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DEPARTMENT OF DEFENSE  
ARMED FORCES EPIDEMIOLOGICAL BOARD

OPEN SESSION

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

2 DR. POLAND: Well, welcome all to this  
3 open meeting session of the Armed Forces  
4 Epidemiological Board. Ms. Embrey, would you mind  
5 calling the meeting to order, please?

6 MS. EMBREY: Absolutely. As the  
7 Designated Federal Official for the Armed Forces  
8 Epidemiological Board, a Federal Advisory  
9 Committee to the Secretary of Defense, which  
10 serves as a continuing scientific body to the  
11 Assistant Secretary of Defense for Health Affairs  
12 and the Surgeons General of the Military  
13 Department, I hereby call this meeting to order.

14 DR. POLAND: Thank you. Since this is  
15 an open session, and as is our habit, we'll go  
16 around introduce ourselves and our distinguished  
17 guests. Ms. Embrey, can we start with you,  
18 please?

19 (Board Members and Guests introduce  
20 themselves.)

21 DR. POLAND: Thank you. Colonel Gibson  
22 any administrative remarks?

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1 COL GIBSON: Yes. Attendees, make sure  
2 that you sign in on the attendance roster out  
3 front. As Dr. Poland mentioned, this meeting is  
4 being transcribed. A reminder to the Board  
5 members, sign and send your 1352s so we can get  
6 you paid. If you need taxis to the airport, see  
7 Karen, she'll help you arrange those. We're  
8 providing lunch and refreshments for this mornings  
9 sessions. It's a catered lunch. It will be in  
10 this next room. CME forms. Karen said if you  
11 need CME forms, raise your hand, she'll bring them  
12 to you. I have one other announcement for the  
13 Board members. Yesterday we talked about the  
14 Defense Health Advisory Board. I got an e-mail  
15 this morning from the committee management office.  
16 It looks like a decision on the Defense Health  
17 Advisory Board will be within the next 60 days.  
18 So by the next meeting we should have very clear  
19 direction on where we're headed from there.  
20 Finally, for this afternoon, the tour is at Hickam  
21 Air Force Base. We'll be leaving here at 1:00.  
22 Spouses are welcome. Actually, we do prefer the

1 spouses go on this. Dress for comfort this  
2 afternoon, because we'll be going to -- those who  
3 are going to the Hawaiian Culture Center will  
4 leave from Hickam in a separate bus for this  
5 evening's dinner and presentation. Bus 1 will  
6 leave to return individuals to the hotel after the  
7 tour at about 3:00. Bus 2 will leave for the  
8 Polynesian Culture Center at 3:30 from Hickam and  
9 then after the Polynesian Culture Center, it will  
10 come back to the hotel. Dinner at the Culture  
11 Center is from 5:00 to 7:00 and the show is from  
12 7:30 to 9:00 so plan accordingly. But please tell  
13 your spouses to come down and we'll leave from  
14 there.

15 DR. KAPLAN: What time will the bus  
16 leave to come back to the hotel, the one not going  
17 to the --

18 COL GIBSON: At 1:00, excuse me. At  
19 3:00.

20 DR. KAPLAN: So the tour is finished at  
21 3:00.

22 COL GIBSON: Tour is finished at 3:00.

1 We'll have one bus coming back to the hotel for  
2 anybody who wants to come back to the hotel, who's  
3 not going with us for the Polynesian Culture  
4 Center. Then we'll leave at 3:30 for the  
5 Polynesian Culture Center from Hickam. before we  
6 begin the first morning session. That's it.

7 DR. POLAND: There were a couple  
8 questions yesterday. The next AFEB meeting is  
9 September 26 and 27, which is the third Tuesday  
10 and Wednesday of September. Again, the host will  
11 be the Naval Academy. All right. Our first  
12 speaker this morning, no stranger to the Board.  
13 However, this is the last time that we're going to  
14 see Colonel John Grabenstein in uniform. He's  
15 retiring from the Army. Before he begins, we'd  
16 like to give him a memento of his time of service  
17 to DoD and the AFEB. John's been coming to these  
18 meetings and providing updates to the board on  
19 virtually any-- everything related to vaccines for  
20 years. His work with MILVAX is commendable and  
21 his dedication making certain that the men and  
22 women who serve as well as their dependents are

1 properly vaccinated to ensure their safety has  
2 been exemplary. John, we thank you. I personally  
3 thank you. To me, the face of military  
4 immunization has been you, and you have always  
5 been there. I marvel that it doesn't matter when  
6 I send you an e-mail or call you, no matter where  
7 you are in the world I get it returned to me  
8 within the half hour, sometimes not knowing you  
9 were in Korea, so I didn't mean to call you that  
10 early, and John was still working away. We thank  
11 you, we wish you the best in your new civilian  
12 life. You're a true friend to the Board, you've  
13 been a true friend to me and so we'd like to  
14 present you with a certificate of appreciation and  
15 a coin.

16 I want to take the opportunity to read  
17 this, because John has been just an outstanding  
18 colleague. "To Colonel John Grabenstein for your  
19 many years of service to the Department of Defense  
20 and Armed Forces Epidemiological Board. Your  
21 outstanding professional knowledge and willingness  
22 to assist and cooperate in all issues brought to

1 the Board through your role as a subject matter  
2 expert and leader in DoD vaccine-related issues,  
3 contributed greatly to the Board's ability to  
4 produce important policy and program  
5 recommendations for the Department. Your  
6 contributions to the Board have been critical in  
7 the Departments efforts to meet our national  
8 obligation to protect and conserve the health of  
9 military men and women for all future deployments  
10 and combat operations. Colonel Grabenstein is an  
11 official friend of the AFEB."

12 (Certificate and coin presented)

13 COL GRABENSTEIN: This coin and the  
14 certificate will have a treasured place in my  
15 collection. It has been my honor and privilege to  
16 assist the Board. What you all do in terms of the  
17 advice you give the Department to help us take  
18 better care of the Soldiers, Marines, Sailors,  
19 Airmen and Coast Guardsmen is vital to the quality  
20 of our programs. It's probably very fitting that  
21 I come to you just having been on tour in Kuwait,  
22 in Qatar and in Bahrain. I had the opportunity to

1 go tour immunization clinics, and speak with  
2 immunization technicians in 11 Army, Navy and  
3 Coast Guard clinics in those three countries.  
4 Visited three command headquarters and help spread  
5 the word, spread the information of how we can do  
6 even better at protecting the troops through  
7 immunization. It's about 110 or 115 degrees in  
8 Kuwait. The weather forecast for July will 130,  
9 140. I can't imagine how much hotter 130 can feel  
10 compared to 110, but they say it does. What was  
11 most remarkable to me, I think in the tour, was  
12 the logistical prowess of the United States to  
13 deliver unlimited quantities of iceberg lettuce to  
14 each of the mess halls that I ate. The variety of  
15 food, the variety of morale recreation and welfare  
16 programs is phenomenal. I'll repeat a comment to  
17 you that I made when we were describing the  
18 smallpox vaccination program back in '03 and that  
19 is how proud I am not of what headquarters people  
20 do, but how the commitment to quality, the  
21 commitment to caring at the military clinics  
22 everywhere in the world, especially the three

1 places I just was, the 11 places I just was.  
2 They're serving with distinction, they're serving  
3 with honor and the medics, the corpsmen are doing  
4 phenomenal jobs. So I always like to test the  
5 system so I got a typhoid vaccination in Camp  
6 Navistar and another anthrax vaccination in  
7 Arifjan, and a yellow fever vaccine at the branch  
8 medical clinic in Bahrain. So I now have gotten  
9 vaccinated by medics and corpsmen and airmen, I  
10 had not previously been vaccinated by a corpsmen,  
11 so I now have all three in my collection.  
12 Probably the most -- Monica, CDR Kueny knows that  
13 I've kind of taken it under my responsibility to  
14 watch out for the interest of the Coast Guard as  
15 we've developed policies and make sure we are  
16 understanding their special needs in the way they  
17 take care of the nation's defenses. There is  
18 indeed the three cutters in Bahrain. The ADAQ,  
19 the Montnemoy and the another one, who's name I  
20 forget. So we visited with the corpsmen in the  
21 Coast Guard clinic and I thought turnabout is fair  
22 play, because next door to the Coast Guard clinic

1 were eight soldiers on a classified mission, and  
2 their care comes from the Coast Guard clinic,  
3 because it's right next door to each other.  
4 Clearly everybody watching out for each other. My  
5 goal this morning is to give you review, a state  
6 of the program address, if you will, on where the  
7 military immunization program is. The military  
8 vaccine agency is a cell within the Army Surgeon  
9 General's Office. We are green, as it were, but  
10 definitely with a purple mission. Always making  
11 sure that we found the solution that works, the  
12 best that we can, for all five services. We  
13 recently went through a mission and vision and  
14 goals kind of exercise, and you see our mission  
15 statement there. I won't belabor each of the  
16 points, but just remark that immunization most  
17 clearly are part of readiness. What is it that  
18 sets immunizations apart from so many other  
19 medical services, it's a matter of planning ahead.  
20 Human beings, quite often, aren't disciplined  
21 enough, as disciplined as they should be in  
22 planning ahead. But the military has certainly

1 dedicated itself, literally from the days of  
2 George Washington to prevention through  
3 immunization.

4 My agenda for the day, I want to give  
5 you some historical perspective, touch on several  
6 disease entities or vaccine products and then  
7 close lingering with that education and quality  
8 initiative which we're rather proud of. In your  
9 packet you have a 44-page document that is, with  
10 my colleagues, our best effort to bring together  
11 the long, rich and proud history of military  
12 contributions to immunizations to protect the  
13 troops and in the long run to protect the nation.  
14 This is an abridged version and there are copies  
15 in the back for anyone who needs it. The abridged  
16 version is going to be published in epidemiologic  
17 reviews. The editor told me that the reviewers  
18 wouldn't sit still for the full version, it was  
19 too long, but I knew that we'd be able to find a  
20 place somewhere for the full version, so didn't  
21 jettison anything, I just kept it and rearranged  
22 it a little bit. Cheryl was talking with Colonel

1 Underwood about this already this morning, surely  
2 there are items in there -- surely there are items  
3 not in there. We've made an effort to cite the  
4 1905 articles by Frederick Russell the  
5 contemporaneous, the original literature, as much  
6 as possible. So if you, with your experiences,  
7 know of anything we've missed, please let me know  
8 so that we can continue making this thing the  
9 definitive piece. And, yes, Figure 1 is my  
10 father's immunization record, Herman Grabenstein,  
11 which is my way of honoring him.

12 One of the most important things we do  
13 is not just giving the shots, but documenting them  
14 to make sure that the medical records are complete  
15 with regard to any given service member. What I  
16 show you here in this picture is a 1941 shot  
17 record, i.e. dog tag. There's the gentleman's  
18 name, he's an officer, and his serial number, his  
19 next of kin and her hometown, P for Protestant, O  
20 for type O blood. And that T 42 and 44 are two  
21 doses of tetanus toxoid he received in those  
22 years. As I tell our folks, sometimes -- we

1 certainly desire the records to be in the  
2 computers, automated in databases, but sometimes  
3 the computers are down and shots have to be  
4 reported on paper. Treat those pieces of paper  
5 like gold I tell them, because shame on us if we  
6 lose them and the service member has to get  
7 vaccinated again because of neglect on our part.  
8 Repeating immunizations is disrespectful of the  
9 soldier.

10 We're approaching Memorial Day and what  
11 I saw in Kuwait, Qatar and Bahrain were examples  
12 of very fine people doing hard work in very  
13 austere circumstances. In my latter years I've  
14 become more and more reflective at Memorial Day  
15 time. This year should be no different for us as  
16 I'm sure you understand very well. Moving forward  
17 with the assistance of the Preventive Medicine  
18 Liaison Officers or staff officers that are here  
19 with us, we've developed a revision to the Army  
20 regulation or Navy or Air Force, or Coast Guard  
21 Instruction on immunizations and chemoprophylaxis.

22 I will repeat the same words I've used

1 for the last six or nine months, "It'll be out  
2 soon." It is in the hands of the microscopic  
3 bureaucrats who look and make sure that everything  
4 is in perfect order and get far more approvals and  
5 authorizations than they need to get the thing  
6 published, be we're getting closer, but the gears  
7 are turning slowly.

8 Let me move on to some product specific,  
9 disease specific topics and start with anthrax.  
10 As you see, our main website is [www.anthrax.mil](http://www.anthrax.mil).  
11 It's been a long and storied history to this  
12 program, which I will not recount in full, because  
13 you don't have enough days here on the islands.  
14 But the most recent history, in October of 2004 a  
15 U.S. District Court Judge deemed that the anthrax  
16 vaccine had not been -- was not indicated for use  
17 in protecting against inhalation anthrax, remanded  
18 a particular document back to the FDA based on the  
19 fact that the FDA had not had a comment period.  
20 Within a few hours the Secretary of Defense  
21 ordered a full stop to the program to comply with  
22 the Judge's injunction. The FDA opened that

1 comment period. In the midst of that DoD and FDA  
2 worked together to establish an emergency-use  
3 authorization for the vaccine. The FDA issued its  
4 final document after the comment period in  
5 December. The EUA expired in mid-January, and so  
6 we are back up and running as a completely, fully,  
7 no-doubt-about-it licensed vaccine. Our  
8 vaccination policy continues to be focused on  
9 CENTCOM and on Korea and designated units forward  
10 deployed in the Pacific and Homeland Defense  
11 units.

12 Policy for how to proceed is under  
13 review now, so it certainly should not say  
14 anything that would limit Mr. Rumsfeld's options,  
15 but that policy is under review and will be  
16 announced when the decision is taken. In the last  
17 eight years, we have give 5.5 million doses of the  
18 vaccine to 1.5 million people. Production is  
19 steady. Now 26 published articles, plus the  
20 Institute of Medicine report. I'm showing you a  
21 website where's there's a one- or two-page summary  
22 on each of those 26 articles. We aren't resting

1       there. We continue to fill in the gaps. There's,  
2       what I refer to as science having an unquenchable  
3       thirst for more information. We have several  
4       studies in advanced development. One is the  
5       publication of a study that Colonel Gibson was  
6       involved with in terms of looking at vision of  
7       vaccinated aviators and unvaccinated aviators  
8       initiative he Air Force. Another is using every  
9       Army, Aviator flight physical from the 1980s to  
10      present is in a automated database with the  
11      physiologic parameters found on the examination.  
12      So we are setting up a cohort study to look at  
13      immunized -- we've already done it, but the (off  
14      mike) coming together to look at immunized  
15      aviators and unimmunized aviators and their  
16      physiologic parameters are the same and that will  
17      be published, shortly I hope.

18                 I never remember what TAIHOD stands for,  
19      but it's the Army's database of disability  
20      evaluations. Comparably we have done and  
21      published a study comparing anthrax vaccinated and  
22      unvaccinated soldiers with regard to disability

1 evaluations. Granting of disability discharges no  
2 differences with a follow up of four years. So  
3 more time has passed and we have started the  
4 process to look again with more time elapsed as is  
5 our responsibility. It was interesting in  
6 compiling that history I found follow up of  
7 mineral oil agivented influenza vaccines from the  
8 '50s where there was 17-year follow up. We are  
9 very much in the footsteps of our predecessors in  
10 following our testimony as with that flu vaccine  
11 or the yellow fever vaccine from the 1940s.

12 We've collaborating with CDC in an  
13 operation called the Vaccine Analytic Unit, the  
14 VAU, which is a CDC, DoD, FDA collaboration and  
15 they've taken on five topics. The first two of  
16 which they've presented results and the first one  
17 of these is anthrax vaccine and the risk of optic  
18 neuritis. This is a very quick summary. The  
19 manuscript has been accepted by Archives of  
20 Neurology, basically a vaccinated, unvaccinated  
21 group. But looking at four vaccines, anthrax,  
22 smallpox, Hepatitis B and influenza with varying

1 observation windows after vaccination six, 12 and  
2 18 weeks. None of the vaccines, non of the  
3 intervals is statistically elevated with regard to  
4 risk of optic neuritis. So one would say that the  
5 risk is the same and there is no vaccine affect.  
6 The largest of the point estimates is with  
7 influenza vaccine at the 12-week level, but I  
8 think none of us are particularly concerned about  
9 any of these vaccines or any of these intervals.

10 Smallpox. Our resources are clustered  
11 at [www.smallpox.mil](http://www.smallpox.mil). This is what I've called the  
12 box score for the last several years as we have  
13 implemented the program. We now are at the point  
14 of having screened over 1,090,000 have vaccinated  
15 -- we recently went over the one million mark so  
16 that there have been essentially 1,010,000 people  
17 vaccinated against smallpox since December of  
18 2002. With the exemption process that we develop,  
19 we implement to the same standards as the CDC  
20 program, the HHS program, we have exempted many  
21 people with atopic dermatitis, for example, have  
22 had none of the severe skin conditions that were

1       troublesome or worrisome. Our education process  
2       is very intricate. 86 cases of autoinoculation  
3       now, 56 have contact transfer. They are almost  
4       entirely wives and adult girlfriends, some sports  
5       partners, but nothing in a ship, nothing in a  
6       plane, nothing a barracks, nothing in a clinic, in  
7       a submarine, in a hospital. So it clearly -- the  
8       risk factor is clearly a very intimate setting  
9       where one is sharing, predominately bed partners,  
10      as a risk. Now, something like 360, I believe is  
11      the number, women vaccinated with smallpox vaccine  
12      before she realized she was pregnant. About 75  
13      percent of them -- actually, either before  
14      conception or so early after conception that no  
15      test would have detected it. 75 percent in that  
16      case, and they have been studied by the group at  
17      Naval Health Research Center and their miscarriage  
18      rate and their birth defect rate is the same as an  
19      unvaccinated group would be expected to be.  
20      Vaccina immune globulin, the antibody product that  
21      basically is an antidote. We expected to use one  
22      per 10,000 times. So we should have used it 100

1 or 101 times by now, have used it three times. We  
2 now have two cases of encephalitis. One in a  
3 primary vaccinee, one in a re-vaccinee. These are  
4 background rates largely. Myo-pericarditis was  
5 the condition that we thought was a European  
6 phenomenon but found among our own folks. Today's  
7 count is about 121. Clinically, relatively a few  
8 cases confirmed by biopsy because of the lack of  
9 acuity to go do a biopsy. Still predominately  
10 probable. Deaths are essentially the same as  
11 we've reviewed before. We are in the final stages  
12 of review of a death case that myo-pericarditis  
13 and we will be providing more information about  
14 that as soon as the review is complete. This  
15 comes from about 1800 VAERS reports and of course  
16 all of our reports through command channels.

17 So this Board collaborated with the ACIP  
18 in conducting a smallpox safety working group.  
19 You are essentially on the shelf or suspended  
20 animation should the need arise. The report of  
21 the committees work or that working groups work is  
22 being prepared for publication. Neurologic

1 events was recently published in JAMA and the  
2 Vaccine Healthcare Centers is developing a  
3 manuscript on the prognosis of the myo-carditis  
4 patients that will be completed shortly.

5 So let's shift to influenza. It's  
6 always easy to make fun of the flu, but it is a  
7 very serious disease as you all well know.  
8 Encountered a quote by General Leonard Wood in the  
9 fall of 1918 describing what was happening at Camp  
10 Funston. He said, "There are 1,440 minutes in a  
11 day. When I tell you there were 1,440 admissions  
12 in a day, you will realize the stain put on our  
13 nursing and medical force." There were at the  
14 time about 40 or 50,000 troops at Camp Funston.  
15 That 1440 number would have -- this quote would  
16 also have applied at Camp Grant in Illinois and  
17 Camp Devins in Massachusetts and several other  
18 places as well. So the pandemic planning is of  
19 course very, very important.

20 So our seasonal, regular, normal,  
21 routine influenza immunization policy is to  
22 protect the force. Total force vaccination

1 policy. Our recommendations for family members  
2 and retirees matches that of the ACIP so we will  
3 be expanding to include broader groups of children  
4 this year. And as we discussed at our meeting in  
5 Colorado, our developing requirement for civilian  
6 healthcare workers at our military treatment  
7 facilities. This of course has to involve  
8 discussions with collective bargaining units and  
9 the like and we want to do it right. But this is  
10 an effort where we are continuing to proceed.  
11 With regard to pandemic influenza, the H5N1  
12 vaccine we've purchased 2.4 million doses based on  
13 a 90 microgram dose. This is the 2004 Vietnam  
14 strain Clade 1 as we've discussed in previous  
15 meetings. Because the seasonal vaccine is going  
16 to be occupying the bottling line for three  
17 months, we decided to have some of it bottled to  
18 keep our options open. The balance is continues  
19 to be held in bulk pending adjuvant trials that  
20 the NIH is conducting, hopefully, with results by  
21 July or so to see if the supply can be stretched.  
22 Our concept of operations is to hold the vaccine

1 and not give it until such time as we progress to  
2 WHO phase 4, which would be sustained  
3 human-to-human transmission. That's policy  
4 decision taken by the Assistant Secretary and the  
5 Secretary of Defense, but that's our working plan  
6 at the moment. HHS has commissioned a pilot lot  
7 of a clade-2 vaccine isolated from Indonesia. We  
8 still think that this -- Colonel Hachey is going  
9 to present some of the cross- neutralization data  
10 in his block coming up next, so I won't steal his  
11 thunder, but just introduce the concept that even  
12 if this were to be the type of virus that were to  
13 become human-to-human transmissible, we don't  
14 think that this product is worthless insofar as  
15 the conventional wisdom would be that an H5N1  
16 vaccine could prime immune system as dose one of a  
17 two-dose strategy. But that is not known  
18 specifically but rather conventional wisdom, but  
19 I'll leave that to Colonel Hachey to deal with  
20 more completely later.

21 Meningococcal vaccine. This slide is  
22 substantially different from the one in your

1 handout because of what happened last week. We  
2 now have a protein-conjugated vaccine. Presumably  
3 has a superior duration of protection so it's  
4 being given broadly to teenagers, or beginning to  
5 be given broadly to teenagers. The Joint  
6 Preventive Medicine Policy Group has directed that  
7 there be substitution of Menactra for the original  
8 polysaccharide product asap, in lower case  
9 letters, with Menomune production being phased out  
10 eventually. We had been receiving shipments of  
11 Menactra but the manufacturer has had difficulties  
12 meeting its production goals and so basically most  
13 of our receipts have largely been suspended and  
14 we're back to menomune the polysaccharide product  
15 for our trainees and any menactra that we do have  
16 would be dedicated to the adolescents where the  
17 prolonged protection would be more valuable.

18 Pertussis. An acellular pertussis  
19 vaccine licensed now. Pertussis is a prolonged  
20 cough illness in adults, but a much more  
21 devastating disease in young children. Two  
22 products licensed ACIP has now recommended it be

1 given as age 11 and as routine boosting doses with  
2 shorter intervals also acceptable. So the JPMPG  
3 directed the service to substitute Tdap for Td as  
4 soon as possible. And in fact I got a dose of  
5 Tdap when I was in Kachenshlatter, Germany, three  
6 or four weeks ago. So this is beginning to be  
7 phased into our inventory in a routine way.

8 Mumps. As of May 18th, CDC has 2600  
9 reports of mump from the State Health Departments,  
10 which about 1300 cases are confirmed and something  
11 over 900 are considered probable. So we have been  
12 very careful in assessing whether this is  
13 affecting DoD sites. Our best assessment is we  
14 continue to see small numbers of cases of mumps,  
15 just like we always do, but nothing related in any  
16 kind of outbreak setting or magnitude. So what  
17 we've instructed the field is there's no need for  
18 anything extraordinary, just make sure you're  
19 following policy, which is to make sure that the  
20 MMR vaccine gets into exceptions, that the family  
21 members are properly vaccinated according to the  
22 ACIP recommendations which are here in gray. I

1 won't belabor that, but it is -- as of -- well,  
2 based on this morning's Blackberry messages or  
3 lack thereof, no mumps crisis within DoD.

4 Adenovirus vaccine is going to be  
5 covered in greater detail in your September  
6 meeting, but I'll just give you a short update  
7 since I'm here. The manufacturing process is  
8 developing itself. Phase 1 trial, well tolerated.  
9 The Phase 3 trial is under planning with a target  
10 beginning date of September. The protocol to  
11 conduct the trial is at the institutional review  
12 boards to allow it to be conducted at Fort  
13 Jackson, South Carolina and Great Lakes Naval  
14 Training Center in Illinois. Food and Drug  
15 Administration asked that the study be enlarged,  
16 which led to planning changes and funding  
17 scrambling and that sort of thing. There is a  
18 meeting between the manufacturer, the FDA in June  
19 and Major Midbow is looking forward to giving you  
20 an update at the September meeting.

21 Here's a second study from the vaccine  
22 analytic unit. It goes to a topic we addressed at

1 the AFEB several years ago, '04 I think. It deals  
2 with the relative safety of multiple simultaneous  
3 vaccination and this is a cross- over cohort study  
4 comparing a 120-day interval after vaccination to  
5 120-day interval before vaccination in the same  
6 people. Cox proportional hazard model. Five  
7 years of data collection, 19,000 people with 195  
8 hospitalizations after the vaccination and 215  
9 before vaccination and here you see the relative  
10 risks of .9, .86, 1.08 and .84 with reasonable  
11 confidence intervals. So the conclusion of the  
12 investigators was not statistically significantly  
13 associated with -- and this has all caused  
14 hospitalization in this case. So they'll proceed  
15 to publication on that.

16 An update from the Vaccine Healthcare  
17 Centers network, a consortium of four clinical  
18 sites, clinical centers of excellence. I've  
19 listed what they've been doing lately. Assisting  
20 DoD clinicians and getting reports into the  
21 vaccine adverse event reporting system. They  
22 conducted the myo-pericarditis registry that I

1 discussed earlier or the toll-free information  
2 line, the life line, consultation line, by e-mail,  
3 or by telephone to our folks around the world.  
4 Case management advice. I have a variety of  
5 research protocols they're coordinating and assist  
6 us at the Military Vaccine Agency with our  
7 educational efforts that I'll describe more in a  
8 minute.

9 As I've always said, what I do is 10  
10 percent immunology and 90 percent sociology. So  
11 this is the vaccines dot mil website. This is our  
12 one-stop shop. So if you click on vaccines,  
13 diseases here you get a laundry list of 20  
14 diseases and vaccines. If you then click on  
15 pertussis you find the FDA information, CDC  
16 information, the package insert, the military  
17 policies, the material -- the medical material  
18 quality control messages, logistical messages and  
19 everything, the vaccine information statements,  
20 our own trifold information. Everything all in  
21 one place. And it's getting to be a Christmas  
22 tree making it kind of hard sometimes to find any

1 one ornament on that Christmas tree, but we're  
2 working on -- trying to put things in several  
3 places if there are several ways that one could  
4 logically go look for it. Here are the crossword  
5 puzzles that we've developed to make training fun  
6 for the medics and so you're all welcome to do our  
7 crossword puzzles. We have a Sudoko puzzle on flu  
8 mist. So if you know the numbers associated with  
9 flu mist it's a lot easier to do that puzzle.

10 The thing I want to spend some time with  
11 you on is the thing we call Immunization  
12 University. You may know that McDonald's trains  
13 its manager with Hamburger University, so we  
14 decided to bring all of our training resources  
15 together in one place and call it Immunization  
16 University, and the bottom line is not reinventing  
17 the wheel, but giving tools to the folks on the  
18 front lines. So what our office thinks of itself  
19 as is a toolmaker. And a tool sharer to get in  
20 front of the shot clinic people the things they  
21 need to do a good job. So I've got a whole bunch  
22 of arrows on -- anything where I don't have an

1 arrow, I'm going to show you in a minute. So the  
2 arrows are there to cue me to tell you some  
3 things. The course catalog I handed out to  
4 everybody but Kevin Kilbane, because I ran out,  
5 but most everybody else should have one. It is  
6 the -- we're trying to use the analogy of a  
7 university and have a registrar and have a course  
8 catalog and a bookstore and do the thing that  
9 universities do to educate. Part of it is  
10 dangling carrots in front of people. We can't  
11 give out diplomas, but we can give the young  
12 enlisted troops promotion points for college  
13 credit -- not college credit, but for training  
14 credit and motivate them that way. We are  
15 collecting up SOPs on clinic operations from  
16 around the world and going to anonymize them and  
17 then post them for others to plagiarize. We've  
18 got -- Dr. Gray mentioned a couple meetings ago  
19 about this book called Fever of War, so we have a  
20 book review of Fever of War about the influenza  
21 pandemic. CE credit for physicians and nurses,  
22 PAs, pharmacists and some other species are

1 coming. Crossword puzzles. We have -- for a  
2 number of years, we've done a three-day training  
3 program called Immunization Leaders Course, that's  
4 what it's called now. It's gone under a variety  
5 of names. But we also developed in February what  
6 we call the immunization basic course because so  
7 many medics and corpsmen, to a lesser extent the  
8 airmen, learn immunization on the job. We wanted  
9 to formalize the educational materials available  
10 to them. So this is a one-day program we debuted  
11 in Camp Casey, Korea in February, then took to  
12 Pearl Harbor, then took to Lonsteul and have done  
13 it a few other places. So we've done it live, but  
14 we put the slides up on the internet on this  
15 website and if the -- our office will never get  
16 everywhere often enough to do the training so the  
17 slides are there and the local expert can look  
18 really impressive because all he has to do is read  
19 the script that's in the speaker's notes and it  
20 should be a good experience for the troops  
21 involved. So that new regulation, new instruction  
22 I talked about will set eight standards for

1 immunization delivery in the Department of  
2 Defense, and they're adapted from the counterpart  
3 documents such as from the National Vaccine  
4 Advisory Committee that apply in civilian  
5 settings. For ours -- there are several kinds of  
6 standards like this. Pediatrics -- Dr. Poland was  
7 involved in the ones for adults from Infectious  
8 Disease Society of America, I think. We've taken  
9 them all into account, but the one we really based  
10 our on was the adult programs in non-traditional  
11 settings, which seemed to be most applicable to  
12 us.

13           One of the key elements is quality of  
14 education so we have template for what's called a  
15 personal competency assessment file. These are  
16 the kinds of things that JCAHO comes and looks at  
17 in terms of quality of training of the staff and  
18 it brings into one place all the trainings that  
19 any individual immunizer has had. And we have  
20 several competency assessment checklists. This  
21 one is how to administer flu mist and you can see  
22 to the steps involved -- and we of course funding

1 one for smallpox vaccine for example.

2 This is one we're really excited about.

3 I have to credit to Captain Allison Crist on my  
4 staff who developed this one. It's our quality  
5 improvement tool or CQUIP is the acronym, but it  
6 basically is a list -- this is just an example,  
7 but it's a list of 100 questions grouped around  
8 the standards, like, when are you open? Are you  
9 open when your customers want you to be open? Do  
10 you educate? Which form do you use to screen?  
11 How often do you check your refrigerator for  
12 temperatures and those kinds of things? So  
13 there's 100 questions, 100 blank spaces for the  
14 local folks to write down what the situation is in  
15 their clinic, and then here are the answers. The  
16 schoolbook -- the schoolhouse answer that is  
17 written a little bit ambiguously to apply both at  
18 large medical centers and also at small clinics  
19 out on the frontier. But life is an open-book  
20 test and we want them -- we want everybody to  
21 realize whatever level of quality they're at and  
22 improve and just keep climbing the ladder,

1 iteratively at every opportunity. And then over  
2 here are a variety of URLs for more details.

3 I've shown you before, this is fuzzy but  
4 it's because it's the best I can do from a screen  
5 shot of the computer, but for -- when we rolled  
6 out our smallpox vaccination program, we had to  
7 train people on four continents and ships at sea,  
8 simultaneously in a matter of a week or two. So  
9 we worked with a technology from a company called  
10 DigiScript and this is -- these are Power Point  
11 slides here with a speaker at a podium in video  
12 and a rolling transcript here and a control box.  
13 We have recently brought into our office the  
14 ability to do this in-house rather than  
15 contracting it out a relatively exorbitant price.  
16 So we'll be working on monthly or quarterly kinds  
17 of training that we can export around the world,  
18 putting more of our products on CD for the ships,  
19 but also in Kuwait, yes they had internet access,  
20 but it took two minutes for each page to refresh  
21 and that's too slow to get any reasonable amount  
22 of training accomplished in that format.

1           This is project immune readiness. I've  
2 described to you previously, there's 52 hours of  
3 training in this format. We're working on adding  
4 more modules and turning it into a paper-based  
5 correspondence course for when people are on  
6 airplane trips or for whatever reason don't have  
7 access to the internet.

8           Immunization Tool Kit. Now in its  
9 fourth edition is a laminated ring-bound product  
10 with a lot of summary tables that has been  
11 embraced quite well by the troops. The reminder  
12 of all this is it's not training for training  
13 sack, but training so we can take better care of  
14 vaccinated people. As we've tried to -- how do  
15 you develop the passion in the immunizer to do a  
16 good job, have developed a variety of tools to  
17 make sure they have the right resources, make sure  
18 they understand the imperative that it's not about  
19 making the line shorter or moving people along,  
20 it's about rendering good care and getting the  
21 right vaccine into the right people. Withholding  
22 it if there's an exemption. And in doing the

1 appropriate things in follow-up after  
2 immunization. We use all the technical media that  
3 we can, whether it's webs or telephone or e-mail.  
4 We've got our guys thinking about pod-casting and  
5 all the new technologies that are coming along to  
6 see if there are ways we can transmit training  
7 programs in bite-size pieces that people would  
8 like to take advantage of, so we'll see how that  
9 progresses over time.

10           This is our to-do list of some of the  
11 bigger things. Correspondence course I mentioned.  
12 I think we probably should develop some sort of  
13 certification exam so that we can -- it's like the  
14 next logical step after the competency assessment  
15 files, more training, videos and posters. Vaccine  
16 monitoring system is an advance from the  
17 electronic diary we developed with the smallpox  
18 vaccination program that will be rolled out bigger  
19 and better and more widely over time. Talked to  
20 you about the flight physicals. The Army is now  
21 beginning to add the five basic training sites  
22 within the Army on the day they come in to have

1 their PPD test placed drawing a tube of blood and  
2 then assessing it for measles, rubella, varicella,  
3 Hep A and Hep B immunity and then withholding the  
4 vaccines that people are already immune to. Or  
5 withholding the vaccines corresponding to the  
6 diseases people are already immune to, to fulfill  
7 one of the 1999 recommendations of the Board. We  
8 think there's been enough new information on  
9 anthrax vaccine that ACIP might be interested in  
10 revising its guidelines, so we're going to be  
11 ready to support them in doing that. This group  
12 of things, I won't go through each one, but it's  
13 one I've come to refer to as guidons. A guidon is  
14 a flag that a Army unit uses to keep itself  
15 together to create its own identity and to move  
16 forward together. So these are pithy little  
17 reminders about making sure the vaccine the cold  
18 chain is observed. Taking care of the patient,  
19 not vaccinating them if they shouldn't be.  
20 Setting training standards for ourselves. Making  
21 sure that we're right when we answer a question or  
22 try to remember what a policy memo said and the

1     like.  So these are the kinds of things we're  
2     doing to get people together to get all the  
3     immunizers working consistently, at a uniform high  
4     standard across the world.

5             The four key values of our operation,  
6     our science, quality, care and confidence and  
7     that's what this slide depicts.  We don't just  
8     have data in a file cabinet or pass up the  
9     opportunity to publish our experience which is, as  
10    we've seen in many, many cases a national  
11    treasure, but get it in the literature and realize  
12    that we don't know everything and we need to be  
13    watching what's happening in the clinics.  Quality  
14    in vaccine administered, people exempted, cold  
15    chain management and documentation, care, it's not  
16    about how long the line is, it's about the  
17    individual in front of you.  Treating a person who  
18    is sick after vaccination regardless of whether  
19    the vaccine caused that problem or not.  If we do  
20    these three we will earn the trust and the  
21    confidence of the troops and their family.

22             We come from a very rich heritage of

1 excellence in science, excellence in medicine,  
2 clinical medicine, excellence in protecting the  
3 troops and it's incumbent upon us to figure out  
4 how to make it even better. Immunization  
5 University is a vehicle for that. We're going to  
6 have some fun with it. One of my goals is that we  
7 reach the NCAA tournament within a few years. Of  
8 course all great universities need a mascot so  
9 we've adopted the armadillo. The armadillo has  
10 its body armor on the outside, vaccines give you  
11 body armor on the inside. So this is what we're  
12 doing. It's about time for me to stop talking and  
13 take your questions. I have three slides to talk  
14 to you about regulatory issues with regard to  
15 vaccine use. I'll stop here and thank the Board  
16 again for all of its advice, all of its wisdom.

17 DR. POLAND: John, I didn't need to use  
18 all the superlatives and adjectives, I should have  
19 just let you speak. That was outstanding and I  
20 can hardly think of a more comprehensive program  
21 or more passionate advocate that I've seen for the  
22 program the he or she is in charge of. Comments?

1 Dr. Shamoo and then Dr. Gardner.

2 DR. SHAMOO: I have several questions,  
3 Dr. Poland. I hope you will indulge me. You  
4 have exceptions for vaccinations and my question  
5 is not regarding that. It's regarding, can a  
6 soldier opt out from any vaccination, especially  
7 if it's not infectious, and why either way,  
8 whatever the answer is?

9 COL GRABENSTEIN: With one exception,  
10 no, you cannot opt out. If you're a service  
11 member and the DoD policy is that whatever the  
12 circumstances are you're to get the vaccine. It's  
13 a required vaccine and the philosophical principal  
14 behind that is that is the mutual interdependence  
15 of teams. That if I opt out, I may have lessened  
16 your chance of returning home safe and I don't  
17 have that right to lessen your chance. There was  
18 one exception and the one exception is anthrax  
19 vaccine under the current policy which is a  
20 continuation of the conditions when were under  
21 EUA, which has now expired. Whether that option  
22 to opt out continues or not will be up to the

1 civilian leadership of the Department of Defense.

2 DR. SHAMOO: Next question I have, in  
3 the training and education you have, do you have a  
4 category where soldiers rights are within the  
5 vaccine system? I saw a lot of casualties, I  
6 didn't see anywhere which gives the soldiers his  
7 own rights within the system.

8 COL GRABENSTEIN: His own rights?

9 DR. SHAMOO: Yes.

10 COL GRABENSTEIN: I'm not sure I  
11 understand.

12 DR. SHAMOO: What are his obligations  
13 and right within the system of he must get a  
14 vaccine. There must be some limitations and/or  
15 duties on your website.

16 COL GRABENSTEIN: What we have is --  
17 what we are embellishing a greater set of  
18 educational materials not just for the staff but  
19 for the service members as well. Largely it's to  
20 help them understand the value of vaccines in --  
21 why we worry about meningococcal disease, why we  
22 worry about pertussis, why we worry about tetanus,

1 for example. But I take your point on the -- the  
2 rights of the service member to get that  
3 education, the right to documentation is  
4 essentially one of these. Our responsibility --  
5 correspondingly it's the responsibility of the  
6 staff.

7 DR. SHAMOO: How do you comprehensively  
8 capture all adverse events reporting during the  
9 clinical trial and post?

10 COL GRABENSTEIN: Well, these aren't  
11 clinical trials. This is clinical use of a  
12 licensed product. So we don't capture every  
13 adverse event. I have a sore arm from the shots I  
14 got last week and that's an adverse event, but I  
15 haven't filed it with VAERS. It's an expected  
16 event. It's a self-limited thing and so we  
17 haven't -- I haven't taken the time to report it.  
18 I can and any service member, any citizen is  
19 welcome to file a VAERS report on any time. We  
20 tend to focus on the serious events, the  
21 substantial ones in terms of making sure the  
22 myo-carditis registry is full, that guillame-beret

1 cases are investigated for example or thing where  
2 there is concern about whether there's an  
3 association with vaccination or not. The nice  
4 thing about the Department of Defense is we aren't  
5 beholding to those VAERS reports. I run into  
6 people all the time who say DoD has a bad safety  
7 surveillance program because of all the  
8 limitations of VAERS. Oh, they don't understand  
9 that we have the Defense center for surveillance  
10 system and we have a whole variety of ways that  
11 the assessment of disability discharges and the  
12 flight physical databases. We don't need samples  
13 we have censuses. We know what's happened to  
14 everybody so we can objectively look at all the  
15 vaccinees and all the non-vaccinees without all the  
16 limitations of a spontaneous reporting system.

17 DR. POLAND: Dr. Gardner.

18 DR. GARDNER: John that was another  
19 virtuoso performance and I'm used to a lucid and  
20 informative, educational and challenging things  
21 from you and we'll miss you enormously. I wanted  
22 to come back to something you mentioned at our

1 meeting, informally, a month or two ago and that  
2 was if you have for your smallpox program a team  
3 of people, sort of a vaccine SWAT team I would  
4 describe it, if there were to be an outbreak, that  
5 are trained to go in and take care of the problem  
6 in an intensive way. It's an intriguing idea as  
7 we now have -- are developing influenza plans at  
8 every little nook and cranny and every little  
9 place. I think that if it actually materialized  
10 we would find cracks and unevenness and I'm very  
11 attracted by the idea of having a group of highly  
12 professional people who could go in and organize  
13 and do this. I'm wondering on what your thoughts  
14 are on that and tell us a little about your  
15 smallpox SWAT team. How many there are and  
16 whether this is a model that you would think might  
17 be feasible for influenza or not.

18 COL GRABENSTEIN: I would invoke the  
19 name of D.A. Henderson in smallpox lore and say  
20 that most anybody can -- barefoot doctors in Asia  
21 and Africa can administer smallpox vaccine, so  
22 it's not a hard function to perform. So

1       technically it's not difficult.  Where we would  
2       need the specialized teams is if we have to give a  
3       product under investigation of new drug conditions  
4       and thus have to have a 20-page case report form  
5       on every vaccinee.  It's more of the paperwork  
6       drill that is the driver to some of those teams  
7       than the clinical issue of injection technique.

8                 DR. GARDNER:  Well, what about the  
9       issues of quarantine and --

10                COL GRABENSTEIN:  Those response teams  
11       are more on the case tracing and case control --  
12       case tracing and surveillance kinds of functions  
13       rather than the vaccine delivery function.

14                DR. GARDNER:  Do you think it would be  
15       an interesting model to pursue for influenza, you  
16       think the DoD dispersed system is more --

17                COL GRABENSTEIN:  I think it exists in  
18       every preventive medicine service public health  
19       service within DoD, the states and the counties in  
20       terms of -- people who have done it before with  
21       tuberculosis or sexually transmitted infection  
22       tracing.  It's those skills.

1 DR. GARDNER: Long ago the CIS officer I  
2 used to organize whenever sole dribs and drabs of  
3 polio were out and we would go out and massively  
4 immunize in a way that seemed beyond what the  
5 local plan was ready to do.

6 COL GRABENSTEIN: So it's an issue of  
7 command and control and additional resources that  
8 are martialled and trained to go in. It's not that  
9 the steal itself is unique, but that there are  
10 people ready to go do it. I think that -- we make  
11 a lot of analogies to the post- Katrina response  
12 and there will be cases where you do need SWAT  
13 teams, in your phrasing, to go help out. But the  
14 time scale between Katrina and the Katrina  
15 response was hours and days, where a pandemic, the  
16 slope is going to accumulate over weeks and  
17 months. There should be plenty of time for  
18 everybody, except the ones at ground zero to get  
19 ready to the extent they haven't already.

20 DR. OSTROFF: Let me just start by just  
21 congratulating you on the presentation. And  
22 speaking from my period as president of the Board,

1 I think you've been a true friend to the Board and  
2 to military medicine in general and your departure  
3 leaves a hole in military medicine that one can  
4 drive an Abrams tank through. So congratulations  
5 to you on the next phase of your career. I have a  
6 couple of quick questions for you. One of them is  
7 do you have any information about while the  
8 anthrax vaccine required informed consent what the  
9 opt-out rate was?

10 COL GRABENSTEIN: The vaccine -- the  
11 antiviral vaccine out of the emergency use  
12 authorization, never required informed consent.  
13 That was not a condition of the FDA. The  
14 requirement was that we provide education and to  
15 show that we had performed the education we had  
16 people signing forms saying I've received the  
17 trifold brochure. But it was not informed consent  
18 which is not appropriate in an EUA situation  
19 because it's not a research program, it's an  
20 emergency access program. Our best assessment  
21 based on data from Ft. Lewis, from southern  
22 California and from Korea was that of those

1 offered vaccine about 50 to 60 percent took it.  
2 Then when you start peeling the onion a little bit  
3 further, the folks who had received prior doses  
4 tended to get more. And the people who had never  
5 been vaccinated tended to say no thank you. I  
6 refer to that as a familiarity effect. The people  
7 who had gotten the vaccine before knew that there  
8 was no monster under the bed and were just  
9 proceeding on. And the folks who had never had it  
10 may have been a little more swayed by rumor or  
11 gossip. I think another piece of it is that  
12 people -- we should hear also from our dentists,  
13 what would be our compliance rate with our dental  
14 prevention programs if we didn't require people to  
15 go to the dentist. I think -- human nature does  
16 not plan ahead in many cases.

17 DR. OSTROFF: My second question is, I  
18 mean, that website looks absolutely spectacular.  
19 I'm wondering to what degree you monitor how much  
20 traffic it's getting because I think it's an  
21 incredible educational tool.

22 COL GRABENSTEIN: Our web guys have the

1 ability to do it and try to figure out what kind  
2 of place folks are coming to. We're try -- there  
3 are limits on -- we don't use cookies or -- the  
4 privacy stuff we're very careful about. But we're  
5 still in the advertising phase. So that was a  
6 lot of the reason for the trips over here was to  
7 make -- was marketing. Was to make sure people in  
8 the shot clinics knew about these goods and  
9 services so they could take advantage of them.

10 DR. OSTROFF: Then my third question,  
11 and it might come up during the next session is I  
12 presume that possibly when we get to influenza or  
13 pandemic Stage 4 that the product that you're  
14 obtaining may not necessarily be licensed. And so  
15 I'm wondering, are you anticipating doing this  
16 under an EUA or some other mechanism?

17 COL GRABENSTEIN: We would be prepared  
18 to do it under an EUA. Anything large scale would  
19 effectively be unimplementable as an IMD. It's  
20 just not suitable. Our understanding is that the  
21 way the 12-03 H5N1 vaccine was made, it would  
22 essentially be considered by the FDA as a simple

1 strain change and should be licensable with some  
2 relative ease. And so we would hope that early in  
3 a pandemic the FDA would consider the evidence and  
4 consider licensing the product.

5 DR. PARKINSON: John, kudos again. I'm  
6 thinking about two things. I hope you really  
7 think about the dissemination of your article with  
8 your colleagues. Much more beyond the usual peer  
9 review. I can see a symposium, outside the  
10 military sponsorship of interested parties. I  
11 tell you from where I sit know, we are dealing  
12 with a health illiteracy in this country of a  
13 magnitude that I don't think most of us really  
14 understand. What I would urge you also to think  
15 about in all of your accumulated experiences with  
16 your colleagues here in the military is writing,  
17 either something that looks like an OPED piece or  
18 what I've learned about risk communication.  
19 Talking to the public. Pros and cons of things  
20 that absolutely work. Let's forget about the  
21 stuff for which we've got little or no evidence  
22 and effectiveness. Immunization work, but we

1 really need a good primer on lessons learned for  
2 education behavior change, risk communication from  
3 your assorted experience which I think would be  
4 invaluable in the field.

5 COL GRABENSTEIN: I glossed over one of  
6 the bullets for that. The bullet about posters  
7 and videos is about making people, or helping  
8 people be glad they got vaccinated. So the video  
9 project we've nicknamed the schoolhouse rock  
10 project, because we want people to just have fun  
11 with it and make it kind of like Bill Nye the  
12 Science Guy kind of approach, let's make learning  
13 fun and it will be remembered that way.

14 DR. KAPLAN: That was a wonderful review  
15 and it won't come as a surprise that I was pleased  
16 to hear you refer in the influenza talk to the  
17 fact that you've taken the pediatric reservoir  
18 into consideration. What other of the many  
19 immunizations is there an active surveillance, not  
20 just in the troops, but in the supporting  
21 personnel, be they children or other dependents  
22 and so on in terms of the epidemiology of disease

1 and protection?

2 COL GRABENSTEIN: For disease counts?  
3 That's beyond my offices purview. It's back in  
4 the preventive medicine and disease surveillance  
5 side. So the way we look for the mumps outbreaks  
6 was not simply limited to service members but was  
7 looking at all beneficiaries through other means.  
8 We definitely consider it our responsibility to  
9 provide the education on all the products. So as  
10 rotavirus vaccine, for example, has been rolling  
11 out in the last few months we're trying to provide  
12 educational resources on that for providers and  
13 for the public.

14 DR. KAPLAN: I haven't had time to look  
15 through it carefully, but does this new academic  
16 institution which you've spawned have a  
17 significant issue or component to dependents --

18 COL GRABENSTEIN: Yes. And every  
19 vaccine preventable disease is included in those  
20 training modules, because they're still  
21 immunization technicians even if they're dealing  
22 with the squirmy little kids.

1                   CDR KUENY: I just wanted to take a  
2 quick moment to thank on behalf of the Coast Guard  
3 and myself Colonel Grabenstein for all the work  
4 that he's done to include the Coast Guard and  
5 actions that are going on within DoD because  
6 frequently we're left out of the entire mix, but  
7 Colonel G has always made sure that we're included  
8 in what's going on. I've had the same experience  
9 with Dr. Poland in that in sending an e-mail I  
10 would get a response nearly immediately. No  
11 matter what time of day or what horrendous  
12 question I may asked. I always got something back  
13 right away and I appreciate it.

14                   COL GRABENSTEIN: If any of you are  
15 musculoskeletal experts, I have Blackberry elbow.

16                   DR. POLAND: I don't doubt it. John,  
17 one last question for you, has a successor been  
18 named?

19                   COL GRABENSTEIN: Yes. I was remiss in  
20 not acknowledging him. The new director will be  
21 Lieutenant Colonel, well, as of July 1st, Colonel  
22 Randy Anderson who is an Army Health care

1 operations expert and he's been with us for the  
2 last year. From the science side the deputy  
3 director for clinical operations is Lieutenant  
4 Colonel Steve Ford. Many of you have met -- he's  
5 been at the last few AFEB meetings or at least the  
6 one in Colorado.

7 DR. POLAND: Thank you. Colonel  
8 Grabenstein is next going to talk about the  
9 potential use of non-FDA licensed vaccine in  
10 military personnel, including how it relates to  
11 southern hemisphere influenza vaccine. This will  
12 be a an important background for the Board in one  
13 of our upcoming recommendations and discussions.

14 COL GRABENSTEIN: So at the last meeting  
15 the Joint Staff I believe it was, John Kelly,  
16 posed a question to you related to use of the  
17 southern hemisphere intended influenza vaccine.  
18 So what I was asked to do was to give you a little  
19 primer on the regulatory categories wherein a  
20 vaccine could fall. So this is three short  
21 slides. A little crammed, but it's so I can get  
22 all the comparable information all in the same

1 place so you can consider it as not exactly  
2 mutually exclusive categories, but sort of, kind  
3 of, a little bit. If you really want to impress  
4 your friends you can correct them when they say  
5 that a vaccine has been FDA approved. The FDA  
6 approves drugs and licenses vaccines. That's how  
7 you can look really cool, like you know what  
8 you're talking about. It falls under the Food  
9 Drug & Cosmetic Act and the Public Health service  
10 act and that -- when you use a product in clinical  
11 practice, those are the -- that's the place in the  
12 law where the FDA has its authority to release a  
13 product or license or -- I think that's the most  
14 literally correct word, to license the  
15 manufacturer or introduce into interstate  
16 commerce, the product. That's the standard  
17 situation. Clinicians in the audience will be  
18 very familiar with the concept of an off-label  
19 use. So for example they'll -- well, smallpox  
20 vaccine is licensed, I think the numbers are age  
21 18 to 65. So if you wanted to give the product to  
22 a 66 year old, could you? You could. A

1 physician, a prescriber and a patient could enter  
2 a one- on-one relationship to give access to that  
3 patient to the vaccine even though it is not  
4 covered within the licensed indications, the  
5 package insert for the product. So you won't be  
6 arrested for using the product in that way. The  
7 FDA does not regulate the practice of medicine.  
8 They state that themselves. That is essentially a  
9 state board function or a state function, but one  
10 has to tread carefully around the issues of  
11 off-label use. It's quite -- pediatricians have  
12 frequently said that many drugs are unlicensed,  
13 unapproved for children and so clinicians to use  
14 them frequently go off label in that setting. DoD  
15 as a corporate entity cannot adopt a policy to use  
16 a product off label. So all of our -- you'll  
17 notice that all of our policy statements stay on  
18 label. So the DoD policy is that smallpox vaccine  
19 and the examine I used is given to people 18 to 65  
20 years of age. If you encounter somebody -- I get  
21 this question once a month or so from a physician  
22 saying, "He's 68. What do I do?" And I say,

1 "Talk to him." DoD could not force or oblige the  
2 person to be vaccinated, but the prescriber is  
3 free to act in the best clinical interest of the  
4 patient. This is off label of an approved or  
5 licensed drug.

6 Third category, the one you're familiar  
7 with, those of you who run clinical trials of an  
8 investigation new -- and IND. And IND is an  
9 investigational new drug. Properly it is the  
10 investigational new drug exemption from the FD --  
11 from the Food Drug and Cosmetic Act. So it's --  
12 you can only ship it in interstate commerce if  
13 it's licensed or approved, the IND is the  
14 exemption to that status. That's during clinical  
15 trials. It's 21 CFR 312. If it's a product used  
16 for force protection then there are other things  
17 we have to follow, 10 USC 1107 EO 13139. Of  
18 course FDA product and is a DoD directive. So the  
19 requirements to use a drug under IND status is  
20 that there must be an institutional review board,  
21 review the product, you have to educate the  
22 subject, the recipient of the product, they must

1 consent and you have to document that and you have  
2 to monitor that. You know, those of you who have  
3 run clinical trials, how many pages of paper that  
4 is per person? So relatively recently 2004 there  
5 has been another category added called Emergency  
6 Use Authorization or EUA. This is the category  
7 wherein we used anthrax vaccine in '05, 21 USC --  
8 that stuff. There's a website where the FDA has a  
9 pretty English-language readable -- URL is pretty  
10 ridiculous, but it's a pretty good summary of what  
11 an EUA is. So EUAs are limited to products that  
12 are countermeasures to chem-bio, radiologic or  
13 nuclear agents or that affect national security.  
14 So and influenza pandemic would affect national  
15 security. Seasonal influenza theoretically,  
16 presumably does not affect national security. It  
17 might be devastating and kill somebody but it  
18 wouldn't affect national security. So the  
19 seasonal could not be used under an EUA authority.  
20 When we used anthrax on EUA it was a licensed  
21 product the Judge deemed it off label for  
22 inhalation anthrax and the way DoD corporately was

1 able to use it was through the EUA process.

2 Questions on that before I go forward?

3 DR. OXMAN: You can argue that influenza  
4 in a critical shift was in fact a national  
5 security issue. And is there any way of  
6 incorporating that thought into military practice?

7 COL GRABENSTEIN: Yeah. Maybe. But it  
8 wouldn't have to be just you convincing me, you'd  
9 have to convince my lawyers, FDAs lawyers, HHS'  
10 lawyers and you can see that it might take a  
11 while.

12 DR. SHAMOO: I want to give a different  
13 spin on off label. You used 6566, which makes it  
14 so reasonable or rational. However the  
15 overwhelming majority use of off label is for  
16 different indications. And if a physician used a  
17 drop which is neither approved nor licensed for  
18 other indications, you really totally on your own  
19 and if everything goes right, which it 99.9  
20 percent does, you're fine. But if the patient  
21 dies, you get sued and there is no protection of  
22 approval or license from the FDA.

1 COL GRABENSTEIN: In the '70s I think,  
2 smallpox vaccine was given to people to treat  
3 herpes. So that would be an off-label use of a  
4 vaccine, drastically off label and completely  
5 unsanctioned by any public health body so it  
6 didn't last very long.

7 So the scenario is that of influenza  
8 vaccine for the southern hemisphere. So the  
9 background is: A. The World Health Organization  
10 actually issues two sets of recommendations every  
11 year for the flu vaccine, and we of course are  
12 northern hemisphere snobs and only go the southern  
13 hemisphere on vacation or other -- WHO issues two  
14 sets of recommendations. One's for the northern  
15 hemisphere, one's for the southern hemisphere.  
16 They're basically offset by six months while we  
17 are enjoying summer here, Australia is having  
18 winter and when we are putting up Christmas trees,  
19 Australia's in the summer. So correspondingly the  
20 peak influenza is offset by six months northern  
21 and southern hemisphere. The northern recipe and  
22 the southern recipe or the northern formula and

1 the southern formula are often the same but if  
2 there's drift in the antigenic strains one or the  
3 other hemisphere will change first. Sometimes  
4 it's northern going first, sometimes it southern  
5 going first. I wasn't able to actually to see if  
6 it's more commonly one than the other but I don't  
7 think there's been any particular pattern. The  
8 vaccine we use in the northern hemisphere, the FDA  
9 licenses expires on the 30th of June each year.  
10 That date is relatively empiric, it is not based  
11 on physicochemical stability of the vaccine. It  
12 is largely based on having it expire, cleaning it  
13 out of the refrigerator before the new stuff comes  
14 in to make sure you don't accidentally get  
15 immunized with last year's formula in case there's  
16 a shift, a change in the formula.

17 What are the options for DoD to use  
18 influenza vaccine intended for the southern  
19 hemisphere -- well the easiest thing of course  
20 would be to use vaccine licensed under the Food  
21 Drug and Cosmetic Act, except there isn't any  
22 which is what creates the dilemma. We could go

1 off label, except that doesn't apply because it's  
2 not -- you could -- maybe you could say that using  
3 the drug past its expiration date, using it on  
4 July 1st, sort of, kind of would be off label, but  
5 that's not the usual meaning of the word off label  
6 or the term off label. It's hard to, you know,  
7 we've got the clinicians engrained and the support  
8 staff engrained to clear the stuff out of the  
9 refrigerator, it wouldn't be the easiest thing in  
10 the world. Third option, we could use unlicensed  
11 vaccine under an IND. We could get product that  
12 was made in Europe intended to be sold in  
13 Australia, there's stuff made in Australia. I  
14 think that CSL, I think they make vaccine in  
15 Australia for example. But it would be -- GAO  
16 could easily audit us and ask, show me all the  
17 case report forms of every member of that aircraft  
18 carrier you just vaccinated at 20, 50, 100 pages  
19 per person. We could use it under emergency use  
20 authorization but you'd have to argue that the flu  
21 was so bad or the ship was so critical, forces  
22 were so critical that it affected national

1 security. I think that's a little bit of a hard  
2 sell. Or you could use, coming back around to the  
3 top again with a different way of doing vaccine  
4 that's licensed under the Food Drug and Cosmetic  
5 Act by saying -- there are four licensed  
6 manufacturers in the United States for flu  
7 vaccine. Two of which have a very large market  
8 overseas, which I believe includes southern  
9 hemisphere sales. That would be Glaxo Smith Cline  
10 and Chiron or Chiron about to change name due to a  
11 merger to Novartis. So if we were to say to them  
12 we'd like you to -- I'm assuming that the plants,  
13 the pipes, the kitchen where the vaccine is made,  
14 is the same set of pipe, the same kitchen and so  
15 the FDA wouldn't have to do a new plant  
16 inspection, they simply would have to look at the  
17 documents that show the southern hemisphere stuff  
18 was made to the same standards as the northern  
19 hemisphere stuff and license it that way. We'd  
20 need a different label, some different color,  
21 different shaped bottle something to help  
22 differentiate northern stuff from southern stuff

1 or put the cap on the bottom. Who knows. So it  
2 boils down to a relatively -- if that is possible,  
3 that last one I just mentioned, I think that's the  
4 easiest route to go. Then the question becomes  
5 what are you willing to pay. How important is  
6 this to you to ask the companies to do something  
7 they've never done before for us and if it's a  
8 premium of 50 percent or 100 percent or whatever  
9 is the disease burden sufficient to warrant the  
10 expense from an operational standpoint. That's my  
11 contribution to the discussion.

12 DR. POLAND: Questions or discussions?

13 COL GIBSON: One point for the Board, we  
14 will put a copy of these slides and a copy of the  
15 transcripts from this part of the meeting in the  
16 next set of briefing books when we formally  
17 address this question with our other experts.  
18 We'll provide subject-matter expertise on southern  
19 hemisphere influenza epidemiology, et cetera.

20 DR. PARKINSON: As the Board tries to  
21 formulate the formal response to this it would be  
22 useful to have that background information, Roger

1 on what the epidemiology has looked like, when has  
2 there been significant years where there's a  
3 difference between southern and northern so that  
4 we codify that a little better. This has been  
5 very useful for me. I think, again, there's so  
6 much we can do in DoD to enlighten the public  
7 about this whole area of off-label, licensed,  
8 unlicensed, et cetera. It's just huge. And the  
9 way you've laid it out here, John, is a very  
10 useful construct for me.

11 DR. OSTROFF: My question is somewhat  
12 similar to what Mike just asked which is do we  
13 have any data to suggest that failure during that  
14 period of June through September has resulted in  
15 much excess morbidity.

16 COL GRABENSTEIN: The story of the USS  
17 Arkansas sailing out of Bremmerton, Washington,  
18 having to put back into port because of the  
19 influenza outbreak was northern hemisphere stuff,  
20 situation. I don't know of a comparable case in  
21 the southern hemisphere. I don't know of the  
22 disease burden. Roger, I don't know if you --

1 DR. POLAND: We are trying to get that  
2 information for our next briefing.

3 COL GIBSON: The next meeting of the  
4 Board in September will go into this in great  
5 depth. I literally could not get the  
6 subject-matter experts to Hawaii to address this  
7 question at this board meeting. I had it on the  
8 agenda early on and just couldn't make the  
9 logistics work so we postponed it until September.  
10 I will say that after talking with Kevin Russell  
11 at NHRC, he has said that they have had some  
12 increase in influenza in ships in the southern  
13 hemisphere in the past. He didn't go into any  
14 more detail than that. He said he'd provide more  
15 information at the next meeting.

16 DR. OXMAN: Putting on my ignorant  
17 taxpayer's hat, it seems to me that if we have  
18 troops deployed in the southern hemisphere that,  
19 by definition should mean that they are deployed  
20 in the interest of national security. If you're  
21 talking about vaccine, you're talking about  
22 something that you have to do in advance of the

1 event. What the Bremmerton issue shows you is  
2 what can happen. And how incapacitating it is.  
3 So I think that you're not likely to have  
4 insufficient time to act on the kind of  
5 information you want. So I think it would be  
6 appropriate for us to think about the taxpayer's  
7 point of view is what's the purpose of the  
8 deployment of the troops in the southern  
9 hemisphere and if in fact that doesn't provide the  
10 national security basis for a decision of that  
11 sort.

12 COL GRABENSTEIN: Sure. The other  
13 thought along those lines is that the State  
14 Department -- half of the embassies are in the  
15 southern hemisphere or something like that. So  
16 there's -- we have other federal partners who  
17 would have issues along those lines as well.

18 DR. POLAND: Colonel Grabenstein, thank  
19 you for an outstanding career of service.

20 COL GRABENSTEIN: Thank you very much.

21 DR. POLAND: Because there is no one  
22 that can follow John, we're going to take a

1 15-minute break just to be fair to the next  
2 speakers. A couple of reminders, if you want your  
3 notebooks to be shipped, please give them to Karen  
4 before lunchtime. After lunch we are not able to  
5 leave any personal items in the room. So we'll  
6 reconvene in 15 minutes.

7 (Recess)

8 DR. POLAND: If we could reconvene,  
9 please. Dr. Hachey here. If we could have Board  
10 members take their seats, we'll continue on.  
11 We're now basically going to have a six-part  
12 briefing on influenza. The first will be  
13 Lieutenant Colonel Wayne Hachey who will provide  
14 us with a DoD pandemic influenza preparedness  
15 update. Wayne, I think your slides were handed  
16 out.

17 LT COL HACHEY: Yes, sir.

18 DR. POLAND: So those should be  
19 available to the people. Okay.

20 LT COL HACHEY: Good morning. This  
21 represents the fourth update that we've made to  
22 the Board regarding avian and pandemic influenza

1 planning. The agenda for this morning will start  
2 with the current status of avian influenza, both  
3 in people and our friends with feathers, to  
4 include changes in the virus, some updates in  
5 regards to modeling, a little bit about  
6 epidemiology and one slide that is not included in  
7 your handout is a status update of the outbreak  
8 currently in Indonesia. We'll follow that with  
9 where we're at with plans, vaccine, antivirals and  
10 strategic communication.

11 The question that everybody's asking is:  
12 Is it here yet? And the answer is: Not yet.  
13 Although it is now in some 58 countries, the issue  
14 of migratory birds being a major player in spread  
15 of disease, fortunately has been squelched a bit.  
16 They've been getting somewhat of a bad rap, I  
17 think, lately. The recent outbreak in Africa  
18 appears to be associated with the importation of  
19 poultry from China, although not proven as  
20 strongly suggested. Even the original outbreak in  
21 Qinghai Lake in China appears to be more  
22 associated with some farm raised bar-headed geese

1       rather than initially being in the wild bird  
2       population. So the migratory birds are becoming  
3       less and less of a issue. In fact, the recent  
4       return of migratory birds from Africa back up  
5       north has proved to be negative for anybody  
6       carrying the disease back into Europe.

7                 The status of the disease in humans,  
8       despite really widespread avian disease, we still  
9       only have 218 cases as of 23 May, reported to the  
10       WHO and 124 deaths. Although disease is spreading  
11       outside of southeast Asia over into Africa and  
12       Turkey, Azerbaijan and Iraq, the epicenter is  
13       sticking right in southeast Asia and that's where  
14       the real hot spots are. What's made the news  
15       recently is a current outbreak in Indonesia, which  
16       had many people concerned that this was  
17       representing our first case of human-to-human  
18       transmission. It involves seven extended family  
19       members with now six deaths. You can make that  
20       eight if you count the person who died who was  
21       considered the index case that was not tested.  
22       That initial family member developed ILI symptoms

1 and died on May 4th. Three cases subsequently  
2 spent the night with her on April 29th while she  
3 had symptoms. The index case we know did have  
4 full on contact with dead poultry, but there has  
5 been no poultry link found with the subsequent  
6 cases identified yet, and the local community has  
7 not really been cooperative. As a matter of fact  
8 they've been really uncooperative with authorities  
9 as far as determining the extent of disease in the  
10 poultry population in that community. The good  
11 news is the genetic sequencing of all eight  
12 segments on two samples that were submitted  
13 demonstrate no mutation from poultry strains  
14 identified in earlier outbreaks in that area.  
15 There's also no resistance to Tamiflu and  
16 currently no evidence of least effective  
17 human-to-human transmission. So we're not at WHO  
18 phase 4 yet. Interestingly though is that despite  
19 some common exposures, it's only been blood  
20 relatives who have developed disease and not the  
21 in-laws, the husbands and wives in that extended  
22 family group.

1           Moving on to containment issues. The  
2 previous issues cited at previous Board meetings  
3 have yet to be resolved. In fact the WHO has  
4 expressed some concern that the delay in reporting  
5 cases to them is surpassing the potential window  
6 of opportunity for containment. Also the lack of  
7 public health infrastructure in many affected  
8 countries not only limits surveillance, but also  
9 limiting response and subsequent assistance.

10           Some recent viral information, the most  
11 recent viral strains appear to be a bit heartier.  
12 They're more heat stable compared to the 1997 Hong  
13 Kong strain, which died after 2 days when exposed  
14 to 37 degrees centigrade, now persists for up to 6  
15 days. It also survives longer in water, creating  
16 some concerns where both humans and folks with  
17 feathers share common water sources. The good  
18 news is that the strain identified in Turkey  
19 representing Clade, at least some of the Clade 2  
20 strains is not resistant to amantadine, which  
21 prompted the WHO to recommend dual therapy with  
22 neuraminidase inhibitors and amantadine providing

1 the virus does not resistance to that medication.  
2 On the other hand, in a recent report, there's  
3 been a significant viremia in some of the  
4 individuals have contracted avian flu which is  
5 felt may facilitate the systemic spread and  
6 perhaps limit the Relenza use. Tied in with this  
7 is the recognition of a hemoglutin in bindings  
8 site in the GI tract which may be one of the  
9 potential routes of exposure.

10 The next issue is modeling. At the  
11 present time there's a number of models out there.  
12 Just like hurricane modeling which you would like  
13 to do is see a convergence as far as the findings  
14 and in fact that's what we are seeing with the  
15 current models that are available. There's the  
16 mother of all models, or a mega-model that is just  
17 being completed and that should be available for  
18 publication through NIH shortly. That hopefully  
19 will tie in all of the models and give us one that  
20 is useful for general use. But the common  
21 findings, as far as the models, is that  
22 interventions have to be early and of a sufficient

1 duration, and that includes both the communities  
2 and individuals. For an example as far as  
3 communities are concerned, interventions, at least  
4 according to multiple models, have to start after  
5 no more than 10 cases have been identified in a  
6 community. As far as individual therapy, modeling  
7 suggests that therapy has to start within the  
8 first day of treatment, which presses some demand  
9 on the need for rapid diagnostics. Closing  
10 schools were effective in 1918 providing you were  
11 in a rural area, not so much in urban settings.  
12 With the modeling, closing schools is very  
13 effective providing you keep kids home. But if  
14 you let them go to the mall instead of to school,  
15 then the transmission rate actually winds up  
16 increasing. Social distancing appears to be  
17 effective and I'll show you some examples of that  
18 with the next slide. However, closing borders and  
19 closing workplaces proved not to be an effective  
20 means in limiting spread. One bonus is that is if  
21 you use non-pharmacologic interventions  
22 appropriately, then your antiviral requirements

1 are significantly reduced.

2           This is an example of a model produced  
3 by Sandia Labs that just illustrates some of the  
4 points. This is an example of baseline peak  
5 infected rate of about 1,000. Total infected  
6 about 5,000. Their baseline population in this  
7 model is 10,000 people. And if you close schools  
8 after just 10 folks presented with symptoms in the  
9 community at outstanding compliance, 99 percent,  
10 but essentially let the kids go out to the malls,  
11 the impact on the pandemic actually is worsened.  
12 But if you keep kids at home and still 99 percent  
13 compliance, you can see that you get a substantial  
14 bang for your buck with really drastic drops in  
15 peak infected, total infected and the mortality  
16 rate. If compliance is less than ideal down to 70  
17 percent, you still see a substantial affect as far  
18 as reducing transmission. Now if you have schools  
19 close and you close workplaces, you really don't  
20 see that much of a benefit. A little bump but  
21 nothing really appreciable. If you let the kids  
22 go to school, but you keep mom and Dadd at home

1 closing the workplace, there's a small drop but  
2 nothing like what you see when you close schools.

3 The next few slides are going to be  
4 discussing some of the more recent epidemiology.  
5 One of the concerns with previous presentations to  
6 the Board is that there's a lack of decent  
7 epidemiology data. In the MMWR in April 28th,  
8 they did present some data based on a 2004  
9 outbreak in Thailand, and it represents both  
10 descriptive data and a matched case control study.  
11 Case definition was a diagnosis of ILI or  
12 pneumonia and positive culture or positive PCR of  
13 H5N1. And, again, the setting was primarily  
14 central Thailand.

15 Had 16 subjects or 16 individuals, age  
16 range was to 58 with a median of 13, with a little  
17 over half being under 15 and about an equal spread  
18 between males and females. Overall mortality rate  
19 was 75 percent, but if you were under 15,  
20 mortality rate was up to 90 percent, where as if  
21 you were over 15 then it was just a little over 50  
22 percent. So a significant difference between the

1 two.

2 Incubation period was a little longer  
3 than what we tend to see with seasonal flu, two to  
4 eight days with a median of three. Everybody  
5 developed symptoms. Almost every had cough and  
6 sputum as well as shortness of breath, but  
7 rhinorrhea was seen only in about 44 percent, and  
8 less so in the pediatric population. And  
9 everybody who died, at least in this series, died  
10 from a rapidly progressive ARDS.

11 This table demonstrates a clinical  
12 progression of H5N1 patients by symptoms after day  
13 following exposure to birds. And you can see that  
14 the onset of illness without a fever, cough or  
15 rhinorrhea was again about four days after  
16 exposure with pneumonia developing about a week  
17 later and ARDS quickly following the onset of  
18 pneumonia. This next slide shows the clinical  
19 manifestations of influenza A, particularly H5N1.  
20 Patients from the onset of illness to hospital  
21 admission by symptoms and age. The two things  
22 that I wanted to point out is the difference in

1 the pediatric population, particularly with the  
2 hematologic criteria that essentially 100 percent  
3 of the folks under 15 years of age, had neutropenia  
4 versus about 30 percent of the adults. And  
5 thrombocytopenia was also much more prevalent in  
6 the pediatric population. That's consistent with  
7 what they also saw in Iraq with the two kids that  
8 presented there, presented with a primary  
9 coagulopathy.

10 The next table just shows that it is not  
11 a good idea to be touching dead poultry that die  
12 from H5. And looking at the odds ratios, the more  
13 contact folks have with infected poultry, the  
14 higher the odds ratios are that you will go on to  
15 develop the disease. And it's something that  
16 we've known about for a while and now is  
17 quantified through this matched case control  
18 study.

19 The current demographics, the current  
20 data really doesn't differ from that case control  
21 study and the descriptive study back from 2004.  
22 Casualties or patients still are skewed towards

1 younger individuals, and it's unknown whether this  
2 represents viral adaptation where the virus  
3 particularly dislikes those who are younger or  
4 whether it's due to occupational/cultural  
5 practices that affect exposure or the fact that  
6 the way kids are being exposed that they're  
7 getting a higher antigen load.

8           These charts, the next few charts are  
9 from the WHO and, again, just demonstrates that  
10 younger folks tend to get more disease regardless  
11 of which country you happen to be from. At my  
12 age, it's reassuring to see that very few people  
13 wind up getting H5N1 when you have as much gray  
14 hair as I, and looking at the mortality, also it's  
15 reassuring to see the older you get the more  
16 likely you are to survive. Again, the younger age  
17 population clearly represents the lion's share of  
18 the deaths as well as the lion's share of the  
19 cases.

20           Which brings us to DoD activities. The  
21 national strategy was released in November of 2005  
22 and the national plan released in May of this

1 year. At the time we prepared the slides, DoD had  
2 116 specific tasks of which DoD had the lead.  
3 Health Affairs, out of that 116, had specific  
4 tasks and from one agency, I think we picked up a  
5 couple more since. Of those 67 we were the lead  
6 in and supporting agency for another 50 tasks. So  
7 the Department of Defense is well integrated in  
8 the national plan.

9 The next two slides is just a laundry  
10 list of some of the tasks that Health Affairs has  
11 as a primary agency. I'll be using this list in  
12 subsequent briefings as a template to describe  
13 where DoD is at in regards to pandemic planning.  
14 Going through the list you can see that we've  
15 already accomplished a number of these goals. For  
16 example, establishing stockpiles of vaccine  
17 against H5N1 or procuring 2.4 million doses of  
18 antiviral medications, updating risk communication  
19 materials. So all of these are either done or  
20 close to completion.

21 In addition to the national plan, each  
22 U.S. Government agency was tasked with developing

1 a pandemic influenza plan and DoD is no different.  
2 And the DoD pandemic plan is in its final draft  
3 stages for SECDEF review and that should be  
4 happening at the end of May. You'll be hearing  
5 more from the COCOMs, but the COCOMs are tasked  
6 with developing their own pandemic influenza plan  
7 and their anticipated following signature of the  
8 DoD plan.

9 Planning is nice and it's good to have a  
10 plan, but you really need hardware to actually act  
11 on that plan, which leads us to our vaccine. As  
12 we said before, we've got 2.4 million doses based  
13 on a 90 microgram dose in our current stockpile  
14 with plans to bottle 1.3 million doses at the end  
15 of June. Following licensure, the current concept  
16 includes administration beginning at WHO phase 4  
17 with licensure anticipated, I've heard, July by  
18 some folks and from the representatives from HHS,  
19 the term "June-ish" was used as far as FDA  
20 licensure. The adjuvant trials should be  
21 available around July of 2006 and as Dr.  
22 Grabenstein had mentioned Clade 2 pilot lot was

1 commissioned by HHS.

2 This year we also saw the reports in the  
3 New England journal regarding the vaccine safety  
4 and immunogenicity trials for our stockpiled  
5 vaccine. The good news is that there's no severe  
6 adverse events. In fact the vaccine is generally  
7 well tolerated. However only those receiving two  
8 doses at 90 micrograms were able to achieve  
9 neutralization antibody titers or  
10 hemagglutination-inhibition titers are greater  
11 than one to 40 and more than 50 percent of the  
12 subjects. It was just barely over 50 percent at  
13 54 and 58 percent respectively.

14 At the last Board meeting there was a  
15 request to actually see the data regarding cross  
16 reactivity of the Vietnamese 1203 vaccine with  
17 Clade 1 and Clade 2 strains. You can see here  
18 here's the antigen and with Clade 1 reference  
19 ferret antisera the response is reasonably good.  
20 However, when you move to Clade 2, except for this  
21 one reference antisera the response is less than  
22 optimal.

1           Moving on to antivirals. First with  
2 Relenza. It's now been approved by the FDA for  
3 treatment and prophylaxis before it was just  
4 treatment. However there's still no clinical  
5 experience with H5N1. There is a concern, as we  
6 mentioned before, that Relenza may not be  
7 effective if the route of exposure is GI or if  
8 there's a significant viremia. It's primarily  
9 because of the route of administration and the  
10 site of action with Relenza being a stimhaler. A  
11 contract has been awarded to Glaxo Smith Kline for  
12 \$5.25 million worth of Relenza that we're planning  
13 to add to our stockpile, and that represents about  
14 240,000 treatment courses with anticipated  
15 delivery around March of 2007.

16           Our mainstay still is Tamiflu. Again,  
17 we have 2.4 million treatment courses that are  
18 prepositioned. One change is that our initial  
19 contract limited use to just phase 6 and now we're  
20 able to use that through a revision in the  
21 contract extending from WHO phase 3 through 6. So  
22 it gives a lot more variability as far as our

1 potential use. Also in our earlier presentation,  
2 it's effectiveness in mice was somewhat  
3 disheartening, that you needed a higher dose and a  
4 longer course of therapy. More recent data with  
5 ferret models show that it's quite effective with  
6 ferrets even with what could be described as a  
7 biblical dose of antigen. With 100 percent  
8 survival in treated ferrets and 100 mortality in  
9 those that did not receive treatment. We're  
10 planning on purchasing another 470,000 treatment  
11 courses with our intention of prepositioning those  
12 at MTFs. Of that 470,000 represents about 10  
13 percent of the population at risk. We hope that  
14 this will facilitate a fairly rapid use during the  
15 initial stages of the pandemic or for primary  
16 zoonotic outbreaks that we've been seeing in phase  
17 3 and perhaps in the future in early phase 4.

18 In regards to communication, we've  
19 developed a number of communication packages for  
20 our beneficiaries that are both web based and  
21 printed. This includes pandemic influenza  
22 information sheets and these two tri- folds. This

1 one actually being my favorite, discussing what to  
2 do if the avian flu hits our shores but it's still  
3 in birds and not in people. Since these have been  
4 developed one potential rate-limiting step is that  
5 all of the public information and material now  
6 have to be cleared through the Homeland Security  
7 office so that may slow it's dissemination a  
8 little bit. Hopefully we'll get these cleared  
9 before the pandemic actually occurs.

10 The watch board is still alive and well.  
11 It continues to evolve. Currently access is  
12 limited to.mil and.gov addresses. It still  
13 includes our current disease status. It will  
14 include a clinical practice guidelines that are in  
15 their final stages of review. And the guidelines  
16 not only include fixed facilities but also include  
17 operational medicine, recognizing that the  
18 limitations in the field require, potentially, a  
19 different approach. It will also include a  
20 one-stop shopping for DoD policy and guidance.  
21 That concludes my brief.

22 DR. POLAND: Questions for Dr. Hachey.

1 DR. McNEILL: Mills McNeill. Just one  
2 comment. Excellent presentation. I appreciate  
3 you making the comment about rapid diagnostics.  
4 My thinking has made a fairly 360-degree turn in  
5 the last few months, particularly when you -- it  
6 was my initial thought that the impact on the  
7 laboratories might not be so great because I think  
8 the parent to the pandemic, once it hits, is going  
9 to be pretty obvious. I think a lot of the  
10 patient management as we do now with seasonal flu  
11 will have to be based on clinical presentation.  
12 However, if we only have the limited amounts of  
13 antivirals available to us and if we want to  
14 reserve the antivirals for the treatment of  
15 pandemic virus, then I think there's going to be a  
16 significant demand on our public health and DoD  
17 diagnostic laboratories for individual patient  
18 management. I don't think we're well prepared for  
19 that, and I think the laboratory community needs  
20 to be thinking about how the laboratory support  
21 will be provided. I think after a time we may  
22 very well be able to go to the rapid test, but I

1 think early on we really want to know what is  
2 pandemic virus and what may be seasonal flu or  
3 other influenza-like illness. So I think the  
4 laboratory piece of this is a significant concern  
5 for all of us, both in the civilian and in the  
6 military community and I would encourage all the  
7 lab managers in all the services to be looking at  
8 this because I think it's going to be a  
9 significant issue as we -- if and when we have to  
10 actually get into the management of a pandemic.

11 DR. POLAND: Wayne, just a follow-on  
12 question to that, when you look at the national  
13 plan test, you list refinement of DoD laboratory  
14 methods, does that include search capacity?

15 LT COL HACHEY: That includes search  
16 capacity and one of the recent changes as far DoD  
17 lab capacity is that all the LRN labs either have  
18 or will have the ability to do PCR specifically  
19 for H5. Also the number of labs that are capable  
20 of doing that is also expanding, actually almost  
21 twofold.

22 DR. POLAND: Mike.

1 DR. OXMAN: That was a super  
2 presentation, Wayne. Two questions. One is when  
3 you talk about the treatment courses, are you  
4 talking about standard or higher dose of the  
5 Tamiflu given the fact that at least some of the  
6 strains are more resistant than the average?

7 LT COL HACHEY: That's just using a  
8 standard.

9 DR. OXMAN: The other question is with  
10 respect to the ability to deploy rapid diagnostic  
11 techniques closer to the field, is there any  
12 progress in developing an equivalent particle  
13 group nation assay for the H5, for that matter H7?

14 LT COL HACHEY: Not that I know of.  
15 We've actually been briefed on some potential  
16 rapid diagnostic new technologies that actually  
17 looked very promising. The problem is that  
18 they're not terribly deployable. So they'd be  
19 very effective in a fixed setting, but sticking  
20 them in back of a Humvee and going out to the  
21 field, the manufacturers were fairly consistent  
22 that it's just not ruggedized to that extent.

1 DR. SILVA: Again, very nice  
2 presentation. I may be stealing Dr. Kaplan's  
3 thunder here but when I read that MMWR and the  
4 cases that occurred, the pediatric group you  
5 referred to, it was striking that glucopenia was  
6 very common in the kids and diarrhea. And we'll  
7 all worried about what the role of the preschool  
8 population can do in spreading this disease. In  
9 addition, the increase of incubation period by a  
10 couple days than we were expecting were both bad  
11 things spread. Spread (off mike) people are at  
12 work. When we're thinking about closing schools,  
13 on a lot of the bases, do they have preschool  
14 nurseries, et cetera? They do don't they? So  
15 that should be put in --

16 DR. KAPLAN: You mean daycare?

17 DR. SILVA: Yes. Sorry.

18 DR. KAPLAN: Child Development Centers.

19 DR. SILVA: Yes. Child Development. So  
20 if you're going to shut schools, those should also  
21 be put in the context of this. Ed, you agree, I  
22 think?

1                   LT COL HACHEY: In the meetings of last  
2 week discussing the mega model, that was one of  
3 the features that the group felt needed to be  
4 added to the master model. That in addition to  
5 closing schools, you also have to close daycare  
6 centers. The daycare centers and nurseries for  
7 that matter.

8                   DR. POLAND: Pierce.

9                   DR. GARDNER: Earlier this month I  
10 attended a symposium in which Nancy Cox and Fred  
11 Hayden were reviewing things and there were two  
12 topics that came up that I thought relevant to  
13 this committee. Fred Hayden presented a very  
14 convincing, mostly convincing, set of data  
15 suggesting that Tamiflu had activity and benefit  
16 much longer than the usual, what we think of one  
17 to two days. In fact, they cited evidence even as  
18 late as a week. I thought that was beyond what I  
19 had originally thought. I think Fred, we consider  
20 him one of our most knowledgeable people, was  
21 pushing this and I think that would change -- I'm  
22 sorry he's not able to be here today, but that

1 would alter some of the ways we approach things  
2 here if that really can be substantiated. We need  
3 to go back and talk to Fred and make sure we pass  
4 these through him. Even in some of their  
5 anecdotal data of who got which of the cases of  
6 bird flu, received Tamiflu -- some suggestions of  
7 benefit. The other point, touch on what Joe just  
8 said, diarrhea has been more prominent in this  
9 group. Nancy Cox was emphasizing the need to stay  
10 away from ingestion of infected chickens. I  
11 gather in the feline population the pathology is  
12 larger in the GI tract, you can recover virus from  
13 stool. And I'm wondering, we've never paid much  
14 attention in our thinking about influenza to any  
15 alimentary canal problems either in terms of how  
16 you get it or how you spread it. I'm wondering  
17 whether we have to do more in that regard? They  
18 both were quite -- again, Fred picked up on this,  
19 he said there's receptors, apparently in the GI  
20 tract and that this made sense. Again, one of the  
21 differences with avian, at least in their minds  
22 was the frequency of gastrointestinal --

1                   LT COL HACHEY: I think with the  
2                   identification of that GI findings now,  
3                   specifically for H5, H5 hemagglutinin that does  
4                   make it a much more worrisome aspect of this  
5                   particular virus.

6                   DR. GARDNER: Goes back to Joe's concern  
7                   about preschools.

8                   DR. HALPERIN: I need some help  
9                   understanding the epidemiology a little bit. In  
10                  one diagram you showed that most of the cases are  
11                  in younger people. If the case control study, age  
12                  is not a risk factor that is assessed. The kinds  
13                  of risk factors that are assessed are exposure to  
14                  dead birds. Is it that children are at higher  
15                  risk or the children have more exposure to dead  
16                  birds? The reason I ask is because a model is  
17                  really, it's kind of encouraging if you keep kids  
18                  at home it looks like you can reduce the problem.  
19                  Is that based on the assumption that the  
20                  communicability is much higher in children than it  
21                  is in adults? Is there any reality to that or is  
22                  it just that there are more cases in children

1 because there's more exposure in children?

2 LT COL HACHEY: As far as the modeling  
3 is concerned, I believe they're using what we see  
4 with seasonal flu, that children are the real  
5 infectors rather than the information that we have  
6 with H5 currently.

7 DR. HALPERIN: Okay. Then let's get  
8 back to the other question. Is it age that is a  
9 risk, children -- the mortality rate given all  
10 ages were similarly exposed would be higher in  
11 children, or is it that children have more  
12 exposure to dead birds, hence the numerator deaths  
13 is higher in children which is what you've shown  
14 here.

15 LT COL HACHEY: I believe that is  
16 something that is yet unknown.

17 DR. POLAND: Let's just have Ed comment  
18 on that.

19 DR. KAPLAN: If you look at the previous  
20 experience, not with H5N1, I don't think that the  
21 bird business is a big factor, just based on what  
22 the literature says. I would be the first to

1 admit that nowhere in the literature does it give  
2 an exposure to bird --

3 DR. POLAND: It's hard to the tease the  
4 two apart.

5 DR. KAPLAN: Tease them apart, but if  
6 you just look at the studies from Michigan and  
7 some of the others that have been done with just  
8 seasonal influenza, you don't see a potential  
9 risk. So that's indirect assuming half a dozen  
10 factors and so on.

11 COL GIBSON: I have just a quick comment  
12 on the case control study. If you look down in  
13 the little writing at the bottom this is  
14 age-matched one year so obviously can't look at  
15 age in that study.

16 DR. HALPERIN: It would be nice if that  
17 study were redone looking at age as another risk  
18 factor.

19 COL GIBSON: Absolutely. Totally agree.

20 LT COL HACHEY: Anecdotally, thinking  
21 back to -- for example the cases in Turkey, it was  
22 the kids that were playing with essentially

1 chicken parts for five days. So clearly their  
2 exposure was higher. Older folks in Egypt had  
3 prolonged contacting because they were plucking  
4 dead swans. It does, in a very uncontrolled  
5 sense, appear to be more exposure driven rather  
6 than age driven, but I've not --

7 DR. POLAND: Let me get Dr. Weber here  
8 and then Dr. Ostroff.

9 DR. WEBER: I have a couple of comments  
10 and questions, and let me preface it by saying  
11 this is my opinion, not necessarily CDC policy,  
12 which I think says otherwise. I will be parting  
13 company from my colleagues across the room here.  
14 I think the need for rapid diagnostics or  
15 diagnostics, period, early in the epidemic is  
16 manifest. I think that's inarguable. But I  
17 really wonder either from a disease control point  
18 of view and from a practical point of view how  
19 much you're really going to want to get people in  
20 for testing once the pandemic reaches a certain  
21 level. That is, what risk are you putting  
22 healthcare workers and other patients at by your

1       insistence of testing to see whether someone has  
2       flu or not. To me it doesn't matter whether it's  
3       seasonal or H5N1. I think some modeling and  
4       further studies need to be done to really clarify  
5       the risk benefit of doing that diagnostic testing,  
6       keeping in mind the comments that were just made  
7       in terms of Tamiflu supply, but also the risk to  
8       other people in terms of bringing them into a  
9       situation where they could easily spread this  
10      virus. When I think -- you've just outlined how  
11      much we want to social distance people and that  
12      really runs counter to that philosophy. Just as a  
13      footnote to that I was at the recent American  
14      College of Physicians session, I did a really  
15      informal poll of people I knew there to find out  
16      how they would react in the pandemic. They're  
17      really, like, I don't want my patients in the  
18      office. I'll call in the prescription for  
19      Tamiflu, I don't really care if it's flu or not as  
20      long as it sounds like they have it in the context  
21      of the pandemic, et cetera. So I think from a  
22      practical matter, obviously, DoD and in-theater

1 forces have different kinds of setups. But in the  
2 community there may well not be that kind of  
3 testing. So I think that's something to keep in  
4 mind. I think that's something that studies,  
5 modeling, et cetera could perhaps illuminate  
6 what's the break point at which we stop insisting  
7 on testing. That's a comment.

8 In addition, you listed the kinds of  
9 things that are being stockpiled and there's, to  
10 me -- and this is something I'm been pressing for  
11 within the CDC and HHS, there is a glaring  
12 omission and that is the thing that is going to  
13 kill so many people with influenza is not  
14 influenza. It is going to be secondary bacterial  
15 pneumonia. There was no mention of  
16 anti-bacterials in this presentation. I may be  
17 getting ahead of myself, but I quickly through  
18 some of the slide here and I didn't see any  
19 mention of that. I really think that has to be  
20 part of any kind of pandemic plan, because one,  
21 people will have these pneumonias. I think we can  
22 make some educated guesses as to what those

1 pneumonia's are going to be. I don't think  
2 they're going to be weird or obscure bugs. It's  
3 going to strep-pneumo, it's going to be MRSA,  
4 probably community-associated type, and some  
5 H-flu, and there are not enough supplies of the  
6 appropriate drugs right now to handle a pandemic.  
7 I think that needs to be part of our planning and  
8 I pushed for that within HHS. We're working on it  
9 in a limited way for looking at inpatients but you  
10 have to start looking about inpatients,  
11 outpatients. Are doctors going to immediately put  
12 people on antibiotic prophylaxis when they feel  
13 they have influenza because of the threat of  
14 pneumonia, especially in the defense forces that  
15 may well be -- I'm not promoting it, but that may  
16 well be a readiness issue, that is if we think  
17 they have flu and we don't want them to die, we're  
18 going to put them on antibiotics. I think that's  
19 something to keep in mind. I don't know if you  
20 want to respond to that, whether that is part of  
21 the planning. It just wasn't mentioned in the  
22 slides.

1 DR. POLAND: Let's just have a very  
2 brief comment on that, and then we've got seven  
3 more presentations and I think some of this  
4 discussion may come out and we have to do that in  
5 the next hour and a half.

6 LT COL HACHEY: As far as the pneumonias  
7 we did present with our last meeting that that was  
8 one of the issues that we were including in our  
9 stockpile in addition to PPE. Currently we've got  
10 a group of subject-matter experts within DoD  
11 representing primarily the infectious disease  
12 community that are developing, essentially, a wish  
13 list and projections as far as exactly which  
14 antibiotics we should be including in our  
15 stockpile. So we're on our way to meeting that  
16 particular --

17 DR. WEBER: We're doing the same thing  
18 from the civilian point of view and I would invite  
19 where we can find the opportunity to have a  
20 discussion offline to figure out what your experts  
21 are thinking, what our experts are thinking and  
22 try to come up with something that maybe, if it's

1 possible, one size fits all, because it's going to  
2 be the same company that have to develop the surge  
3 capacity, et cetera.

4 DR. POLAND: All right. Thank you very  
5 much. We're going to move on here to Major Peter  
6 Breed who will update -- I'm sorry. That's right,  
7 we decided to switch those a little bit. Sorry.  
8 Major Randy Smith from J-4, who will brief us on  
9 the Joint Staff pandemic influenza preparedness.  
10 Do we have your slides Major Smith?

11 MAJ SMITH: I believe these were handed  
12 out yesterday afternoon. Good morning Dr. Poland,  
13 Colonel Gibson, Ms. Embrey, members of the Board.  
14 I'd like to give a brief overview from the Joint  
15 Staff perspective on pandemic influenza planning.  
16 Hopefully this presentation will follow logically  
17 from Colonel Hachey's presentation and then lead  
18 into Major Breeds, because what I intend to do is  
19 give an overview of the overall planning effort  
20 from the COCOM perspective and Joint Staff  
21 perspective and then go into more specifics with  
22 Major Breed.

1           Talk a little bit first about some  
2 policy overview. How we got to this point, some  
3 planning guidance that's been issued so far, and  
4 I'll briefly summarize each of the Combatant  
5 Commanders CONPLANS. Discuss common issues both  
6 where they're similar and where they're different  
7 around the world and then take any questions you  
8 may have.

9           Many of us are very familiar with the  
10 policy guidance that's led us to this point.  
11 Essentially this is being driven by the Homeland  
12 Security Council and there's been a series of  
13 documents that have been published since November  
14 of last year including the National Strategy for  
15 pandemic influenza. The Department of Health and  
16 Human Services plan, from that time frame and very  
17 recently the National Strategy for pandemic  
18 influenza implementation plans was published a few  
19 weeks ago. As Colonel Hachey indicated, DoD is  
20 responsible for 116 tasks and we're the lead  
21 agency for 32 of them. To actually implement our  
22 requirements there have been several policy

1 guidance that have been put out Health Affairs,  
2 and those are listed there for your reference.  
3 The DoD has also made reference to the World  
4 Health Organization Global Influenza Plan. It's a  
5 key reference document, though not necessarily  
6 considered a policy document.

7           What have we been doing in Joint Staff  
8 on this process? In September we put out a  
9 planning guidance letter asking each of the  
10 Combatant Commands to develop plans for the  
11 pandemic influenza issue. This was superseded by  
12 a planning order with more operational detail that  
13 was specified on 14, November of last year. The  
14 actual tasking evolved into each of the  
15 geographical combatant commands have to produce a  
16 CONPLAN, a contingency plan and we received each  
17 of these plans in mid-April. They all came in by  
18 the deadline, and we're currently reviewing them  
19 in the JPEC process, the Joint Planning and  
20 Execution Community, evaluation process for  
21 planning. As a matter of fact, this week, there is  
22 the third planning conference that's going on

1 right now at the National Defense University for  
2 the review and refinement of these plans. Each of  
3 the COCOMs has a representative attending. How do  
4 these documents relate to the overall DoD plan?  
5 This has been a subject that's been much  
6 discussed. A way of thinking about it is that the  
7 DoD plan that Colonel Hachey referenced is going  
8 to basically be a strategic document that's  
9 intended to meet the requirements of the Homeland  
10 Security Council tasking and provide overall  
11 policy guidance. The operation details for how  
12 DoD would actually respond practically around the  
13 world in our theaters of operation are going to be  
14 found in the COCOM CONPLANS. Consider the DoD  
15 document to be a thin cover document and then the  
16 COCOMs would have more operational details.

17 For reference this just gives an  
18 overview of the geographical areas and how they're  
19 covered by the unified command plan.

20 These are the CONPLANS that have been  
21 published right now that are in final review.  
22 NORTHCOM, PACOM, UCOM, CENTCOM and SOUTHCOM all

1 have documents. The functional commands,  
2 TRANSCOM, SOCOM, JFCOM and STRATCOM, they do not  
3 have a tasking to produce plans, but they will  
4 ultimately produce supporting plans to these  
5 documents.

6 Brief summary of the NORTHCOM plan.  
7 NORTHCOM has the unique mission since they support  
8 the civil authorities mission inside the  
9 continental United States. These are the key  
10 tasks that are specified in their plan, and they  
11 have a very tight interagency communication and  
12 interaction with the state and local authorities.  
13 They're currently envisioning establishing a  
14 series of joint task forces if this were to become  
15 a pandemic inside the United States. They would  
16 also be responsible for DoD assistance to Canada  
17 and Mexico.

18 I'll largely the PACOM CONPLAN briefing  
19 to Major Breed. He'll have much more information  
20 on this.

21 USEUCOM CONPLAN 4690, basically is  
22 geared toward their mission of Europe and Africa

1 and they're responsible for coordinating their  
2 efforts for department of State, host nation and  
3 international partnership. The unique issue that  
4 EUCOM has is that they operate in two vastly  
5 different environments. In the European theater  
6 there's a great deal of public health  
7 infrastructure in place; however in the Africa  
8 environment there is very little. The demands  
9 will be significantly different.

10 USCENTCOM CONPLAN 1210. Again, they  
11 have a similar mission to the others to support  
12 domestic and international partners. Their unique  
13 issue, obviously, is their combat operations that  
14 they're currently working on right now and how  
15 difficult their operational environment is. The  
16 CENTCOM is highly dependent upon movement into and  
17 out of theater, and a pandemic could constrain  
18 this.

19 U.S. Southern Command is the last one  
20 that I'll talk about specifically. They have a  
21 fairly unique theater in that they have very few  
22 installations and very few forward deployed troops

1 right now and they're highly dependent upon  
2 Department of State, USAID efforts. They would be  
3 in a clearly supporting, subordinate role to this.

4 An issue that's come up right now is  
5 you'll see the term "phase" talked about a lot in  
6 the COCOM CONPLANS and they don't match up exactly  
7 among themselves or with the World Health  
8 Organization's definition. Now all of the  
9 combatant commands use and make reference to the  
10 World Health Organization phases but we have a  
11 little bit of a disconnect right now that Joint  
12 Staff is currently working to try to resolve about  
13 the different phases. What will probably happen  
14 is that the plans will go forward with this  
15 current construct and during the next review  
16 period, perhaps six months from now, they will be  
17 synchronized.

18 Some of the common themes that we found  
19 in all the COCOM plans, it must be remembered the  
20 DoD is always in a supporting role to a larger  
21 U.S. government response effort. And that DoD has  
22 other assigned missions that they will need to

1 complete. Protection of DoD personnel and  
2 beneficiaries is a priority and no COCOM has the  
3 resources to be able to meet these requirements  
4 fully. We will likely have to provide  
5 transportation and logistical support both CONUS  
6 and OCONUS. A common mission that NORTHCOM  
7 anticipates is having to provide logistical and  
8 transportation support to state and local  
9 authorities in moving stockpiles and providing  
10 logistical support. OCONUS as well. The  
11 Department of State will likely ask DoD to move  
12 things back and forth quite a bit. There is a  
13 great deal of concern among all the COCOMs about  
14 obtaining access to the antiviral medications in  
15 the DoD stockpile. We've made great progress on  
16 that and Health Affairs efforts to stockpile  
17 vaccine -- stockpile antivirals have given us some  
18 flexibility, but all of the COCOMs feel that they  
19 would have to tap into that stockpile sooner than  
20 they would have liked to. The additional purchase  
21 of the 470,000 courses that Dr. Hachey talked  
22 about will probably alleviate this situation a

1 little bit. Also there's common concern about  
2 U.S. citizens living abroad. The COCOMs  
3 anticipate that there will likely be non-combatant  
4 evacuation operations due to civil unrest in many  
5 parts of the world. The "treat in place" doctrine  
6 is currently what everyone seems to be leaning  
7 forward. Minimal aero/medical evacuation.  
8 Perhaps in some cases, but the idea would mostly  
9 -- the COCOMs are assuming is that they would have  
10 to treat in place. And medically underserved  
11 areas such as Africa and Southeast present unique  
12 challenges. The bottom line probably will result  
13 is that there will have to be a national  
14 prioritization of missions. Where does OEF and  
15 OIF fit into the overall response efforts.  
16 Priority of efforts will have to be established at  
17 the Presidential and Homeland Security Council  
18 level.

19           Some of the unique issues that each of  
20 the COCOMs have confronted is that CENTCOM is  
21 combat operations. Will force flow continue both  
22 in and out of the theater. And supporting efforts

1 such as EUCOM providing medical treatment at (off  
2 mike) Regional Medical Center. They have very  
3 difficult choices to make if they shut off that  
4 flow. NORTHCOM's relationships with the other  
5 U.S. government partners in the services is  
6 evolving and there is some concern about roles and  
7 responsibilities. EUCOM's highly dependent on the  
8 host nations in Europe for medical care. Tri-Care  
9 remote and Tri-Care Europe has done much of our  
10 medical care for U.S. DoD beneficiaries for  
11 years, and there is some concern about access to  
12 this in a pandemic. Also there's somewhat of a  
13 legal issue involved the EUCOM has raised: Would  
14 U.S. citizens be allowed to partake or be  
15 permitted to participate in European containment  
16 operations with non- FDA licensed products.  
17 EUCOM's Africa responsibilities are much  
18 different. We would probably have to evacuate  
19 citizens. There would probably be a greater  
20 chance of civil unrest and the host nations would  
21 need significantly more support. We would  
22 probably have provide significantly more support

1 to the host nation if requested by the Department  
2 of State. SOUTHCOM, very few assigned forces and  
3 bases and they would have the challenge of being  
4 highly dependent on overall U.S. government  
5 response efforts. And Major Breed will have more  
6 information about PACOM, but they have vast  
7 transportation distances to contend with, as well  
8 as a mix of domestic and international roles and  
9 responsibilities. In the State of Hawaii, they  
10 have a domestic support to civil authorities  
11 mission. However in the western pacific, they  
12 have host nation roles and responsibilities. And  
13 I like to take any questions you may have.

14 DR. POLAND: Thank you. Actually, I  
15 think we'll hold questions until after the next  
16 presentation given the interplay between them.  
17 We'll go right on then to Major Peter Breed who  
18 will update us on PACOM influenza preparedness  
19 activities. I'd ask the remaining speakers, be as  
20 succinct as possible given what we need to get  
21 through in the next hour.

22 MAJ BREED: Am I obligated to stand

1 behind this, sir?

2 COL GIBSON: Just so the transcriber can  
3 pick you up. If she starts shaking her head, get  
4 back to the microphone.

5 MAJ BREED: Good morning, ladies and  
6 gentlemen. Thank you for your time. On behalf of  
7 Admiral Burkhart, the PACOM Surgeon, we say Aloha  
8 and thanks for letting us have some of your time  
9 this morning. I won't talk through all these,  
10 because we've already talked about the time  
11 constraints we have, but I would like to mention a  
12 point here on particularly on preparation  
13 activities. I've got some issues here that we're  
14 going to bring out because we at PACOM think we  
15 are going to be an execution arm out here if a  
16 pandemic truly hits. So it's important that we  
17 share within the medical communities some of the  
18 challenges that we see coming down the road. I  
19 don't want to be whiner, but I want to be  
20 forthcoming on what we see are problems. This is  
21 the old brief. We'll move on by that.

22 Within the plan itself J57 within our

1 planning function has the lead on this. This is  
2 essentially a war plan. War plan is not the right  
3 terminology, but this is not a medical plan. It's  
4 this is the DoD plans so it will be within our  
5 standard planning function. Key bullet on that  
6 slide in my mind, since much of that's already  
7 been discussed this morning is that fact that  
8 PACOM published an Instruction back in August of  
9 '05, and those, you know, that understand the  
10 coordination process and how long it takes to  
11 publish anything within DoD, know that that means  
12 we've been working this issue for quite some time  
13 along with lots of other folks. PACOM certainly  
14 had their ear to it. Much of this you've covered  
15 already. We had suspense from the Joint Staff for  
16 31 March. We expect additional guidance but we  
17 know we had to address those issues already. In  
18 light of time, we'll fly past these.

19 PACOM its mission statement. We know,  
20 number one, we have to take care of our own.  
21 We've got to protect our forces and maintain  
22 operational capability if we're going to be able

1 to do anything. So if folks like I get sick and  
2 all of our docs get sick, we can't take care of  
3 our pilots and our ship drivers, that sort of  
4 stuff, take care of our own and then leverage  
5 ourselves to participate in international  
6 operations, support operations. The key issue  
7 there is being we're a support role. We  
8 understand that. PACOM is not going to run out  
9 and conquer the world on pandemic influenza. We  
10 will help as needed within the medical community  
11 across the world. Again, our priorities at the  
12 bottom, maintain operational readiness, support  
13 domestic and international efforts. As Major  
14 Smith alluded to, we've got our own phasing  
15 constructs built. And an important thing to note  
16 and sort of a reason to justify, within the  
17 military community, within the planning community  
18 we have a set way we do plans. Within the JOC  
19 structure we have terminology that we use.  
20 Therefore we had some challenges with simply  
21 taking the WHO definitions of phasing and the  
22 evolution of a virus and making that fit into the

1 mindset of a tank driver, ship driver, that kind  
2 of stuff. So there is some justification why  
3 there seems to be a lot of phasing. There, in  
4 fact, are a lot phasing, but that's the primary  
5 reason behind it. In many ways semantic, but it's  
6 important to the guys that do planning.

7 Phase 0, we've already passed. That's  
8 us building relationships within our theater. We  
9 need to do that, we need to continue to do that.  
10 We are now in Phase I, that's where we focus on  
11 enhancing capability. There is capability out  
12 there. DoD and PACOM in particular needs to  
13 figure out how we fit in to enhancing capabilities  
14 in a lot of these nations across our theater.  
15 We're working that. Money would help. Phase II,  
16 we are not due to contain yet, but we believe we  
17 could well be asked to go help contain and initial  
18 outbreak. We have a lot of people that are easily  
19 told what to do and we put them on planes, we can  
20 move them quickly. A lot of people think, let's  
21 ask the military because they can help us out. So  
22 we need to plan for that contingency. Then we

1 move into Phase III, which is respond, which is to  
2 go in -- the pandemic has not been contained.  
3 It's out there, what are we going to do to  
4 maintain ops, support civil authorities, support  
5 host nation authorities, that kind of stuff.  
6 Then, lastly, recovery, how do we take those  
7 governments that suffered damage or whatnot, try  
8 to restore some stability. As I stated, we are in  
9 Phase I right now.

10 This is a quick picture of the PACOM  
11 AOR, when you think of the whole globe as a  
12 substantial area. Again, I think the slides you  
13 have in your book are slightly different than  
14 this. You will see that there should be colored  
15 dot on the Korea theater of operations. The point  
16 of this slide is that even within our theater, we  
17 have three very significant operational commanders  
18 when we talk about addressing a pandemic. We have  
19 a combined support force which we're handing off  
20 to MARFORPAC that if things happen out in that big  
21 area, that task force will take the lead on behalf  
22 of PACOM. If it happens in the Y or the protector

1 area, the Joint Task Force Homeland Defense steps  
2 in. And you see Homeland Defense language in lots  
3 of other things, so there's an overlap, Homeland  
4 Defense, Homeland Security, that kind of stuff.  
5 And we also have, as I've indicated, and I believe  
6 it's in your slides is the Korean theater of  
7 operations has their own structure, their own  
8 command authority up there so we are managing  
9 plans for each of those within the PACOM umbrella.

10 Where are we today? Admiral Fallon, our  
11 four star, signed out our plan 21 of March. In  
12 addition to that h signed out the first four  
13 annexes, essentially he passed them on, the  
14 directors signed them out. They are an  
15 information management. Often we talk about B as  
16 intel, but we know that this is a public health  
17 issue and we can't get hung up on terminology  
18 that's going offend people or turn them off or  
19 make them suspicious of us. It's information  
20 management. F is public affairs. Q is our  
21 medical information that we have at this point,  
22 and V is an interagency annex. We know that

1 interagency cooperation and coordination is  
2 critical to this. So those were the first four  
3 out of the barrel. As mentioned earlier they're  
4 in the JPEC process, meaning all the other COCOMs  
5 are currently chewing on each other process -- on  
6 each other's plans. Where we take those and how  
7 we get over our phasing construct and our  
8 challenges, we'll have to see. PACOM also has  
9 issued its own planning Directive down to its  
10 subordinate commands. The Air Force contingency,  
11 the Navy, the Army, the Marines, as well as those  
12 Joint Task Force I talked about. Again, this  
13 slide is in error now that the USFJP should not be  
14 there, but Korea and ALCOM certainly have their  
15 own planning responsibilities. The precursor on  
16 that is we are currently being directed to do a  
17 great deal of things. A lot of effort and right  
18 now it's all coming out of hide and we understand  
19 that, but to plan correctly we need the money.

20           Quickly, here. I was asked to talk  
21 about what PACOM has done with regarding  
22 preparedness. I've taken us back almost a year.

1 Fourth quarter of last year we published an  
2 instruction, as I said, we developed a CONOPS.  
3 It's always that evolutionary process within the  
4 planning stage. Then we moved into first quarter  
5 of '06, we did PHEO training. We called in all of  
6 our public health emergency officer from across  
7 the AOR, brought them here, sat in a room for two  
8 days and talked nothing but influenza and pandemic  
9 influenza. Some of you folks in the room  
10 contributed to that. Thank you very much. It  
11 went very well. We need to keep focused on that  
12 kind of issue and those kind of people, because  
13 they will carry the load when this stuff really  
14 happens. We also had a preliminary exercise that  
15 really turned out to be a great working group, a  
16 great discussion group. Probably in hindsight  
17 doesn't really meet the definition of an exercise  
18 so we need to keep that on the table. We did  
19 start a watch board that -- sort of that first  
20 pictorial slide you saw is something we produce  
21 out of the surgeon's office every weekend. It  
22 goes out across the command, ALCOM, USFK, the

1       Australians, lots of folks out there love it, they  
2       like to see it every week so we keep pushing it  
3       out there, as well as a number of websites within  
4       PACOM and MARFORPAC. We finalized that CONOPs  
5       back then and that moved us into the second  
6       quarter where we wrote the COMPLAN which we've  
7       already talked about. We developed some  
8       educational tools. We have presentations for the  
9       basic soldier and his commander, healthcare  
10      workers that provide care and healthcare workers  
11      that don't provide care, those packets have all  
12      been pushed across the command a couple of times  
13      now, so those tools are out there. Also of note  
14      in that second quarter is we really started  
15      international engagement. We met with the  
16      People's Liberation Army in China, we met with the  
17      Royal Thai Army, we met with the TNI in Indonesia.  
18      We're meeting with these folks in these militaries  
19      to say, "Hey, how are you guys going to handle it?  
20      How can we work together?" We're taking baby  
21      steps, but we've got to do that if we're going to  
22      come to grips with how we fit into an

1 international community to fight a global disease.  
2 Moving ahead, we're not there yet. Again, this is  
3 a wish list. We've got (off mike) but we are  
4 currently exercising in bird flu scenario in a  
5 military field exercise right now. We're keeping  
6 it a bird flu because we can't crush the exercise,  
7 but we're getting those mindsets out into the  
8 common troops so they understand, watch out for  
9 birds, public health issues, hygiene issues, those  
10 kinds of things. We're working, as we have in the  
11 past with plans development. We've got a couple  
12 guests in the back from Hawaii that it's been  
13 absolutely wonderful to work with. We will  
14 continue to work with them and we're working with  
15 them on exercises that we move forward. Lots of  
16 other great things that we're going to keep  
17 working on. In fact, you see -- take on one just  
18 prior to here at 9:00 we were talking to Deputy  
19 Undersecretary Lawless about how we can work with  
20 some of the other countries out there on bi-lat  
21 and tri- lat Initiatives to break some of the  
22 barriers and use a reasonably non-threatening, but

1 high interest issue like pandemic influenza to get  
2 over some political battles.

3           These are some proposed field activities  
4 that we at PACOM have. Again, we're trying to  
5 figure out what can we do forward that fits into  
6 the larger U.S. government construct to get things  
7 done, improve capability, improve surveillance,  
8 but improve our ability in our operating. So  
9 we've got a number of things here, a number of  
10 countries. We've got -- most of these -- all the  
11 light green means they've been approved. There's  
12 only three up there that truly have been funded at  
13 this point. Again, we're going back to these are  
14 good things to do, everybody agrees they're good  
15 things to do, but we need the cash. Just wanted  
16 to share with you that we, as an operational arm  
17 of your military, are trying to help make a  
18 difference out there in a planning perspective.

19           Challenges. Here's where I don't want  
20 to waste a whole lot of your time, but really want  
21 to share some of our major concerns. We've moved  
22 that to backup so you have it. This slide sort of

1 mimics some of the stuff that Major Smith talked  
2 about. One piece that I would like to action a  
3 little bit is that our -- facing left -- facing  
4 right column, U.S. Government National Response  
5 Plan. That is yet another phasing construct  
6 within the U.S. Government that we have to deal  
7 with. Right now our paperwork says, Joint Staff  
8 will worry about that column. The COCOMs will  
9 worry about this column and help the FERISYS  
10 direct all the installations -- you have to worry  
11 about that column. How can we execute that? I  
12 don't think we can. So phasing is a significant  
13 issue within DoD from an operational planning  
14 perspective. Note at the bottom is there is so  
15 much political interest in this topic right now,  
16 that there are meeting flying out of every window  
17 and we don't know where to look to figure out  
18 who's got a real handle on all of them. I don't  
19 think anybody ultimately will, but right now there  
20 are so many coming at us, we have a difficult time  
21 keeping track of them, let alone, funding people  
22 to come from Hawaii to go these. So, somehow is

1       there an overall lead. We know there's lots of  
2       folks that have titles that say their the lead  
3       planner, but we still feel a little bit  
4       disconnected.

5               These are some issues that were talked  
6       about by both Colonel Hachey, Major Smith. Some  
7       of this has been addressed. We would like to just  
8       foot stomp a couple concerns. With regard to  
9       Tamiflu, our current policy says that if your  
10      sick, you go to the hospital, but are not  
11      hospitalized, we're going to send you home with no  
12      medicine. I don't want my wife coming home and  
13      making sick and I'm going to go back and I'm going  
14      to go back infect the PACOM staff. So we have a  
15      challenge with that from a public health  
16      perspective. That doesn't seem to make sense to  
17      send sick people home to expose pilots and ship  
18      drivers and that kind of stuff. So we work --  
19      Colonel Hachey made that point. I think there is  
20      some light at the end of the tunnel that that may  
21      flex a little bit. But right now that's a  
22      concern. Again, the argument of we access to the

1 strategic national stockpile, most of the pacific  
2 theater, most of PACOM does not. We are  
3 considered overseas to the Department of Homeland  
4 -- Health and Human Services. Prophylaxis issue.  
5 Current policy limits us to 30 percent, and we  
6 understand that. But when we do the math, we're  
7 skewing some numbers a little bit by saying the  
8 portion of the DoD stockpile, it is DoD stockpile,  
9 but the portion of that that resides within our  
10 theater, when we do the mathematics, we have way  
11 too much for what we would project as a worse-case  
12 treatment scenario. We can only use 30 percent of  
13 that for prophylaxis to support a U.S. national  
14 government containment procedure, that ends up  
15 leaving this middle 30, 40 percent untouched in a  
16 warehouse. We'd just like the flexibility to  
17 access that if we need to. Again, I think there's  
18 some light on that, but that is a concern for us.  
19 The math doesn't fit for us. DoD and DHHS have  
20 stockpiles. Again, Colonel Hachey some of the  
21 relief authorities look at that -- if we can get  
22 through today if we need it; however, the

1 combatant commander really wants access to that  
2 stuff very quickly, and is concerned with the time  
3 delay it may take to run a formal request process  
4 back to D.C. and come back down. I know that's  
5 not a new one ma'am, but I'm obligated to bring  
6 that up again. We'd like access to that stuff or  
7 release authority at a lower level.

8 Antibacterials. I think that discussion's already  
9 been brought up. The vaccination -- Clade 1  
10 vaccination. To me this is a risk communication  
11 management expectation. I think Colonel Hachey  
12 addressed it a bit. Our question is: If we have  
13 the vaccine yet don't really talk about a policy  
14 of use yet, that leaves our consumer base  
15 scratching their heads saying, "What's going on?  
16 There's a vaccine out there, why aren't we getting  
17 it?" If the right answer is "Your risk is not  
18 that high today." We have to tell them that. If  
19 the right answer is "Your risk isn't that high  
20 today, but when we hit Phase IV, that's when we're  
21 going to go ahead with this." We just need to  
22 communicate that. I think that's the vaccine

1 issue that we see now. I'm going to quit  
2 grumbling about the fact that we have a vaccine  
3 and we're not sticking people, but that's the  
4 issue.

5           Some of these issues, as we go across  
6 surge capability, do we have it? Don't we have  
7 it? When we talk to our MTFs we don't have it.  
8 We've scaled back our MTFs so much that there  
9 really isn't a surge capability so something like  
10 this is really going to hammer them. Diagnostic  
11 capabilities. We've already talked that to some  
12 degree. It is lacking. It's not out there. The  
13 expanse within the LRN network is great, but that  
14 means we have now four or five labs within the  
15 pacific theater that can confirm H5N1. Why we  
16 can't drive that into every MTF where we have  
17 qualified lab folks is a question and a challenge.  
18 Training. No established, formal training  
19 program. Communication needs to be better. I see  
20 you're watching the clock so I'll press ahead.

21           Surveillance networks. I think we've  
22 talked about that and folks talked about it

1 earlier. We just are concerned that there's not  
2 enough information coming from far enough out.  
3 Again, we are a consumer of information in this  
4 case, we'd like to see more of it out there.  
5 Modeling. We understand that, yes, there are  
6 models out there I'm going to use flu surge. As  
7 of today you ask anybody in the various  
8 installations or within the commands across DoD,  
9 none of us have an agreed upon model, nor do we  
10 have a model that goes beyond predicting bed space  
11 and some basic med supply issues. We don't get  
12 into secondary effects, third effects, which are  
13 important to a four star that runs 50 percent of  
14 the planet. PPE. We very much appreciate that  
15 Health Affairs some money for this and is pushing  
16 it out to the services. We definitely want to see  
17 that come down range and get to the MTFs and into  
18 their hands; however the planning factors are one  
19 mask per provider per day and I haven't talked to  
20 any provider to say, "Well, when I've got a bunch  
21 of flu patients coming to my ER, one mask is all I  
22 want and I'll be happy with that." Health Affairs

1 is doing what they can, but we desperately need  
2 more.

3 Summary and conclusions. There we are.  
4 We think it's a viable threat. We're not panicked  
5 yet. It's out there, we're planning for it.  
6 We've got some annexes going. We've talked about  
7 the challenges. We really would like to see some  
8 overarching program management. We talk about  
9 this as a program within DoD now. It's a  
10 deliberate planned program. There's no funding  
11 line. There's still no single, sole belly button  
12 for everything, which we think is needed in a true  
13 deliberate planned program. One person has a  
14 plan, one person has activities, one has a speaker  
15 engagement, that sort of stuff. We need one belly  
16 button. And the bosses foot stomper is within DoD  
17 we really, truly need a good exercise that really  
18 test the medical system. What shortfalls do you  
19 really see in your MTFs when you have the patient  
20 show up. We think we've got a good idea, but we  
21 really need to go through it to validate it. With  
22 that, sir -- sorry that that's slightly different

1 than the handout you got earlier this morning, but  
2 I think the gist is still there.

3 DR. POLAND: Any very high priority  
4 questions? Otherwise we're going to proceed  
5 along. Thank you. Colonel Mike Brumage will  
6 introduce the next set of speakers.

7 COL BRUMAGE: Thank you very much.  
8 Before I introduce our next set of speakers from  
9 Tripler Army Medical Center, I'd like to recognize  
10 two friends and colleagues from the Hawaii State  
11 Department of Health. Dr. Paul Efler, is the  
12 state epidemiologist and sitting next to him is  
13 Dr. Sara Park, who is the lead for the State of  
14 Hawaii on pandemic preparedness and response. As  
15 you know, one of the best things about working at  
16 Tripler Army Medical Center is -- other than  
17 living and working in a tropical paradise, is that  
18 we have quality people that work there and we have  
19 a spirit of innovation that permeates the  
20 organization. Today the Board will hear two  
21 presentations from Tripler that serve as models of  
22 pandemic preparedness and response. I'm first

1 going to introduce Dr. George Underwood, Colonel  
2 Retired Dr. George Underwood. He's the Director  
3 Informatics Clinical information section,  
4 Information Management Division. He's also staff  
5 physician, pulmonary disease service at Tripler  
6 and Associate Clinical Professor of Medicine at  
7 the University of Hawaii School of Medicine.

8 DR. UNDERWOOD: I'm going to talk today  
9 about a project the pandemic influenza tracking in  
10 the DoD community on Oahu. In January, Mike came  
11 to our informatics group with a concern. And the  
12 concern was that if in fact we get to a pandemic  
13 influenza outbreak that we don't have the tools,  
14 at least in the local community, the DoD community  
15 to manage and track the disease. With that  
16 challenge we set together a working group to  
17 develop the data, tracking and management for our  
18 command and public health perspectives. We wanted  
19 to facilitate managing the epidemic or pandemic as  
20 it occurs. We wanted something that would be easy  
21 to use. We wanted something that would use the  
22 standard DoD tools and I want to digress, for the

1 civilians in the audience, I'm going to use CHCS  
2 or CHCS legacy which is the Department of Defense  
3 medical information system that's been in use for  
4 the past 15 years and then going to use AHLTA,  
5 previously known as CHCS II, which is the current  
6 system which is being deployed throughout the  
7 military health system. Although the two work in  
8 conjunction today, ultimately, AHLTA will replace  
9 CHCS or CHCS legacy. So we wanted to develop  
10 something that both front ends could use and we  
11 wanted something that we could use for data  
12 retrieval. We recognize that ultimately we want  
13 data retrieval out of the AHLTA clinical data mark  
14 or clinical data warehouse. Those two are  
15 evolving. So today we didn't have a repository to  
16 run reports. So we used a locally developed  
17 clinical repository that has met our needs very  
18 well. We put together a tracking group with a lot  
19 of representation, both within the Tripler  
20 community, the public health service community.  
21 Our pharmacy, infection control. We had  
22 Tri-Service and other representation on an ad hoc

1 basis. Our data model. We wanted to use AHLTA or  
2 CHCS as our front-end data capture. AHLTA and  
3 CHCS send data to the CHCS box. This has our lab  
4 data, our prescription information, our ambulatory  
5 data collection, our ICD-9 codes, et cetera.  
6 Those, in turn, feed the military health system  
7 clinical data repository, which ultimately, at  
8 some point in the future, will feed the clinical  
9 data mark and data repository. Ultimately reports  
10 would need to be run out of this system. However,  
11 for a long time, in fact we've had this clinical  
12 outcome's data repository since 1995 complete with  
13 data from CHCS all the way back, well over 110, 15  
14 million records. So we've been feeding data into  
15 this repository and from this repository we're  
16 developing reports that feed a web dashboard that  
17 you will see. We're also developing a secondary  
18 database within the CEO to capture some additional  
19 data elements that are not yet captured within  
20 AHLTA. We're also wanting to link this to our  
21 TAMC employee database so that we can truly track  
22 our employees, determine which ones have been

1 infected, which ones are now ready to go work on  
2 our wards since they have a relative immunity.

3           So we wanted to use for a front-end  
4 AHLTA, we developed an alternate input method  
5 form, and AIM form, and I'll show you the examples  
6 of that, to capture the data. We're also  
7 capturing ICD-9 codes and orders from legacy CHCS.  
8 We've also made arrangements to use paper copies  
9 of our AIM form in the emergency room where  
10 they're not using AHLTA or during AHLTA down  
11 times.

12           We submitted our standard AIM form for  
13 influenza to the AMED and, in fact, just this week  
14 the AMED has approved and released our influenza  
15 and influenza-like illness as a Department of  
16 Defense supported AIM form. So it is now  
17 available to be used within the MHS community.  
18 For those of you who haven't seen AHLTA or the AIM  
19 forms, this is a tabbed metaphor, you click on the  
20 tab and you pull up the appropriate page. This is  
21 the history of present illness page. It's pretty  
22 much point and click through the presentation of

1 your patient. This is a surveillance tab.

2           These are data elements that are not  
3 currently captured within AHLTA, and so this would  
4 be captured -- at least not captured as discrete  
5 data elements. These were to be captured as free  
6 text and our preventive medicine folks will  
7 transcribe this into our repository. For example,  
8 did the individual have travel to a foreign  
9 country within the previous two weeks, yes or no?  
10 If "yes" where? Has the person had prior use of  
11 antivirals or statins, yes or no? If so, which?  
12 Et cetera. So these data elements would get into  
13 our supplemental database which would then be able  
14 to be reported against. This is the review of  
15 systems tab. For the standard, just check yes or  
16 no. You have the option of adding free text if  
17 you wanted to check one of these free text box. A  
18 standard physical examination, point and click.  
19 We're also asking some additional test result  
20 information, pretty much yes or no.

21           We also have a guidelines page to  
22 provide additional information to the clinician

1 who's talking with the patient. One of the things  
2 we learned was that our clinicians did not really  
3 know how to do a nasopharyngeal wash so we added  
4 the directions right on the form so that now they  
5 can refer to that when they send the patient for  
6 that particular study. These are the common  
7 influenza- like ICD-9 codes, which we are  
8 recommending to be captured during an encounter  
9 for an influenza-like illness, whichever one seems  
10 most appropriate. For purposes of the reports  
11 that I'm going to show you, we're capturing those  
12 that start with 487. We also created an order set  
13 within AHLTA so it's basically just point and  
14 click for the standard laboratory orders as well  
15 as pharmacy orders.

16           These can modified on the fly by the  
17 site, by the way, as the practice changes. We  
18 develop two report avenues, one with public data  
19 for our military health system personnel at  
20 Tripler, you have to be on our network, and the  
21 other has protected health information and only  
22 the planners have access to that information.

1 This is the Tripler intranet main home page.  
2 Influenza information has a prominent spot right  
3 up front. That takes you to our influenza main  
4 page. This is our command dashboard with the  
5 avenues to the reports of general interest and  
6 these patient specific reports.

7 We also have other information,  
8 influenza announcements. This was an ABC  
9 broadcast that looked at influenza and air travel  
10 and the Honolulu airport, which we found quite  
11 elucidating. We also track the minutes of our  
12 meetings on this website. Once you click into one  
13 of these, we'll click into the reports of general  
14 interest, these are reports that we have come up  
15 with thus far. This is a report -- and this is  
16 real data. We started that data collection  
17 October 1st, which we considered, for all purposes  
18 the start of the flu season. And this tracks  
19 patients by age.

20 We're following the reporting  
21 requirements in this case for the state of Hawaii  
22 although we've broken out this age range so that

1 we can separate our adolescent and child  
2 population from our early young active-duty  
3 population. These are our influenza patients by  
4 status. 28 active duty, 61 dependent of active  
5 duty, all the way down to 6 retired. I want to  
6 call your attention to the 29 active duty.  
7 Because here we're tracking our patients by  
8 disposition, and we readily found out that we  
9 don't believe this data. The disposition field in  
10 AHLTA is automatically set at released without  
11 limitations.

12           And if the physician doesn't do anything  
13 to that field, that's what's tracked. So we  
14 really believe that most of our active duty were  
15 probably placed on quarters. But the physician  
16 just working through real quickly did not change  
17 the disposition field. We really don't believe  
18 this is appropriate data, and perhaps AHLTA should  
19 be changed to mandate a change in that particular  
20 field if we want the disposition data to be  
21 reliable. These are the cases that we've had by  
22 month. Notice that we had a bi-modal peak in

1 November and February. We don't have a ready  
2 explanation for that. We also have the ability to  
3 track by day. We could develop tracking by week  
4 and so forth.

5 Now let's go into the patient specific  
6 reports. This is locked by security to authorized  
7 users only and you will readily see why. We have  
8 a number of reports. We'll run through them.  
9 This is an alpha list of everyone who has been  
10 coded with influenza-like illness that 487 code  
11 that you saw and I'm obscuring the protected  
12 health information. We had the ability to sort on  
13 any of these column headings, and in fact, here  
14 I've sorted on the military unit and low and  
15 behold, this is one of our Tripler physicians who  
16 was in Tripler Medical Company B. So we're able  
17 to readily ferret out who has presented to our  
18 island community and what military unit they  
19 belong to if they are active duty. We also have  
20 the ability to do a simple right click on this  
21 screen and we can export this data to Excel for  
22 any further detailed analysis that needs to be

1 done.

2 This is a listing of all patient  
3 appointments and you'll notice that we've gotten  
4 some patients who had multiple appointments for  
5 the same condition. This is certainly going to be  
6 useful as we look at the severity of illness in  
7 individual patients.

8 This is a comparison of whether these  
9 patients who had the flu shot or not which we are  
10 intrigued by. We will lose this capability when  
11 we migrate to the AHLTA method of collecting  
12 immunizations. Currently with the exception of  
13 Hickam, our island community has been using a  
14 locally developed product for immunizations, that,  
15 oh by the way, does report to MEDPROS. But when  
16 we make that migration we will lose this ability  
17 locally. However, should this application  
18 concepts migrate into AHLTA, that would, in fact,  
19 be part of the AHLTA package.

20 These are our influenza-identified  
21 patients and pertinent labs. This would allow us  
22 to look at the leucopenia, if you will, or other

1     pertinent laboratory findings. And here are our  
2     patients, looking specifically at the presence of  
3     having had specific viral studies done. In fact,  
4     of our 137 patients, 20 had labs, 15 percent.

5             This is a list of all patients who had  
6     the influenza studies done, whether they were  
7     diagnosed with the 487 code or not. So this will  
8     pick up additional patients who perhaps were coded  
9     inaccurately.

10            This is a comparison of our medications  
11     allowing us to look at our patients looking at  
12     drugs so we can look at the affect of statins. We  
13     can look at specific patients, in this case, our  
14     patients who got Tamiflu. Here we can look at all  
15     patients who got Tamiflu. Whether they were  
16     identified in our database or not. Pharmacy is  
17     very excited about being able to use this as a  
18     tracking tool.

19            This is the percent of encounters for  
20     influenza-like illness in our database. I want to  
21     call your attention to the fact that we are  
22     encompassing the island. You've got Hickam up

1 here, Koneohe Aviation Medicine, Scofield Family  
2 Practice, Scofield Acute Care, Pediatrics, et  
3 cetera. We've got a number of additional reports  
4 on our drawing board. I won't bother to go into  
5 those in the interest of time. One of the  
6 interesting things we started doing is exploring  
7 the feasibility of geographic information service  
8 mapping.

9           So we worked with Pacific Disaster  
10 Center to send them a sanitized subset of our  
11 data. This is a result of that as a prototype.  
12 This is a map of Oahu. Each red dot represents  
13 one of our cases. This is Koneohe, here's Waikiki  
14 down here, there's Tripler. We can hone in, you  
15 can see the red dots closer in, you can hone  
16 further in, Tripler is the H in the upper-right  
17 corner, this is military housing area around  
18 Tripler. This led to one of the discussions about  
19 privacy. And we know that some nefarious  
20 individuals have been able to reverse engineer  
21 something like this. So I've decided to show a  
22 large red dot to help facilitate that. One of our

1 lessons learned is that addresses don't match up  
2 well, so we need to do a better job of capturing  
3 addresses in our CHCS and AHLTA.

4 In summary, what we've done is developed  
5 a relatively unique ability to help us track  
6 pandemic flu in the event that it happens, which  
7 of course we hope it doesn't. We're learning as  
8 we're going. None of us have ever done this  
9 before, so we're guessing the types of reports and  
10 things that we will find beneficial. And we're  
11 certainly open to suggestions about other types of  
12 things, that with your experience you may find  
13 that we would benefit from. We are able to rapid  
14 prototype so it's been working very smoothly. I  
15 don't know if we have time for questions. I will  
16 be around subsequently afterwards for any further  
17 discussion.

18 DR. POLAND: That's fine.

19 DR. UNDERWOOD: Do you want to take  
20 questions?

21 DR. POLAND: No. We'll hold on  
22 questions and keep moving on. Thank you.

1 COL BRUMAGE: Thank you very much, Dr.  
2 Underwood. Our next presenters are Major David  
3 Aut, who is the G-4 of Pacific Regional Medical  
4 Command and the Deputy Chief of Logistics at TAMC,  
5 and Mr. Craig Imhoff, Logistics Systems Analyst.

6 MAJ AUT: Thank you very much. I am  
7 glad to be here. I want to let you know this.  
8 But you are all very distinguished and experts in  
9 this field and I can tell you that when I was  
10 asked to speak in front of this Board, I was a  
11 little nervous to say the least about getting up  
12 here and presenting what we're doing at TAMC. I  
13 can tell you that we have taken this very, very  
14 seriously.

15 Myself and Mr. Imhoff here have really  
16 taken this seriously to the point where we had to  
17 come up with something that wasn't there before.  
18 You've had a lot of presentations today from  
19 PACOM, from higher than that up at the Army level  
20 -- well, I think at the lowest level right now  
21 that we're making plan -- that's probably about  
22 where we're at the MTF level. And we kind of dual

1 hat in the PRMC level in there. I tried to come  
2 up with a joke about this, but I really can't come  
3 up with a joke, because you know what? It's not a  
4 joking matter.

5 But I can tell you one thing that was  
6 kind of funny. I get to sit in the logistics  
7 teleconference from MEDCOM and this came up as an  
8 issue and we were talking at the MEDCOM level.  
9 They were asking how lessons learned from Katrina  
10 can be moved over and used to learn something for  
11 planning for the pandemic influenza. I can tell  
12 you that no one really came forward and said  
13 anything, and I can tell you that there is one  
14 true fact on a lesson learned, when this happens,  
15 and everything goes to heck, and I won't use the  
16 explicit, they're going to turn around and say,  
17 "Mr. President, what are you going to do?" That  
18 is the absolute truth.

19 That being said, and I know it's not  
20 very funny, where you're looking at now is the  
21 Army has a new motto called the Army of One. I  
22 can tell you what, I am the Army of One for

1 logistics at the TAMC and the Pacific Regional  
2 Medical Command. I dual hat in both things and I  
3 get put on a lot of committees. One being this  
4 right here, which is the pandemic influenza  
5 committee. Next slide.

6 Let's really talk about the problem.  
7 What task was I given? The main task that we were  
8 given here is they broke it down into some pieces.  
9 We received the op order from MEDCOM which looks  
10 similar to the way the PACOM model looks, and the  
11 task was: What are you going to need to handle  
12 outbreak.

13 That's a very broad question. And  
14 specifically coming down to a logistician, I have  
15 to tell you what am I going to need for a pandemic  
16 influenza outbreak. To sum it up in as an  
17 analogy, how do you eat an invisible elephant,  
18 because that's really what we're looking at here.  
19 It is something that hasn't materialized and  
20 clinically -- and I saw bullets on other slides  
21 and it's not really on here, but very pertinent,  
22 the clinicians really aren't familiar with how to

1 treat this because they're not sure how to treat  
2 this. Which we'll get into some issues later on,  
3 those really become issues, but what have we done  
4 here. First of all, we identified the problem  
5 very clearly. I have to come up with Class 8  
6 requirements. The issue on the Class 8  
7 requirements really that fell on to me were the  
8 med/surg items. It was very easy to get the arms  
9 around, what PPE we were going to require. What  
10 staff is, you know what the patient estimate is  
11 when it comes down there. So we broke this down  
12 into pieces and we're going to go right into the  
13 model here. Slide.

14 This is basically what we did. When  
15 they did the PPE, Steve Yumata and I -- I stole a  
16 lot of people's work to come up with this. Steve  
17 Yumata right here used the CDC model. This model  
18 is the very beginning of our spreadsheet. It  
19 shows -- this is the medium presentation of what's  
20 going to happen. It's linked to the patient  
21 category, or the patient by week, up here on the  
22 top, on how they are going to present in this AOR.

1 We use that as the only information that we had  
2 going into it. Then me and Colonel Brumage, we  
3 sat down and we had to make a lot of assumptions.  
4 This is an assumption-based model. What we did is  
5 we assumed some assumptions. Children, how many  
6 children out of that were going to be affected?  
7 How many will be outpatients? We're going to come  
8 along with that. So very key things. Next slide.

9 The key here is this gives me as a  
10 logistician all the information I need to answer  
11 questions that I get from PACCOM and MEDCOM on how  
12 much are you going to need to get this done. We  
13 did that -- these are the cost summary issues.  
14 But we broke this down into basically eight  
15 subcategories. How do you break it down? We did  
16 ICU, ICU patients, inpatients we did the regular  
17 inpatients, we did pediatrics. We broke those  
18 down into pediatrics and non-pediatrics. And then  
19 we did the outpatients, which basically breaks  
20 into four categories, pediatric, adult, infected,  
21 not infected. The key to this model is on the  
22 front page. And we're going to go right to the

1 model. We brought this up because we weren't sure  
2 if we were going to be able to demonstrate the  
3 model. Let's just go ahead and bring the model up  
4 and we'll kind of show you.

5 In this model, if you change anything in  
6 this model, if I changed the CDC, if this thing  
7 hits in Asia and the CDC updates their model of  
8 how it's going to present in Asia. Now we know,  
9 first week, no longer are we going to get eight  
10 people, we're going to get 108. We can address  
11 the population here for the military and it will  
12 automatically update my cost estimates. And it  
13 will do that realtime.

14 So you will get -- we can get a cost  
15 summary of how much that's going to affect your  
16 total outcome, we can get the weekly presentation  
17 of what supplies are going to be required. This  
18 only has medical/surgical items loaded into this  
19 model right now. So none of the pharmaceuticals  
20 -- the pharmaceuticals did a separate estimate for  
21 influenza and stuff. But everything could be  
22 added to this eventually, and we want to add it to

1 see what the real picture would be. So that's  
2 basically what you're looking at here.

3 The next is the total cost. Total cost  
4 summary, and if you look up -- but if you look on  
5 this it's about 1.8 million for the total cost of  
6 what we're looking just in the medical/surgical  
7 items for an eight-week outbreak. And that's for  
8 looking at DoD folks that we support and that's  
9 the population base that we're looking at support.  
10 So very useful model, but I can tell you that this  
11 was to get me into the ballpark. How do I answer  
12 the mail back to MEDCOM? How do I answer mail  
13 back to other folks on what are you going to  
14 require for an outbreak. So this is it. Now  
15 there are some added things in here. We have  
16 populated this base on our material section. We  
17 have all the ordering information for all the  
18 items that are going to be required. We have cube  
19 so we also make the model tell us how much storage  
20 space.

21 If I order 1,000 cases of IV solution,  
22 how much storage space and I going to have to have

1 to put that on the ground. Some of things that  
2 we're looking at doing in the future and adding to  
3 this is once -- and this is a work in progress, so  
4 I'm going to just claim this. This is very much a  
5 work in progress. It needs to be validated  
6 clinically, and pretty much it's been validated  
7 mathematically. So very, very good tool for me as  
8 a logistician to answer questions up higher. And  
9 clinically it's also useful. Let's go ahead. The  
10 model will be available later on.

11 Any field that you change will update  
12 the running costs, the total costs and everything  
13 in the field.

14 I would like to demonstrate it, but I  
15 know we're running short on time. That's the  
16 model in a nutshell. It gives me a tool to answer  
17 questions from my higher headquarters of how much  
18 resources we're going to require. And I think  
19 you've heard it over and over, we need resources  
20 to actually prepare for this, and when we get to  
21 the issue slide, that's on my issue slide. The  
22 real key here is this can make, I can do some

1 further research.

2           Once I know the quantities, I can also  
3 find out the lead times of what it's going to  
4 require to get here on the island. I can't store  
5 everything for this model. It's just not -- but  
6 if it's n to coconuts, macadamia nuts or water, it  
7 comes in by ship or plane, here to this island.  
8 So some real logistical problems are going to come  
9 across, especially if planes stop flying and boats  
10 stop coming in, we're going to be really hurting  
11 here. The whole idea is when we get resources,  
12 and we're hoping we get some resources that we can  
13 put towards this, we can make some very  
14 intelligent decisions on what do we have to have,  
15 and what can we wait a little bit longer to get  
16 down the road. Some big things here limited  
17 resource-wise. I've taken all this out of hide.  
18 We're talking at least 40 to 80 hours for Mr.  
19 Imhoff, not to include my time.

20           This has kind of been an additional  
21 duty, but very, very important. The disclaimer on  
22 the data validation -- some of the clinicians

1 spent a lot of time with this. Other clinicians  
2 did like other people. We don't know how to eat  
3 this elephant. I don't know how to treat a  
4 patient that we have no idea what it's going to  
5 be. So they took their best guess at it and  
6 that's all I asked them to do was take their best  
7 guess at it. There were some assumptions made,  
8 everything can be changed in this model on the  
9 front page. All the assumptions, all the patient  
10 stuff -- Next slide please. Questions?

11 DR. POLAND: Thank you. Again, I think  
12 we'll hold on questions if you'll be here and  
13 people can approach you for questions. Let's move  
14 on then to our next speaker, Dr. James Campbell.  
15 He's here with us today to provide an operational  
16 slant to pandemic flu planning. His bio is in  
17 your notebook for those of you that were sitting  
18 at our table. It's of interest that he swam the  
19 English Channel not knowing there were sharks in  
20 the Channel. He's going to talk about planning.  
21 We have about 10 minutes if that will work.

22 DR. CAMPBELL: Thanks very much. I

1 appreciate the opportunity to address the Board.  
2 The last time I addressed this Board was several  
3 years ago when I was active duty so I appreciate  
4 the opportunity as a civilian to come back and  
5 address again.

6 As was said, there's a slight different  
7 aspect to what I'm presenting. This is not so  
8 much a description of disease spread, it's a  
9 description of the effects on operation, so it's a  
10 little bit different, but I think very, very  
11 important. What I'll do is very briefly summarize  
12 some capabilities that we have at the national  
13 laboratory in Washington that we're bringing  
14 together into a center for prediction and analysis  
15 in complex systems, because from the presentations  
16 I've heard today there may be some people who  
17 would like to discuss it with me offline in  
18 context of their own work and then get to a pilot  
19 demonstration and notional data of the impact of  
20 pandemic outbreak on military operations.

21 This prediction analysis and complex  
22 system center, I described consists of several

1 components. The first has to do with sampling.  
2 You're all familiar with the challenges of  
3 sampling. We must sample within feasibility  
4 constraints. How many samples are needed? In  
5 which populations? At which locations to ensure  
6 confident decisions? And we can't sample 100  
7 percent. Do I need to determine in a clean-up  
8 operation, how clean is clean? And simply,  
9 sampling analysis costs often a major part of  
10 overall costs. DoD has some challenges in this  
11 regard because of the variability and complexity  
12 of numerous sampling objectives by various  
13 planning response teams and agencies. We work  
14 with a lot of other federal players and they bring  
15 different capabilities to the fight.

16 Geospatial analytics is another part of  
17 this center and a fundamental challenge for any  
18 sort of visual analytics is the masses of data  
19 that we have in different formats and types from  
20 different sources with highly varying degrees of  
21 confidence bases within time frames required for  
22 rapid decision making to reduce risk from exposure

1 to pandemic disease and bioterrorism. An example  
2 of what we call a spatially-related database is  
3 the systems that we have that develop the software  
4 systems at the lab are called starlight, inspire,  
5 things like this. What this enables you to do is  
6 take different databases, very, very different  
7 databases.

8 For instance, this could be a database  
9 of dead animals, or animals that were found and  
10 found positive for avian flu, for instance. This  
11 would be major waterways and roads. Population  
12 centers, vegetation, maybe cultural or ethnic  
13 aspects and then a composite of this. So this is  
14 overlaid in a manner so you come up with this  
15 composite on the bottom. A candidate data set for  
16 pandemic geographical information system would be,  
17 say, bird migration, routes, outbreak locations,  
18 detected bird sites on down to hospital beds,  
19 vaccine stores.

20 I'll skip all this wording, but what  
21 we're trying to get here the challenge we're  
22 facing is that we need to create, implement a

1 forward-looking visual analysis capability.

2 Forward looking to predict, prevent and  
3 respond to emerging pandemic diseases and to and  
4 evolving dynamic and unexpected array of terrorist  
5 attacks. Massive amounts of data, understanding  
6 the risk in the context of a dynamic threat  
7 environment and integrating sensor data including  
8 databases with completely different ontologies.  
9 Very, very big challenge.

10 Prediction of pandemic disease. We  
11 think of pandemic disease as a complex system  
12 because you're talking about wild animals,  
13 migratory birds, domestic poultry, poultry  
14 handlers, secondary-human contact. Definitely a  
15 complex system. I will just highlight the red  
16 pieces, because that's the emphasis of my talk.  
17 We have a need to predict the effects of pandemic  
18 disease on a continuity of military operations and  
19 civilian operations. On the bottom, we have  
20 limited modeling and simulation capabilities to  
21 predict potential effects of pandemic disease.

22 The approach that we take is a

1 two-pillared approach. On the left here involves  
2 a sampling. We take samples, either traditional  
3 serum samples or non-invasive salivary -- exhaled  
4 breath sort of thing. And to the OMIX analysis,  
5 comparative genomics, (off mike) come up with  
6 bio-signatures that characterize the organism or  
7 the response to exposure to the organism. On the  
8 other side is a public health database integration  
9 piece where you integrate medical, veterinary,  
10 pharmaceutical and perhaps school absentee  
11 records. We've talked with Clair Broom at CDC and  
12 the office of Emergency Management in New York  
13 because they're doing the same thing.

14 Make sure that we learn from them and  
15 that we're not duplicating in our research what  
16 they're doing already, and also to share with them  
17 the computational tools we develop at the national  
18 lab to help in their programs. This enables you  
19 to develop epidemiological patterns for the  
20 earliest discovery of an outbreak, you don't  
21 necessarily know what it is, but something's  
22 happening, get some public health people in there.

1 On the other side you develop bio- signature  
2 patterns that characterize the organism or the  
3 response in the reservoir or in the patient to  
4 exposure. These two different sets of data are  
5 put together with computational tools we develop  
6 to integrate them and develop concepts of  
7 operations so that you can visualize and predict  
8 the impact. A big impact in L.A. not so much in  
9 San Antonio for instance.

10 Now I'd like to slip into the example of  
11 notional impact on a military operation. These  
12 are notional data, notional objectives. Plausible  
13 scenario avian flu migrates to human-to-human  
14 form, mutates and begins to come into this part of  
15 the country, concurrent with a big military  
16 operation. The objectives of this demo are to  
17 demonstrate the ability to model and address  
18 potential impacts of global pandemic on continuity  
19 of strategic airlift operations and achievement of  
20 mission objectives.

21 How would a pandemic impact operations?

22 Well the impact would be based on a number of

1 factors, some of which are listed here. Duration  
2 of flu, duration of operation, flu start relative  
3 to the start of operations and the days of  
4 influence on operations.

5 This graph is intended to show you a  
6 notional 100-day flu with an operation duration of  
7 60 days. If the flu began greater than 100 days  
8 before the operation, it would have zero effect,  
9 because it's finished before the operation starts.  
10 If it began 40 days before, it would have  
11 continued through the entire operation so we'd  
12 have maximal effect.

13 This graph is broken up into five zones,  
14 which each has a mathematical relationship behind  
15 it. Here's a graphic demonstration, 3-D of a 50,  
16 100, 150 and the 200- day flu duration. And as I  
17 said in the previous one, in case of the 50 day,  
18 if the flu began greater than 50 days before the  
19 operation it has zero effect on the operation and  
20 so on.

21 This could be represented in a bimodal  
22 distribution if the flu occurred in two ways, like

1     it likely could.     So the outcome is how much  
2     influence a pandemic will have on an operation is  
3     a complex non-linear function we found depending  
4     on the flu duration, et cetera.     It may not affect  
5     the operations at all or it may very seriously  
6     affect the operations.     There's two ways that our  
7     model enables you to analyze these data.

8             The first is to fix the operations  
9     performance matrix.     You have to accomplish a  
10    certain goal and then vary the assumption sets  
11    about the flu.     This is important because we  
12    really don't understand the biology of this virus,  
13    we don't understand the natural history of the  
14    disease because it's an emerging threat.     And so  
15    if you fix the operation performance matrix you  
16    must meet some parameter of your operation and  
17    then vary the assumption sets, you will see that  
18    at a certain point under the different assumption  
19    sets you reach what we call the critical attrition  
20    point.     That's the point at which the impact of  
21    the operation becomes unacceptable.

22             And in this example it reaches at a

1 different percentage total attrition based on the  
2 assumption sets. This is important because as I  
3 said, you don't know that characteristics of the  
4 outlay, you just make some assumptions and predict  
5 the affects. You can take mitigation strategies  
6 based on those predictions. The alternate way of  
7 looking at it is to fix the assumption set.  
8 You'll have certain characteristics and then vary  
9 -- take a look on different military objectives,  
10 for instance, the total number of sorties  
11 completed, total cargo, or if it's a hospital  
12 setting, number of surgeries performed, ER  
13 admissions, prescriptions filled something like  
14 that. Again, you look for the critical attrition  
15 point, the point at which each one of those  
16 objectives fails. And if the commander has set  
17 that all of those must be met then the overall  
18 critical attrition point is the point at which the  
19 first one fails. In this case, objective one  
20 fails here at a critical attrition point here,  
21 that is your overall critical attrition point  
22 under that assumption set.

1           General modeling flow is here.  
2       Determine the operations performance matrix that  
3       you're interested in, specify the input assumption  
4       sets about the disease, generate attrition rates,  
5       put them in with the model and compute the  
6       performance and the critical attrition point. We  
7       did this for an air base and modeled it for the  
8       affects on different categories of personnel.  
9       Baseline up to 50 percent and then these are -- is  
10      a histogram showing the personnel that remain  
11      available at the different levels of avian flu  
12      stress.

13           This one if you put the mark on the  
14      little button and change the infection rate and it  
15      continuous you can set the infection rate, the RZO  
16      wherever you want and click it over time, if you  
17      decrease the infection rate you can see that  
18      there's more people available over time. If you  
19      alternatively decrease the recovery rate, you see  
20      there's few as is pretty obvious.

21           The overall summary of this impact on  
22      these notional data that we have here is that over

1 time as AI attrition increases, the total aircraft  
2 departures falls off and the total diverts  
3 increases. A divert is an airplane that must be  
4 sent to another base to land, because the airport  
5 it was coming into cannot meet it. This is  
6 obviously pretty important when you consider the  
7 geography of Hickam.

8 This is a summary overall. If the  
9 commander has decided at the airbase to meet his  
10 objectives, he must have 95 percent of his  
11 baseline passengers unloaded. 90 percent of his  
12 cargo loaded and 65 percent of the airplanes must  
13 land for him to meet his mission. Then you can  
14 calculate the critical attrition points for each  
15 one of those parameters and the one that fails  
16 first, in this case it's the baseline cargo fails  
17 at this point, this is the overall critical  
18 attrition point, because at that point the  
19 commander can no longer meet his mission.

20 So the model enables you to make these  
21 predictions based on an assumption set of the flu,  
22 not even knowing how the flu is going to break

1 out, you make some assumptions. Just summarize  
2 again in notional data, in the example we too, in  
3 the 80-day shortfall 38,000 tons -- that  
4 translates into 22 extra days to get the cargo out  
5 to the fight. And that's obviously of great  
6 importance to the commander.

7 I won't go through these recommendations  
8 because I was actually pleased to hear that most  
9 of these are already addressed. I'm not  
10 necessarily in touch with all these and I  
11 appreciate it. Drop down to the very bottom here  
12 because this is what I was focusing on is the  
13 assessing effects on the continuity of operations  
14 and I very respectfully request, recommend that  
15 the AFEB recommend to DoD that they include  
16 predictive effects modeling, which is what I've  
17 been talking about in pandemic disease  
18 preparedness and mitigation plans and to engage  
19 national laboratories where it's appropriate to do  
20 so. That's it.

21 DR. POLAND: We've got about three or  
22 four minutes for questions. I might add that in

1 the first paper product that we gave back to the  
2 Assistant Secretary regarding critiquing plans, we  
3 did talk about using chaos and gain theory to try  
4 to build models like this. Questions at all? We  
5 have a few minutes. No? We're on a roll then.

6 Pandemic influenza preparedness. Is  
7 this a race to prevent a global epidemic? How big  
8 of a threat is this really? Is time running out  
9 for preparation? Secretary Leavitt said the virus  
10 that causes bird flu could become one of the most  
11 terrible threats to life that this world has ever  
12 faced. Or is it a pandemic of fear? Has the  
13 Disney Company lied to us about why Donald Duck  
14 died? Is the duck of death on his way to the  
15 U.S.? I have got to wake some of you guys up.  
16 What about the reports of a lethal avian influenza  
17 outbreak among birds now in Florida at a Florida  
18 trailer court? We've gone there and investigated  
19 that. It turns out not to be true. One of the  
20 many hoaxes and rumors. Even the transcriptionist  
21 liked that one.

22 So will a pandemic occur is the question

1 that we're all sort of wrestling with. And let me  
2 just get right to the point. Yes, it's going to  
3 occur. It absolutely is going to occur. There is  
4 not chance we won't have a pandemic. It is going  
5 to occur. But as you might have guessed, by my  
6 making such a dogmatic statement, we don't know  
7 when, we don't know with what virus, we don't know  
8 how severe it will be. We have three know  
9 historical points on the line that we can draw  
10 inferences from. About a million U.S. deaths in  
11 1918. About 70,000 in 1957, and about 40,000 in  
12 1968.

13 But there are a lot of things that are  
14 different there and as all of the speakers have  
15 reflected we need to be prepared though we hope  
16 for the best. What about the morbidity and  
17 mortality and the case burden? I won't go into  
18 detail other than to just show you this bottom  
19 part here that given similarities to 1918 virus,  
20 the estimations are that new infections and  
21 ensuing deaths would double every three days. So  
22 how do you prepare for and get ahead of a pandemic

1 where those double every three days.

2 So with that as background in the very  
3 beginning of December 2005, Secretary Winkenwerder  
4 sent a memo to us the AFEB to form a select  
5 subcommittee of experts that would have this task  
6 advising the surgeons general and himself on  
7 matters related to PI including, but not limited,  
8 to providing recommendations for optimizing  
9 surveillance and preparations.

10 So with that we did pull together a  
11 subcommittee. The members are listed there. I  
12 should add that Dr. Dottile, a meritus from CDC  
13 has also been or will be appointed as a consultant  
14 to the subcommittee.

15 We looked at our goal as critically  
16 reviewing the DoD plan in assisting and making it  
17 feasible, comprehensive and effective and sort of  
18 the overall philosophy that I've been trying to  
19 guide it with is first we encourage the  
20 development of an umbrella plan with fill in the  
21 blanks for local sites. And second, to urge  
22 development of a comprehensive playbook for all

1 sites and all contingencies including development  
2 of scenarios, et cetera.

3 I'm pleased to see that a lot of that  
4 has already occurred. We've had teleconferences,  
5 we had a very productive meeting with Secretary  
6 Winkenwerder and each of the Armed Services  
7 Surgeon Generals. That was a particularly  
8 gratifying meeting. There was lot of back and  
9 forth, a lot of attention paid to it. I felt like  
10 the subcommittee's input was valuable and was  
11 being well taken. We had another face-to-face  
12 meeting at our February 2006 meeting and a lot of  
13 e-mail back and forth. What did we produce so  
14 far?

15 A discussion paper about what we know,  
16 what we don't know and what the critical  
17 assumptions are. We have circulating among the  
18 subcommittee now immediate recommend -- a paper  
19 called immediate recommendations for pandemic  
20 preparedness considerations and we've constructed  
21 nine scenarios that we would like, or we hope,  
22 might be used for planning throughout DoD.

1           We have also provided formal comments on  
2           the policy for release of the antiviral  
3           oseltamivere stockpiled during a pandemic and the  
4           value of pneumococcal vaccine's in relation to  
5           pandemic influenza. So we've been busy. I won't  
6           go through all of the cases. Wayne actually had  
7           the more updated numbers. Every time I talk about  
8           this you have to go back in and add four or five  
9           depths to this, and I give a talk on this weekly.  
10          But it does involve now, ten countries, the latest  
11          one being Chabuti.

12                 Just a point to make, because we do  
13          focus on H5N1 and that point is that may -- that's  
14          the current culprit and the one under the light  
15          that we can see, but there are a variety of  
16          influenza A strains that have pandemic potential,  
17          which are novel viruses and which have caused  
18          human infections. So I will stop there and ask  
19          about any questions about our subcommittee. This  
20          is just a quote from Albert Camus talking about a  
21          different kind of plague in a different time.

22                 MS. EMBREY: I just wanted to ask, I

1 think one of the biggest things that we're  
2 struggling with and you talked about some of the  
3 products.

4 I'd like to formally ask that, in your  
5 subcommittee deliberations that you address the  
6 issue of the use or utility of masks for various  
7 scenarios. We have been asked to participate in a  
8 group with CDC on the subject, but frankly we need  
9 to look at this in the context of the operations  
10 for our military and look at it in the context of  
11 some challenges that we have to overcome. Is  
12 there utility in the use of masks and what types?

13 DR. POLAND: Understood. It's a good  
14 question, and there's controversy because  
15 different organizations have recommended different  
16 things. Other comments or questions.

17 Subcommittee members, if I've reflected our  
18 deliberations fairly or other comments? Steve?

19 DR. OSTROFF: In terms of the  
20 deliberations, I'm really curious as to the  
21 perspective of the subcommittee around all these  
22 modeling exercises because when I looked at the

1 various models particularly the one's that have  
2 been published and then I look at the one that  
3 Colonel Hachey presented, these interventions look  
4 absolutely fabulous. I mean, if you look at ring  
5 prophylaxis, it's 90-some percent effective and  
6 now you look at school closures it seems to be  
7 90-some percent effective. It seems like  
8 everybody has their own personal perspective on  
9 which of these interventions is the magic bullet  
10 for a pandemic.

11 I'm wondering -- it seems to me there's  
12 an epidemic of modeling going on that I don't -- I  
13 must confess, I don't know how to put in context  
14 because when I hear that intervention like school  
15 closures that look 97 percent effective, it makes  
16 me ask why are we wasting our time with antivirals  
17 and vaccines? And I'm wondering to what degree is  
18 the subcommittee trying to provide guidance to the  
19 Department about how to use these various models.

20 DR. POLAND: Actually it's a good  
21 question. But actually most of this modeling  
22 information has become available since February.

1 So we actually have a task at hand and that is  
2 we're going to have to dig into this and answer  
3 the question that you asked. We haven't really  
4 done that yet. Like you, I'm suspicious of the  
5 proliferation of models and the assumptions behind  
6 some of the model output. Dr. Shamoo.

7 DR. SHAMOO: I think everything should  
8 be on the table to consider. There's masks,  
9 voluntary quarantine, mandatory quarantine,  
10 vaccination, voluntary vaccination and medication  
11 and even involuntary and the combination thereof.  
12 And at what situations one has to do. And I think  
13 we need to consider all the social as well as  
14 ethical issues and I think the subcommittee should  
15 not remove any of these because it depends on the  
16 severity and magnitude of the problem. Which we  
17 cannot predict.

18 DR. POLAND: I thank everybody for their  
19 attention. What I'd like to do now is turn the  
20 gavel over to the president emeritus of the Board,  
21 Steve Ostroff, who I've tried to model my tour  
22 after and ask him to make closing comments and

1       then to dismiss us.  If I could also remind the  
2       subcommittee and Colonel Gibson, we're going to  
3       have lunch together as part of our meeting.

4                 DR. OSTROFF:  I'll just make some very  
5       quick comments because I know people have to check  
6       out and I know that I'm standing between you and  
7       lunch.  All I'll say is that I'm really pleased to  
8       be back and I'm very impressed at the quality of  
9       the output that's coming from the Board.  I  
10      clearly left things in very capable hands.

11                There's great spirit and enthusiasm  
12      amongst the Board members and it's a thrill to  
13      once again see all the marvelous work that's being  
14      done by people in military public health.  So  
15      congratulations to you.  I'm looking forward to  
16      bigger and better things from the Board under  
17      whatever new guise it happens to be in and I think  
18      the future looks great.  And so with that I'm  
19      really happy to be handed back the gavel one more  
20      time and I'm going to wrap it and close the  
21      meeting.

22                                 \*   \*   \*   \*   \*

