigens.

7           (Slide)

8           Glanders is a much less mature effort  
9 as far as vaccine development, but it's certainly  
10 one of the areas that we're looking at, and you can  
11 see by the bullets there that the kind of efforts  
12 we're looking at are, again, those 6-1, 6-2 kind of  
13 efforts -- finding those targets, identifying  
14 animal models, that type of work. So, again, much  
15 more immature from the other efforts that I've  
16 already discussed.

17          (Slide)

18          When it comes to therapeutics under  
19 bacterial, what we do, what our primary emphasis is  
20 is to look at licensed antibiotics and  
21 investigational antibiotics and to evaluate them  
22 for our BW threat. We do have a very specific  
23 program right now looking at a number of  
24 antibiotics that we've sort of worked out a list

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1 with the FDA for plague.

2 In addition to  
3 antibiotics/antimicrobials, we're also looking at  
4 immunotherapies and immunomodulators primarily at  
5 antibody type therapies.

6 (Slide)

7 In virology, again, objective and JFOC  
8 are pretty much the same, just substitute virus for  
9 bacteria and, again, we'll start with the details  
10 and then go into the other two areas.

11 (Slide)

12 The multiagent vaccine isn't specific  
13 for virology, but it was managed in the Virology  
14 Division and that's why we talk about it here.  
15 What this was was working toward the development of  
16 a vaccine delivery platform, a platform that can  
17 deliver multiple vaccine antigens simultaneously.  
18 The lead candidate for this was an RNA replicon,  
19 which of course first into the virology area, but  
20 they've also looked at DNA vaccines and a number of  
21 other different potential delivery platforms. We  
22 look at this as more an enabling detail rather than  
23 a specific product. Only when this DTO is married  
24 up with those vaccine antigens can we really talk

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1 about a product.

2 (Slide)

3 Medical countermeasures for Equine  
4 Encephalitis. This DTO was actually focused quite  
5 a bit. We're looking at vaccine countermeasures  
6 and we're looking specifically at VEE. The results  
7 of this, a vaccine candidate has been transitioned  
8 to the advanced developer. It's a live attenuated  
9 VEE vaccine. There are three primary subtypes of  
10 VEE that we're concerned with as far as  
11 pathogenicity to humans -- it's not the complete  
12 list, but three that we're primarily interested in.

13 And we found that our candidate, the lead  
14 candidate, 3526, is efficacious. Well, it's a  
15 little premature to say three, but against two of  
16 them, and in two weeks we have an IPT that's going  
17 to look at that data, and I'm very, very confident  
18 that the IPT will also recommend the 3526 BR  
19 candidate for that third subtype of VEE.

20 (Slide)

21 We actually have our first -- this is a  
22 new detail that started this year, our first  
23 therapeutic base detail in looking at therapy for  
24 smallpox and other orthopox viruses. We're looking

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1 specifically at Cidofovir, which is a licensed  
2 antiviral. It inhibits viral DNA polymerase. This  
3 work, when we work with Variola, is all done at the  
4 CDC, so we -- not we, but the PI and the  
5 technicians and the vets pack their bags and go  
6 down to Atlanta for extended periods of time to use  
7 their facilities, but here at USAMRIID we have  
8 monkeypox and cowpox models that preliminary work  
9 can be done before moving down to the CDC.

10 (Slide)

11 As far as other viral vaccines, our  
12 goal with equine encephalitis is a multivalent  
13 vaccine that incorporates VEE, Eastern and Western.

14 We're using the same technology or applying the  
15 same technology, but having a little bit more  
16 difficult time with Eastern than Western. They are  
17 a bit more difficult to find efficacious vaccine  
18 candidates. However, at this point, we do have a  
19 Western candidate that we are moving towards non-  
20 human primate trials after success in rodent  
21 trials.

22 (Slide)

23 In addition, the filovirus vaccine  
24 actually is being cheated by the two lines I gave

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1 it here. There's actually a pretty extensive  
2 effort in the development of filovirus vaccine.  
3 The ultimate goal is a -- kind of in that bottle  
4 that was shown earlier -- a single vaccine to  
5 provide protection against both Ebola and Marburg.

6 We have leveraged a lot of the work that's been  
7 done on the multiagent vaccine technology, looking  
8 at among other things adenovirus vectors as far as  
9 a delivery platform. We're looking at both vector  
10 vaccines and also recombinant protein vaccines.  
11 One thing that's been -- actually received a lot of  
12 press is the viral-like proteins that can actually  
13 be applied to both techniques or to both strategy  
14 for vaccine. We have a very small effort looking  
15 at a next-generation smallpox vaccine looking at  
16 actually a DNA-based vaccine.

17 (Slide)

18 As far as viral therapeutics, this is a  
19 kind of general model of drug development, I think.

20 And when we talked about the bacterial or  
21 antibacterials, we're looking at licensed or  
22 investigational -- but we can kind of start in the  
23 center here at the in vitro evaluation and move our  
24 way up. When we're talking about both viral and

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1 for the toxin therapeutic, this is much more a drug  
2 discovery effort. So we're pretty much starting at  
3 the bottom, identifying those targets, identifying  
4 assays that we can screen large libraries of  
5 compounds against, finding lead compounds,  
6 optimizing those leads, and moving up. So much  
7 more labor intensive, much more intense effort to  
8 develop these viral and toxin therapeutics.

9 (Slide)

10 Antivirals for smallpox. In addition  
11 to the injectable, the IV Cidofovir we've already  
12 talked about and to the DTO, we are looking at a  
13 pro-drug for Cidofovir which can be given orally.  
14 This is almost entirely being done on extramural  
15 partnership and actually some very, very favorable  
16 results that we've found. In addition, we've been  
17 directed to look at a second therapeutic using a  
18 different mode of action than the Cidofovir, a non-  
19 DNA polymerase target.

20 Antivirals for filovirus, if you read  
21 those bullets they pretty much read the same as  
22 that triangle I showed you. So, again, a very  
23 basic effort looking for those targets and how to  
24 evaluate large libraries.

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1 (Slide)

2 In filoviruses, the main emphasis is  
3 looking at immunotherapy, looking at antibodies  
4 from multiple sources, both equine IgG, monoclonal  
5 antibodies, we're looking across the board looking  
6 for immunotherapies for filoviruses.

7 (Slide)

8 As far as toxinology, the toxins again,  
9 the objective and JFOC pretty much the same, and  
10 we've got a couple of DTOs in that area.

11 (Slide)

12 One is the alternate delivery. Again,  
13 this is one of those enabling DTOs, not very  
14 specific to toxinology. The idea here is -- again,  
15 it was just managed under this area, so that's  
16 where we put it -- looking at, again, alternate  
17 delivery ways -- respiratory, aerosol, nasal,  
18 transdermal, oral delivery, one, for convenience,  
19 but, two, to hopefully enhance immune response by  
20 stimulating both the humoral and mucosal immunity.

21 We're not in the business of developing these  
22 delivery systems, this is done completely with  
23 partnerships between industry to evaluate their  
24 systems for our different vaccine antigens. In

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1 addition, we're looking at a number of different  
2 vaccine adjuvants. What you have on that slide are  
3 a number of Becton Dickinson products that we're  
4 looking at in this program.

5 (Slide)

6 We do have a new DTO for Ricin vaccine.

7 Ricin is something that has been looked at for a  
8 long period of time, and a number of vaccine  
9 candidates have been developed. The current  
10 vaccine is an A/B chain toxin. We're looking at  
11 the A-chain and mutants of the A-chain. Some of  
12 the problems with the prior vaccines where they  
13 retained some of the toxin activity, they weren't  
14 very amenable to large-scale manufacture. They  
15 clumped. The current vaccine candidate seems to  
16 have overcome those problems and, in addition, in a  
17 rodent model they've shown 100 percent protective  
18 efficacy against an aerosol challenge, and this is  
19 moving towards non-human primates.

20 (Slide)

21 As far as the non-DTO toxin vaccines,  
22 really, we have a relatively small investment here.

23 That's because the two areas that we're concerned  
24 about we're dealing with very, very mature product.

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1 The pentavalent recombinant BoNT vaccine has been  
2 transitioned to the advanced developer, and the  
3 Staph Enterotoxin A and B vaccine candidate we feel  
4 is ready for transition to the advanced developer.

5 At this point, our efforts are pretty much just  
6 maintenance of these products.

7 (Slide)

8 As far as therapeutics, toxin  
9 therapeutics, and specifically therapeutics for the  
10 Bot neurotoxins is the largest area of investment  
11 within the Med/Bio Defense Research Program. A lot  
12 of those dollars are spent extramurally with our  
13 partner. The diagram shows sort of a strategic  
14 plan at least in a pictorial way of our efforts in  
15 this area. We're looking primarily right now at  
16 passive immunotherapy, active-site inhibitors, the  
17 proteus inhibitors are our leads in the active-site  
18 inhibitors, and looking at primarily monoclonal  
19 antibodies, looking at cocktails of monoclonal  
20 antibodies that together can provide hundreds of  
21 times more efficacy than the current VIG, for  
22 example.

23 One of the other parts of this effort  
24 is investing extramurally in those infrastructure

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1 acids that are necessary to screen the large  
2 libraries of compounds.

3 (Slide)

4 Relatively speaking, therapeutics for  
5 SE and Ricin are very, very small and very, very  
6 tech-based. Some interesting work with blocking T-  
7 cell activation -- these are super antigen toxins  
8 which have the ability to recruit very large  
9 numbers of T-cells, and to interfere with that. It  
10 provides actually some broad-spectrum therapeutics  
11 for these types of toxins.

12 (Slide)

13 Diagnostics, well, that's a little bit  
14 different as far as objectives. We're looking at  
15 primarily to develop an integrated diagnostic  
16 system, integrated meaning looking at multiple  
17 biomarkers and using multiple methods to identify  
18 those biomarkers. These needs to be, again,  
19 deployable far forward, easy to use. This is a  
20 very step-wise approach -- and I think I have my  
21 slides in a little bit backwards, but the third  
22 slide I'll show shows that step-wise approach a  
23 little bit more clearly.

24 (Slide)

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1           The first step was the common  
2 diagnostic system. This is based on nucleic acid  
3 technology. This has been transitioned to the  
4 advanced developer. In addition -- and it's on  
5 this slide, but it doesn't exactly belong here --  
6 the diagnostic systems folk have transitioned quite  
7 a few assays and reagents to the critical reagents  
8 program, Bot for the common diagnostic system or  
9 nucleic acid base, and also for the  
10 immunodiagnostic system.

11           (Slide)

12           The second step in the development of  
13 this integrated system is the immunodiagnostic  
14 platform. This is the new DTO, something we're  
15 looking at now primarily to look at toxins. They  
16 don't have nucleic acids, but secondarily, but  
17 maybe just as importantly, to provide confirmatory  
18 assays. Again, we want to look at multiple methods  
19 of looking at these multiple biomarkers just to  
20 increase our confidence level. Right now we're  
21 looking at a number of options. They're not all  
22 shown here. At the end of this year, we'll select  
23 a couple and probably look more clearly at those  
24 before moving this to the advanced developer.

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1 (Slide)

2 And this is the slide I probably should  
3 have shown you first, but this kind of describes  
4 the evolutionary strategy looking at the nucleic  
5 acids, the diagnostic, and then moving towards an  
6 integrated system.

7 (Slide)

8 Genetically engineered threats, like I  
9 said, pretty much a new program for us. We have  
10 received dollars from other sources that we've been  
11 with over a couple of years at least in a row for a  
12 change, and we again have carved out a portion of  
13 our program to continue to address this. This is  
14 pretty much a bioinformatics program ability to --  
15 we want to be able to codify virulence and toxic  
16 factors into searchable databases so that we can  
17 identify motifs that are associated with function.

18 The idea is to be able to readily identify  
19 engineered threats or newly emerging threats.

20 (Slide)

21 The DARPA -- I imagine you're mostly  
22 familiar with it. DARPA is the Defense Advanced  
23 Research Projects Agency. They do cutting-edge,  
24 out-of-the-box, whatever acronym or cliché you like

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1 to use type of research.

2           There was a problem when they did have  
3 promising products or promising candidates, what  
4 happened to them. So over a five-year period we  
5 received about \$48 million to support those  
6 projects and move them forward hopefully to IND.  
7 As of this time, we have eight projects under  
8 contract, another one pending, and another one that  
9 we have intentioned to fund to finish out this  
10 program.

11           What's been very -- what's worked out  
12 quite well with this program is the fact that the  
13 projects we've selected and funded have had  
14 application across the program, as far as viral,  
15 bacterial, toxin threat, both therapeutic and  
16 vaccine and diagnostics. It also gave us a chance  
17 to look at things that we really would have a very  
18 difficult time looking at. Funding for everybody  
19 is tight, so this gave us an opportunity to look at  
20 some of those weirder things that we would have a  
21 very difficult time being able to invest in versus  
22 some of the more conventional things that we are  
23 looking at.

24           (Slide)

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1           The next two slides are our roadmaps.  
2 I've talked a lot about, or at least I hope I've  
3 talked a lot about transition and made the point  
4 that we have a number of vaccine candidates that  
5 have been recently transitioned or are certainly  
6 ready to transition, and what this slide shows you  
7 is just our -- again, our roadmap, how these  
8 products go from the tech-base program, from the  
9 S&T program, to our advanced developer. This one  
10 shows the vaccines.

11                   (Slide)

12           On this slide we're looking at the  
13 diagnostics. The JBAIDS has Block 1 and Block 2  
14 that are two DTOs that do nicely, and the  
15 therapeutics is sort of a growing program as far as  
16 we're concerned. We certainly include Cipro there.  
17 We're looking at the Cidofovir and looking  
18 specifically at the plague therapeutics that I  
19 mentioned.

20                   (Slide)

21           Another thing that we do beside our  
22 core program is we do manage a number of  
23 congressional interest measures, and these are  
24 added. They are not part of the President's

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1 budget. What we do is we meet with these folks and  
2 we do the best we can to shape and focus the works  
3 that they intend to do to be as beneficial to our  
4 program as possible.

5 I made a mistake. This slide includes  
6 a couple of chem congressionals, the mustard gas, I  
7 think that's pretty obvious, and this one is  
8 actually a device for delivering atropine. But all  
9 the rest are specific to our program and, like I  
10 said, I think we can leverage these, that's our  
11 goal, and in most cases I think we've done quite a  
12 good job of using this work to our benefit as much  
13 as possible.

14 (Slide)

15 Actually, Gen. Martinez-Lopez touched  
16 on this quite a bit this morning, but a couple of  
17 things. We talked about NIAID being our advanced  
18 developer, so to speak, for rPA for the next  
19 generation anthrax vaccine. I talked about our work  
20 with the CDC and the smallpox.

21 Probably the biggest thing here is the  
22 Biodefense Campus. NIAID has received money in '03  
23 to build a BL4 facility that will happen here. In  
24 addition, NIAID and USAMRIID are building an animal

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1 containment, BL3 animal containment facility. The  
2 long-range goal and the planning is to build a  
3 Biodefense Campus involving NIAID, USAMRIID,  
4 hopefully a new USAMRIID building, FDA, and  
5 certainly with room for other partners.

6 (Slide)

7 And what are we worried about for the  
8 future. Actually, everything that's on here are  
9 things that we're already doing, things that I've  
10 already mentioned, but the things that I think we  
11 need to put more of an emphasis on, genetically  
12 engineered might speak for itself. Looking at some  
13 alternate therapy, especially the immunomodulators.  
14 We're looking at them as far as adjuvants for  
15 vaccines to enhance the speed and degree of immune-  
16 response to vaccines. The multiagent vaccines and  
17 alternate vaccine delivery I talked about.

18 One thing I didn't mention but is  
19 certainly part of our program is looking -- as far  
20 as another biomarker, looking at host response  
21 rather than looking at specific markers that are  
22 organic to the organism. Although that becomes a  
23 very complicated matter, we have quite a bit of  
24 work along those lines, including a couple of

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1 those. And I think that's it. So, if unless you  
2 have any questions, I'm done for this afternoon.

3 DR. OSTROFF: Thank you very much for a  
4 very breath-taking inventory of activity (inaudible  
5 words). What I'll do is open it up to the Board  
6 for questions.

7 (No response.)

8 I have one for you.

9 (Audio system failure.)

10 LTC. SKVORAK: I guess if you could --  
11 do you mean what changes have we seen in the  
12 program that have sort of been directed for us to  
13 move in, or are you saying what kind of specific  
14 accomplishments have we had in the last year?

15 DR. OSTROFF: Well, you could address  
16 both of them.

17 LTC. SKVORAK: Careful what you ask. I  
18 think Gen. Martinez asked this question to you  
19 rhetorically this morning, about changes in the  
20 program specifically talking about dollars, and I  
21 guess maybe the whole world we judge both pre- and  
22 after 9/11, and really we haven't seen any big  
23 changes or received any specific guidance that has  
24 directed us to shift our emphasis.

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1           Certainly it wouldn't be very difficult  
2 to make an argument that anthrax therapeutics or  
3 next generation anthrax vaccine carries a lot more  
4 urgency than Brucella, but we continue to move  
5 along along those lines with Brucella. Certainly,  
6 relatively speaking, within the program that  
7 emphasis is very small in comparison.

8           But, again, as far as dollars or  
9 specific dollars to the program to say move here  
10 rather than there, that has not occurred. And I  
11 really think that the biggest advances over the  
12 last year -- I mean, the things that are big  
13 picture doesn't count all the very, very, very many  
14 scientific accomplishments is the fact that we have  
15 either had two and have another couple of vaccine  
16 candidates that are ready for transition. I think  
17 that's something we need to tell people more about.

18           In addition, something that never gets  
19 any press is just the work that the diagnostic  
20 systems people do in providing the reagents and  
21 assays to the critical reagent program that then  
22 become available across -- well, I'm not sure how  
23 far across -- but generally available to the  
24 community.

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1 DR. OSTROFF: Other questions?

2 DR. CIRONE: John, you had a slide  
3 where you indicated that you were looking at  
4 therapeutic (inaudible words).

5 LTC. SKVORAK: Yes, and Jenison  
6 (phonetic) is No. 1 on that list, and I used to  
7 know -- I think it's a list of five that we kind of  
8 prioritized with the FDA. I can't recite the list  
9 to you, I just know that Jenison is No. 1 on that  
10 list, and doxy and --

11 DR. CIRONE: (Inaudible.)

12 LTC. SKVORAK: I think so. I think  
13 we're going to probably try to follow the same  
14 protocol, in a sense, that we did with the Cipro.  
15 I mean, we took a licensed, or had a licensed  
16 antibiotic that the pharmacokinetic data was  
17 available on, and then we can apply that  
18 information to the data we got from our animal, and  
19 together we could put that towards the FDA. I  
20 think we certainly have the opportunity to do that  
21 with the Jenison and the other plague antibiotics.

22

23 I think one of the things we're doing  
24 here that will take a little bit of time is

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1 developing a thick, in a sense, animal model for  
2 plague. So not just looking at pre-exposure  
3 prophylaxis or early treatment, but also looking,  
4 in addition, to looking at later treatment of these  
5 cases.

6 DR. CIRONE: Do you have a timeline?

7 LTC. SKVORAK: I'm sure the folks in  
8 the Bacteriology Division could probably provide  
9 you that, but I really can't. We had proposed this  
10 as a DTO. It got shot down. And the DTO only had I  
11 think a two-year duration. So that was our plan.  
12 And that was to get through the entire list.

13 DR. OSTROFF: (Inaudible.)

14 LTC. SKVORAK: Well, first of all,  
15 research follows the money, and our entire program  
16 is about \$100 million, and they got \$1.2 billion in  
17 '03. I mean, it's logical sense that we decide to  
18 work with them. But it works maybe even stronger  
19 the other way, that fact that -- and I think Gen.  
20 Martinez-Lopez said this this morning -- we were  
21 for a long time pretty much the only game in town,  
22 as far as the folks we have here, the capabilities  
23 that we have here, the work that we've done here.  
24 That expertise is something that they need to

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1 leverage to be able to appropriately make the  
2 changes -- not the changes -- but the advances and  
3 develop the products that they plan to develop.

4 I think also with the change in  
5 ownership as far as management and execution of  
6 this program, I think our cooperation and  
7 collaborations with NIH or NIAID specifically are  
8 going to become more and more important to us,  
9 certainly to USAMRIID, as far as their place in the  
10 program.

11 DR. OSTROFF: Are there specific  
12 interactions (inaudible words)?

13 LTC. SKVORAK: No, there is a  
14 Memorandum of Agreement with NIAID that has been  
15 signed, and it's been around for a few months -- or  
16 more than a few months, probably more than six  
17 months, I'm not really sure -- but it does outline  
18 -- it includes that animal confinement facility  
19 that I mentioned, but it does talk about very  
20 specific types of areas of research that we need to  
21 cooperate in working on. So, yes. I mean,  
22 scientifically at the PI level, that kind of  
23 arrangements are in the works.

24 DR. OSTROFF: Thanks very much.

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1 (Inaudible words.)

2 LTC. SKVORAK: Thank you, sir.

3 DR. OSTROFF: Are there other questions  
4 before we move on?

5 (No response.)

6 I'd like to, before we get to the next  
7 presentation, just welcome an additional Board  
8 member who comes (inaudible), who is attending his  
9 first meeting, Dr. Dan Blazer. I wonder if you  
10 wouldn't mind taking a minute to give us a brief  
11 synopsis of your background.

12 DR. BLAZER: Dan Blazer (inaudible  
13 words.)

14 DR. OSTROFF: Thank you so much, and  
15 welcome. We look forward to (inaudible words).

16 Let's turn to our next presentation,  
17 and this is a presentation we look forward to  
18 hearing every year, and while they're (inaudible  
19 words).

20 LTC. CLAYSON: Thank you. I'd like to  
21 start off by introducing myself. I'm the Acting  
22 Joint Product Manager for the Joint Vaccine  
23 Acquisition Program, and I would like to thank the  
24 Board for providing me the opportunity to come up

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1 here and talk to you. I've had numerous requests  
2 lately for briefings like this, and I like to take  
3 every opportunity to provide those briefings  
4 because there's a lot of misinformation out there  
5 about the JVAP, and I'd like to take the  
6 opportunity to clarify a lot of that.

7 (Slide)

8 In those requests for briefings and in  
9 numerous requests from all over the place, I  
10 commonly get asked four questions: What is the  
11 JVAP? How do we do business? Where are we in  
12 accomplishing our mission? And the last one that's  
13 not on the slide is, what are the impediments in  
14 vaccine development? And I pulled that section out  
15 of this brief because I noted that this is only a  
16 30-minute brief. However, after listening to this  
17 morning's session, I really regret doing that now.

18 I normally talk about things like  
19 bioshields, collaborations with NIAID,  
20 collaborations with NIH, funding impediments, et  
21 cetera, and I'll be more than happy to talk with  
22 you about those during the discussion period, but I  
23 won't have slides for that process.

24 (Slide)

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1                   This is our mission statement. I'm not  
2 going to read it to you, but I would like to point  
3 out the most important part of that is we're here  
4 to protect the warfighter. I have to say that  
5 because there's a huge effort right now to set up a  
6 similar program on the civilian side, and JVAP is  
7 not in the mission of going out and protecting  
8 civilians. We are concentrated on protecting the  
9 warfighter. And as a consequence, a lot of our  
10 programs and a lot of our direction are different  
11 than that going on in the civilian side.

12                   (Slide)

13                   What is the JVAP? It's a chartered  
14 product management office. Often when someone from  
15 the DOD stands up here and throws up an  
16 organizational slide, it looks like a spaghetti  
17 chart, with lines going in all kinds of different  
18 directions and you really can't make heads or tails  
19 of who's doing what to whom. I really don't have  
20 that problem.

21                   This represents the JVAP down here. I  
22 work for the PM for the Chem/Bio Medical Systems,  
23 Col. Dave Danley, who gave the presentation last  
24 year, and he works for the Joint Program Executive

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1 Office for Chem/Bio Defense.

2 My funding comes through the OSD,  
3 through the Deputy Assistant to the Secretary of  
4 Defense for Chem/Bio Defense, and my requirements  
5 come from the Joint Requirements Office which is an  
6 arm of the Joint Chiefs of Staff.

7 (Slide)

8 I use this slide to illustrate several  
9 points. And OSD staffer recently stood up in front  
10 of a committee and made the statement that it takes  
11 12 years to develop a vaccine. It's been 12 years  
12 since the Gulf War. And we're no better off today  
13 than we were at the Gulf War. And the statements  
14 were directed -- some people perceived those  
15 statements to have been directed to the JVAP. Now  
16 I would like to point out a few things with regard  
17 to that.

18 (1) The JVAP contract started in 1998,  
19 a mere five and a half years ago. (2) The program  
20 up until 1995 was managed by the Medical Research  
21 Materiel Command. At that time it was transitioned  
22 to an office called the Joint Program Office for  
23 Biological Defense, which later morphed into a PEO  
24 for Chem/Bio Defense, and last month morphed into

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1 the Joint Program Executive Office for Chem/Bio  
2 Defense.

3 Up until the JVAP contract started,  
4 funding for the program was in the onesy to twosy  
5 millions of dollars per year. There was a number  
6 thrown out this morning about -- I believe it said  
7 industry spends about \$300 million to develop a  
8 vaccine. I'm going to throw out a number a little  
9 bit later that says \$500 million. But,  
10 nevertheless, whether you use \$300 million or \$500  
11 million, you're not going to get very far if your  
12 funding lines are more than \$2 million a year.

13 After the JVAP started, we moved up  
14 about 10 or 20 fold in funding, but I would still  
15 contend that we were still grossly underfunded to  
16 do what it is that we need to do.

17 (Slide)

18 This is my organization chart. I just  
19 want to point out a few things here. You see this  
20 word "Acting" here five times on the chart, and  
21 you'll see that my busiest employee is this guy  
22 named "Vacant", which you'll also see five times on  
23 the chart. We're truly an office in transition at  
24 the moment. I have enough actors to create a drama

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1 club. I'll go into this in a little bit more detail  
2 later, but my TDA lists two people on it, myself  
3 and my deputy. Everybody else is matrixed -- and,  
4 again, I'll go into that in a few more minutes.

5 (Slide)

6 How do we do business?

7 (Slide)

8 One of the toughest parts of my job is  
9 to convince people that a vaccine is more than just  
10 a few drops of liquid in a little glass vial. It's  
11 an entire system, and all the pieces of that system  
12 have to be managed or else problems can creep up.

13 I think everyone in the room  
14 understands protective antigens and adjuvants are  
15 the key ingredient in the vaccine that makes this  
16 thing work. There are preservatives, vaccines can  
17 be lost to licensure if the preservative is not  
18 managed.

19 When we think of vaccines, we think in  
20 terms of a delivery system for a vaccine. We think  
21 in terms of a needle and a syringe, but that's not  
22 the only delivery system. For the smallpox vaccine,  
23 for example, we use a bifurcated needle and, oh, by  
24 the way, there was a tremendous education program

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1 that was involved in that, and we'll talk about  
2 that in just a few minutes, but there are oral  
3 vaccines, a potential for oral vaccines. There's a  
4 potential for transdermal vaccines. So the  
5 delivery system needs to be managed.

6 Package and labeling, as Sal Cirone has  
7 mentioned, that's really the whole crux of the  
8 matter. If it's not on the label, then the DOD  
9 can't set a policy that says you can go out and use  
10 this.

11 Manufacturing. I usually pause at this  
12 time to tell three relatively long stories, which  
13 I'm not going to tell here because I think most of  
14 you know the background. I will say, though, that  
15 we lost the adenovirus vaccine. We lost the plague  
16 vaccine. And we just very nearly lost the anthrax  
17 vaccine because we did not pay attention to the  
18 manufacturing issues on those vaccines. If DOD  
19 does not manage the manufacturing of those  
20 vaccines, we're liable to lose them.

21 Logistics and training: Storage and  
22 transportation is regulated by the FDA. We need  
23 to manage that, which should be an education. If  
24 anthrax vaccine didn't teach us anything else, it

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1 taught us if you don't educate recipients of the  
2 vaccine, you're going to have problems.

3 Provider training, bifurcated needles  
4 and smallpox. The use of bifurcated needles was  
5 very common in the '60s and '70s. Virtually all  
6 physicians knew how to use them. Move forward 30  
7 years, those docs have retired, we have a new  
8 couple of crops of docs, and many of them have  
9 never even seen a bifurcated needle, much less know  
10 how to use it. So training the providers is an  
11 issue that needs to be managed.

12 Underlying all of that is information  
13 management. Both the DOD 5000 and the FDA have  
14 requirements for managing information, and if  
15 that's not managed you can lose the products. All  
16 of these things must be managed as a system in  
17 order to ensure a supply of vaccine for the DOD.

18 (Slide)

19 We are using a prime systems contact  
20 approach in the acquisition of these vaccines.  
21 That's not an approach that's new to the DOD, we've  
22 been using that approach to acquire airplanes and  
23 ships and tanks and weapons, et cetera, but this is  
24 a rather new approach in the development of medical

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1 products.

2 The contract was awarded in 1997, but a  
3 protest arose and so it really didn't get started  
4 until 1998, and the contract has a duration of ten  
5 years. For those acquisition-minded in the crowd,  
6 it's a cost-plus award fee type contract for the  
7 development of the vaccines. Once the vaccines are  
8 developed, then we go into a firm-fixed price CLIN.

9 I'd like to point out that the contract  
10 has options for up to 18 biological warfare agent  
11 vaccines. We're nowhere near funded to develop 18  
12 vaccines. I'd like to point out again for those  
13 acquisition folks, it's the earned value management  
14 system. It's nothing new to the DOD. It is the  
15 first time that it's been used on a medical product  
16 like this. It's a system that allows us to go into  
17 the contractor's books. We know exactly where he's  
18 spending his money, when he's spending it, on what  
19 projects, who he is providing that money to, and it  
20 provides us a mechanism to gauge the progress of  
21 the contract.

22 I think I'll skip the rest of the  
23 points that are in this slide.

24 (Slide)

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1 I use this slide to demonstrate that  
2 the JVAP really is a "lean, mean, fighting  
3 machine". I mentioned that my TDA has two people  
4 on it, myself and my Deputy. Everybody else is  
5 matrixed from some other organization. The four  
6 Vaccine Managers are government positions which are  
7 matrixed out of USAMDA. I receive acquisitions,  
8 scientific, legal, regulatory affairs support,  
9 logistics support, and a special immunization  
10 program support from MRMC. I receive contracting  
11 support from the Missile Command. I also receive  
12 support from my parent organization, CBMS, in terms  
13 of financial management, regulatory affairs, and  
14 acquisition program management.

15 Now, how do I utilize these people?  
16 Our prime systems contractor, Dynport Vaccine  
17 Company, has a product development team for each of  
18 the products it's developing. And so for each  
19 product that's being developed, I have a Vaccine  
20 Manager that is part of that team, attends all the  
21 meetings of that team, participates in the  
22 technical aspects of the development of the  
23 product.

24 But most importantly, this company is

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1 made up primarily of scientists. Scientists are  
2 great at taking something and tinkering with and  
3 improving it, and tinkering with it a little bit  
4 more and improving it, and tinkering and improving.

5 It's what they do. Where I come from, it's what  
6 they do best. However, I need a product, and I  
7 need it yesterday.

8 So I need them to take that product out  
9 and get it developed. And so one of the biggest  
10 jobs for these four Vaccine Managers is to make  
11 sure that the company stays on track, doesn't go  
12 off and do a scientific study that's not needed for  
13 an FDA licensure. If they do do those studies,  
14 they need to be assured that the DOD will not pay  
15 for those studies, and that usually does cease the  
16 desire to go down that path.

17 (Slide)

18 I'm often asked how do we decide what  
19 products to develop. I think you are all familiar  
20 with the Joint Requirements Office. It's an arm of  
21 the Joint Chiefs of Staff. They develop a list  
22 called the Joint Priority List. The last list that  
23 was published was in FY '02. It had 72 items on  
24 it. I think 18 of them were medical products.

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1 They develop this list based on the Chairman's  
2 Treat List and also based on current and potential  
3 technologies that they're aware of at the time.

4 So, we take that list and we look at  
5 the vaccine candidates which come from places like  
6 USAMRIID, but they don't have to come from  
7 USAMRIID. They can come from industry. They can  
8 come from our Coalition partners. And we take our  
9 available funding and then we go into a planning  
10 mode, and we prepare a lot of planning documents,  
11 and that's a lot of what my staff does, is a lot of  
12 planning, developing acquisition strategies,  
13 integrated master plans which contain work  
14 breakdown structures, schedules and cost estimates,  
15 and we develop risk management plans.

16 Once the planning phase is done, we go  
17 into what I call "work mode". We do a lot of  
18 budget submissions, a lot of contract  
19 modifications, but we also manage the contracts.  
20 We manage, too, an acquisition program baseline,  
21 and we use earned value management system as a tool  
22 to manage that baseline. The better we plan, the  
23 better the product is.

24 (Slide)

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1           So where are we in accomplishing our  
2 mission?

3           (Slide)

4           For anthrax, we have a licensed  
5 vaccine, Biothrax, licensed for pre-exposure use  
6 only. The license has a 6-dose vaccine. As Col  
7 Grabenstein pointed out earlier, there's a lot of  
8 evidence that would suggest that the vaccine is  
9 just as effective after two or maybe three doses,  
10 but not enough to convince the FDA. So Congress  
11 has mandated a study that the CDC is conducting to  
12 look at reducing the number of immunizations for  
13 that vaccine. That study I believe is a six-year  
14 study with a preliminary report -- it's a five-year  
15 study with a preliminary report coming out in about  
16 8 months, I believe -- somewhere in that  
17 neighborhood, 6 to 8 months. That preliminary  
18 report might be able to reduce it from a 6-dose to  
19 a 5-dose, but it's going to take the full five  
20 years before we can get FDA approval to reduce this  
21 down to maybe a 3- or 2-dose vaccine.

22           Due to time, I'm not going to go into  
23 some of these other products that we're not  
24 actively working on, but would like to point out

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1 that we are working on a recombinant PA vaccine.  
2 In fact, we're already in clinical trials on that  
3 vaccine. In fact, we're the only organization at  
4 this time in clinical trials on the rPA vaccine,  
5 despite the fact that NIAID has two new contracts  
6 for that, and they are also collaborating with  
7 USAMRIID on what is essentially a third candidate.  
8 All four candidates of that vaccine are nearly  
9 identical from a technical perspective.

10 (Slide)

11 Let's move on to smallpox. We have a  
12 licensed Dryvax vaccine. The DOD has acquired 1.5  
13 million doses of that vaccine. You've already  
14 heard some of the results of our immunization  
15 program this morning. There are some problems with  
16 this vaccine. You heard some of the safety  
17 problems this morning. It's also not particularly  
18 what I would call a "clean" vaccine. It's  
19 literally made from scraping the bellies of cows.  
20 We're working on a cell-culture vaccine. By  
21 looking at cell-culture, we can avoid a lot of the  
22 problems or contaminants of the vaccine as with the  
23 DryVax vaccine. That vaccine has completed a 350-  
24 person Phase I safety trial. That trial had five

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1 cohorts, the fifth cohort being a dilution study.  
2 Nearly 100 percent take rate at all dilutions. The  
3 greatest dilution was down to 1:50.

4 Health and Human Services, as you  
5 probably are aware, also has a contract with  
6 Acambis for 155 million doses of vaccine which has  
7 already been manufactured and bottled at the same  
8 dose as the original DryVax vaccine. That's an  
9 important point for the following reasons: Our  
10 results demonstrate that our vaccine, which is very  
11 nearly identical to the Health and Human Services  
12 vaccine except that ours is grown in human cells,  
13 theirs is grown in a cell line derived from African  
14 green monkey kidney cells.

15 Our vaccine is able to be diluted down  
16 to 1:50 and still have a 100 percent take rate. We  
17 believe that as you dilute the vaccine, you have at  
18 least a potential to reduce the safety problems  
19 with the vaccine, or to present a better safety  
20 profile.

21 Health and Human Services vaccine is  
22 already bottled. There's nothing they can do about  
23 that without remanufacturing the vaccine at a  
24 higher dilution. We're still in the manufacturing

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1 process. We have the capability to bottle our  
2 vaccine at whatever dose we choose to do so.

3 There's a panel that's set aside to  
4 look at both the Health and Human Services vaccine  
5 and the DOD vaccine to determine which direction  
6 the DOD would like to go. Regardless of that  
7 panel, I'm running out of money at the end of this  
8 year. Unless I get some funding relief, I'll have  
9 no option but to terminate this program.

10 (Slide)

11 Botulism, there are no licensed  
12 products. There are, as you may be aware, seven  
13 serotypes of the toxin, five of which are of  
14 importance to the DOD. However, we don't have  
15 enough money in our budget to develop a pentavalent  
16 vaccine, so we got the combat developer to agree to  
17 do this in a stepwise fashion.

18 We're developing an A/B vaccine as a  
19 Block 1, and as funds become available we'll  
20 develop either a pentavalent or a CEF vaccine as a  
21 Block 2. And we hope to be in clinical trials by  
22 next year.

23 (Slide)

24 Plague vaccine. We lost the Greer

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1 (phonetic) vaccine, but from a BW perspective, a  
2 biodefense perspective, it really wasn't a loss  
3 because that vaccine was not protective against  
4 aerosolized challenge.

5 We have an F<sub>1</sub>V vaccine candidate which  
6 originated from USAMRIID, which should be in  
7 clinical trials next year. In addition to the U.S.  
8 candidate, the Brits have an F<sub>1+V</sub>, if I will. This  
9 was a fusion candidate -- theirs are two separate  
10 proteins -- for which they have done a small  
11 clinical trial in Germany. This vaccine has  
12 undergone a non-human primate study, and we know  
13 that this vaccine is effective against an aerosol  
14 challenge. We're not sure yet whether U.K. vaccine  
15 is effective. We have planned to do a study this  
16 fall with the U.K. vaccine to determine whether it  
17 is effective against an aerosolized challenge.

18 (Slide)

19 A whole group of viruses known as  
20 encephalitis viruses -- I think this group already  
21 knows that. There are no licensed products. There  
22 are some vaccines that have been stockpiled, made  
23 primarily back in the offensive BW warfare days to  
24 protect at-risk laboratory workers.

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1           The VEE vaccine is effective, but it's  
2 effective by making you sick, which is not really  
3 acceptable in the military setting. USAMRIID has  
4 developed an infectious clone vaccine which does  
5 not make animals sick as the old legacy vaccine  
6 does. So we should be in clinical trials next  
7 year.

8           (Slide)

9           Tularemia, one of my favorite pets.  
10 There are no vaccines available. There is this  
11 live vaccine strain which is incredibly similar to  
12 the strain that the Russians used for nearly 70  
13 years, which they used to eradicate disease in  
14 areas of concern to them. It's a vaccine that  
15 USAMRIID has been using for decades to protect at-  
16 risk laboratory workers. It seems to work like a  
17 charm. The only problem with this program is that  
18 funding is cut in '04 and '05 -- I mean, completely  
19 eliminated in '04 and '05 and directed at  
20 nonmedical program. Without funding, we can't  
21 enter the clinical trials, and I'm being forced to  
22 terminate this program and transition it over to  
23 NIAID, who I won't say is reluctant to take it, but  
24 is not taking it with open arms, might I add.

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1 (Slide)

2 I usually at this time talk about  
3 problems of integrating the DOD 5000 process and  
4 the FDA process, and this slide -- I use this slide  
5 to talk about that. That's not really what I want  
6 to focus on today, though. What I'd like to focus  
7 in this group is even though the JVAP has only been  
8 around for five and a half years, we've got  
9 products across the entire spectrum here. There is  
10 Biothrax which is into production and which John  
11 uses that at every opportunity. We try to stay  
12 ahead of him, and so far we've managed to do so,  
13 until the policy changes.

14 Dryvax, we have a stockpile of that,  
15 but the manufacturer is not going to manufacture  
16 that vaccine any further. We have Vaccinia  
17 Immunoglobulin, which I haven't mentioned  
18 previously. As I believe this group is aware, this  
19 vaccine does cause reactions and you need to have  
20 VIG to treat those reactions, and VIG is in the  
21 last stages of the clinical trial, just prior to  
22 BLA submission and FDA approval. We have the  
23 smallpox -- cell-cultured smallpox vaccine which is  
24 completed the five-cohort Phase 1 study and is into

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1 just shy of consistency lot production. And the  
2 rest of these vaccines are in various stages of  
3 process development, process validation. Next  
4 generation anthrax vaccine is actually in a Phase 1  
5 clinical trial.

6 (Slide)

7 I'd like to talk about a few industry  
8 benchmarks. These are published figures from a  
9 report to Congress. Industry claims in numerous  
10 places that it invests around \$500 million for each  
11 vaccine that it develops. They also claim that it  
12 takes them 8 to 12 years to develop a vaccine. And  
13 DOD is often asked "How come you guys don't have a  
14 vaccine when you've only been around five and a  
15 half years and you're spending less than \$1 million  
16 on vaccine?"

17 (Slide)

18 I use this slide to talk about our  
19 funding. Where you see the line going across the  
20 board, those are programs that are fully funded to  
21 go to FDA licensure. I mentioned earlier that I  
22 have options under contract for 18 different  
23 products. I think you can see here I'm fully  
24 funded to take two of them across the finish line.

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1           My smallpox funding dries up at the end  
2 of FY '03. Unless I get additional funds, I'm  
3 going to be forced to terminate that program.

4           The tularemia program was fully funded  
5 to licensure until the '04 and '05 piece was taken  
6 out, and I cannot enter into clinical trials  
7 without adequate funding to pay for the entire  
8 trial, so I'm going to be forced to terminate this  
9 program at the end of the year and transition it  
10 over to NIAID.

11           The funding that was out here in '06  
12 through '09 I'm going to realign towards VEE in an  
13 attempt to make VEE a fully funded program. At the  
14 moment, though, the funding for VEE dries up and  
15 that program will end in FY '05 unless I receive  
16 additional funds.

17           As John mentioned a little earlier, the  
18 SE program is ready to transition. All the  
19 documents and paperwork are ready. We could hold  
20 the meeting today. But without adequate funding, I  
21 can't move forward with it, and so that program  
22 will sit on the shelf waiting for additional funds.

23           Next generation anthrax program is  
24 funded through FY '04. That came down in a

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1 specific program decision memorandum which directed  
2 us to (a) manufacture a lot, and (b) conduct a  
3 clinical trial, and that's it. So my intentions  
4 with that program are to produce a -- to  
5 manufacture a clinical lot, which I've done, and to  
6 do a clinical trial, which I've already started,  
7 and at the end of the trial terminate the program  
8 unless I get additional funding.

9 That's the end of my presentation. Are  
10 there any questions?

11 DR. OSTROFF: Thanks very much. I'll  
12 open it up at this time for questions.

13 DR. SHOPE: The Joint Chiefs provide  
14 you with the requirement, and then you -- do they  
15 furnish you -- have something to say about the  
16 funding?

17 LTC. CLAYSON: Do they have something  
18 to say about the funding. I think the best way to  
19 answer that is if you stack up all of the  
20 requirements in the DOD and you stack up all the  
21 available funding, there's enough funding to take  
22 care of about 1/3 of the requirements for the DOD.

23 (Technical malfunctions prevented  
24 adequate recordation of discussion.)

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1 LTC. CLAYSON: I think I've got a  
2 couple of additions to that. One is -- maybe the  
3 point went by real quick, but if you do take all of  
4 DOD requirements, medical and nonmedical, and you  
5 stack up with the available funding, there's only  
6 enough funding to fund the top third of those  
7 requirements. So the rest of those requirements go  
8 unanswered.

9 The second, you mentioned the billions  
10 of dollars going to NIAID. I recently attended a  
11 lecture from Tony Fauci, Director of NIAID, for  
12 where that money is going, and you'd be surprised.

13 Only about \$300 million, or a little over \$300  
14 million of that is actually going towards vaccine  
15 development. Around \$700 million of that is going  
16 into facility development. Those facilities are  
17 going to be BL3, maybe BL4 facilities, none of  
18 which will have the capability of doing aerosolized  
19 challenge. That doesn't leave very much left of  
20 the \$1.2 billion budget. So I say that just to put  
21 that into perspective. When you hear the term \$1.8  
22 billion or \$1.2 billion going to NIAID, only a  
23 small portion of that is actually going towards  
24 vaccine development.

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1                   (Technical malfunctions prevented  
2 adequate recordation of discussion.)

3                   LTC. CLAYSON: You're going to ask me  
4 to philosophize, which I'm very willing to do, but  
5 -- the DOD has the processes in place to make this  
6 work, we just don't have the funds. I would  
7 contend that NIAID and Bioshield will not fix the  
8 problem. NIAID does not really have the processes  
9 in place to take a vaccine all the way to FDA  
10 licensure, and Tony Fauci will be the first one to  
11 tell you that.

12                   What they do best is to generate  
13 candidates, do a Phase 1 clinical trial, and then  
14 throw it over the fence hoping that industry will  
15 pick it up.

16                   What Bioshield pretends to do -- and  
17 keep in mind that there are about a dozen different  
18 versions of Bioshield out there, so each version is  
19 a little different -- but what it pretends to do is  
20 provide an incentive to industry to go ahead and  
21 pick that vaccine up, to go ahead and pour \$100 or  
22 \$200 million of their own money into developing a  
23 manufacturing plant to manufacture the vaccines,  
24 then to do their Phase 2 clinical trials on their

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1 own dime. When they get ready to enter a Phase 3  
2 clinical trial, Bioshield then kicks in and pays  
3 for that trial, pays for the procurement of the  
4 vaccine, and guarantees the purchase of x-number of  
5 doses of vaccine. That's the way it's envisioned  
6 to work.

7 Some people have hope in that, others  
8 argue that will never work. I've heard countless  
9 number of industry people who say "There's not  
10 enough money in Bioshield to cause us to go out and  
11 spend \$200 million developing our own  
12 infrastructure and doing our own clinical trials  
13 just for the promise that there may be money out  
14 there to buy it in the end". The whole market is  
15 driven by the market -- I should say the whole  
16 industry is driven by the market. When they go out  
17 and look to see which vaccines they're going to  
18 manufacture, it's usually done based on the market  
19 and what they think their profit margins will be.  
20 They're looking for the neighborhood of \$300 to  
21 \$500 million a year profit on their given vaccines.

22 You don't have to be a math wizard to figure out  
23 that that's about \$1 million a day.

24 When they are developing the vaccines

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1 in industry, every day they're not on the market is  
2 \$1 million lost. So they take every shortcut they  
3 can take. It still takes them 8-12 years to do.

4 DR. OSTROFF: I think we're going to  
5 have to break. Again, I thank you for the  
6 (inaudible). Why don't we take a five-minute break  
7 and come back at 3:00 o'clock so we can get started  
8 with the next (inaudible).

9 (Whereupon, a short break was taken.)

10 DR. OSTROFF: I think we need to get  
11 started. We will hear a series of presentations  
12 from three of the services concerning the physical  
13 examination requirements, and I'll point out the  
14 genesis of the presentations is a question  
15 specifically to the Board, which is to identify the  
16 appropriate content, methodology and periodicity  
17 for routine medical examinations in the Armed  
18 Forces to be applied uniformly across all Services,  
19 and consider aligning the requirement with Health  
20 and Human Services Preventive Task Force  
21 recommendations to meet military operational  
22 requirements where appropriate.

23 So we'll have a series of  
24 presentations. The first is by Col. Bob DeFrait

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1 on the Army physical exam requirements.

2 COL. DeFRAITES: I'm here, but these  
3 are not my slides. This is the question -- oh,  
4 Lynn's going to go first. Okay.

5 MS. PAHLAND: I'm Lynn Pahland. I'm  
6 from the Office of the Deputy Assistant Secretary  
7 of Defense for Program Policy, and we're the office  
8 that is bringing this question to you today. This  
9 question was originally devised eight or nine  
10 months ago, and we're finding that there are many  
11 layers to this onion.

12 (Slide)

13 The question we're asking is for you to  
14 identify the appropriate content, methodology and  
15 periodicity for routine medical examinations in the  
16 Armed Forces -- by routine medical examinations, we  
17 are referring to both periodic complete physical  
18 examinations and routine provider delivered  
19 preventive assessments and services. We are not  
20 referring to self-assessment tools, which we will  
21 be questioning the Board at a later time, nor are  
22 we referring to specific occupational examinations.

23 The question relates to policy for all  
24 beneficiaries and especially and separately the

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1 appropriate policy for all service members in the  
2 context of a uniform program across the services.

3 (Slide)

4 Validated national guidelines such as  
5 those from the U.S. Preventive Services Task Force  
6 may be appropriate for our civilian beneficiaries  
7 and, as a minimum, a starting point for our service  
8 members. Most of our Active Duty service members  
9 are in very stressful occupations to begin with  
10 that require long hours, physical fitness, frequent  
11 family separation, and exposure to environmental  
12 hazards. In addition, these service members are  
13 potentially deployable to environments which may be  
14 primitive, harsh, and extremely stressful. In  
15 deployment, the health of each individual is  
16 mission-critical.

17 (Slide)

18 We have existing mandates to accomplish  
19 and exceed Healthy People 2010 goals and  
20 objectives, and to implement Put Prevention into  
21 Practice. We would like you to consider aspects of  
22 medical evaluations for health promotion purposes,  
23 and not just for the identification of illness and  
24 injury or separation from the military.

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1 Force health protection applies to the  
2 total force, Active and Reserve, which involves  
3 complete initial health assessment on accession and  
4 periodic updates of health status for employment  
5 and medical readiness purposes.

6 DOD now has a policy on individual  
7 medical readiness. The objective is to ensure that  
8 we have a healthy and fit force focused on optimal  
9 health status and protected from disease and  
10 injury. Also, we have legal and policy mandates  
11 that are currently in effect.

12 That's our question. Any questions on  
13 the question?

14 DR. OSTROFF: Thanks very much. Now  
15 let's move on to the presentation from the  
16 services. Col. DeFraitres?

17 COL. DEFRAITES: Thank you very much.  
18 My title is the Deputy Functional Proponent for  
19 Preventive Medicine at the Army Surgeon General's  
20 Office. As such, I'm really taking Jeff  
21 Gunzenhauser's place. Normally he would be up here  
22 making these presentations.

23 I don't know if the Board is aware, but  
24 Col. Gunzenhauser is preparing to retire from the

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1 Army, and this week he is out in California looking  
2 for a home and a job. So I guess you've already  
3 seen him at the last meeting, it was the last  
4 meeting he will be attending. I don't know if he  
5 announced it at the time there, but I thought you'd  
6 want to know where he is. So I'm taking his place  
7 for these presentations. Let's go to the next  
8 slide.

9 DR. OSTROFF: Unfortunately, the last  
10 meeting was --

11 COL. DEFRAITES: Oh, right, that was  
12 the snow meeting, right.

13 (Slide)

14 My slides, unfortunately, don't cover  
15 the scope that Lynn mentioned in terms of Army  
16 policy for examinations of all classes of  
17 beneficiaries, and also there's a one-page  
18 information paper on the examination policy for  
19 Army, specifically talking about soldiers. It  
20 doesn't really get into beneficiary exams.

21 This first slide shows the division of  
22 the policy from Active Component -- that is the  
23 soldiers that are on Active Duty from the Reserve  
24 Component, which is the U.S. Army Reserve and the

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1 Army National Guard. So you can see here what the  
2 requirements are for a periodic medical/physical  
3 examination. The regulation that we turn to for  
4 guidance on this type of approach is an Army  
5 Regulation 40-501.

6 You can see that Congress -- there's  
7 not a law that mandates physical examinations for  
8 Active soldiers, but there is a law that mandates  
9 the Reserve Component exam. Next slide, please.

10 (Slide)

11 This, in general, is the scope of the  
12 periodic physical, and you can read that for  
13 yourself. And this applies to males, of course,  
14 the testicular exam. I'll talk about the female  
15 exam in a moment. So it's the same for all males  
16 up to age 40, then after age 40, electrocardiogram,  
17 prostate exam, and intraocular pressure are also  
18 added. Next slide, please.

19 (Slide)

20 In terms of laboratory screening, it's  
21 covered on this slide. And, again, at age 40 kicks  
22 in an additional screening. For the Army we start  
23 screening for prostate cancer with a PSA at age 40.  
24 FBS stands for fasting blood sugar. I think the

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1 other abbreviations are pretty straightforward.

2 Next slide.

3 (Slide)

4 For women on active duty, an annual  
5 pelvic exam with a PAP smear, and for under age 25,  
6 screen for chlamydia. And the annual breast exam.

7 And then for mammography for women starting at age  
8 40, every two years until age 50, and then  
9 annually. Next slide.

10 (Slide)

11 Then for those women in the Reserve  
12 Components, again, because of course the Reserve  
13 Components are not on active duty the entire time,  
14 so as far as benefiting from care, they don't. So  
15 essentially their requirements kick in if they are  
16 on active duty tour for one or more years. And if  
17 they are not on active duty, then pelvic exam with  
18 the PAP smear is part of the five-year physical.  
19 We don't have a mandate for any type of annual  
20 screening for mammography for women in the Reserve  
21 Component.

22 That's the end of my remarks. I'll  
23 just say as far as other screening opportunities,  
24 other Army Regulations including the regulation for

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1 health promotion address some of these other  
2 issues, but in terms of a physical examination  
3 requirement, it's pretty much covered in what I  
4 just said. I'll be happy to take any questions, I  
5 hope I can answer them.

6 DR. OSTROFF: Thank you very much. Let  
7 me just ask this question (inaudible).

8 COL. DeFRAITES: I'm not sure if they  
9 mandated the periodicity of them, I don't know.  
10 I'm not that familiar with the law.

11 (Technical malfunctions prevented  
12 adequate recordation of discussion.)

13 COL. DeFRAITES: Well, I think the  
14 periodicity of the physical examinations has been  
15 altered in at least the last five years which  
16 dropped most of the requirements for physical  
17 examinations for active service members under the  
18 age of 30, except for the accession physical of  
19 course.

20 DR. SHOPE: (Inaudible.)

21 COL. DeFRAITES: It's not in the  
22 regulation, not by regulation. I would say just one  
23 thing, there is -- you know, for general officers,  
24 I didn't talk about the general officer medical

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1 program. They get an annual physical examination  
2 and it's much more in-depth for general officers.

3 DR. PATRICK: (Inaudible.) What  
4 percentage would fall in that category?

5 COL. DeFRAITES: As many occupations as  
6 are in the Army, depending on what the job  
7 description is would drive what additional  
8 examinations -- you know, if you're working with a  
9 nerve agent, you would get cholinesterase  
10 periodically. But in the regulation itself, I'm  
11 not that familiar with which occupations are  
12 singled out as having additional physical exam  
13 requirements.

14 DR. HERBOLD: Just a question for  
15 clarification. If you don't fall into any  
16 occupation health in these requirements, you would  
17 not require a periodic examination (inaudible)?

18 COL. DeFRAITES: That's right, after  
19 accession until age 30.

20 DR. ALEXANDER: My question is similar.  
21 (Inaudible.)

22 COL. DeFRAITES: I'm sorry, what was  
23 your question?

24 DR. ALEXANDER: How is this taken into

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1 consideration?

2 COL. DeFRAITES: It's not in the 40-501  
3 Regulation. In terms of consideration of whether  
4 they data are available, I suppose they are. I  
5 didn't realize that was the question you were  
6 addressing. Maybe I don't understand the question  
7 still.

8 MS. EMBREY: (Inaudible.)

9 COL. DeFRAITES: Well, the way we  
10 interpreted the question was at what time are you  
11 mandated by the Army to come in and have a  
12 physical, no matter what, and that's what those  
13 slides address. That's the minimum. Clearly, in  
14 our routine readiness preparation for deployment,  
15 for example, there is a rudimentary review of do  
16 you have a cast. Well, the usual things that are  
17 covered on the pre-deployment questionnaire, for  
18 example, in the routine medical preparation for  
19 deployment, the individual readiness items, one of  
20 which is are you physically ready to deploy and, if  
21 not, what's the problem.

22 So, that's beyond the scope I thought  
23 of this question. That goes beyond -- we don't  
24 have a birth month medical exam, for example. We

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1 have a requirement for an annual dental exam, but  
2 not a requirement for any kind of medical  
3 examination in the Army.

4 DR. OSTROFF: Thanks. Let's move on to  
5 the next presentation from Capt. Yund, and I  
6 hesitate to say that this is also his last meeting  
7 (inaudible.)

8 CAPT. YUND: Well, that saved me from  
9 having to mention it, but I'm moving on to sunny  
10 Sicily for a three-year tour as the Officer in  
11 Charge of the Preventive Medicine Unit there, and  
12 I'm expecting quite a change of pace from life  
13 inside the Beltway.

14 DR. OSTROFF: And we are envious.

15 (Slide)

16 CAPT. YUND: Well, as with the other  
17 services, we have multiple types of physical  
18 examinations. These are a few of the biggies. I'm  
19 going to talk a little bit about the periodic or  
20 general duty exam, and then I'm going to talk a  
21 little more about a new thing we have called the  
22 Preventive Health Assessment.

23 (Slide)

24 These are just some of the many other

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1 types of examinations, physical examinations that  
2 are required for certain occasions.

3 (Slide)

4 I won't really talk any specifics about  
5 the physical examination on entry into the service.

6

7 (Slide)

8 As far as the periodic physical  
9 examination, as far as the content of the physical  
10 exam, it's very similar to the Army's exam, maybe a  
11 few differences here and there, but the periodicity  
12 is where the major difference comes, and the  
13 periodicity is from entry into service the exam  
14 needs to be done every five years until age 50, and  
15 then every two years from 50 to 60, and then  
16 annually after age 60.

17 (Slide)

18 I want to talk about special duty  
19 examinations such as aviation exams.

20 (Slide)

21 I do want to talk a little more about  
22 the Preventive Health Assessment, the instruction  
23 that mandates the Preventive Health Assessment is  
24 not quite a year and a half old, hasn't been

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1 completely and fully implemented throughout the  
2 Navy and Marine Corps, but the instruction is a  
3 dual-signed OPNAV, which means it's signed by  
4 someone under the Chief of Naval Operations, in  
5 this case the Surgeon General of the Navy, and also  
6 by someone from Headquarters Marine Corps, in this  
7 case the Assistant Commandant of the Marine Corps.

8 So this covers the Marine Corps also. It's  
9 based generally on U.S. Preventive Services Task  
10 Force recommendations, and the purpose according to  
11 the instruction -- I won't read, but it's to try to  
12 make sure that we do all of these good things every  
13 year for people.

14 (Slide)

15 It's an annual -- not a physical  
16 examination, but an annual interview, at least,  
17 with whatever health interventions are identified  
18 as appropriate being ordered or taken care of at  
19 that point.

20 (Slide)

21 It's documented on the DD 2766, and  
22 immunization records, we have a number of those but  
23 this is the new one that has all the blocks in it  
24 to record all the information that's required by

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1 law.

2 (Slide)

3 And now I'll get to some of the  
4 specifics of the Preventive Health Assessment:  
5 blood pressure measurement, height and weight,  
6 colorectal screening as appropriate for age, lipid  
7 screening again as appropriate for age,  
8 cardiovascular risk factor screening, medical  
9 readiness for deployment. The instruction doesn't  
10 really get into a lot of detail about medical  
11 readiness for deployment, but tomorrow at the  
12 Preventive Medicine Update I'll have some more  
13 information for you about the new individual  
14 medical readiness policy for DOD, and how the  
15 services will be applying that, or implementing  
16 that.

17 (Slide)

18 Immunization status, occupational risk  
19 and surveillance examinations -- again, there are  
20 many different types of exams depending on what the  
21 particular job is that a person does, specific exam  
22 and specific labs for certain types of paints, for  
23 pesticide applicators, for fuel handlers. DOD has  
24 a program, I guess you would call it, called the

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1 Medical Matrix, which allows you to print out the  
2 history form and the physical examination form for  
3 someone for whatever constellation of occupational  
4 exams they have, or occupational risks that they  
5 have. Someone may have multiple occupational  
6 risks, and with this Medical Matrix all of these  
7 requirements are accommodated on a single form  
8 combined for the three or whatever types of exams.

9 Female health screening, again,  
10 according to whatever risk factors or whatever is  
11 appropriate for the woman. Similar male health  
12 screening, and health risk appraisal. This is not  
13 really something that we have implemented in a  
14 mandatory fashion. And I'll just go ahead and take  
15 questions now.

16 DR. OSTROFF: Questions?

17 DR. HERBOLD: (Inaudible.)

18 CAPT. YUND: Yes. When everybody in  
19 the Navy and Marine Corps gets lined up behind this  
20 instruction and we start implementing fully, that's  
21 what will happen, an encounter which will then  
22 generate whatever consults are required for  
23 specific examinations that are age and gender  
24 appropriate.

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1 CAPT. SCHOR: (Inaudible.)

2 DR. PATRICK: (Inaudible.)

3 CAPT. YUND: Again, depending on the  
4 age and risk factors of the individual, it  
5 certainly would be an annual exam for sexually  
6 active women under the age of 25, and modifications  
7 to that as appropriate.

8 MS. EMBREY: (Inaudible.)

9 CAPT. YUND: That's an excellent  
10 question, and I really don't think I have the  
11 answer. This was well along in the process of final  
12 coordination when I landed at BUMED. Ken's looking  
13 like he has more information on this than I do, so  
14 I'll let him take a shot at it.

15 CAPT. SCHOR: (Inaudible.)

16 DR. OSTROFF: Jeff, it wasn't  
17 specifically stated, but (inaudible).

18 CAPT. YUND: Yes, there is a difference  
19 between what's done for Active duty and Reserves.  
20 I believe that the requirement in the Navy and  
21 Marine Corps is the same statutory requirement that  
22 Col. DeFraithe mentioned, and that's an exam every  
23 five years, and I'm not aware that the Preventive  
24 Health Assessment applies at all to Reserve

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1 Components.

2 CAPT. SCHOR: The only other thing I  
3 can add is that there is an annual (inaudible).

4 DR. PATRICK: (Inaudible.)

5 CAPT. YUND: Absolutely. And that's  
6 all specifically addressed in the instruction,  
7 which is actually only five pages long, but the  
8 appropriate counseling for smoking cessation, for  
9 physical activity, for weight reduction, for  
10 modifying dietary habits in order to get lipids  
11 under control, all of the appropriate counseling is  
12 discussed and specifically required by the  
13 instruction.

14 (Technical malfunctions prevented  
15 adequate recordation of discussion.)

16 CAPT. YUND: Well, my understanding is  
17 that 15 or 20 years ago -- and Dr. Zimmel may be  
18 able to clarify our memory on this -- at one point  
19 there was a requirement for an annual physical  
20 examination, and that went for a brief period of  
21 time to an exam every three years because of the --  
22 at least I'll say -- obvious lack of utility in  
23 doing a complete physical examination every year in  
24 young healthy people, went to three years for a

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1 brief period of time, and that was superseded by  
2 another even sort of number that sort of pops into  
3 your head -- well, let's try five years -- and five  
4 years is where it has stuck except for I think the  
5 Air Force has some interesting other policies  
6 besides a physical examination at all. But, no,  
7 certainly the five years is not something that we  
8 found data to say this is the interval that's  
9 appropriate to do a full physical examination on  
10 people. It evolved from something that was too  
11 frequent to something that was less frequent to  
12 something that was a little less frequent than that  
13 yet.

14 DR. ZIMMEL: I can't argue with that.

15 DR. OSTROFF: Other questions?

16 (No response.)

17 Let me just point out before we move to  
18 our next presenter, this is also I believe the last  
19 meeting for Capt. Schor who (inaudible).

20 CAPT. SCHOR: I'll be over in the  
21 Pentagon.

22 DR. OSTROFF: We will finally get to  
23 someone (inaudible), Col. Woodward, who has a  
24 presentation about the program for the Air Force.

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1 LtCOL. WOODWARD: Good afternoon. I'm  
2 LtCol. Kelly Woodward, from Air Force Medical  
3 Operation Agency. I'm going to talk to you briefly  
4 about the Air Force policy for periodic health  
5 assessment, and I'll show you the continuation of  
6 the spectrum of going to more and more years  
7 between examinations.

8 (Slide)

9 The Air Force -- first of all, our  
10 periodic health assessment program is based on a  
11 premise of assumption of fitness for duty. Once  
12 people have an entrance examination which is  
13 required, and they are qualified, then after that  
14 we have no requirement for a general what I would  
15 call screening medical exam for Active duty  
16 personnel, that being asymptomatic well people are  
17 not required to have any regular medical  
18 examination other than a dental examination. This  
19 is not to say -- and what I don't show up here --  
20 we do have a myriad of occupational exams for  
21 innumerable specific occupational fields that do  
22 drive very specific requirements such as people who  
23 are in flying status, people in noise exposure  
24 situations, and what have you, but those are

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1 targeted specific examination requirements driven  
2 by their unique occupations. So our lowest common  
3 denominator is no periodic medical examination.  
4 However, we have a very aggressive program where we  
5 expect providers -- and this is a work in progress  
6 -- to address -- whenever they see service members,  
7 to address their qualification for duty -- in other  
8 words, to ask the question when we see someone in a  
9 medical encounter, is this condition that they are  
10 presenting with impacting their qualification for  
11 continuing military service, and at the same time  
12 asking questions about and assessing the need for  
13 preventive services as represented by the U.S.  
14 Preventive Services Task Force.

15 What we do require, however, which I'll  
16 talk about in more detail in a moment, is an annual  
17 Preventive Health Assessment that will mirror  
18 somewhat what you've heard from the Navy. Our  
19 Preventive Health Assessment program began in 1997.

20 This program is Air Force-wide now. The Reserve  
21 Component does continue to have the five-year  
22 physical examination requirement, however, our  
23 Reserve Component is actively ramping up an annual  
24 Preventive Health Assessment program much like we

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1 have for the Active forces, but that's a work in  
2 progress.

3 And then, finally, there is a provision  
4 that a service member at the time of retirement or  
5 separation may have a complete physical examination  
6 if they so desire or if they are being  
7 involuntarily separated, but they are actually not  
8 required even at that point to have a physical  
9 examination.

10 (Slide)

11 The Air Force Annual Preventive Health  
12 Assessment Program which, as I stated. began back  
13 in 1997 and has been continually improving.  
14 Basically it has at a minimum a records review. It  
15 does not even necessarily drive an encounter with  
16 the member if he or she does not have any issues or  
17 if nothing has been identified that they are due  
18 for, but the minimum is to identify any changes in  
19 health status that are reflected in the medical  
20 record or other information that are available to  
21 arrange for any evaluation, if needed, also to  
22 ensure some individual medical readiness  
23 requirements are up-to-date. Again, some of these  
24 things may end up driving an encounter, but our

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1 common denominator is not to start with an  
2 encounter.

3 Our emphasis, though, in that same  
4 program is to assess each individual's need for  
5 clinical preventive services. We follow the U.S.  
6 Preventive Services Task Force recommendations and  
7 we use such things as age and gender, behaviors and  
8 other risk factors to determine which clinical  
9 preventive services are needed. These clinical  
10 preventive services are not policy requirements,  
11 they are recommended clinical services, just like  
12 other clinical care. We do not mandate that a  
13 service member have these things done, but we  
14 certainly make every effort to encourage it, and to  
15 the point where in our tracking systems we look to  
16 see how the performance is going at all of our MPFs  
17 (phonetic) and down to the provider level, we  
18 provide reports back to the providers to show how  
19 they are doing in ensuring that people complete  
20 recommended clinical preventive services as a way  
21 to foster that these are recommendations, this is a  
22 partnership with the individual, these are not  
23 drive by policy but by good clinical care. And so  
24 that performance feedback is really our tool, not a

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1 policy that says "Thou shalt have a colonoscopy at  
2 age 50".

3 In our clinical preventive services,  
4 the things that we are emphasizing in our  
5 performance feedback include cervical cancer  
6 screening, breast cancer screening, colorectal  
7 cancer screening, lipid screening, immunizations,  
8 chlamydia screening. Those are among the main  
9 things that we emphasize.

10 (Slide)

11 A couple of things that we do look at  
12 regularly that do cover some of the recommendations  
13 for periodic screening. During our annual dental  
14 exam, which is a place where unless your teeth fell  
15 out you do have to present in person, unless you  
16 can send your teeth in. People do come into the  
17 dental clinic, so at that point we screen  
18 everyone's blood pressure. So we do have an  
19 opportunity ever year to do some things if we find  
20 it necessary, but we are not piling everything on  
21 to that annual requirement. However, blood  
22 pressure is screened at that point and acted upon.

23 Secondly, during our annual fitness  
24 testing, we do measure ever member's height and

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1 weight and calculated BMI, profile that feedback to  
2 them. We're probably going to be transitioning to  
3 measuring waist circumference as a highly valuable  
4 measure for predicting morbidity and mortality.  
5 And then also we assess their smoking, their use of  
6 tobacco products as well as their physical activity  
7 level.

8 And then, finally, we track the  
9 completion of the requirements to have the  
10 preventive health assessment again in our automated  
11 tracking system, and the compliance with that is  
12 reported all the way up to the Surgeon General on a  
13 very regular basis with a performance feedback  
14 process to improve compliance.

15 So that's the Air Force program in a  
16 nutshell.

17 DR. OSTROFF: Thanks very much. I  
18 neglected to mention before that the next time we  
19 see Kelly he will be a full colonel.  
20 Congratulations.

21 LtCOL. WOODWARD: Thank you.

22 DR. OSTROFF: On question I do have is  
23 do you check the blood pressure before or after  
24 they do --

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1 (Laughter.)

2 LtCOL. WOODWARD: We take it before  
3 because, interestingly, they have a very low  
4 threshold in their dental clinics for people's  
5 blood pressure. If it's at all elevated, they  
6 don't like to do any dental interventions in anyone  
7 whose blood pressure isn't stone cold normal.

8 DR. OSTROFF: Just the thought of  
9 having my teeth worked on elevates my blood  
10 pressure.

11 LtCOL. WOODWARD: Yes. I'm surprised  
12 more people aren't running out of the dental chairs  
13 to get their blood pressure evaluated. It's  
14 surprising.

15 DR. OSTROFF: (Inaudible.)

16 LtCOL. WOODWARD: No, there was a  
17 previous every five year policy that was replaced  
18 by this policy.

19 DR. OSTROFF: When did that occur?

20 LtCOL. WOODWARD: I believe it was in  
21 '97. I think it was all one -- the new program  
22 started and the old one ended. I didn't check  
23 exactly the lineup of those dates, but I believe  
24 that's about when it occurred.

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1 DR. ATKINS: This is more a clarifying  
2 question for Col. DeFraités. Do you build a  
3 requirement for (inaudible).

4 COL. DEFRAITES: (Inaudible.)

5 DR. OSTROFF: Do I make the assumption  
6 that (inaudible).

7 LtCOL. WOODWARD: Yes, they do, though  
8 my understanding is they are trying to look for  
9 ways to not get out of that requirement or to  
10 figure out some way to satisfy that without having  
11 to do the actual physical exam. I guess we're  
12 trying to follow the spirit that there isn't a  
13 recommendation -- or I should say the U.S.  
14 Preventive Services Task Force does not recommend  
15 otherwise healthy people have a periodic screening  
16 examination.

17 DR. OSTROFF: Other questions?

18 DR. LUDWIG: If a person is not  
19 significant as (inaudible).

20 LtCOL. WOODWARD: Well, a couple of  
21 things. The dental exam is required, so we'll  
22 always get them. In order to fill that square, you  
23 have to get your blood pressure checked with your  
24 dental exam. But to answer your question, an

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1 individual will have intervention because we've  
2 found that everybody at some point passes through  
3 our health system and is seen, and that's the point  
4 where we should identify if they have signs or  
5 symptoms of any conditions. But, yes, we would not  
6 -- so far as I'm aware, have not compelled someone  
7 to get a clinical preventive service -- I don't  
8 know if my colleagues have any experience with  
9 that, but I have not heard of us compelling someone  
10 to complete recommended clinical preventive  
11 services. We actually only very recently  
12 eliminated requirement for an annual PAP smear.

13 DR. LAUDER: Is there actually any data  
14 captured on how effective (inaudible).

15 LtCOL. WOODWARD: I believe some of  
16 that -- if I might just throw this out -- I believe  
17 some of that was -- that question was the basis of  
18 the U.S. Preventive Services Task Force at some  
19 point in addressing the question of is there value  
20 in doing a physical examination on someone who  
21 otherwise has no complaints or no specific  
22 symptoms.

23 COL. DeFRAITES: (Inaudible.)

24 CAPT. SCHOR: The answer to the

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1 question is no, I don't think there's a database  
2 just for aviators. I think in all branches there's  
3 a central database for all (inaudible).

4 Just a couple of quick comments that  
5 may (inaudible), and that is (inaudible). For  
6 instance, in the Marine Corps which probably has  
7 the highest turnover, 68 percent of the Marine  
8 Corps is in first enlistment in any data in any  
9 year. (Inaudible words.) The number that is  
10 quoted is that it costs about \$100,000 to \$300,000  
11 to repatriate one accessionist. (Inaudible) it's a  
12 very expensive issue whether (inaudible) for six  
13 months or more at a time, or whether we actually  
14 send them overseas for long periods of time.  
15 (Inaudible) and that whole issue of creating a  
16 document (inaudible) documenting your health care,  
17 that creates a whole different issue than the  
18 standard practice (inaudible).

19 LtCOL. WOODWARD: I might just through  
20 in one anecdotal observation for the Air Force in  
21 implementing our program is that we do have a  
22 significant proportion of people who still have an  
23 expectation that they will have some sort of  
24 periodic examination, and we're sort of evaluating

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1 that right now because perhaps our -- we're trying  
2 to evaluate whether that's really the minimum, some  
3 expectation at certain age intervals to have a  
4 discussion or make sure they're fully informed  
5 about what the recommendations are for their  
6 specific age in a more active way than our system  
7 is doing right now. We have had people who come in  
8 at certain ages and say "All they did was review my  
9 record, they said there's nothing wrong with me.  
10 Why didn't I get my PHA test, and why didn't I get  
11 my prostate checked, I was expecting that", so  
12 we're kind of working both sides of that at the  
13 same time. We've swung all the way to following  
14 the hard and fast recommendations, but recognize  
15 that our expectations of our members -- we probably  
16 have to make sure we're meeting those as well.

17 DR. ATKINS: Are there data on those  
18 kinds of incidents where a soldier is deployed  
19 (inaudible)?

20 (Technical malfunctions prevented  
21 adequate recording of discussion.)

22 COL. BRADSHAW: (Inaudible.) In terms  
23 of the Academy recommendation, there's a lot of  
24 different organizations and bodies that made

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1 recommendations out there. And as Dr. Atkins can  
2 well tell you, a lot of times (inaudible words)  
3 when you're trying to make policy. But the Air  
4 Force has pretty much -- because of the history of  
5 the task force (inaudible words), and we've kind of  
6 chosen them as kind of the gold standard in the  
7 minimum requirement, and in some cases -- for  
8 instance, like on prostate screening -- with our  
9 own policy we've actually kind of danced a little  
10 with North American (inaudible), so we don't have  
11 the knowledge that (inaudible).

12 DR. LAUDER: (Inaudible.)

13 DR. OSTROFF: (Inaudible.)

14 COL. BRADSHAW: I jut want to make sure  
15 everybody knows that the services do all have  
16 specific programs with specific databases for their  
17 occupational health. For the Air Force it's the  
18 (inaudible), and the database has specific  
19 occupational health requirements for specific job  
20 descriptions, and the other services have something  
21 similar. And there's also a program being  
22 developed to track this (inaudible).

23 (Technical malfunctions prevented  
24 adequate recording of discussion.)

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1 DR. OSTROFF: I hate to bring this  
2 spirited discussion to a close (inaudible).

3 (Whereupon, at 4:30 p.m., the open  
4 session of the meeting was concluded.)  
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