

UNITED STATES OF AMERICA  
DEPARTMENT OF DEFENSE  
ARMED FORCES EPIDEMIOLOGICAL BOARD

OPEN SESSION

Annapolis, Maryland  
Tuesday, September 26, 2006

ANDERSON COURT REPORTING  
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1 P R O C E E D I N G S

2 DR. POLAND: I'll have to speak up.  
3 Hopefully everybody can hear me okay. Yes? Good.  
4 Thank you.

5 Welcome, everybody, to the meeting of  
6 the Armed Forces Epidemiological Board. We have a  
7 pretty full agenda, as you have seen in your  
8 notebooks, so we'll get started. Ms. Embrey,  
9 would you call the meeting to order?

10 MS. EMBREY: Thank you, Dr. Poland. As  
11 the Designated Federal Official for the Armed  
12 Forces Epidemiological Board, a federal advisory  
13 committee to the Secretary of Defense which serves  
14 as a continuing scientific advisory body to the  
15 Assistant Secretary of Defense for Health Affairs  
16 and the Surgeons General of the military  
17 departments, I hereby call this meeting to order.

18 I also would like to thank Vice Admiral  
19 Rempt, who will join us later this morning, for  
20 his willingness to host this meeting and the  
21 outstanding support that he and his staff have  
22 provided to the Armed Forces Epidemiological Board

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1 staff. Thank you.

2 DR. POLAND: Thank you, Ms. Embrey.  
3 Just a notice for those when they speak: You need  
4 to speak directly into these microphones. They're  
5 not the all-directional kind.

6 If we could, and I've tried to establish  
7 this now as a tradition of the Board, that we  
8 would stand for one minute of silence to honor  
9 those that we're here to serve.

10 (A minute of silence was observed)

11 DR. POLAND: Thank you. We have five  
12 new members of the Board, one of which has  
13 previously served on the Board. Dr. Luepker,  
14 where did you go? Right there, okay. Actually,  
15 what I think we'll do is, we'll go around and  
16 introduce ourselves. I'll ask Colonel Gibson to  
17 start. We'll go around the table and then to both  
18 sides.

19 COL. GIBSON: Colonel Roger Gibson,  
20 Executive Secretary, Armed Forces Epi Board.

21 RADM. HIGGINS: Paul Higgins, Director  
22 of Health and Safety, United States Coast Guard.

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1 DR. HALPERIN: Bill Halperin, Chair of  
2 Preventive Medicine at New Jersey Medical School,  
3 and Chair of Quantitative Methods at the School of  
4 Public Health.

5 DR. SHAMOO: Adil Shamoo, University of  
6 Maryland School of Medicine, a bioethicist.

7 DR. MILLER: Mark Miller, Director of  
8 Research at the Fogarty International Center, NIH.

9 DR. PRONK: Nico Pronk, Vice President  
10 and Executive Director of HealthPartners Center  
11 for Health Promotion in Minneapolis, Minnesota.

12 DR. GARDNER: I'm Pierce Gardner,  
13 Professor of Medicine and Public Health at State  
14 University of New York at Stonybrook.

15 DR. KAPLAN: Ed Kaplan, Professor of  
16 Pediatrics at the University of Minnesota in  
17 Minneapolis.

18 DR. PARKINSON: Mike Parkinson,  
19 Executive Vice President of Lumenos, which is part  
20 of WellPoint.

21 DR. LEDNAR: Wayne Lednar, Vice  
22 President and Director of Corporate Medical at the

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1 Eastman Kodak Company.

2 DR. LAUDER: Tamara Lauder, physical  
3 medicine and rehabilitation, Ministry Medical  
4 Group, Woodruff, Wisconsin.

5 DR. SILVA: Joe Silva, Professor of  
6 Internal Medicine at the University of California,  
7 Davis.

8 DR. WALKER: David Walker, Chair of  
9 Pathology, University of Texas Medical Branch at  
10 Galveston.

11 DR. CLEMENTS: John Clements. I'm the  
12 Chair of Microbiology and Immunology at Tulane  
13 University in New Orleans.

14 DR. CATTANI: Jackie Cattani, Professor  
15 of Public Health and Director of the Center for  
16 Biological Defense at the University of South  
17 Florida.

18 DR. McNEILL: I'm Mills McNeill. I'm  
19 the State Epidemiologist and Director of the  
20 Public Health Laboratory in Mississippi.

21 DR. BROWN: Can you hear me? I'm Mark  
22 Brown. I'm with the Office of Public Health and

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1 Environmental Hazards, part of the Department of  
2 Veterans' Affairs in Washington, D.C.

3 COL. SNEDECOR: I'm Mike Snedecor. I'm  
4 the Chief of Preventive Medicine, Air Force  
5 Surgeon General's Office.

6 (Audience introductions)

7 LCDR. Luke: Lieutenant Commander Thomas  
8 C. Luke. I'm a preventive medicine officer at the  
9 Bureau of Medicine and Surgery.

10 LTC. STANEK: Lieutenant Colonel Scott  
11 Stanek, preventive medicine staff officer, Army  
12 Office of the Surgeon General.

13 CDR. CARPENTER: David Carpenter,  
14 Medical Attache, the Canadian Embassy.

15 (Audience Introductions)

16 MGEN. COL: Joe Col, the Joint Staff  
17 Surgeon.

18 MS. EMBREY: Ellen Embrey, Department of  
19 Defense designated official.

20 DR. POLAND: Or as we fondly call it,  
21 the DFO. I'm Greg Poland from Mayo Clinic in  
22 Rochester, Minnesota.

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1           For this meeting we'll have refreshments  
2           for this morning, and tomorrow at both morning and  
3           afternoon sessions. After we finish this  
4           morning's session, we'll have a catered working  
5           lunch for the Board members, the preventive  
6           medicine officers, the distinguished guests and  
7           the speakers.

8           Others may proceed to the Officers Club,  
9           which is basically across the way, very close  
10          here, for lunch. Alternatively, there are some  
11          restaurants downtown, and it's not very far to  
12          walk. It's about four blocks to get to downtown.  
13          Lots of restaurants down there.

14          A tour of the Academy after lunch today.  
15          Everybody is welcome. If you decide to leave  
16          after the morning session, there's going to be a  
17          shuttle bus to take you back to the parking lot.  
18          The vans will pick you up out front of the hotel.  
19          They'll do that until 1:30, so if you're going to  
20          leave after that and your car is at the stadium,  
21          you might have problems.

22          Restrooms are located outside, and see

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1 Karen for faxes and other types of messages. We  
2 get three and a half CEUs for this meeting today.  
3 You have to fill out the CME attendance roster  
4 there and then pick up the evaluation and  
5 attestation statements. For the Board members,  
6 those are in your books.

7 You signed in on the general attendance  
8 roster when you came in. I appreciate that. This  
9 meeting is being transcribed. It's a federal  
10 advisory committee, so we do transcribe these  
11 meetings. Make sure when you talk, you state your  
12 name before speaking so the transcriber can pick  
13 that up, and use the microphones.

14 And I want to remind everybody to meet  
15 in the lobby of the hotel tonight, the Historic  
16 Inns hotel, at 7 o'clock. You all can come to  
17 dinner. We're going to have dinner at the Treaty  
18 of Paris, which is basically a block and a half  
19 from the hotel. The Rockfish place we found last  
20 night was about a mile away. It's a little hard  
21 to walk there. So this hotel is a famous place,  
22 good food. You will need to let Karen know by 2

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1 o'clock today how many people -- by noon today how  
2 many people.

3 How many people right now are going to  
4 go to dinner with us?

5 (A show of hands)

6 COL. GIBSON: Okay, the Calvert Hotel  
7 lobby, the one where you checked in, that's where  
8 we'll be meeting tonight, and we'll walk from  
9 there to the hotel.

10 Finally, the next meeting will be the  
11 5th and 6th of December. It's going to be at the  
12 Navy Amphibious Base at Little Creek, which is  
13 near Norfolk, and Portsmouth Navy Hospital will be  
14 our host.

15 That's all I have.

16 DR. POLAND: Okay, we're right on time  
17 here. Our first item of business is a question to  
18 the Board on Southern Hemisphere influenza  
19 vaccine. Board members who were here at the last  
20 meeting will remember that presentations related  
21 to this question were postponed due to  
22 unavailability of speakers.

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1           The question we're asked to deliberate  
2           on is at Tab 2, and deals with the risk of  
3           Southern Hemisphere variants of seasonal influenza  
4           to military service members, and the use of  
5           Southern Hemisphere influenza vaccines that are  
6           not currently approved by the Food and Drug Administration  
7           (FDA). The question was presented to the Board by Joint  
8           Staff. We have General Col here. Did you want to make any  
9           comments?

10           MGEN. COL: I think that's a very good  
11           summary. The concern was, we have a fairly large  
12           number of people who frequent the Southern  
13           Hemisphere, and often spend extended periods of  
14           time there, and are they adequately protected  
15           against influenza that they will be exposed to  
16           there?

17           DR. POLAND: So that's the question  
18           before us. The first speaker, Dr. Ann Moen,  
19           Associate Director for the Influenza Division at  
20           the Centers for Disease Control and Prevention,  
21           (CDC) will start us off with a briefing on Southern  
22           Hemisphere influenza epidemiology.



1 the two separate hemispheric vaccines? So  
2 hopefully by the end of this talk we'll have some  
3 more information to address those questions.

4 The first slide is just the typical  
5 graphic, shows the seasonal occurrence of  
6 influenza. In the green you can see the typical  
7 seasonality of viruses circulating in the Northern  
8 Hemisphere, where they are circulating through the  
9 winter months, beginning in October and then  
10 usually peaking sometime in December, January, or  
11 February.

12 And then the red is showing Southern  
13 Hemisphere, where we have the opposite, and they  
14 are usually circulating and peaking sometime in  
15 the winter months in the Southern Hemisphere, in  
16 June through August.

17 And then in tropical zones you see flu  
18 circulating year-round, sometimes there's a  
19 virology, and it really varies by country, and  
20 that's why each country needs to collect their own  
21 data to decide their seasonality.

22 So the history of it, vaccine strain

1 selection takes place every February for the  
2 Northern Hemisphere, and then vaccine is produced  
3 following that for October vaccination in the  
4 Northern Hemisphere.

5           And since '99 there has been a second  
6 formal vaccine strain selection needed to decide  
7 strains for the Southern Hemisphere. This takes  
8 place in September for vaccination the following  
9 March or April in the Southern Hemisphere. And at  
10 least twice prior to the formalization of this  
11 process, the Southern Hemisphere vaccine was  
12 updated informally to try and cover newly  
13 circulating predominating strains.

14           So what I did to address these questions  
15 was, I looked at all of the Southern Hemisphere  
16 recommendations, and then I identified when the  
17 Southern Hemisphere vaccine recommendations were  
18 updated prior to the Northern strain, so that we  
19 can see when the Southern Hemisphere vaccine was  
20 essentially ahead of the Northern Hemisphere, and  
21 there would be a different strain in the arms of  
22 the troops that were vaccinated versus what was

1 now being currently recommended for the Southern  
2 Hemisphere.

3           And then for each of these instances I  
4 looked at all of the surveillance and isolate  
5 data, both globally and then specifically for the  
6 Southern Hemisphere, between the time of the  
7 Southern Hemisphere vaccination, which would be in  
8 March, to the next September when the Northern  
9 Hemisphere vaccine would then again be updated.

10           And so I looked at all the frequency  
11 tables, going back to the beginning of 1999 when  
12 there started to be two separate vaccine strain  
13 selections, and looked at the viruses that were  
14 all characterized in HI tests using ferret anti-  
15 sera against vaccine strains and other commonly  
16 circulating strains, to see what new strains were  
17 predominating.

18           And so on these slides, if the virus is  
19 a "like" virus, it is antigenically similar to the  
20 vaccine strain, and if it's designated as "low"  
21 that means there is a four-fold or greater  
22 reduction against ferret anti-sera raised against

1 that strain. And then I'll show you the  
2 percentages of the circulating strains that were  
3 submitted to the CDC and to other World Health Organization  
4 (WHO) Collaborating Centers.

5 There are three other WHO Collaborating  
6 Centers, one in Japan, one in Australia, one in  
7 the U.K., and then CDC is the fourth. And these  
8 are the four main centers that come together every  
9 February and every September to make vaccine  
10 strain decisions.

11 So, in looking at all the data, the  
12 Southern Hemisphere decisions are in yellow and  
13 the Northern Hemisphere decisions are in white,  
14 and what I did was compare to see when there were  
15 changes. So I found since there were two formal  
16 decisions made, there are actually six times when  
17 there were differences in strains which included  
18 five vaccines.

19 So the first time was in the Southern  
20 Hemisphere vaccine for 2000. There were two  
21 strain changes, one for the H3N2's and one for the  
22 H1N1's. So all of the red colored times show when

1 we updated the Southern Hemisphere ahead of the  
2 Northern Hemisphere, and we'll go through each one  
3 of these individually.

4 This shows the more recent times when  
5 this happened. In 2004 the H3N2 was updated ahead  
6 of the Northern Hemisphere. Again in 2005 the  
7 H3N2 was updated again ahead of the Northern  
8 Hemisphere. And then in 2006 the Bs were updated  
9 ahead of the Northern Hemisphere.

10 The good news is that this year there  
11 was no strain change. Last week the decision was  
12 made in Geneva for the Southern Hemisphere  
13 vaccine, and there were no strain changes, so you  
14 actually have a little bit more time to make your  
15 decision because the vaccines are exactly the same  
16 for Northern Hemisphere and Southern Hemisphere  
17 this year.

18 So the first time in 2000 when there was  
19 a strain change in the H3N2 viruses, the Southern  
20 Hemisphere recommended A/Moscow/10/99, but the  
21 troops that were vaccinated with Northern  
22 Hemisphere vaccine would have had A/Sydney/97 in

1 their arms.

2           Then I looked at the data for April 2000  
3 to September 2000 in the Southern Hemisphere, and  
4 I looked at both total global isolate and then  
5 Southern Hemisphere isolate. And since we're  
6 concerned about what's circulating in the Southern  
7 Hemisphere, I left off the total global  
8 percentages, but strangely they are very similar  
9 for most years with few exceptions. They weren't  
10 that different in what was circulating globally.

11           So in 2000, between April and September,  
12 69 percent of the viruses were A/Sydney-like, so  
13 they would have matched the Northern Hemisphere  
14 vaccine that was in the troops' arms. Then 28  
15 percent were A/Moscow- like, and 3 percent were  
16 A/Moscow-low, so those would have been a mismatch  
17 to the vaccine that was in the troops' arms but  
18 would have matched the Southern Hemisphere  
19 vaccine. This is the one case in all of the  
20 examples I've been showing you where the Northern  
21 Hemisphere vaccine was actually fairly  
22 well-matched to the predominantly circulating

1 strain in the Southern Hemisphere.

2           Again in 2000 there was also a strain  
3 change with the H1N1 viruses. The Southern  
4 Hemisphere recommended New Caledonia, and the  
5 Northern Hemisphere, which the troops would have  
6 been vaccinated with, contained A/Beijing. If you  
7 look at the percent of circulating viruses, 85  
8 percent of the viruses circulating during that  
9 time in the Southern Hemisphere were A/New  
10 Caledonia-like, so it would have been much better  
11 to have that H1N1 component in the vaccine.

12           And A/New Caledonia-low, 1 percent,  
13 A/Johannesburg-like, 14 percent. And again, these  
14 two viruses, although they don't match the vaccine  
15 strain for the Southern Hemisphere, they also,  
16 they also are way off from the A/Beijing, so  
17 really none of the H1N1 viruses circulating would  
18 have matched very well to the Northern Hemisphere  
19 vaccine.

20           The third time there was a strain change  
21 was when the Southern Hemisphere updated the H3N2  
22 in 2004, and the Southern Hemisphere recommended

1 A/Fujian but the Northern vaccine contained  
2 A/Moscow.

3 So again, looking at the percentage of  
4 strains circulating from April 2004 to September  
5 of 2004, 87 percent of the viruses were  
6 A/Fujian-like, which would have matched the  
7 Southern Hemisphere vaccine. 5 percent were  
8 A/Fujian-low, and then there were 7 percent  
9 California-like viruses and 1 percent  
10 A/Wellington.

11 Wellington was kind of a strange virus  
12 that circulated mostly in the Southern Hemisphere,  
13 mostly only in Oceania, and in Australia/New  
14 Zealand. You didn't see it in South America.

15 So here we see that if the troops had  
16 had the updated vaccine, the A/Fujian, it would  
17 have been a much better match to what was  
18 circulating had they been deployed to the Southern  
19 Hemisphere, and actually for the following winter  
20 as well, when this vaccine was actually updated in  
21 the Northern Hemisphere.

22 So the next time was the following year,

1 in 2005. Again, the H3N2 component of the vaccine  
2 was updated, and the Southern Hemisphere  
3 recommended A/Wellington where the Northern  
4 Hemisphere contained A/Fujian. So these data are  
5 exclusively from the WHO Collaborating Center in  
6 Australia, so you see a lot more isolates than the  
7 CDC data, and I looked at data depending on where  
8 things circulated.

9 Like I said, A/Wellington did not really  
10 circulate, either in the U.S. or in South America,  
11 Southern Hemisphere, and so the percentage of  
12 viruses circulating exclusively in  
13 Oceania/Australia/New Zealand were A/California 49  
14 percent and then A/Wellington were 51 percent. So  
15 an update to this strange strain change, and it  
16 was actually a strange virus. It only stayed in  
17 the vaccine for one year. But still the vaccine,  
18 the Southern Hemisphere vaccine, would have been  
19 better matched had the troops had the updated  
20 A/Wellington than the A/Fujian.

21 Okay, the special case of B viruses. As  
22 many of you probably know, there are two lineages

1 of B viruses that have been circulating since the  
2 mid-1980s. There is the B-Yamagata lineage that  
3 has circulated globally the entire time, and then  
4 for approximately 10 years there were B-Victoria's  
5 that circulated almost exclusively in China, but  
6 have spread globally since 2001.

7           And in two years -- I'm not sure if you  
8 noticed, but you've got the slide -- the vaccine  
9 strain tables, where the vaccine strain  
10 recommendations are made, it actually was two  
11 viruses. And they instructed local authorities to  
12 choose the strain that was most relevant to their  
13 country at that time, because both of those  
14 viruses started circulating.

15           So both of these B lineages continue to  
16 circulate today, which poses a challenge for  
17 vaccine strain collection because it's almost but  
18 not quite like two strains of B. It's almost like  
19 H1 and H3, although there are differences.

20           Studies have shown that most adults have  
21 been exposed to both viruses, and that vaccination  
22 with either strain generally shows a boost in

1 titer to both virus lineages, although a lower  
2 titer for the mismatched lineage. And Vaccination  
3 of naive children usually shows a titer rise only  
4 against the vaccine strain.

5 So the first time there was a B change  
6 for the Southern Hemisphere in 2001, the Southern  
7 Hemisphere recommended a B/Sichuan which was of  
8 the B/Yamagata lineage, and the Northern vaccine  
9 had contained B/Beijing, which is also a  
10 B/Yamagata.

11 So if you look at the viruses that were  
12 circulating between April of 2001 and September of  
13 2001 in the Southern Hemisphere, 69 percent were  
14 B/Sichuan-like, which would have matched the  
15 updated Southern Hemisphere vaccine strain, and 31  
16 percent were B/Sichuan-low, so not a perfect match  
17 to the updated strain. But the good news is that  
18 all of the vaccine strains and the circulating  
19 viruses were B/Yamagata, so there would have been  
20 some protection, although not perfect.

21 The Southern Hemisphere again updated  
22 the B component of the vaccine in 2006. The

1 Southern Hemisphere recommended B/Malaysia, which  
2 is a B/Victoria lineage this time, but the  
3 Northern Hemisphere vaccine would have contained  
4 the B/Shanghai, which is a B/Yamagata lineage.

5           When we look at the percentage of  
6 circulating viruses from February 2006 to August  
7 2006 -- this is the most recent data -- 50 percent  
8 were B/Ohio-like, and B/Ohio is antigenically  
9 equivalent to B/Malaysia, so these were considered  
10 the same, a vaccine match. That would be  
11 considered a match. Thirty-four percent were  
12 B/Ohio-low, so even though they were low, it's of  
13 the same lineage, B/Victoria.

14           Then about 15, 16 percent of the viruses  
15 circulating actually matched the B/Yamagata  
16 lineage.

17           So if somebody was vaccinated with the  
18 Northern Hemisphere vaccine, only about 16 percent  
19 of the viruses circulating would have matched that  
20 lineage, and it would have been much better in  
21 this case for someone to be updated with the  
22 Southern Hemisphere vaccine which would have

1       matched the major lineage, B/Victoria, that was  
2       predominantly circulating.

3               So this is just a summary of the six  
4       times that we just went over. If we look at the  
5       H3N2's, in 2000 there was actually a 69 percent  
6       match to the Northern Hemisphere vaccine. In 2004  
7       there was 87 percent well-matched to the Southern  
8       Hemisphere vaccine. In 2005 approximately 51  
9       percent matched the Southern Hemisphere vaccine,  
10      which was when we had that A/Wellington that only  
11      circulated sort of in that area, mostly.

12              And if we look at the H1N1's, 85 percent  
13      matched to the Southern Hemisphere vaccine in  
14      2000. And when we look at the B's, there was a 69  
15      percent match to the Southern Hemisphere with a  
16      100 percent match to the lineage in 2001, and then  
17      in 2005 there was a 50 percent match to the  
18      Southern Hemisphere vaccine and an 84 percent  
19      match to the lineage, which would have offered  
20      cross-protection, some cross- protection.

21              So if we go back to the question with  
22      these data in mind, the first one, are common

1 circulating influenza viruses different enough to  
2 warrant separate vaccines for the hemispheres, and  
3 the answer is yes, sometimes.

4           And if so, that's when WHO makes a  
5 strain recommendation, so if they're really  
6 different, then there's the virus vaccine change  
7 and the vaccine is updated. If not, just like we  
8 saw this year, there was no strain change, so  
9 there wasn't something significantly different  
10 circulating.

11           The next question is, is there  
12 insufficient cross-reactivity between the two  
13 vaccines to actually warrant DOD procurement of  
14 the two separate vaccines? So what we've looked  
15 at here are differences based on antigenic  
16 characterization which are not considered perfect.  
17 They don't correlate perfectly with human antibody  
18 response.

19           So there's some degree of cross-  
20 reactivity that's likely present from strain to  
21 strain, but you can't predict. It's not -- you  
22 can't make a blanket statement about the cross-

1 reactivity of vaccines. There is usually,  
2 depending.

3 It depends on the person, how healthy  
4 they are. If they're older, there's probably not  
5 good cross-protection, but if they're younger and  
6 make good antibodies, then there could be more or  
7 less a degree of cross- reactivity between the  
8 vaccine strains, but you can't put your finger on  
9 exactly how good it is.

10 There are some other considerations,  
11 caveats, at the end, in the conclusions that I  
12 would make and offer for consideration. As I just  
13 said, some viruses are more cross-reactive than  
14 others, such as A/Sydney and A/Moscow are fairly  
15 cross-reactive, so some cross-protection would be  
16 afforded by a mismatched vaccine but you can't say  
17 exactly how much. Again, correlation between  
18 ferret antibodies and human antibodies is not  
19 perfect.

20 So it is possible for some viruses to  
21 circulate for short times and in limited areas,  
22 like the A/Wellington which I mentioned, so you

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1 can't predict which viruses are going to circulate  
2 where. Sometimes it's very different and, as it  
3 says below, flu will remain unpredictable and you  
4 can predict what will happen, so it might be  
5 prudent to take precautions.

6           There could be some sampling bias in the  
7 data that I showed you, because the WHO  
8 Collaborating Centers request the unusual strains  
9 in addition to representative isolates.

10           So I'm sure there is probably a little  
11 bit of sample bias, but I think still it's a  
12 pretty good picture of what is circulating  
13 globally.

14           Just because the strain is changed, that  
15 doesn't mean that it circulates predominantly.  
16 You might go out and say that we need the H3N2  
17 vaccine because it got updated, and it could be  
18 that B's circulate that year or H1's circulate  
19 that year, so every year you can't predict exactly  
20 which strains will circulate, either. So just  
21 because it changed doesn't mean it will  
22 predominate.

1                   And then I think from these data you can  
2 say that the most recent vaccine is probably the  
3 best vaccine because that would offer the most  
4 protection to anybody being vaccinated. And there  
5 are other considerations about vaccine  
6 availability that I know the next speaker will  
7 talk about.

8                   I want to acknowledge all of the centers  
9 that send us samples. We share samples with the  
10 WHO Collaborating Centers. There's the WHO Global  
11 Influenza Program. It has national influenza  
12 centers in about 86 or 87 countries now that share  
13 samples with us. DOD Global Emerging Infections  
14 Surveillance (GEIS) has been very generous in sharing  
15 samples. We have great collaboration with Naval Medical  
16 Research Unit 2 (NAMRU2) and NAMRU3, who have shared samples  
17 with us. And the staff of the Influenza Division who did  
18 all this ground work to look at these viruses day in and day  
19 out, year after year.

20                   You do have a one-year reprieve because the  
21 vaccine didn't change, and if you can't come up with a  
22 better recommendation, you can have the troops gargle.

1 (Laughter)

2 DR. POLAND: Thank you. We've got time  
3 for some questions. Ed, and then Mark.

4 DR. KAPLAN: Do you have -- and maybe  
5 I'm getting ahead of the story -- but you talk  
6 about circulation and the six times when there  
7 were significant differences. Are there any data  
8 -- maybe somebody else knows -- about illnesses  
9 that may have occurred in people who got "the  
10 wrong vaccine"?

11 DR. MOEN: One of the next speakers is  
12 going to talk about some outbreaks in military  
13 populations.

14 DR. KAPLAN: But is it correlated with  
15 the discrepancy in the vaccine, if that's the  
16 right word?

17 DR. MOEN: I haven't seen his talk yet,  
18 but I think Fred will talk about that. I think  
19 that there isn't--we don't get sera from the  
20 military to do these types of studies, and I think  
21 it might be good if we can do some of these types  
22 of studies where you're comparing the -- I don't

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1 know if those studies would necessarily be done to  
2 --

3 DR. KAPLAN: Greg, does anybody from the  
4 military, are they able to give us some data, or  
5 will that be covered in another talk?

6 DR. POLAND: I think we're going to hear  
7 something.

8 DR. KAPLAN: Okay, okay. Thank you.

9 DR. MILLER: Mark Miller. The  
10 antigenicity tests are primarily based on  
11 hemagglutinin. Do you also look and test for  
12 neuraminidase or other components, to see whether  
13 there's cross-reactivity between the hemispheres?

14 DR. MOEN: The CDC does. I didn't look  
15 up any of that data. I mean, other things that  
16 are taken into consideration for making that new  
17 strain are the NI tests and also the human  
18 serology tests. We use samples from healthy  
19 adults and also pediatric sera, to look at how  
20 well the new vaccine is reacting against -- or the  
21 proposed vaccine would produce antibodies in the  
22 sera. So we looked at human serology panels, we

1 looked at NI data, and we looked at Health Affairs (HA)  
2 data, but I haven't looked at anything else.

3 DR. KAPLAN: And just a quick second  
4 question: How relevant is it for the B component?  
5 Is it possible or feasible, from a vaccine  
6 manufacturing perspective or a recommendation, to  
7 recommend two AH3 components as opposed to  
8 omitting the B component, which seems to be  
9 recirculating the same every year?

10 DR. MOEN: Is the question to have two B  
11 components?

12 DR. KAPLAN: No, two AH3 components,  
13 when necessary.

14 DR. MOEN: Oh, I think that once the H3  
15 begins to circulate, I mean, they usually change  
16 out. They change out, so you see that that's part  
17 of the change. I don't think you would want to  
18 have a sort of hybrid Southern- Northern  
19 Hemisphere vaccine, because the trend is usually,  
20 as they change the vaccine, as the new strain  
21 begins to predominate you see less and less of the  
22 older strain. So it would almost make more sense

1 to have two B components, because those two  
2 lineages are not going away. Each strain fades  
3 out and something new takes over.

4 DR. POLAND: Joe, then Mike.

5 DR. SILVA: Silva. Thank you. That's a  
6 very nice review. And I'm going to ask you a  
7 question, and I don't know if anyone has the  
8 answer. But in the Southern Hemisphere, what  
9 percent of the populations are immunized versus  
10 the northern population?

11 DR. MOEN: I don't have that data. Ray,  
12 do you know that?

13 CAPT. STRIKAS: Australia vaccinates, I  
14 would say, a proportion equal to what we do in the  
15 U.S. but a somewhat better percent. And there  
16 have been efforts in South America, largely in  
17 Argentina, to use vaccine, but it's sort of  
18 lagging behind what Europe and the U.S. Does.  
19 Australia does very well. And then in the  
20 tropics, places like Hong Kong and the like are  
21 much less interested in the influenza vaccine.

22 DR. POLAND: Mike.

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1 DR. PARKINSON: A naive question. I'm  
2 not an influenza expert. Mike Parkinson. But  
3 what were the historical factors -- I might  
4 imagine what they were -- for the decision to move  
5 to two different vaccines in '99, given that we've  
6 had 50 or 100 years of experience with a lot of  
7 vaccinations in influenza?

8 And the second question is, as I just  
9 kind of look at your summary of the six times that  
10 there was a difference in the composition,  
11 southern versus northern, what struck me as kind  
12 of a naive observation is it was rare indeed when  
13 the first change to the southern vaccine was  
14 subsequently incorporated in the northern vaccine.  
15 I mean, I just did a quick count. It looked like  
16 maybe two of the six times.

17 Okay, but anyway, I guess the question  
18 is, the theory would be that if we're detecting  
19 something that's clinically significant in the  
20 south, that it would either stick to some degree  
21 in a global pandemic, such as to be picked up in  
22 the northern vaccine in the next cycle, and I

1 didn't see a lot of that. I mean, that's a very  
2 naive observation, but does the stuff that pops up  
3 in the south stick in the north? I mean, in a  
4 very unscientific question.

5 DR. MOEN: I would have to go back and  
6 look. There were a couple of times when the  
7 strains -- and Wellington pops to mind -- where it  
8 was a very unusual virus that sort of circulated  
9 regionally and then sort of burned out, and then  
10 there was a better vaccine update.

11 With regard to the history, and I've  
12 only been in the Influenza Division seven years,  
13 my understanding is that they started recognizing  
14 that as the Southern Hemisphere -- I mean, South  
15 America was using more and more vaccine, Australia  
16 was using more vaccine, and other countries were  
17 trying to use more vaccine -- it made sense to  
18 update the vaccine so that it was relevant to  
19 those in the Southern Hemisphere that were using  
20 the vaccine, so they would have better protection.

21 And at least twice, I have been told,  
22 prior to that they saw viruses changing that were

1 very significant and predominant, so they made  
2 informal changes. And then in '99 WHO decided  
3 that it was just a good idea to, since two batches  
4 of vaccines could be made, and viruses, influenza  
5 is notorious for quick mutations and changes, they  
6 decided it was best to have a vaccine that was  
7 most relevant to the Southern Hemisphere when they  
8 were producing a vaccine for the Southern  
9 Hemisphere. I don't know if anything else played  
10 into it, but that's my understanding.

11 COL. GIBSON: Colonel Gibson. Do you  
12 have -- I know the data, there's issues with  
13 sampling -- but do you have any understanding of  
14 the difference between the tropical and non-  
15 tropical with respect to stability? There are the  
16 strains that circulate in the tropical area, are  
17 they more stable because they're circulating over  
18 a long period of time, or basically all of the  
19 time?

20 DR. MOEN: Usually when you see a strain  
21 change and the virus tends to change, I mean, you  
22 usually see that circulating everywhere, and so

1 the old strains sort of die out and new ones  
2 evolve. And so I'm willing to say that in the  
3 tropics they circulate more stably. I mean, they  
4 get exposed to all the same strains that are  
5 circulating globally, and they change out.

6 DR. KAPLAN: Kaplan. One short  
7 question. The sampling that you do from the  
8 Collaborating Centers and so forth seems to be in  
9 a limited number of places. Is that perception  
10 correct?

11 The reason I ask the question is, I just  
12 wonder -- and maybe it's an unfair question -- but  
13 how does that sampling geographic distribution  
14 match with the deployment of troops in the  
15 Southern Hemisphere?

16 DR. MOEN: I'll let somebody else speak  
17 about the deployment issue, where troops are  
18 mostly deployed, but with regard to the sampling,  
19 there are about 87 countries that produce  
20 influenza samples for the WHO, so there are huge  
21 gaps in Africa, some gaps in the Middle East, but  
22 less so in samples from that area. There's pretty

1 good coverage in Asia.

2 We're slowly building capacity, and we  
3 try to get representative samples from as many  
4 countries in the WHO system as possible. And then  
5 on top of that, DOD has routinely added samples  
6 and covers 6 to 10 countries that we can't cover  
7 through the WHO system.

8 But I would say you're right to some  
9 extent, because some countries don't have the  
10 resources to participate like they really should,  
11 but we do have very good and improving coverage in  
12 many places in South America. That has grown  
13 tremendously over the last 10 years. We get  
14 really good sample coverage from South America,  
15 Australia, New Zealand, some of the islands.

16 Asia is increasing. We get great  
17 samples from China. Of course that's the Northern  
18 Hemisphere. Indonesia is improving. So I think  
19 that the coverage is probably the worst in Africa,  
20 and there are some other gaps, but I think that  
21 the representation globally is not bad, but could  
22 be better.

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1 DR. KAPLAN: Thank you.

2 DR. POLAND: Joe?

3 DR. SILVA: Silva. This is a question  
4 for Dr. Miller, who was around in those days, as  
5 this picture shows. Ed Kaplan. I'm sorry. Ed,  
6 what's that hanging around those kids' necks? I  
7 notice a number of them have a band, a cloth.

8 DR. KAPLAN: I'm embarrassed to tell you  
9 that was before my time.

10 (Laughter)

11 DR. SILVA: I wonder if those are  
12 camphor bags or something of that sort, which was  
13 popular on kids?

14 DR. KAPLAN: That's probably right, but  
15 I never wore one, Joe.

16 (Laughter)

17 DR. SILVA: Okay. Thank you.

18 (Applause)

19 COL. GIBSON: Admiral Rempt will be here  
20 in about 2 minutes, so we'll just sit still for  
21 just a second, and then we'll call the room to  
22 attention when he comes in.

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1 (Recess)

2 VADM. REMPT: Good morning. It's a  
3 privilege to be here, to have a chance to chat  
4 with you a little bit. Let me add my welcome to  
5 the Naval Academy. How many of you have ever been  
6 here? Well, I hope you have a few minutes to walk  
7 around and enjoy the place, and a chance to stop a  
8 few Midshipmen and talk to them or ask them a  
9 question, because I think that's the best way to  
10 get a feel for it, if you can have a chance to  
11 walk around and see it and actually interact with  
12 the Midshipmen.

13 I'm glad you have come here to Annapolis  
14 and get a chance to see what we do and what's  
15 important to us with respect to the issues that  
16 you all address. So it's an important visit to us  
17 from our perspective, and I hope it's productive  
18 for you and your time. I think you've been to  
19 West Point previously, and the Air Force Academy,  
20 so you will be a unique group of Americans who  
21 have seen all three academies, because that's not  
22 something that very many people get to do.

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1 tell you working with 4,500 18-to-24 year olds is  
2 no small challenge, but it's also very rewarding  
3 and very encouraging to see the excitement and the  
4 enthusiasm. Hopefully it keeps me young during  
5 this time, but it's still a challenge.

6 We pay attention to our mission here,  
7 very much, because it drives us and it's  
8 essentially the foundation for what we do. Our  
9 mission is to develop Midshipmen morally,  
10 mentally, and physically, and to imbue them with  
11 the highest ideals of duty and honor and loyalty  
12 in order to provide graduates who are dedicated to  
13 a career of naval service and have potential for  
14 further development in both mind and character to  
15 assume the highest responsibilities of command,  
16 citizenship, and government.

17 And we have very good examples of those  
18 right now. In command, the Chairman of the Joint  
19 Chiefs, General Pace, the Vice Chairman, Admiral  
20 Giambastiani, the Chief of Naval Operations,  
21 Admiral Mullen, Vice Chief of Naval Operations,  
22 Admiral Willard, Commandant of the Marine Corps,

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1 General Hagee, all are graduates of the Naval  
2 Academy. So from the command perspective we have  
3 very good representation in the higher levels of  
4 command in our country.

5 On the citizenship side, I think a lot  
6 of different areas, but I like to think NASA. The  
7 Naval Academy has produced around 57 astronauts.  
8 Currently we have two very active, former  
9 astronaut Wendy Lawrence and astronaut Nowak, both  
10 Academy graduates. Wendy Lawrence, Class of '81,  
11 just completed her fourth Shuttletrip, the trip  
12 before last. She had three earlier Shuttle  
13 flights, and that's a long part of her career.

14 So again in citizenship, on the  
15 government side I could pick any number of people.  
16 Of course the one who is in the news all the time  
17 now is John McCain, Class of '58 from here, naval  
18 aviator, prisoner of war, got involved in  
19 politics, and hasn't looked back since that  
20 occurred. Of course my great fear is, he's going  
21 to declare for President, and we happen to have  
22 his son here as a sophomore, so then I'll have the

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1 Secret Service over here in Bancroft Hall.

2 The moral part of our mission comes  
3 first and is the most important. It's something  
4 that drives everything we do here. It's not  
5 enough to be educated or be physically fit. That  
6 doesn't make an officer. An officer must have  
7 extremely high values and strength of character to  
8 make the right decisions, even when he's under  
9 pressure to do something else. We want our  
10 Midshipmen to not only learn what honor means,  
11 take a class in honor, but to take it into their  
12 souls, to become honorable naval officers and have  
13 the courage to act when it's very hard to do so.

14 We help these young people develop into  
15 moral leaders who have the highest ethical  
16 standards and a keen sense of personal honor, with  
17 strong values and the moral courage that's  
18 necessary to get through the tough days. And our  
19 hope is when Midshipmen leave here that they have  
20 a firmly established personal integrity and moral  
21 courage, and they're ready to lead as an officer  
22 in the Navy, and that's really what we're about.

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1 That's a huge part of what we do here. We don't  
2 always get it right, but we strive very mightily  
3 to get it right.

4 And it's a challenge sometimes to get  
5 18-to-24 year olds to even think about honor, much  
6 less talk about it and change their view of it.  
7 So it's a challenge that we have but it's one we  
8 take on willingly, because it's such a neat thing  
9 to see them progress from wide-eyed plebes,  
10 freshmen, all the way through the senior, first  
11 class or seniors who are very responsible in  
12 taking on significant leadership roles.

13 On the mental side, the second part of  
14 our mission, we know that academic smarts gives  
15 our graduates the ability to assess facts and make  
16 decisions based on information, not just on  
17 seat-of-the-pants or gut feeling. They need a  
18 strong technological background, because the Navy  
19 and Marine Corps are very technical. And they  
20 must have a good understanding of their ships and  
21 systems and aircraft if they're going to lead  
22 their marines and sailors with confidence.

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1                   They have to be able to write and speak  
2 well, so they can communicate plans and guidance  
3 to their units and platoons. They need an  
4 understanding of human nature, so they can learn  
5 how to motivate their sailors to excel and to be  
6 more than they ever thought they could. Our  
7 belief is, a great education leads to success in  
8 the fleet, and that's a key part of what we're  
9 trying to do here.

10                   The third part of our mission is to  
11 develop Midshipmen physically, and athletics  
12 aren't just about physical stamina, although  
13 certainly strength and speed and agility is what  
14 we work on. We want them to learn teamwork and  
15 determination. We want them to keep going when  
16 the chips are down or the scoreboard is against  
17 them.

18                   We want them to learn what it takes to  
19 win, that you can't just show up. You have to be  
20 well-prepared and practice and review and do all  
21 the hard work that leads to success when you're  
22 under the gun. That's not an easy thing to learn,

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1 but sports helps teach that.

2           How do we know if we doing this? Well,  
3 they're required to participate in a sport every  
4 season. Now, we have 4,500 students here right  
5 now, and Ohio State, for instance, has 65,000, and  
6 they have 35 varsity sports and we have 31. We  
7 have a whole bunch of club sports, and everyone  
8 else plays intramural. It's a pretty engaged  
9 sport program here.

10           And if you come here, certainly any day  
11 of the week, when you wrap up your meeting today,  
12 this is Tuesday, you're going to see about 2,400  
13 who participate in intramurals and varsity sports  
14 and other things that are going on. Plus it's a  
15 great stress reliever for them after a tough day  
16 in class.

17           They take physical education classes  
18 every semester, boxing, including martial arts,  
19 personal conditioning. They're required to take a  
20 physical readiness test, pushups and situps and  
21 running, every semester, and what we strive is to  
22 see that they improve their scores over the four

1 years, and in fact they do. The scores from the  
2 entering plebes to the graduating seniors increase  
3 about 30 percent, so it's a pretty successful  
4 program as far as motivating them to continue to  
5 increase their strength and speed and how they  
6 feel comfortable with what they can do.

7           These three pieces of the mission --  
8 moral, mental, physical -- come together with our  
9 other significant focus, which is our leadership.  
10 Our goal is to produce leaders, not just give them  
11 book learning, which we do, they learn the  
12 principles, but to give them practice, to give  
13 them experience, so when they walk out the gates  
14 with a commission, they've already had a chance to  
15 experience leadership and set their own style.

16           We want them to leave here with  
17 confidence, so they're ready to lead, ready to  
18 fight, ready to do their job in the global war on  
19 terror, and that's what they're doing. They're  
20 serving all over the world as leaders. They don't  
21 hide from this responsibility. They don't shirk  
22 it. They seek it.

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1                   This last year I had 200 slots for  
2 Marines and there were over 300 that wanted to be  
3 Marines. I had 21 slots for Navy Seals, and I had  
4 48 that were whittled down from some 200 that  
5 wanted to be Seals, went through all the  
6 competition for four years preparing; 48 of them  
7 fully qualified, and I could take 21.

8                   This is a competitive, demanding  
9 process, but it's one that they seek. "Put me in,  
10 coach." "Send me to the front line" "Send me  
11 where the action is." "I want to go and make a  
12 difference." "I want to make a difference in  
13 people's lives." That's why they're here.

14                   I don't know if you've had a chance to  
15 read any of the stuff from the current generation.  
16 There's a good book called "Millennials Rising"  
17 How many of you have it? You know, how kids from  
18 16 to 25 have got it right.

19                   These kids want to serve, they want to  
20 contribute, they want to participate, they want to  
21 be part of something bigger than themselves.

22                   They're unselfish. Last year our

1 brigade racked up over 30,000 hours of volunteer  
2 service in the Washington/Baltimore/Annapolis  
3 area, including a whole group of Mids who in a  
4 duty section they described, they decided  
5 themselves to man a hospice over the weekends.

6 I could go on and on. They build  
7 Habitat for Humanity houses. They do all this.

8 This is what they do in their "free"  
9 time. Okay? They're pretty amazing young people.  
10 They really are great to watch. We should be very  
11 proud of them, proud of what they're doing and  
12 their commitment and their service and their sense  
13 of contributing to others.

14 Well, you all of course affect this a  
15 great deal in the things that you're working on  
16 with respect to health policy, and it plays a big  
17 part here, I can tell you that. We depend on our  
18 physical mission to teach teamwork and  
19 determination, so the things you all help us with  
20 indirectly there are pretty important.

21 They maintain a demanding schedule every  
22 day. They're up at 5:30, 5:45, complete physical

1 training, go to classes in the morning, after  
2 that, military training, sports, meetings and  
3 lectures in the evening, and then back to their  
4 rooms for studying and they start all over again.  
5 It's a pretty demanding schedule, and of course  
6 they have to be pretty healthy for that.

7 We pack our 4,500 18-to-24 year olds  
8 into Bancroft Hall, which is a relatively close  
9 environment, 1,744 rooms over there. And I can  
10 tell you if we get a bug over there, it goes  
11 around pretty quick, much like an aircraft  
12 carrier, an enclosed environment situation that we  
13 see.

14 When they graduate, of course they  
15 immediately scatter all over the world, and  
16 they're in unrestrained areas compared to the  
17 safety of, they call it "Mother B" over here,  
18 "Mother Bancroft." But any kind of a bug a virus  
19 or something can impact us pretty dramatically, as  
20 you are well aware. We're dependent on vaccines  
21 and a degree of vigilance in order to assure we  
22 remain healthy here.

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1                   We have a superb medical staff who are  
2 focused on this, so we're very, very pleased and  
3 very fortunate to have that. We had a very good  
4 case last year of real vigilance that paid off  
5 when we diagnosed and treated a cases of  
6 meningitis, and we were able to prevent it, to  
7 isolate it in that single Midshipman. We did not  
8 have any further outbreak.

9                   So that was a pretty significant problem  
10 from my perspective, a pretty scary one not only  
11 for the staff and faculty here, but for the 8,000  
12 parents, 6,000 grandparents, and brothers and  
13 sisters all across the country. Of course all  
14 they saw in the press was meningitis at the Naval  
15 Academy.

16                   So how we managed that, we're a little  
17 microcosm for you to look at, the Academy, because  
18 we're living in a really enclosed situation. So  
19 your decisions and recommendations have a direct  
20 impact, and we're pleased that you are here  
21 looking at what -- you know, if there's something  
22 unique here, I don't think there's a lot unique

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1 here, but it certainly is a good place for you to  
2 look.

3           Each year we commission the finest young  
4 officers. Young men and women who are 22 years of  
5 age or so are in charge of dozens of sailors and  
6 marines, launching cruise missiles, operating  
7 multimillion dollar nuclear power reactors, and  
8 flying the Navy's finest aircraft.

9           And they're out there serving, and  
10 they're prepared to lead. They're prepared to  
11 provide the leadership and the vision and the new  
12 ideas that will lead our country in this new  
13 millennium. And they're wonderful young people  
14 who are dedicated to this, who have spent their  
15 young lives to this point preparing themselves to  
16 be leaders.

17           So your support and your efforts  
18 directly help them, help them do the job. I  
19 believe that this generation of young people will  
20 provide the leadership that our country needs. It  
21 will give us a chance to figure out how to get  
22 through some of today's tough problems, and

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1 certainly be a huge contributor in fighting the  
2 global war on terror which is going to be with us  
3 for a while, as I'm sure you all know.

4 Now let me see if there are one or two  
5 questions about the Academy I could answer before  
6 I let you get on with your work. Anybody?

7 DR. POLAND: You've already won the  
8 prize for which one is the best academy.

9 VADM. REMPT: That's right. Well, you  
10 know, it's fun for me that the three  
11 superintendents would be talking a whole lot, you  
12 know, the three big academies, Merchant Marine  
13 also, and the Coast Guard of course. There are  
14 many more similarities than there are differences  
15 in the academies.

16 We each have our unique -- you know, we  
17 do most of our training out here on the Bay, in  
18 sailboats and yard patrol craft. The Army runs  
19 around the mud up there in New York, and the Air  
20 Force has an airfield that they do glider training  
21 and flight training. So we each kind of focus in  
22 our area, but the character and value of honor

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1 objectives remain the same in the academies. And  
2 we struggle, I mean, we're in a fishbowl, and the  
3 American people expect us to be the best, and  
4 that's our mission, is to be the best, and that's  
5 what we do.

6 DR. POLAND: On behalf of the Board and  
7 the Assistant Secretary for Health Affairs, we'd  
8 like to present you with a Certificate of  
9 Appreciation and our coin.

10 VADM. REMPT: All right, a coin. Look  
11 at that. This ought to get me in a few medical  
12 facilities.

13 DR. POLAND: That's right. You may not  
14 be aware, but one of our previous Board members,  
15 Greg Gray, has a son here who I believe would  
16 probably be a second, possibly third year  
17 Midshipman.

18 VADM. REMPT: I appreciate any direct  
19 feedback. That's always a good thing. Thank you  
20 all.

21 (Applause)

22 DR. POLAND: We also have a Certificate

1 of Appreciation for Lieutenant Waller, who spent a  
2 number of hours working with Colonel Gibson to get  
3 this meeting arranged. Lieutenant, thank you.

4 (Applause)

5 DR. POLAND: Thank you. Our next  
6 speaker this morning is Commander Fred Landro, who  
7 I understand 36 hours ago was sitting in Singapore  
8 -- is that right? -- from Navy Preventive  
9 Medicine. He will provide a risk analysis on the  
10 non-pandemic period of Southern Hemisphere  
11 influenza based on a Southern Hemisphere influenza  
12 outbreak that he was involved with. So, Commander  
13 Landro, good to see you, and thank you.

14 CDR. LANDRO: Thank you, Dr. Poland, Ms.  
15 Embrey, distinguished members of the Board.

16 Colonel Gibson asked me to come and talk  
17 about the outbreak that I was involved in. I  
18 guess the task name is risk analysis, but really  
19 he just wanted it to be like an information brief  
20 as you are considering this question of the  
21 Southern Hemisphere vaccine, to just take a look  
22 at the back yard that the military plays in. You

1 know, how big is it, what's the force composition,  
2 and because of this outbreak, you know, what's the  
3 realities that we have to deal with down there?

4 Here's what Talisman Sabre is. The  
5 Commander, United States Pacific Command, sponsors  
6 this exercise every other year, and this is  
7 designed to take the United States Seventh Fleet  
8 commander's staff and the Australian staff, their  
9 joint exercise staff, and say, "Okay, guys, we're  
10 going to do a wartime scenario together. How do  
11 we do this? Can you guys collaborate? Can you  
12 guys communicate together? Can you guys integrate  
13 your units?"

14 So it's a key exercise, and it really  
15 helps train Australians and the U.S. forces in  
16 combat operations. Again, it's biennial, and the  
17 period chosen in 2005 was the 10th through the  
18 30th of June.

19 And here's the landscape. I'd like to  
20 start off right up here in Townsville. Townsville  
21 is the center of the operations. It historically  
22 in World War II was the largest base that the

1 United States had in the South Pacific. There's  
2 an airfield there. There's Lavarack Barracks,  
3 which is the largest Australian Defense Force (ADF)  
4 facility, and there's a medical center.

5 So that's where the Talisman Sabre is  
6 centered out of. The main operating area is just  
7 south, the Shoal Water Bay training area. It's a  
8 fairly large place, a little smaller than the  
9 State of Rhode Island, and it's a good place to  
10 have a mock war. And all these other highlights  
11 here are places where our ships will go to. So  
12 we're talking about almost 3,000 miles here, and  
13 then there's up at Darwin where there's an area at  
14 our station there. It's a big place.

15 Here's our force composition. U.S.  
16 Forces, 10,000 personnel; Australian, 5,000.  
17 Eight vessels were involved in 2005. Kitty Hawk,  
18 Blue Ridge, Boxer were the largest, then we have  
19 destroyers, cruisers. A P-3 squadron. A Marine  
20 Corps element was there.

21 I think, though, 2,500 Marines were  
22 scaled back due to Tsunami relief and Iraq.

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1 2,500, that's a Marine expeditionary unit. That's  
2 the basic building block of going to war for the  
3 Marines. It involves a number of different ships,  
4 too. So these were cut out of the exercise. So  
5 10,000 is a low number. If you include the 2,500  
6 Marines that would have been there, plus the ships  
7 and the support staff, we'd be up to 15,000. So a  
8 large land-based element did not participate in  
9 Talisman Sabre 2005.

10 The U.S. Army element was there, mainly  
11 air troopers and special operations folks, and a  
12 U.S. Air Force element. They had their special  
13 operations folks there, and some flight surgeons,  
14 as well as C-17s and C-130s and so forth were  
15 there.

16 Australia had 18 vessels. Six were  
17 amphibious vessels, and then smaller. A P-3  
18 squadron. They had Army elements and their Air  
19 Force elements.

20 A quick note on the Army elements. They  
21 have a lot of reservists that come and play in  
22 these exercises, so these guys will be at home,

1 and a week before kiss the wife and kids goodbye  
2 and then they'll come out and they'll go play war  
3 games at Shoal Water Bay training area.

4 So it's not like our forces, that have  
5 already deployed and they've already been aboard  
6 ship, away from home for a sizeable time. These  
7 guys can be home and be in these training  
8 exercises within a week.

9 Influenza experience. Influenza  
10 outbreaks occurred in the past three years during  
11 these military exercises at Shoal Water Bay  
12 training area. The prior number of confirmed  
13 cases were less than 50 for each year, but  
14 nonetheless they had them going on, and it had  
15 become, as the Colonel said, a bit of a bother,  
16 mainly on the public affairs issues.

17 There was a high level of suspicion that  
18 yes, again during Talisman Sabre '05, influenza  
19 would again present during this exercise, and  
20 because of that the Australians decided they would  
21 do influenza planning, specific influenza  
22 planning.

1                   In early May they had a meeting to  
2                   prepare for Talisman Sabre '05. Lavarack Barracks  
3                   Medical Center, the personnel there got together  
4                   with the Tropical Health Unit -- that's sort of  
5                   like their big county health unit -- and the  
6                   Townsville Medical Center public health folks.  
7                   They all got together. They chatted about what  
8                   are we going to do when we get another influenza  
9                   outbreak during this exercise, because we've had  
10                  one in the past three years, and we anticipate  
11                  we're going to have one again.

12                  The U.S. was not there at that meeting.  
13                  Part of the reason, a big part of the reason that  
14                  there was no U.S. representation is that when that  
15                  Marine Corps element was cut, there was a  
16                  corresponding public health unit. A  
17                  forward-deployed preventive medicine unit was  
18                  going to be put in place in Australia. Well, when  
19                  the Marines got cut, the public health unit got  
20                  cut. Because that got cut, nobody had any  
21                  visibility really on the meeting and it dropped  
22                  off.

1                   During this meeting they set a case  
2 definition for influenza-like illness. They said,  
3 "Okay, fever, cough or sore throat." And they  
4 also published recommendations for management of  
5 an influenza outbreak. So here we have the  
6 Australians getting all ready: What are we going  
7 to do when this happens? Not if this happens.

8                   Now, I put this up here. This comes  
9 from Dr. Morgan at the Tropical Public Health  
10 Unit. The day I got on the ground she gave this  
11 to me. I just want to put this up here because it  
12 just shows you the magnitude of cases they had to  
13 deal with. Let's not talk about  
14 suspected/probable, because I'm not so certain  
15 about the title, but the numbers of magnitude is  
16 what's important here. They were dealing with  
17 upwards of sometimes 60 folks a day presenting,  
18 saying, "I think I've got the flu."

19                   The next curve is what I'd to take a  
20 look at. This is lab-confirmed cases. This is  
21 our epi curve. Let's take a look at this.

22                   Now, the exercise started the 10th of

1 June, and I've already said that the Australians  
2 were waiting for an influenza outbreak. They were  
3 already monitoring. They already had their case  
4 definition. They had RAPID tests they use. They  
5 were geared and ready to go. When they got their  
6 first positive there on the 14th, they said,  
7 "Okay, we'll sit and we'll monitor the situation,"  
8 and so they started collecting.

9 Now, as you can see, it peaks somewhere  
10 around the 22nd and then it dies off.

11 This only represents 99 lab-confirmed  
12 cases. Eventually there were 116 in all their  
13 final testing. So it starts because they were  
14 prepared and they were looking for cases, and it  
15 ends because at the end of the exercise, the way  
16 they stopped their epidemic was, they took the ADF  
17 and they said, "We're sending you guys home."

18 DR. POLAND: So just a clarification.  
19 The last two slides pertain only to Australian  
20 forces?

21 CDR. LANDRO: Oh, no. These are all  
22 cases. These are all cases.

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1 DR. POLAND: Okay, and were the  
2 Australian forces immunized?

3 CDR. LANDRO: No. The Australian  
4 Defense Force does not have a mandatory influenza  
5 immunization policy. It's all voluntary. Sounds  
6 strange, since they have mandatory immunization  
7 policies for many other diseases, but influenza is  
8 one that is just voluntary.

9 DR. GARDNER: And if they were  
10 immunized, were they immunized with the Southern  
11 Hemisphere vaccine, or were they immunized --

12 CDR. LANDRO: With the Southern  
13 Hemisphere vaccine.

14 DR. GARDNER: So the U.S. troops and the  
15 Australian troops received different vaccines.

16 CDR. LANDRO: Yes, sir.

17 DR. GARDNER: Thank you.

18 CDR. LANDRO: That's right. So that's  
19 how this ends, is the ADF said, "We've had enough.  
20 The exercise is over. You guys are going home."  
21 Now, they did do a mass immunization. They have  
22 that right, where the Tropical Health Unit, the

1 county public health doc, can say, "Hey, this is  
2 an urgent problem. We're going to do mass  
3 immunization." But it takes two weeks for that  
4 vaccine to be effective, now, since it's in your  
5 arm, so they're a little late.

6 But anyhow, I just wanted to show this.  
7 Here's our epi curve. Here's a summary of cases.  
8 I think this is probably the slide that you'll be  
9 interested in. 442 nasopharyngeal aspirates were  
10 collected. 116 were confirmed positive for flu A,  
11 110 out of Australian forces, 6 out of U.S.  
12 forces. Subtypes were identified. As you can  
13 see, Wellington and California, there were 70  
14 cases in Australians for Wellington, 4 in U.S.  
15 For California, 29 cases Australian, 2 U.S. And  
16 two cases of influenza B.

17 Now, I put the attack rates down. You  
18 can sit and you can play with numbers. Sometimes  
19 numbers have magic, but I think you can just take  
20 a look at the Australian forces. They had 110,  
21 and U.S. forces had 6.

22 So here are some considerations on that.

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1       Why the difference between U.S., why the  
2       difference with Australian?

3                 We had a reduced U.S. ground presence by  
4       2,500 Marines. That's considerable. That may  
5       account for the fact that we did not have as many  
6       folks ashore as normally we would during this  
7       exercise. Most of our forces concentrated on  
8       vessels. We had the Kitty Hawk. She was offshore  
9       the whole time. So that's about 5,000 personnel  
10      isolated.

11                Reduced mixing with local populations.  
12      Sure, I got in a taxicab, the driver, you know,  
13      the driver told me about all the Americans he  
14      drove around and where they went and so forth.  
15      But really most of our guys were busy working, and  
16      really not having any direct contact or prolonged  
17      contact with local populations.

18                U.S. military with mandatory influenza  
19      immunization policy. That's key. In my  
20      correspondence with the folks who were on the  
21      ground, they told me that as far as they could  
22      tell, all the folks, all the U.S. military

1 personnel who even developed influenza had  
2 received the 2005 Northern Hemisphere vaccine.  
3 Immunization cross-connectivity, I think Ann went  
4 through that.

5 Australian forces without a mandatory  
6 influenza immunization policy, and the Australian  
7 forces are at home. Greater mixing with local  
8 populations, especially the forces that were out  
9 of Townsville themselves. They pretty much lived  
10 at home, and in the daytime they went and did  
11 their job. So it is the influenza season normally  
12 in Australia, and so they may be carrying this  
13 back from their home, from their kids, and taking  
14 it into the military setting.

15 Editorial comments. My primary reason  
16 for going down for this outbreak was not to  
17 collect attack rates. My primary reason to go  
18 down to Talisman Sabre was to see how things such  
19 as the preplanning meeting, why we didn't get  
20 involved; take a look at is it useful to have  
21 preventive medicine officers present during  
22 planning sessions and at the military exercises.

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1                   Medical command and control. We had  
2                   certain junior physicians on the ground who were  
3                   talking back to their bases in Tampa but not  
4                   informing the Seventh Fleet surgeon of what was  
5                   going on on the ground, and that created a lot of  
6                   problems.

7                   For example, you have a young surgeon,  
8                   he's in charge of a special operations group, and  
9                   he wonders, "How should I treat this group?

10                   How should I manage influenza in this  
11                   group?" You know, you would think he would call  
12                   his chain of command and go through the Seventh  
13                   Fleet surgeon, who is designated to be the chief  
14                   surgeon for this exercise, but he doesn't. He  
15                   calls his friends or folks he knows back in the  
16                   States to get that kind of guidance. So there was  
17                   some confusion on our side.

18                   Immunization policies. Laboratory  
19                   impact. Their lab was swamped with nasopharyngeal  
20                   aspirates. Appropriate distribution of  
21                   antivirals, particularly Tamiflu.

22                   Here's another issue, that the

1       Australians literally gave out Tamiflu to our  
2       young docs on the ground, who were using it quite  
3       liberally both for assumed treatment and for  
4       prophylaxis. And when the Australians said, "You  
5       guys are just using too much of our Tamiflu, get  
6       your own," the young docs called the Pacific  
7       commander and said, "We'd like 5,000 courses of  
8       Tamiflu. Can you send them to us?"

9                They then referred the young physicians  
10       to the Seventh Fleet surgeon, who said no. And  
11       that's when I got my cell phone call back in  
12       Hawaii about, "What's going on? We need you out  
13       here. We have a riot, and we need the medical  
14       Texas ranger to come out."

15               So quarantine, isolation cohorts,  
16       restrictions, how to we effect that in an  
17       influenza outbreak? How do we actually use the  
18       concepts, the operationalized concepts of  
19       quarantine, isolation? How do we put cohorts  
20       together? How do we use restrictions that make  
21       sense in order to maintain the military  
22       operations, and also civil to military planning?

1                   Very key. The Australians had it right.  
2 They sat down with their civilian counterparts and  
3 they worked out what they were going to do, a  
4 very, very smart thing to do. That's something we  
5 need to consider.

6                   Finally, this last bullet here just  
7 below, in light of this, two public health doctor  
8 positions were created. Two preventive medicine  
9 officer positions were created and filled, one for  
10 Seventh Fleet and one for Sixth Fleet medical  
11 staff.

12                   Captain Bob Kaiser, Pacific Flight (PACFLT)  
13 surgeon, I spent a whole day debriefing him on a lot of  
14 these issues, and even more editorial comment issues  
15 came up with this idea that he'd like to just  
16 permanently put a prevmed officer on Seventh Fleet  
17 staff and one on Sixth Fleet staff. So that's  
18 happening. A good colleague of mine is going to  
19 Seventh Fleet, so I think he's going to have his  
20 work cut out for him.

21                   I'd like to acknowledge these folks:  
22 Dr. John Hodge, Robert Norton, Dr. Anna Morgan,

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1 and Ms. Phillipa Smith, who endured my presence  
2 for the four days down there doing some data  
3 collection. They were very, very busy folks.

4 I don't have a funny comic thing at the  
5 end, but I do have this. This is from Townsville.  
6 This is their Bulletin. It sort of looks like  
7 Texas, because it was rodeo days.

8 And it says, "Super Virus Strikes  
9 Cities," and there's a great sentence in here. It  
10 talks about the Australian general practitioners:  
11 "General practitioners were concerned the flu had  
12 been brought to Townsville by sick American  
13 soldiers in the region for Operation Talisman  
14 Sabre." So these fine people really wanted to  
15 talk to me some more, but they had their hands  
16 busy, not only doing medicine but also doing  
17 public affairs presentations.

18 So with that, I'll end my talk, just for  
19 the informational part of it. Do you have any  
20 questions, please?

21 DR. GARDNER: Pierce Gardner. Thank  
22 you. That was a wonderful presentation, and it

1 certainly has many lessons in our flu preparedness  
2 and about how the operational aspects are  
3 difficult. That brings me back to my idea of  
4 maybe a SWAT team for influenza is what we truly  
5 need.

6 My real question, though, it sounds like  
7 the Australians did a great job of preparation,  
8 but if I heard correctly, they decided finally to  
9 take all these folks who might be incubating  
10 influenza and send them all home.

11 CDR. LANDRO: Yes.

12 DR. GARDNER: And that's exactly what we  
13 worry about. That's how you start epidemics  
14 rather than how you solve epidemics. So I  
15 wondered, they seemed to be so good up until that  
16 point, but I would give them low marks for that  
17 decision.

18 CDR. LANDRO: Well, and they would look  
19 at me and say, "I've got reservists. Their time  
20 is up. They want to go home. And then I've got  
21 all of these other soldiers, their time is up,  
22 they're going to go home." And then they would

1 say, "It's seasonal flu."

2 DR. POLAND: Of course that one's not  
3 under our control. What is under our control is  
4 what happened with the Americans. And that, it  
5 wasn't a very good advertisement for our own part.

6 DR. GARDNER: But one of our scenarios  
7 that we run through is, what about the troop ship  
8 that's having Avian flu? And I think our idea  
9 was, we're going to keep them out there until this  
10 thing is over, because we don't want to send them  
11 all home to their communities where they'll get  
12 something going.

13 CDR. LANDRO: That's a great point.  
14 Some of these young docs who were on the ground  
15 and wanted to liberally use Tamiflu, I said,  
16 "Well, what about using quarantine, isolation, and  
17 just restriction of movement?"

18 "Well, that's too hard." So they wanted  
19 to shoot Tamiflu, I mean, they wanted to give  
20 Tamiflu to every U.S. Personnel on the ground,  
21 but they do not understand quarantine. They do  
22 not understand isolation, restriction of movement.

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1 And that brings up a lot of problems for future  
2 engagements. That's what we're not teaching them.

3 DR. POLAND: Ed, and then Mark.

4 DR. KAPLAN: Kaplan. One other  
5 question. The U.S. troops are Northern Hemisphere  
6 people, immunized with Northern Hemisphere  
7 vaccine. Do they go back to the Northern  
8 Hemisphere after the exercise is over?

9 CDR. LANDRO: That was -- yes, they get  
10 back on a plane and they go right back to Okinawa,  
11 or they go back to Yukota, or they go back to --

12 DR. KAPLAN: So not just the Australian  
13 troops, but the American troops go home also.

14 CDR. LANDRO: Absolutely, and as I flew  
15 out, I went through Sydney, and there must have  
16 been thousands of people at the airport from all  
17 over the world, mixing there. So it's just not  
18 U.S. troops, it's tourism, too.

19 DR. KAPLAN: I think this is an  
20 important consideration in the sense of global  
21 spread, or the potential for global spread.

22 DR. POLAND: Okay. Mark, and then Bill,

1 and then Roger.

2 DR. MILLER: Mark Miller. Looks like  
3 the numbers -- I don't know if the forces were  
4 intermingled very much, but if they were not, it  
5 looks like it was 22 to 1, based on the numbers  
6 below.

7 CDR. LANDRO: Yes.

8 DR. MILLER: You have a very interesting  
9 natural experiment here, and the epi curve was  
10 quite interesting, that it peaked actually in only  
11 eight days and normally you would expect it to go  
12 out a bit further. So what happened at that  
13 eighth day? And representing that natural  
14 experiment, was there quarantine at that time?  
15 One would have expected it to go much higher.

16 CDR. LANDRO: Yes. The Australians were  
17 -- they weren't dabbling or experimenting.

18 They were implementing as much  
19 quarantine and isolation as they could.

20 DR. MILLER: So it works?

21 CDR. LANDRO: Well, they think it did,  
22 yes. It would have been better had they

1 vaccinated their people.

2 DR. MILLER: Sure.

3 DR. HALPERIN: Is there consideration,  
4 or perhaps you've already done it, to turn this  
5 kind of thing into a scenario or essentially an  
6 epidemic war game for training purposes?

7 CDR. LANDRO: The Talisman Sabre?

8 DR. HALPERIN: Or some other similar,  
9 maybe even concocted, but where decisions about  
10 respirators versus quarantine versus Tamiflu have  
11 to be made, rather than a didactic lecture or in a  
12 manual. Rather, a training exercise where people  
13 go through making the decisions who ultimately may  
14 be confronted with making the decisions.

15 CDR. LANDRO: Out in Hawaii I've been  
16 through around about three, four, five, six pan  
17 flu tabletops where we get groups involved with  
18 that, not on a grand scheme but on a lower scheme,  
19 where we're shipping off some outbreak kits to the  
20 Third Marine Expeditionary Force, and we're going  
21 out there and teaching them how to use them and  
22 talk about -- to the younger docs with the Marines

1 -- What is quarantine? What is isolation? What  
2 is restriction of movement? How to do testing,  
3 how to collect specimens, you know, who you call.  
4 So that --

5 DR. POLAND: Bill, just to answer  
6 briefly on that, too, the Select Subcommittee on  
7 Pandemic Preparedness did prepare, I think it's  
8 nine scenarios, and that's actually one of the  
9 scenarios.

10 COL. GIBSON: A quick question, Fred.  
11 You said that they started an immunization program  
12 in the middle of this thing. Did that include any  
13 of our folks? Were our U.S. troops being  
14 immunized?

15 CDR. LANDRO: Well, that was the  
16 question that I was still -- I spent 12 hours on a  
17 cell phone with one guy, listening to desperate  
18 pleas from one of the young docs.

19 COL. GIBSON: The second, just a point.  
20 Your primary isolate was the Wellington strain,  
21 H3N2.

22 CDR. LANDRO: Yes.

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1 COL. GIBSON: The vaccine that was  
2 available that year was the Fujian strain, so the  
3 issue is whether it provided -- I'm sure that it  
4 drove including the Wellington strain in the 2005  
5 vaccine, but the issue is the cross- reactivity  
6 and how much protection we had from that vaccine  
7 during the summer.

8 CDR. LANDRO: Yes. I'll let Ann -- you  
9 know, put her on the spot to answer anything about  
10 cross-reactivity. But a lot of our U.S.  
11 Soldiers, sailors, airmen and marines have also  
12 been immunized for more than just one year.  
13 They've been immunized for a series of years, too,  
14 so that's something else.

15 DR. POLAND: Ann? Use the mike, please.

16 DR. MOEN: Yes. Ann Moen. From this  
17 data, it looks like there was pretty good cross-  
18 protection. We had a very low attack rate in our  
19 troops and they ere all vaccinated. So I would  
20 say it looked like the Northern Hemisphere vaccine  
21 served them pretty well.

22 DR. SHAMOO: I think the observation

1 Pierce made and you made is really part and parcel  
2 of our culture, the tension between public health  
3 and individual liberty. So it's not very easy  
4 just to say, "Okay, let's quarantine 5,000 or  
5 10,000 people." So we have to be aware of it. We  
6 have to think it through thoroughly before we just  
7 say, "Let's quarantine."

8 DR. WALKER: Were both A/Wellington and  
9 A/California circulating in the Australian general  
10 population at this time?

11 CDR. LANDRO: Yes, sir.

12 DR. PARKINSON: Mike Parkinson. It was  
13 striking to me, getting back to the question the  
14 Board has been asked, we're being asked is there  
15 enough risk -- my term -- of exposure and  
16 subsequent disease in U.S. personnel in the  
17 Southern Hemisphere to warrant a Southern  
18 Hemisphere-specific vaccine?

19 And yet our biggest and strongest ally  
20 with large troop concentrations, Australia, which  
21 probably knows more about the actual clinical  
22 morbidity and population impact of influenza in

1 the Southern Hemisphere, chooses not to immunize  
2 at all or to make it voluntary.

3 So can you help me understand a little  
4 bit -- and I know you're not speaking for the  
5 Australian military force. I don't think we have  
6 a representative. But what is the thinking as to  
7 why they would have tens of thousands of people  
8 not getting the routine Southern Hemisphere  
9 vaccine as a matter of military requirements?

10 CDR. LANDRO: I asked that question and  
11 got a lot of smiles. The best answer I have is a  
12 political hurdle they can't get over. There's a  
13 lot more of the anti-immunization, and so it's  
14 very hard for them to get over that. I mean,  
15 they've been immunized against many other things,  
16 but influenza is just one thing they just cannot  
17 do.

18 And you also raised -- if we do -- the  
19 Pacific Command does a lot of bilateral exercises,  
20 and they're increasing, what's called security  
21 cooperation. The Indonesians, they don't have a  
22 vaccination policy. If we start ramping up and

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1 doing more exercises with them, now that tensions  
2 are actually easing and military relations are  
3 getting better -- and you have other countries in  
4 Southeast Asia, too, that do not have immunization  
5 policies or the capability to do that. What do we  
6 do, if we interact with them? And this is not the  
7 only exercise in Australia that we participate in.  
8 We participate in many others.

9 DR. POLAND: One more question, then  
10 we're going to need to move on. Captain Johnston?

11 CAPT. JOHNSTON: Just one question. I'm  
12 intrigued by the difference between the demand for  
13 Tamiflu and the actual reported attack rate. I  
14 wondered if you had a comment on that.

15 CDR. LANDRO: If I get the question, did  
16 Tamiflu work, I guess is the --

17 CAPT. JOHNSTON: I was thinking more, is  
18 there an issue with ascertainment? Were there  
19 more cases than were actually being reported, or  
20 was Tamiflu being used more than perhaps it should  
21 have been?

22 CDR. LANDRO: I don't have the data to

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1 show that. I just know that on the U.S. side, the  
2 docs on the ground wanted to use it for  
3 prophylaxis even on folks who had only a fleeting,  
4 a fleeting presence in the sight of somebody who  
5 did have symptoms. And so in that case, yes, it's  
6 -- we would have over-used it.

7 In fact, my recommendation was cut off  
8 all Tamiflu altogether. Our guys were not at high  
9 risk for this. Their health, they don't have any  
10 comorbid, this business. They really shouldn't be  
11 participating. And just cut off all the Tamiflu  
12 for our guys.

13 For the Australians, they used it for  
14 treatment.

15 DR. POLAND: Okay. Thank you. Our next  
16 speaker will be Captain Ray Strikas, a long-time  
17 friend and colleague, now with the National  
18 Vaccine Program Office, Department of Health and Human  
19 Services (DHHS), who will brief us on barriers to the  
20 acquisition of the Southern Hemisphere vaccine.

21 CAPT. STRIKAS: Thank you, Dr. Poland,  
22 and good morning. Having the podium, before

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1 giving I begin the program, just some  
2 observations. The first is, the slides I'll show  
3 you are slightly different than the ones in the  
4 packet, but not terribly different.

5 I think the presumption I worked under  
6 in developing this presentation was to identify  
7 options and barriers for force protection, so U.S.  
8 personnel and perhaps some civilian sector is one  
9 way to think about this, and also a reminder that  
10 the advisory immunization practices  
11 recommendations for civilians say that those  
12 traveling in the Southern Hemisphere should have  
13 been vaccinated once with the most current vaccine  
14 available in the United States.

15 That's Northern Hemisphere vaccine. And  
16 if they haven't been vaccinated, they should  
17 receive it the spring before they would travel.

18 And, lastly, I'll throw out the  
19 consideration, although it's a highly politically  
20 charged item: Is it feasible that the United  
21 States could urge, surely not require, but urge  
22 that joint forces operating in exercises such as

1 the one we just discussed receive influenza  
2 vaccine before they join such exercises during  
3 influenza season?

4 So the topics I want to cover is briefly  
5 mention what are the options for receiving  
6 Southern Hemisphere vaccine. Even if it's not  
7 licensed in the United States, perhaps it could be  
8 licensed, and the potential population that could  
9 receive the vaccine are Department of Defense  
10 personnel, government civilians such as CDC staff  
11 or State Department staff who are deployed or  
12 stationed in such areas, and tourists in the  
13 Southern Hemisphere as well.

14 The options, if licensed vaccine is not  
15 available, include Investigational New Drug  
16 protocols or Emergency Use Authorization. I'll  
17 touch on those. And the other options that are  
18 mentioned, that could be done now, is using  
19 Northern Hemisphere vaccine -- which is certainly  
20 what the military is doing at the present -- or  
21 the other option to consider is vaccination upon  
22 arrival for an extended stay in a Southern

1 Hemisphere location with Southern Hemisphere  
2 vaccine that is licensed in that location.

3 So the three vaccines that I know of  
4 that are produced by the manufacturers for  
5 Southern Hemisphere formulation are Sanofi  
6 Pasteur's vaccine in France; CSL, which is  
7 headquartered in Australia, and CSL is proposing a  
8 U.S. license for Northern Hemisphere vaccine in  
9 2007; and GlaxoSmithKline produces vaccine in  
10 Germany for the United States, but also Southern  
11 Hemisphere vaccine in the same facility.

12 So, is something to look at that we  
13 could have perhaps a licensed vaccine? The FDA has  
14 told me that if they have licensed the facility  
15 for Northern Hemisphere vaccine, licensing a  
16 strain change for Southern Hemisphere vaccine is  
17 not that big a deal. Of course the manufacturer  
18 has to be interested in doing so, but it is  
19 something that could be explored to see if it's  
20 available.

21 Investigational New Drug protocols, many  
22 of you here know more about those than I do, but

1 they require a fair bit of work, science, and so  
2 on and so forth. Is an option to acquire such  
3 vaccine more cumbersome?

4 I talked to Colonel Pierson at Fort  
5 Detrick, and he thought it was possible -- and  
6 maybe he can comment further -- but I know this  
7 has been done for anthrax vaccine and protocols  
8 have been developed for smallpox vaccine. One  
9 could perhaps consider doing that for Southern  
10 Hemisphere vaccine, if this group and others  
11 thought it was worthy of that sort of  
12 authorization.

13 Again, the other options to think about  
14 are to assure that all forces receive the Northern  
15 Hemisphere vaccine, but to do that optimally you  
16 may want to have the vaccine available beyond its  
17 expiration date, which is June 30th of every year.  
18 And we've talked about virus match, and I'll talk  
19 about it some more.

20 So an extension requires a license  
21 supplement, which again might be fairly difficult  
22 to do, to get the manufacturer to do that. You

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1 could also use extended or expired U.S. Northern  
2 Hemisphere vaccine beyond June 30th with an Investigational  
3 New Drug (IND) or an Emergency Use Authorization (EUA).

4 It would seem simpler, of course, to get  
5 a license supplement rather than to do these other  
6 protocols, and just document the stability of the  
7 vaccine. And again I'm told by FDA the vaccine is  
8 fairly stable beyond June 30th. Expirations occur  
9 on June 30th each year because they don't want to  
10 confuse it with the forthcoming Northern  
11 Hemisphere vaccine for the following fall.

12 Again, vaccination upon arrival in the  
13 Southern Hemisphere, the challenges include making  
14 sure vaccine is available in the country where  
15 you're going, and as Commander Landro said, it  
16 takes two weeks to have protection from the  
17 vaccination.

18 So, Dr. Ann Moen showed you a different  
19 version of this slide, and I've summarized it in a  
20 different way. The point is, for the nine years  
21 in question, including the current year and the  
22 forthcoming year in the Southern Hemisphere, I've

1 got the year for the Northern Hemisphere on the  
2 left-hand side, the Northern Hemisphere strains in  
3 the second column, the Southern Hemisphere strains  
4 and the changes are in yellow, and then a summary  
5 of the changes.

6           And in these nine years there have been  
7 five years with changes and a total of six strain  
8 changes, as Ann told you. And actually the  
9 strains were the same in almost half those years,  
10 four of the nine, only one strain change in four  
11 of the five years and two in one year.

12           The antigenic similarity, again as  
13 stated, was only true in one of the six years with  
14 strain changes. And it is of note that, as we've  
15 just discussed, although as Commander Landro said,  
16 U.S. forces in Talisman Sabre were somewhat  
17 isolated from the town and from Australian forces,  
18 they all received Northern Hemisphere vaccine and  
19 the other population didn't, and there seemed to  
20 be over 90 percent vaccine effectiveness, in this  
21 sort of rough observation that Commander Landro  
22 was able to do.

1           And there are a variety of reports that  
2           receiving any influenza vaccine is a lot better  
3           than receiving none, even if it is mismatched. So  
4           assuring that the forces receive vaccine is the  
5           first and most important thing, and then  
6           secondarily what we're talking about today is,  
7           assuring that they receive the most current  
8           vaccine available is also essential.

9           So then to summarize what I've covered  
10          and what my outline said I was going to cover,  
11          there are three companies that produce Southern  
12          Hemisphere vaccine, none of which is licensed in  
13          the United States, but it's conceivable that we  
14          could ask one company to start a licensing, and  
15          CSL may be willing to consider this. As Ann said,  
16          we don't have to rush into the decision about  
17          Southern Hemisphere vaccine because for '07 the  
18          strains are the same in both the Northern  
19          Hemisphere that we have now and in the '07  
20          Southern Hemisphere vaccine, so there's again some  
21          time to consider this issue.

22                 The other option is to acquire Southern

1 Hemisphere vaccine, if that was desirable, by IND,  
2 or Emergency Use Authorization may be simpler  
3 under certain circumstances. And keep using  
4 Northern Hemisphere vaccine, and I would encourage  
5 you to do that. Again, in the military it's not a  
6 problem. You've got a young healthy population  
7 that responds well to vaccination and obviously  
8 maintains antibody for a long time, witness the  
9 Talisman Sabre experience.

10 And again, the last and least desirable,  
11 since I'm told there are either some logistical or  
12 legal constraints on using a product licensed also  
13 but not in the U.S., is vaccination on arrival for  
14 extended stays in the Southern Hemisphere. The  
15 logistics of that are to be determined, but at  
16 least one vaccine company, Sanofi Pasteur, spoke  
17 to me last week and said they would be interested in  
18 supplying vaccine to the U.S. military if they are in places  
19 where they have vaccine available.

20 So the last and most important point is,  
21 don't be like this fellow from the CSL web site.  
22 Please get your flu shot every year, and don't end

1 up looking like this man.

2 Thank you. I'm happy to take questions.

3 (Applause)

4 DR. POLAND: We have a few minutes for  
5 questions. Roger?

6 COL. GIBSON: Just one point. We talked  
7 earlier about this. It seems as though the DOD is  
8 not alone in this issue. There's folks at the  
9 State Department, some folks at HHS, CDC, even the  
10 Peace Corps folks that are going down there. Do  
11 you know from working with those people, are they  
12 under the same sort of constraints that we are on  
13 not using FDA- approved products or products that  
14 are not approved for FDA, as part of their  
15 mission?

16 CAPT. STRIKAS: I don't know for sure,  
17 and colleagues here at CDC can tell me if there is  
18 any constraint on receiving a vaccine in- country.  
19 I'm told the Department of State tends to do that  
20 in some cases, so it's something to explore.

21 Again, I think the preferable option is,  
22 for extended stays in-country, is to get a

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1 licensed Southern Hemisphere vaccine in the United  
2 States, which I need to do further exploration in  
3 collaboration with your designee to see how likely  
4 that is, given we have one company with licensed  
5 vaccine in the U.S., and again it's a strain  
6 change, and a second company who may have products  
7 here within a year, in time to do something for  
8 '08 that's most relevant. So I think that's the  
9 preferred option, if you and others wish to have  
10 Southern Hemisphere vaccine available.

11 DR. POLAND: Thank you, Ray.

12 DR. GARDNER: One other, following up on  
13 Colonel Gibson's, the other groups, certainly the  
14 practice of travel clinics is now expanded  
15 greatly, and this would be an issue for travelers,  
16 to people who are going to mix with civilian  
17 populations, and that would be even a larger group  
18 probably than the military.

19 CAPT. STRIKAS: I spoke to Dr. Phyllis  
20 Kozarsky, the senior travel medicine physician at  
21 Emory University, and she said this would be of  
22 great interest to her and her colleagues. They

1       could not offer me estimates as to how many U.S.  
2       travelers actually go for any length of time in  
3       the Southern Hemisphere during influenza season, I  
4       expect you're right. It's probably a sizeable  
5       number of folks, and I think this is a population  
6       of interest as well.

7                 DR. GARDNER: I'm a little nervous about  
8       taking too much weight to the difference between  
9       attack rates in the U.S and the Australian troops,  
10      given the fact that most of the U.S. folks were  
11      sequestered on ships offshore and didn't really  
12      have the opportunities to mix, so I think those  
13      rates are going to be less good than just looking  
14      at the overall rate.

15                CAPT. STRIKAS: Yes. I mean, influenza  
16      illness, vaccine effectiveness against  
17      influenza-like illness, which is most of what the  
18      data on this slide showed, in other data from the  
19      Northern Hemisphere we see antigen mismatch in  
20      vaccines from 30 to 50 percent at best, which is a  
21      lot better than zero but it's not 90 percent which  
22      these figures suggest. You're right.

1 DR. KAPLAN: Kaplan. Am I unjustly  
2 concerned about the other direction, that is,  
3 about tourists, and in the case of the previous  
4 talk, troops coming back from the Southern  
5 Hemisphere into the United States? Is that, I  
6 mean, doesn't that provide perhaps even  
7 theoretically a greater risk than for people from  
8 the Northern Hemisphere going to the south?

9 CAPT. STRIKAS: You're talking, sir,  
10 about a risk of troops--

11 DR. KAPLAN: Either troops or tourists.  
12 We were talking about what happens when people  
13 from the north go to the south. It seems to me we  
14 should be equally concerned about people coming in  
15 the other direction.

16 CAPT. STRIKAS: Fair enough. You know,  
17 the only good answer I can offer you is that  
18 everybody ought to receive influenza vaccine.

19 DR. KAPLAN: But is it non-FDA approved  
20 Southern Hemisphere vaccine? I mean, doesn't that  
21 pose a potential, I guess, food for thought?

22 CAPT. STRIKAS: I mean, are you

1 suggesting that people receive non-FDA approved  
2 in-country vaccines?

3 DR. KAPLAN: I'm not suggesting  
4 anything. I'm asking a question. From an  
5 epidemiological point of view, doesn't it worry  
6 you just as much about people coming from the  
7 south to the north, tourists or what have you, as  
8 for people going from the north to the south?

9 CAPTAIN STRIKAS: I'm sorry. I didn't  
10 follow you. Ann may have a comment as well. No,  
11 I think epidemiologically I can't quantify the  
12 risk. But the risk is probably equivalent for  
13 bringing viruses one way versus the other way, so  
14 I think in that sense I would agree. Ann?

15 DR. MOEN: Ann Moen. Yes, I just wanted  
16 to comment that we see sporadic cases throughout  
17 the year, and sometimes we see them coming back in  
18 travelers, but flu just doesn't circulate that  
19 much during the summer months, so we don't usually  
20 see outbreaks related to travelers bringing back  
21 sporadic cases of flu. I mean, if it was maybe an  
22 old folks' home that went on a trip and then came

1 back, there might be an outbreak there or  
2 something, but we usually don't see it continue to  
3 cause problems.

4 CAPT. STRIKAS: The other example that  
5 throws a curve ball is of course we see cruise  
6 ship outbreaks in early fall, and nursing home  
7 outbreaks, and one wonders how those happen. That  
8 may have lent credence to the idea that it was  
9 brought from someplace else, if the cruise ship  
10 crew came from someplace else and infected all the  
11 passengers. So it happens in a variety of ways.  
12 I don't think it's a concern in this.

13 DR. POLAND: Wayne, and then Joe.

14 DR. LEDNAR: Wayne Lednar. From a  
15 national, maybe a military point of view, we  
16 should not forget many universities have found it  
17 very fashionable to include in their academic  
18 experience, studying abroad, and most universities  
19 provide this opportunity to their students, and  
20 some of them will go from the Northern Hemisphere  
21 to the Southern Hemisphere.

22 Some of them will come right back in to

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1 dormitory environments and may in fact be  
2 incubating something derived from the Southern  
3 Hemisphere back to the their home universities.

4 In a military relevant way, to the  
5 extent that there are summer training exercises,  
6 and for example a training cruise in the summer to  
7 the Southern Hemisphere, we will be sending  
8 military trainees into potentially influenza  
9 season, and then of course they'll return home and  
10 come back to service academies or other kinds of  
11 situations. So I think our vigilance of this  
12 issue is a little bit light to know just exactly  
13 where we are at the moment.

14 DR. POLAND: Joe?

15 DR. SILVA: Yes. Joe Silva. I was also  
16 struck by the paradox, why this thing didn't  
17 ripple further with the mismatch, but I wonder how  
18 long it took for the troops to come back to the  
19 Northern Hemisphere? Could it take two or three  
20 weeks by ship?

21 CAPT. STRIKAS: I defer to Commander  
22 Landro. How long, Fred, did it take to--

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1 DR. SILVA: Do they go by plane or by  
2 ship?

3 CDR. LANDRO: Many of the troops  
4 actually came in by C-17, so they left. That's  
5 the ground component, perhaps the ones at greatest  
6 risk. Perhaps the U.S. troops at greatest risk  
7 were the ground component troops, and they all  
8 left by C-17 back to the Northern Hemisphere.

9 DR. SILVA: So quickly they returned?

10 CDR. LANDRO: Correct. Within a day or  
11 two.

12 DR. WALKER: Walker. Are there any  
13 examples of Southern Hemisphere departments of  
14 defense that immunize their troops against  
15 Northern Hemisphere influenza?

16 DR. POLAND: In other words, other  
17 countries?

18 DR. WALKER: Yes. I mean, they deploy  
19 troops to the Northern Hemisphere.

20 CAPT. STRIKAS: We'll try to get that  
21 for you. I don't know at this point.

22 DR. POLAND: Any other questions or

1       comments?  If not, we will take a 20-minute break,  
2       a little bit longer because we're ahead of  
3       schedule, and we'll reassemble at 10:30 sharp.

4                       (Recess)

5                       DR. POLAND:  If we can all take our  
6       seats, please, we'll get started.

7                       Our next speaker this morning is going  
8       to be Mr. Howell; Major Eric Midboe from the U.S.  
9       Army Medical Readiness & Materiel Command; and Dr.  
10      Paul Wilson and Dr. Tauber from Intercell.  
11      They'll provide an update on the adenovirus and  
12      Japanese encephalitis virus.

13                      MR. HOWELL:  Thank you very much.  First  
14      of all I want to thank the Board for taking these  
15      two briefs, because I actually asked them to take  
16      them.  I know you've had some interest, obviously,  
17      in the adenovirus vaccine for quite a while.  So  
18      we're getting to the eve of the typical Phase  
19      2/Phase 3 trials, so I thought it was a worthy  
20      time to come say hi again and let you know where  
21      we are, what we're doing.  Eric Midboe will have  
22      that for you.

1           I have to tell you very quickly, this  
2           has been sort of an adventure, because the way we  
3           started this particular piece, we thought this was  
4           a simple tech transfer, going from Wyeth to Barr.  
5           And as it turned out, and once we had talked for  
6           almost a year and a half to get Wyeth to give up  
7           their technology, then we found out it would be  
8           harder.

9           And in truth and in fact, the particular  
10          project has turned from a tech task more into a  
11          discovery phase, and we found that out the hard  
12          way in dealing with the FDA as we went through the  
13          process. We also saw when the manufacturer  
14          started to make the first particular capsules or  
15          the tablets, they had a little trouble with the  
16          stability, so we've had little problems along the  
17          way.

18          And so together that's made this thing  
19          go from what we thought was going to be a nice  
20          four, maybe five year outside sort of project, to  
21          something that's going to be a little bit longer.  
22          So we'll talk to you as to where we are in the

1 game plan for it.

2           And the other reason I wanted to get up  
3 here, Eric has been the project manager now for  
4 about three years, and he has the joy of leaving  
5 it behind, unfortunately. Today is his last  
6 official action, probably, with this particular  
7 project. He's going to Army staff from here.

8           Replacing him -- come on up here, Eric  
9 -- replacing him is Art Brown, if you would stand  
10 up real quick too, Art, Colonel Art Brown, who is  
11 going to fall in behind Eric, so we are obviously  
12 not going to leave this thing uncovered and moving  
13 it forward. But I do want to say in a public  
14 forum that I'm very fortunate that Eric had this  
15 thing, because it has been -- it has turned into a  
16 heck of a lot more of an effort than we thought it  
17 was originally, and he has done a great job trying  
18 to keep everybody together, re-baselining, going  
19 back to Health Affairs for money. As we've seen,  
20 the project has changed in its scope along the  
21 way. So I think he has done an outstanding job in  
22 a pretty tough situation, and I will leave him

1 then to take all the tough questions when he's  
2 done.

3 MAJ. MIDBOE: Thank you. Thank you for  
4 giving me the opportunity to speak today. Again,  
5 Major Eric Midboe, project manager, adenovirus  
6 vaccine.

7 At the start here I'll just talk a  
8 little bit about where I'm going to go. An  
9 overall program review, talk about manufacturing  
10 of the vaccine, regulatory, clinical trials, how  
11 we're managing the quality of the program, and the  
12 initial procurement of the vaccine, funding, steps  
13 going forward, and then the risks.

14 I want to highlight here first off that  
15 the Defense Health Program requirement established  
16 by Dr. Winkenwerder, this was -- you know, this  
17 came after many AFEB recommendations to reacquire  
18 this vaccine. Since receiving the Defense Health  
19 Program requirement from Dr. Winkenwerder, we've  
20 also staffed the Initial Capabilities Document for  
21 infectious disease. Now, this is a broad document  
22 that includes many infectious disease threats.

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1 Adenovirus is included within that document, and  
2 this has just gone through the Joint Requirements  
3 Oversight Council, and I believe it should be  
4 pending approval right now.

5 In addition, the Capabilities Production  
6 Document is another requirements document that's  
7 important for this program. Again, this is  
8 specifically defined for adenovirus vaccine, so it  
9 defines the performance parameters of the vaccine  
10 that we're seeking, the quantities that we're  
11 eventually going to be purchasing, some of the  
12 logistics aspects of it.

13 All of these documents, again, help to  
14 affirm that there is a requirement. They help  
15 with the overall funding that's necessary, and  
16 they also just clarify to the services what we're  
17 doing with this product.

18 The overall objective is to provide a  
19 safe, effective, FDA-approved adenovirus vaccine  
20 for type 4 and type 7 to protect U.S. military  
21 trainees from acute respiratory disease caused by  
22 adenovirus type 4 and type 7.

1 I always like to remind people  
2 specifically of the unique nature of the tablet.

3 What you're looking at here in the inner  
4 core is a formulation of the live virus, and then  
5 it's encapsulated with this outer enteric coating,  
6 polymer coating, so that it actually will remain  
7 intact for an hour within the stomach, and then  
8 within 30 minutes it dissolves within the small  
9 intestine. So it is a live virus infection of the  
10 small intestine.

11 I also want to give you an overall  
12 perspective of the program. It's kind of  
13 colorful, but what I'd like to make sure we think  
14 about other than just the vaccine is where we've  
15 been and where we're going to. I'm going to step  
16 out here just a little bit.

17 You know, we can see where the initial  
18 contract base period was and this "tech transfer"  
19 occurred, with materials and processes that were  
20 transferred. In addition, we have the  
21 construction of a dedicated tablet facility. We  
22 have process development and pilot lot production

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1 that would occur. Some of the pilot production  
2 was done at the Walter Reed Army Institute of Research  
3 (WRAIR) virus production facility.

4 Manufacturing scale-up, when we transferred some  
5 of the processes to the Barr Virginia facility, which is  
6 again the dedicated facility for both tableting and also  
7 lyophilizing the process. Assays, the Phase 1 trial, again,  
8 there are regulatory bits throughout.

9 As you can see, we're right on the eve  
10 of starting the Phase 3 trial, and just right in  
11 here we're looking at -- well, first here we had a  
12 Milestone B review with General Schoomaker, the  
13 commander of the Medical Research and Materiel  
14 Command, where we went over the entire cost and  
15 performance of this program, and he approved the  
16 program going forward if we had sufficient  
17 funding, as I'll talk about a bit later.

18 When we get out to this point, I wanted  
19 to tell you, as I'm going to talk a little bit  
20 later, we have to, after we get a milestone  
21 review, after the Phase 3 trial, we're looking at  
22 doing low rate initial production so that we're

1 prepared to actually meet initial operational  
2 capabilities in '09. So there are still some  
3 negotiations that have to occur in this time frame  
4 where we're looking at what risks are we going to  
5 take in purchasing a vaccine prior to its actually  
6 being licensed so that we can go ahead and meet  
7 this initial operational capability, or do we wait  
8 until it's licensed and then we ramp up the  
9 manufacturing?

10 So there are a lot of steps that still  
11 need to be worked out as we're going forward.

12 Throughout this you'll see I went ahead  
13 and starred all the AFEB briefings. There have  
14 been several over the past years. And throughout,  
15 again, you know, what's helping this is the  
16 funding. We just went through the '08 to '13 Program  
17 Objective Memorandum POM, where we were able to secure  
18 funding for this program that's allowing us to go forward.

19 I put this slide up here because I  
20 always like full disclosure. Back in December  
21 when you were briefed, this is the plan that we  
22 had at the time, and at that time there was about

1 an eight month slip, primarily due to  
2 manufacturing, as they transferred and scaled up  
3 from the WRAIR virus production facility lab to  
4 the Forest, Virginia facility with Barr. There  
5 were some challenges with validating the system  
6 down there. We overcame that.

7           However, you know, since that time we've  
8 still had another five months slip overall in  
9 initiating the Phase 3 trial. And again, it's  
10 linked to both having the product available, and I  
11 think not to put all the blame on manufacturing, I  
12 think there are challenges with developing a  
13 clinical protocol in this unique environment.

14           We're going to military recruits, and  
15 there are significant hurdles of multiple services  
16 Institutional Review Boards (IRBs), over seven scientific  
17 review committees and IRBs combined on both the Navy and  
18 Army side. So even if we had been able to overcome the  
19 manufacturing sooner, we still would have had big  
20 delays because of just that process.

21           The other thing we ran into is, at the  
22 end of the Phase 2 meeting the schedule was based

1 on an accelerated review by the FDA. They denied  
2 that request, and that added some additional time  
3 to the overall schedule for the time that it would  
4 actually take for the FDA to review and approve  
5 the product. So the current time line is May '09  
6 to have the vaccine available.

7 This schedule was briefed to Major  
8 General Schoomaker for Milestone B. This is the  
9 schedule that he has approved. Any breach of the  
10 threshold, which was based on a quarter, would  
11 require to go back to review the program again.  
12 So there's a lot of attention being made to the  
13 schedule to make sure that we get the product to  
14 the soldiers as soon as possible, a safe and  
15 effective product.

16 So the things that we have accomplished  
17 here, this is the virus bulk formulation. That's  
18 actually done at BioReliance in Scotland. It's  
19 then shipped here to the Forest, Virginia  
20 facility, the dedicated Barr manufacturing  
21 facility, where it's tableted -- actually where  
22 it's first lyophilized and then it's tableted.

1 They have developed the processes here and they  
2 have done the successful transfer of that  
3 technology, again, from the WRAIR process to the  
4 Virginia facility.

5 For the Phase 3 trial we have -- the  
6 first lot is available for both type 4 and type 7  
7 with matching placebos. They have been  
8 prepackaged and they will be ready for release for  
9 this trial that will start this Saturday.  
10 Additional lots that are necessary, because we're  
11 actually doing -- this study will also be used to  
12 demonstrate lot consistency -- will be available  
13 in January, and so there will be actually three  
14 lots that will be used in this study, or actually  
15 a total of eight, because you have the two  
16 placebos and you have three for each, type 4 and  
17 type 7.

18 Again, I do want to highlight some of  
19 the regulatory milestones that we've gone through.  
20 We had the pre-IND meeting back in May of 2004.  
21 We also had, we submitted the IND, or I should say  
22 Duramed submitted the IND in July of 2004. And

1 Duramed is the IND sponsor for this product.

2 The Phase 1 clinical trial started in  
3 Fort Sam Houston, starting on August 14, 2004, and  
4 was completed in April of 2005. The clinical  
5 study report, as you can see, was 2005.

6 We just had the end of Phase 2 meeting  
7 with the FDA back in June. And most recently, on  
8 September 12th we got comments back from the FDA  
9 really allowing us to go forward.

10 However, there were some comments where  
11 they wanted to change, modify some of the  
12 exclusion criteria, which required us to go back  
13 or the investigators to go back and make some  
14 changes to the protocol and submit it back through  
15 the IRBs. Again, each time you think, you know,  
16 concurrent, but seven IRBs, that's a task, and  
17 they've done a great job and within that limited  
18 time frame to turn it around. Fort Jackson, they  
19 will be able to start this weekend. Great Lakes  
20 will be probably delayed until the following week.

21 Here is the Phase 3 clinical trial, a  
22 randomized, multi-center, double-blind, placebo-

1 controlled study. Overall, the objective is to  
2 demonstrate efficacy of the type 4 reduction, case  
3 reduction of acute respiratory febrile disease.  
4 For type 7, because the incidence rate of type 7  
5 is lower, we're looking at seroconversion rates  
6 for the type 7, and then we're going to use that  
7 for both the -- seroconversion for both type 4 and  
8 type 7 as the basis to demonstrate effectiveness  
9 for type 7.

10 We're looking at a population of 4,000  
11 military recruits. The size was dictated, in  
12 large part, first by the FDA wanting at least  
13 3,000 for safety. That was the primary. The  
14 other aspect of the large study size is just to  
15 make sure we capture the incidence rate so we can  
16 demonstrate effectiveness for the vaccine.

17 There is a nested cohort, because you'll  
18 notice we are going directly from a Phase 1 to  
19 essentially a sort of a Phase 3, so that there is  
20 a nested Phase 2 cohort within this Phase 3 trial  
21 that the FDA recommended and we all were in  
22 agreement to. So the first 780 will have an

1 extended diary where they will be monitored real  
2 closely. And then following that, in the spring  
3 they'll start the second portion of the Phase 3  
4 where they'll complete enrollment of the other  
5 3,000 subjects.

6 At 2,000 subjects there will actually be  
7 -- the Data Monitoring Committee will also do an  
8 interim analysis, and this analysis will be used  
9 first off to determine whether or not we have  
10 enough subjects in the study. So if the incidence  
11 rate is actually lower than what we are  
12 anticipating, we may have to increase the study  
13 size. The FDA has always said that this interim  
14 analysis would not be used to stop the trial  
15 earlier, it is only to extend the study of the  
16 population.

17 The two sites that I mentioned before  
18 are Great Lakes, where Commander Russell is the  
19 principal investigator, and Fort Jackson, where  
20 Colonel Kushner is the investigator. Commander  
21 Russell was unable to be here today. Colonel  
22 Wyeth, one of the subinvestigators, is here if you

1 all have specific questions about the site at Fort  
2 Jackson.

3           There are -- it's a 3 to 1 ratio, ADV-4  
4 and ADV-7 given simultaneously, versus the  
5 placebo. The sites, this is kind of an  
6 oversimplification of what it has taken for the  
7 investigators to set up these sites. Fort Jackson  
8 and Great Lakes, neither of them, they're not set  
9 up to do clinical trials, obviously.

10           And the communities there, you know, it  
11 takes a lot of effort to inform and communicate  
12 with command and also the instructors. They're  
13 going to be getting recruits on an ongoing basis.  
14 We're obviously having to hire full-time CORE  
15 staff. There are site renovations. Ancillary  
16 part-time trained.

17           Just fitting into the schedule of the  
18 initial -- and I believe the concept here, we're  
19 going to actually be vaccinating the first three  
20 days of basic training. Actually it's at the  
21 reception station. So a soldier is going to come  
22 in and, you know, on day one basically we're going

1 to do some initial screening. We're going to have  
2 to give them informed consent. And then by day  
3 three, when they get their normal vaccinations,  
4 they will be vaccinated if they enrolled and  
5 they've met all the inclusion/exclusion criteria.

6 That's difficult to fit into something  
7 that's already jam-packed with other required  
8 in-processing procedures, both medical and so  
9 forth. So what is happening, we actually have to  
10 do a lot of it on a Saturday, basically. We have  
11 had to move around, so that we're not actually  
12 doing it in the mid-week. We're trying to  
13 minimize the impact on the training command,  
14 because otherwise we just probably would not be  
15 able to do the study at all.

16 Quality assurance, overall, you know,  
17 Duramed is the sponsor. Duramed is responsible to  
18 the FDA to ensure the quality of the product and  
19 the process, the manufacturing, as well as  
20 ensuring clinical practices are carried out on-  
21 site. Obviously the clinical investigators are  
22 there also. The Medical Research and Materiel

1 Command office is also providing oversight of the  
2 processes and procedures that Duramed is  
3 following, and ultimately the FDA is ensuring  
4 quality of product and process throughout.

5 I wanted to highlight procurement of the  
6 vaccine, because ultimately we can do all these  
7 studies but if we can't procure the vaccine, we  
8 haven't accomplished the mission if we can't get  
9 it to the soldiers.

10 Previously we had presented that we had  
11 had some difficulties getting detailed cost  
12 estimates on the price of the vaccine going  
13 forward. There have been some changes within  
14 Duramed and Barr, actually. We have been getting  
15 better cooperation. There is also additional  
16 information to use as the basis for getting more  
17 accurate and complete vaccine cost estimates, so  
18 that's going to help, but there is still  
19 significant work ahead of us in determining the  
20 fair and reasonable price for the vaccine that  
21 allows us to provide the vaccine to soldiers.

22 Following the Milestone B review, a

1 draft procurement contract would be let to  
2 Duramed, or I should say Barr Laboratories. And  
3 then, like I talked about earlier, I talked about  
4 low rate initial production is scheduled to begin  
5 during the fourth quarter of FY '08 if we make the  
6 decision that we're willing to support a  
7 procurement contract prior to licensure. If we're  
8 not willing to take that risk, then there's going  
9 to be an additional delay, or Duramed or Barr  
10 could assume that risk and start producing the  
11 vaccine with the expectation that it would be  
12 licensed, and we would purchase it when it was  
13 licensed.

14 This is a big thing, even though it's  
15 just one line. It's always nice to have a program  
16 that's funded -- and this is the first time I've  
17 ever been able to -- well, this is the first time  
18 I've been able to say this, but also it's a  
19 current program that's fully funded.

20 You know, whenever you're talking about  
21 cost, schedule, and performance, you're balancing  
22 things. Change happens, but right now we're in a

1 good position going forward. We're just  
2 finalizing the contract modification that was  
3 necessary to support the Phase 3 trial, in which  
4 there was a significant cost increase from what  
5 was initially envisioned to support a Phase 3  
6 trial to what we are paying today for that same  
7 Phase 3 trial. We're looking at going from 1,000  
8 to 4,000 subjects. That's significant.

9 Moving forward, again we'll be releasing  
10 additional vaccines for the Phase 3 trial, I guess  
11 in January, in two additional lots for type 4 and  
12 type 7. There is ongoing stability testing for  
13 the vaccine. We are overall looking to  
14 demonstrate a two-year shelf life for the vaccine.

15 We're initiating the Phase 3 trial this  
16 Saturday at Fort Jackson. Hopefully we'll be  
17 starting the Phase 3 trial at Great Lakes the  
18 following week. There is a Data Monitoring  
19 Committee that's meeting, and they will be  
20 reviewing the 780 subjects who will participate in  
21 a safety review, and an interim analysis at 2,000.

22 Again, program risks. You know, when I

1 presented this before, we knew that we had gotten  
2 approval, or at least for Fort Jackson. But I  
3 would just again highlight the fact, the  
4 significant accomplishment of the investigators on  
5 both the Army and the Navy side to get these  
6 protocols reviewed and approved, and the boards.

7 I mean, the boards were very cooperative  
8 in this process, but it does take a lot of  
9 coordination.

10 Regulatory guidance, unfortunately we  
11 received the guidance that the FDA was supporting  
12 the current protocol after I had submitted this  
13 presentation. I think we've met that goal right  
14 now, unless there's additional challenges ahead of  
15 us.

16 This I think is the biggest challenge,  
17 one of the biggest challenges going forward,  
18 enrollment. They have done mock enrollments at  
19 the sites, and again, the timing that it takes to  
20 bring soldiers in, coordinate with their  
21 instructors, to get informed consent, to take  
22 blood samples, to test, to get the results back,

1 specifically for pregnancy, and then to vaccinate,  
2 it all takes a tremendous amount of time, and we  
3 have a very limited ability to do this. And  
4 you're also assuming that someone who is fairly  
5 healthy is willing to take an investigational  
6 product, and the implications of whether or not  
7 there is a conflict on that or not.

8 The vaccine performance. There's always  
9 production failures. Completing the contract  
10 modification that actually allows us to go  
11 forward, that should be signed this week. And  
12 overall vaccine cost, making sure that we can  
13 continue to procure vaccine in the long term.  
14 We're looking at an investment, you know, a  
15 limited investment base, I think, for many  
16 vaccines, and we are looking at specifically the  
17 military as the primary or only buyer. We're  
18 having to maintain that investment base. That's a  
19 significant cost. We can't spread that investment  
20 base over a larger area.

21 So any or all of the above could affect  
22 our scheduled performance. Any further questions?

1 That's my brief.

2 DR. POLAND: Dan?

3 DR. BLAZER: I was curious about your --  
4 I don't know how much concern you have that you  
5 don't have the power to calculate correctly the  
6 clinical trial. It seems to me like this is one  
7 of the best-tracked pieces of information that the  
8 military had, the rate of adenovirus infection.  
9 I'm just curious about why you have some doubts  
10 that maybe you have underestimated.

11 MAJ. MIDBOE: First off. Commander  
12 Russell is definitely the expert in this right  
13 now. He has just recently published some work  
14 from 1999 to 2006, looking at the surveillance of  
15 adenovirus on the base training sites of all  
16 services.

17 That was used, but it wasn't a matter of  
18 significant discussion with the FDA. When Barr  
19 initially went to the FDA, they proposed a 1,000  
20 subject study, and the FDA rejected that.

21 Again, it was based on the belief that  
22 we could do that with 1,000 subjects. The larger

1 population would have come from the same  
2 perspective.

3           However, I know the incidence of  
4 adenovirus fluctuates, and sometimes it's higher  
5 and sometimes it's lower. And depending on when  
6 you're enrolling at that time, at that site,  
7 whether it's going to be higher or lower is in  
8 question. I think that's why we're doing that.

9           DR. POLAND: But that's a reason to  
10 power the study on the lower estimate. Do you  
11 know, at least qualitatively, where the study was  
12 powered for efficacy?

13           MAJ. MIDBOE: No. And you're more than  
14 welcome to answer that question.

15           COL. GIBSON: Go to a mike.

16           DR. POLAND: So the question is, was the  
17 efficacy part of the clinical study powered on a  
18 low estimate of circulating wild virus?

19           COL. BROWN: Yes. The problem with  
20 these estimates is that the incidence of disease  
21 at every one of these training posts -- Army,  
22 Navy, Air Force, and Marine -- varies within the

1 year, month to month. It varies within the  
2 training schedule of each training company or  
3 battalion, if you will, and it varies for training  
4 sites. So it's hard to make a really hard and  
5 fast estimate as to incidence of disease over an  
6 extended period of time, particularly over a  
7 two-year-long study like we're proposing now. But  
8 we made that estimate on power based on the lowest  
9 assumption of that incidence.

10 DR. POLAND: Other questions? Roger?

11 COL. GIBSON: A couple of quick ones.

12 These are more technical, probably.

13 In your scheme, whether you're  
14 individually randomizing or group randomizing, if  
15 you're individually randomizing, are you concerned  
16 about shedding to individuals in the same platoon?

17 And the other question was, what was  
18 your enrollment rate for your mock enrollment?

19 COL. BROWN: I'll address the first  
20 question first. This concern has been addressed  
21 in a couple of papers in the late '60s, early  
22 '70s, I believe one was done by Stanley, where

1 they looked at the rate of transmission of vaccine  
2 virus from trainees that received the vaccine, and  
3 they essentially found that this transmission was  
4 nil. There was no real transmission of vaccine  
5 virus to other trainees.

6           However, if you looked at the same  
7 scenario in families, a similar study was carried  
8 out in which one member of the married couple  
9 received the vaccine and the other did not. There  
10 was a substantial transmission of vaccine virus,  
11 particularly if a child received the vaccine.  
12 Transmission of the vaccine virus from child to  
13 adult occurred much more readily.

14           It's hypothesized that because of the  
15 more intimate contact among family members, this  
16 facilitates transmission of the vaccine virus,  
17 whereas in a military training facility type  
18 environment we're not expecting that kind of  
19 contact.

20           Now, the second question, the second  
21 question is what was our--

22           DR. POLAND: Enrollment rate.

1 COL. BROWN: --enrollment rate for the  
2 mock trial. We queried the mock volunteers after  
3 they went through the exercise to see whether they  
4 would be willing to take part in the study.

5 Every one of them indicated they would.

6 DR. POLAND: You mean you would have had  
7 a 100 percent enrollment?

8 COL. BROWN: If we based it on that one  
9 mock exercise, two weeks, that we went through at  
10 Fort Jackson, every one of them indicated that  
11 they would volunteer in the study. Now, I'm  
12 expecting a much lower rate. In the Phase 1 trial  
13 our enrollment rate was 42 percent.

14 MAJ. MIDBOE: I might mention, when  
15 Commander Russell did his mock, I think he had  
16 closer to 50 or 60 percent participation. But  
17 again, when you're looking at enrolling on the  
18 weekends, you're only catching those people that  
19 are carried over on the weekend, so you're already  
20 looking at a smaller subset of the population, and  
21 then you're further reducing that by your  
22 percentage of lack of participation.

1 DR. POLAND: As you know, the Board has  
2 had along interest and history with this vaccine.  
3 The Board has had a long history of frustration  
4 with trying to get this program moved along, and  
5 this may be a bit simplistic, but I think  
6 virtually every time line that we have been  
7 presented with has not been met.

8 And so the question that I have for you  
9 is, it might be better to present realistic time  
10 lines to us. I'm a little concerned, even with  
11 this one, that you're going to start a two- year  
12 Phase 3 trial and have an approved and distributed  
13 vaccine three years later. I would be very  
14 surprised at that.

15 And please take this as observations of  
16 the process, not criticisms of the people  
17 involved, but many of these things and these risks  
18 are knowable. There is nothing new about carrying  
19 out a Phase 3 trial and the difficulties, which I  
20 appreciate are enormous, that is newer today than  
21 six years ago when we initiated this program.

22 So my question for you is this: Are you

1       aware of any issues -- biologic, regulatory,  
2       manufacturing, etcetera -- that you think could  
3       reasonably and significantly impact the time line  
4       of this program?

5               MAJ. MIDBOE: Absolutely. Enrollment of  
6       the soldiers. And I think right now, I mean, some  
7       of the things that we learned, and it's an  
8       incremental thing, as you discuss with the FDA  
9       what your plan is and your process is, as you  
10      become more familiar with the sites, you gain  
11      better clarity of the challenges.

12             I think you're defining those changes in  
13      an understanding of the schedule. I think it's  
14      unlikely that, but I don't know that it will take  
15      more than one year to enroll all of the subjects.  
16      We may go out to these sites, and we may have  
17      phenomenal enrollment and participation, and we  
18      may have great incidence that will allow us to  
19      gather evidence. And then at the same time we  
20      may have terrible enrollment. We may continue to  
21      find challenges.

22             I mean, one of the things that some of

1 the sites are looking to do is actually reduce the  
2 number of days that they in-process soldiers, so  
3 if they do that, that further restricts our  
4 ability to enroll them. For me, for the Phase 3  
5 trial, I think the primary issue is how long is it  
6 going to take to complete the trial, how long is  
7 it going to take to enroll those subjects.

8 I'm less concerned about manufacturing.  
9 Manufacturing is definitely a challenge. When  
10 they transferred the technology to the Barr  
11 Virginia facility, I think that the process took  
12 longer than Barr anticipated. We are linked at  
13 the hip with Barr, the sponsor, going forward, and  
14 as a contractor to give us adequate information on  
15 which to make decisions and to give the schedule  
16 and time lines.

17 I think, that said, all of us will  
18 continue to become more aware of some of the  
19 challenges. I mean, as much foresight and  
20 forethought as we would like to have, sometimes we  
21 simply don't have that.

22 DR. POLAND: Let me also ask, on behalf

1 of the Board, that where there are significant  
2 concerns or barriers, that the Board be made aware  
3 of those. The Board has been and can be helpful,  
4 perhaps, in overcoming some of them or at least  
5 influencing some of them. And I think given the  
6 amount of time and interest that the Board has put  
7 into this, I'd like to request that of you and  
8 your superiors, that where there is a significant  
9 barrier or a problem identified, that we be made  
10 aware of that.

11 And also it might be worthwhile on the  
12 time lines to present to us perhaps two cases, the  
13 best case, which is what we typically see, and  
14 perhaps a case that takes into account, "Well, our  
15 enrollment is 50 percent of what we thought it  
16 would be," or experience would suggest that  
17 there's going to be a six-month delay working with  
18 FDA in this part of the regulatory compliance.

19 Dr. Shamoo?

20 DR. SHAMOO: Yes. I'm not going to  
21 comment on the 100 percent volunteerism example he  
22 gave, other than that one of the things -- think

1       it's a DOD-wide issue, and I'm really sympathetic  
2       to the delay. I have more experience with the FDA  
3       than some of you have. You cannot really predict  
4       how much they're going to delay you at all. Even  
5       though it's a federal agency, it's independent,  
6       etcetera.

7                       And I also find now that we can  
8       streamline a great deal of what I heard here.  
9       Seven IRBs. Some of them have 20 or 30 IRBs.  
10      That's no longer really necessary. And also the  
11      discussion with the FDA, the DOD could muster some  
12      expertise with the FDA, one office which is very  
13      familiar with the FDA, the way they operate, and  
14      interaction.

15                      And also an agency like DOD, with their  
16      interaction with the FDA, it's not like a company.  
17      A company can mobilize resources very quickly to  
18      adapt to the FDA requirement. The DOD is, to me,  
19      not as flexible as especially small biotech  
20      companies, what they could do.

21                      So I'm saying is there an office to  
22      streamline these? Because my experience is, I

1 hear bits and pieces, there is so much variation  
2 and it's all the time reinventing the wheel. Like  
3 why in the world do you want to go to 7 IRBs or 30  
4 IRBs? Or why in the world do you interact with  
5 the FDA, and you get all these weird answers which  
6 you have to go back and try to re-adapt them,  
7 because you didn't know what the heck to expect  
8 from them? Real people who deal with the FDA,  
9 they know. Really they can predict better what  
10 the FDA is going to say.

11 DR. POLAND: Did you want to make a  
12 comment?

13 MR. HOWELL: If I could make a quick  
14 comment, first of all, you're absolutely correct  
15 on the IRBs, and I have to tell you right now that  
16 we're in the process -- the Army started something  
17 which the rest of DOD has. We've already looked  
18 at that investigational piece, especially since  
19 this is joint within the services. Our head of  
20 the Office of Research Protection is already  
21 starting now to go look at how can we take that  
22 seven IRBs and get it down to three, basically.

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1 So this has become a stepchild --

2 DR. POLAND: There was -- and Dick  
3 Miller will remember it because he was the Executive  
4 Secretary of the committee that I sat on -- a full Institute  
5 of Medicine (IOM) committee that looked at this issue of the  
6 feasibility to basically shepherd a -- this was on  
7 the biologics countermeasures side -- to do this.  
8 And it's problematic, as you're pointing out, all  
9 the way up and down the process.

10 MR. HOWELL: So my point is, it's  
11 certainly in our sights now, so we're going to  
12 work on it. What we may get to in the end I can't  
13 tell you, but certainly the intent is to try and  
14 streamline this.

15 The second piece I'd like to address is  
16 your talk about the FDA. I think the biggest  
17 problem we've had in the FDA, they themselves  
18 didn't know what the hell they wanted to do with  
19 the compound. They didn't know if it was a tech  
20 transfer until they started to see the data to  
21 determine it wasn't a tech transfer, and how much  
22 did you actually have to change the product itself

1 technically to get there.

2           So I think all of us went into it with  
3 an idea, because we went to the FDA before we even  
4 started and kind of laid out what our game plan  
5 was. And they said, "Well, that sounds like a  
6 reasonable approach to it." But as we started to  
7 discover what Wyeth did not have in the way of  
8 documentation and stock and the infrastructure  
9 really to build upon, then all of a sudden we had  
10 to kind of, I don't want to say make it up on the  
11 fly, but we had to take the experiential data that  
12 Barr had.

13           As we went along and discovered that,  
14 the FDA went, "Well, whoa, now I'm getting more  
15 uncomfortable, now I'm getting more  
16 uncomfortable," until we finally ended up  
17 basically doing a Phase 3 trial that looks the  
18 same way as if this was basically a new product.

19           So the FDA, I don't want to put any  
20 blame really on the FDA's shoulders. They've been  
21 pretty responsive to us.

22           DR. SHAMOO: Please do.

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1 DR. POLAND: All right. We need to move  
2 on, I think, to the Japanese Encephalitis Vaccine (JEV)  
3 aspect of the briefing.

4 MR. HOWELL: Eric, thank you for all the work  
5 you've done on this. Thank you. (Applause)

6 MR. HOWELL: Let me transition, then.  
7 Thank you very much. We're going to bring in  
8 Intercell AG, which is the actual manufacturer of  
9 a new Japanese Encephalitis Vaccine. I want to  
10 make sure we set the stage.

11 The original one that the Army and the  
12 services had been using was made by Viking and  
13 basically sold through Aventis. Aventis came to  
14 us about two years ago and said, "We're going to  
15 change the manufacturing process, and we're going  
16 to take our line off for a while, manufacturing  
17 line off for a while." And they estimated  
18 somewhere around a three-year time period that  
19 they would be off.

20 They also told us, "Oh, and by the way,  
21 if you want U.S. licensure, you're the only ones  
22 really using this thing, you're going to have to

1 pay for it." So all the testing and such, we'd  
2 have to go through that.

3 We called a quick group, looked at all  
4 the people who were doing it, found three  
5 companies, two other companies besides them who  
6 were working on this particular product. It turns  
7 out that Intercell had a construct that was very  
8 similar to the way that Sanofi or Viking was going  
9 forward. They said they could do it without any  
10 of our help, and so we stepped back and we  
11 watched. And what you're going to see today is  
12 the results of their Phase 3 trial, which I think  
13 you'll find are very, very good.

14 The question that I sort of would like  
15 to leave with you all is, when we left the scene  
16 two years ago, we went and bought about four to  
17 five years' worth of inventory to make sure we had  
18 that break period covered. Now it looks like, at  
19 the rate that they're going, that Dr. Tauber will  
20 talk to you about, we'll probably have new product  
21 available within about a year, maybe a little over  
22 a year's time period, depending on how long it

1 takes to look at the regulatory piece.

2           So we're going to have an inventory  
3 that's still going to be on hand, and we'll have  
4 new product available. And we're sort of  
5 quizzical from a clinical standpoint: Is there a  
6 need -- financially I know the answer -- but is  
7 there a need clinically for us to move away from  
8 the old product to this new one? Or do we  
9 continue to use the old one until that inventory  
10 has expired, and move over to the new one  
11 accordingly, which could be a fairly lengthy  
12 period of time in the process. Certainly the  
13 company would like to see us move over, but they  
14 base their sales on not just us but others.

15           Anyway, Dr. Erich Tauber from Intercell  
16 AG.

17           COL. GIBSON: For the Board members, a  
18 copy of the report that we have on JE vaccines is  
19 in Tab 3.

20           DR. TAUBER: Thank you, Bill. Dr.  
21 Poland and Board members, it's a great pleasure  
22 and honor for me and for Intercell to give you an

1 update on our development plan to date. This is  
2 the agenda for my presentation. I'll give you an  
3 update on our product profile and key results from  
4 our Phase 3 clinical trials, an update on  
5 regulatory issues, especially with FDA for the  
6 United States, and an update on our manufacturing  
7 and supply chain.

8 As Intercell was starting a development  
9 program for our second generation Japanese  
10 encephalitis vaccine, our goal was to develop and  
11 gain licensure for a JE vaccine which is at least  
12 as immunogenic as the commonly licensed JE-VAX but  
13 with a better safety and immunogenicity profile.

14 As Bill has mentioned briefly, the  
15 current JE vaccine will no longer be available.

16 Japanese manufacturers had stopped  
17 production of vaccines three years ago due to  
18 their unsafety, and this was a big change for our  
19 development program, with a new goal to accelerate  
20 and expedite the licensure process of our JE  
21 vaccine, especially for world travelers and also  
22 for military troops.

1                   Here is the product profile of our  
2                   second generation vaccine on one slide. It's a  
3                   second generation vaccine. It's based on the  
4                   well-known Aventis strain 14-14-2. This is the  
5                   same strain which has been used in China for a  
6                   long time, and it's used in millions of doses to  
7                   immunize Chinese kids there.

8                   It's produced on Vero cells. It's then  
9                   purified, it's inactivated, and we use alum as an  
10                  adjuvant to increase potency. It's a kind of  
11                  classic approach for vaccines.

12                  Another difference to the current  
13                  vaccines is that we don't use any stabilizers or  
14                  preservatives. It's without Thimerosal, and we  
15                  represent it as a two-dose primary immunization  
16                  regime. We also aim for a single dose vaccination  
17                  schedule for those who come when there is a need  
18                  for it. Also it will come in a liquid, pre-filled  
19                  syringe formulation.

20                  Here is a direct comparison of the  
21                  current vaccine on the left-hand side and our  
22                  vaccine. As I've mentioned, we use an attenuated

1 virus strain. We use Vero cells to produce our  
2 growth, our virus. We don't use any stabilizers,  
3 especially gelatin, which is used in JE vaccine  
4 and also used in many other vaccines. They are  
5 associated with some side reactions like  
6 hypersensitivity. We use alum to increase  
7 potency. It comes in liquid pre-filled syringe,  
8 and two doses, as I have mentioned.

9           Approximately one year ago, I think it  
10 was on the day a year ago, we have started our  
11 Phase 3 program. In total, we have agreed with  
12 FDA and with the European agency to have a Phase 3  
13 program consisting of at least seven clinical  
14 studies.

15           Two of them, the pivotal immunogenicity  
16 and pivotal safety study, they will be the  
17 foundation of our license application, and both  
18 studies have been completed. The other studies,  
19 like long-term immunogenicity, a concomitant  
20 vaccination study, they will be supported studies.  
21 All these studies are either completed or on their  
22 way, and we are expecting to finally start

1 production early next year.

2 This is a slide of the immunogenicity  
3 study, which is I would say the most important  
4 study of our development program. It's an 867-  
5 subject study, done in the United States and in  
6 Europe, and it's a head-to-head comparison with  
7 the end point of immunogenicity, comparing JE-VAX  
8 to our vaccine.

9 It's an observer-blinded, one-to-one,  
10 randomized, multicenter study, and the end points  
11 are seroconversion rate and Geometric Mean Titer (GMT).  
12 Seroconversion rate, for those who are not familiar with  
13 this term, is the percentage of subjects who can be  
14 deemed to be protected. GMT is the geometric mean  
15 titer. This is a measure of how immunogenic is a  
16 vaccine to the subject.

17 We have agreed that the primary endpoint  
18 and objective was non-inferiority, which means  
19 that the seroconversion rate and GMT need to be at  
20 least as good as or better than for JE-VAX.  
21 Safety and also durability and sustained  
22 tolerability are also endpoints.

1                   These are the results of the  
2 seroconversion rates. As you can see in the blue  
3 bar, 96 percent of the subjects immunized with our  
4 vaccine had resultant seroconversion, and 94  
5 percent of the subjects vaccinated with the  
6 three-dose schedule of JE-VAX had seroconverted.

7                   The specific analyzer we employed was a  
8 risk difference estimator using the Mantel-  
9 Haenzel approach, and we have demonstrated that  
10 our vaccine was non-inferior to JE-VAX at the .05  
11 percent significance level, which was one of the  
12 endpoints of our study.

13                   The next endpoint was GMT, geometric  
14 mean titer. Our vaccine resulted in a GMT of 243,  
15 whereas JE-VAX resulted in 102. And likewise with  
16 a seroconversion rate that met the primary  
17 endpoint for immunogenicity, and we also here  
18 demonstrated the non-inferiority of .05 percent  
19 significance level.

20                   To summarize the results of this study,  
21 we haven't seen any critical safety concerns,  
22 safety observations, in this study. There was one

1 serious adverse event which was unlikely to  
2 be--it wasn't a part of it. The local  
3 tolerability profile of our vaccine appeared to be  
4 favorable compared to JE-VAX, especially for  
5 redness, swelling, and hardening around the  
6 injection site. Pain, and all other safety  
7 findings, are quite similar to the JE-VAX.

8 The full results of this study will be  
9 presented at the November meeting of American Society of  
10 Tropical Medicine and Hygiene (ASTMH), but we will share the  
11 full results of our study with experts from WRAIR and from  
12 the U.S. Army Medical Research and Materiel Command.

13 A few weeks ago we completed the  
14 analyzing of our safety study, and here is the  
15 design of our large placebo-controlled safety  
16 study. We have enrolled 2,700 subjects and  
17 randomized them into either our JE vaccine or  
18 placebo. It was a double-blinded study, and the  
19 endpoint was safety and local tolerability of the  
20 vaccination.

21 The study was done in the United States  
22 and also in Germany, England, Romania, Australia,

1 and New Zealand. In this study we also had one  
2 Navy site and one Army site, and the Army site was  
3 done by WRAIR and the Navy site was in Norfolk.

4 Also here the results are quite  
5 promising. We have treated approximately 2,000  
6 subjects with our vaccine, and we didn't see any  
7 critical safety findings at the time of this  
8 slide. Of course we had disease in the last  
9 study, but none of those was deemed to be  
10 critical. The local tolerability and the safety  
11 profile of our JE vaccine was more or less  
12 identical to placebo.

13 JE-VAX is associated with some kind of  
14 hypersensitivity reactions which occur a few days  
15 after the vaccination, and this study did not  
16 reveal any of these adverse events, and from our  
17 manufacturing regime we wouldn't expect those  
18 safety findings. We will present the full results  
19 of this study early next year in Vancouver, but  
20 also here we have shared the full results with  
21 experts from the WRAIR.

22 This is a brief update on how we stand

1 with FDA. We plan to apply to FDA for adult  
2 travelers and military personnel. Initially we  
3 will focus on U.S. licensure and European and  
4 Australian licensure.

5 We have very positive and ongoing  
6 dialogues with FDA. We have had our pre-Biologic License  
7 Application (BLA) meeting only last Tuesday. We will aim  
8 for facility inspection early next year. We are right  
9 now preparing our BLA, and we anticipate our FDA  
10 approval in the second half of next year.

11 The manufacturing of our vaccine is done  
12 in our own manufacturing facility in Livingston,  
13 which is in Scotland. This facility is 100  
14 percent dedicated to produce our JE vaccine. And  
15 we are confident that, as we noted, our  
16 manufacturing capacity is big enough to meet the  
17 market demands in the Western world, both public  
18 and military markets.

19 I think this is now a great opportunity  
20 for me to thank our military collaborators here.  
21 The first Cooperative Research And Development Agreement  
22 (CRADA) for this product has been done already more than 10

1 years ago at WRAIR. The Army is still a patent holder for  
2 this vaccine, or a co-patent holder.

3 WRAIR have entirely done the Phase 1 and  
4 Phase 2 clinical trials. They have started  
5 manufacture based on Phase 2 clinical trial.  
6 WRAIR and the Naval Medical Research Center (NMRC) have been  
7 participating in the Phase 3 studies. They have consulted  
8 us with the entire trials and have recruited subjects for  
9 these studies, and many other things like assay  
10 development, process development. WRAIR had a key  
11 role in this, and also they are always supporting  
12 us when we have discussions with FDA.

13 To summarize, these Phase 3 trials were  
14 designed to meet licensure endpoints as requested  
15 by FDA and the European agency. Pivotal Phase 3  
16 data suggest that our vaccine is at least as  
17 immunogenic as JE-VAX, with a good safety and  
18 convenience profile. We anticipate licensure for  
19 the second half of the year 2007, and we can  
20 guarantee adequate production capacity for the  
21 military and private demand. That is my last  
22 slide. Thank you.

1 (Applause)

2 DR. POLAND: Thank you. We've got a few  
3 questions. Pierce, and then Mark.

4 DR. GARDNER: Yes. I was involved in  
5 the Advisory Committee for Immunization Practices (ACIP)  
6 recommendations roughly 10 years ago, and I have about three  
7 questions for you.

8 The big issue, of course, was this delayed  
9 hypersensitivity. I've never understood the biology of the  
10 delayed anaphylaxis, but it was occurring largely in  
11 travelers -- it wasn't seeming to be reported from the  
12 indigenous populations that were receiving it -- at a  
13 frequency, I forget, but it was something of the  
14 order of 1 per 10,000 or so.

15 And I don't think we can be -- one of  
16 the concerns I have, you've got 2,000 people  
17 immunized at this point, I hope that -- the data  
18 are all wonderful, but I think it's too early to  
19 -- you're using basically the same antigens as you  
20 did before, the same seed virus, so I think we  
21 still have to keep our fingers crossed to make  
22 sure we don't run into a rare reaction.

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1                   But that was the total thing that  
2 dominated the thinking at the time the ACIP made  
3 its recommendations, plus the fact that at least  
4 among the estimated 2.5 or 3 million travelers to  
5 the endemic areas of the world that might be  
6 exposed, there had only been an average of about  
7 one case per year for the previous decade. So  
8 that's question number one.

9                   Secondly, do you have any data regarding  
10 the duration of vaccine protection, and does it  
11 differ from the previous vaccine?

12                   And, third, just for my own curiosity,  
13 most of the vaccine -- the Japanese have used this  
14 vaccine in their own populations for a long time,  
15 and other parts of Southeast Asia -- during this  
16 period of hiatus, are they continuing to make  
17 vaccine for the indigenous populations, or are  
18 they also having to go without?

19                   DR. TAUBER: The first question was, I  
20 believe, about delayed onset of hypersensitivity,  
21 but you say that you didn't understand the biology  
22 of this. I think it's fair to say that nobody

1 really has a clue on it.

2 I would say that there is speculation  
3 that it has to do with the gelatin. And there are  
4 some more arguments, because in Europe there is a  
5 similar, a very similar one which is the big one,  
6 sort of like this, and vaccines against it in  
7 Europe, and some manufacturers which have used  
8 gelatin have had similar findings.

9 DR. GARDNER: Interesting.

10 DR. TAUBER: So we are quite confident  
11 that we won't see this, and up until now we have  
12 vaccinated approximately 4,000 subjects we've  
13 already seen, and we didn't see it so far, and we  
14 hope that we won't see it ever.

15 DR. GARDNER: Duration?

16 DR. TAUBER: Your next question was the  
17 duration, and we have the license application with  
18 6-month durability data, and the 12-month  
19 durability data. So we haven't heard, we haven't  
20 seen this data yet, but what we have seen in Phase  
21 2 is that the duration of our immunogenicity was  
22 at least as good as for JE-VAX. So we have seen

1 100 percent seroconversion rate for those who  
2 participated in the study. Your vaccine is very  
3 well compared with the current vaccine.

4 And the third question about the  
5 Japanese manufacturers, it's also quite typical  
6 because Japanese manufacturers quite often told in  
7 meetings -- these viruses are always a topic --  
8 that they never understand why the Western world  
9 is so -- why the JE vaccines have such a bad  
10 reputation in the Western world. But in the last  
11 year they have stopped their strong recommendation  
12 to vaccinate Japanese children, and the reason for  
13 that was that there are associations of  
14 encephalitis with the vaccination.

15 DR. GARDNER: So they continue to supply  
16 it, they continue to manufacture it and use it in  
17 Japan?

18 DR. TAUBER: They have stopped  
19 manufacturing, and there is still vaccine  
20 available, but it's not part of their national  
21 immunization program. Only adults who live in  
22 high endemic areas still get the vaccine, and the

1 manufacturers, they tried to say you should use  
2 this, but it will take a few years before these  
3 vaccines are available.

4 DR. GARDNER: Thank you.

5 DR. POLAND: Mark?

6 DR. MILLER: Mark Miller. Just two  
7 quick questions. Very impressive immunogenicity  
8 data, but you did show one serious adverse event (SAE)  
9 which is of concern. Just could you comment a  
10 little bit about what was the age of that patient,  
11 why you think it was unlikely related?

12 Was there no timing associated with the  
13 vaccine?

14 And a second question: Is this  
15 preparation and construct from the original  
16 Chinese vaccine that was relying on the hamster  
17 cell kidney lines?

18 DR. TAUBER: The SAE you referred to was  
19 observed in a 51 years old man in the United  
20 States. He was three weeks after immunization, and  
21 the subject had then bypass surgery thereafter.  
22 So he had received the vaccine, but he had had

1 atherosclerosis for many years, so the  
2 investigator should not have enrolled him because  
3 he was not healthy.

4 And the second question?

5 DR. MILLER: Whether this construct was  
6 the one that came from the original hamster cell  
7 kidney line.

8 DR. TAUBER: It originally came from  
9 hamster cells, and WRAIR did then try some work to  
10 develop, to transfer the manufacturing into glial  
11 cells.

12 DR. POLAND: A couple of quick  
13 questions. Remind us what the incidence of the  
14 delayed hypersensitivity reaction was with the  
15 Viking vaccine.

16 DR. TAUBER: It was in the range of 1 in  
17 6,000 subjects.

18 DR. POLAND: One in 600,000?

19 DR. TAUBER: 6,000.

20 DR. POLAND: In 6,000. Okay, so, I  
21 mean, it's still an ongoing concern that obviously  
22 you're going to be monitoring for, but you haven't

1 even studied 6,000 folks yet.

2 The other thing is, can you comment on  
3 what the production capacity will be? How many  
4 doses per year, for example, do you anticipate  
5 being able to make?

6 DR. TAUBER: We are still in the process  
7 of completing our supply chain and plant  
8 production scheme. The only thing I can tell you  
9 right now is that we can exceed the private and  
10 military demands.

11 DR. POLAND: Okay. Thank you. Any  
12 other questions? If not, we'll keep moving along.  
13 Thank you. The next speaker is Colonel Jim  
14 Neville, commander of the Air Force's Institute  
15 for Operational Health (AFIOH), who will provide a  
16 briefing on an Air Force research effort regarding  
17 QuantiFERON Gold-In Tube. His slides are behind  
18 Tab 4.

19 COL. NEVILLE: Thank you very much.  
20 It's a pleasure to be here at the Board, and  
21 before I start my presentation to the Board  
22 members, this needs to be -- if you want to pencil

1 it in, the Principal Investigator is supposed to be  
2 there, Dr. Goodwin, who works for the Air Force Research  
3 Laboratory (AFRL) in AFIOH, and Dr. Mazurek from CDC.

5 I'll move forward to look at slide five here,  
6 unless you want me to go through the history -- you want me  
7 to pull the microphone up? -- I won't try and go through the  
8 history of TB screening, the tuberculin skin test and the  
9 problems with that and so forth. This is what I  
10 plan to describe, the effort to evaluate the Gold  
11 In-Tube test as well as automating the results  
12 themselves and exporting them to military records.

13 This study that I'll describe was  
14 actually funded and sponsored by AETC, Air  
15 Education and Training command, the Air Force's  
16 training command, with this study that I'll  
17 describe being part of their Air Force basic  
18 military training.

19 So the characteristics of the  
20 QuantiFERON Gold In-Tube are that this is the  
21 third generation of the QuantiFERON test. The  
22 first one used exposed the blood cells, the blood,

1 to Atypical Tuberculosis (ATB) antigens. The second  
2 generation exposed that to two proteins specific to  
3 antigenic bacterial organisms. And this generation advanced  
4 those antigens on the inside of the tube itself.

5           So this is a blood test for screening,  
6 for testing for tuberculosis -- not the skin test.  
7 There is a machine here, and the intent is to  
8 automate that process in the lab, which makes it  
9 less likely to be subject to errors. The test  
10 should be, the results should be available within  
11 24 hours, or could be available in 24 hours. It  
12 can be stored, the blood specimen itself can be  
13 stored for up to two months without loss of test  
14 accuracy, and its specificity is improved and  
15 sensitivity maintained compared to the skin test.

16           This is an outline of the time line for  
17 this study, this trial, beginning in October  
18 hopefully within a short period time here,  
19 starting with staffing and instrument calibration.  
20 And I have a slide here about different aspects of  
21 the actual -- essentially of the trainings, and we  
22 have set a training goal of next year, so within a

1 year we're ready for this.

2 As far as the cost goes, the majority of  
3 the funds were supplied by the Air Education and  
4 Training Command, although the manufacturer of the  
5 machine, the analytical machine, is donating that  
6 instrument, and the manufacturer is also donating  
7 the reagents. The laboratory facility, that will  
8 use existing space.

9 So this begins a series of slides --

10 MS. EMBREY: Can you go back a slide?

11 Follow-on sustainment will be a service (DHP) Operations and  
12 Management (O&M) bill?

13 COLONEL NEVILLE: Right.

14 MS. EMBREY: Do you know what that would  
15 be?

16 COLONEL NEVILLE: I don't know what that  
17 would be. That is a separate issue for  
18 discussion, which will be an analysis all on its  
19 own. Theoretically there are going to be some  
20 savings to doing this, for instance training all  
21 technicians how to apply the test, how to read the  
22 test, theoretically there would be fewer people

1 training in this case. So altogether it may be a  
2 cost savings.

3 MS. EMBREY: Can you tell what that  
4 means?

5 COLONEL NEVILLE: Right, right. So it  
6 would be perhaps a cost savings. Altogether it  
7 means the best test will offer cost savings.

8 Okay, so at the beginning, the  
9 validation of the actual machinery and so forth,  
10 this is where the CDC is involved. The CDC  
11 prepares known and unknown specimens to analyzed  
12 at AFIOH and CDC for comparison to existing  
13 protocols.

14 So overall, the blood specimen is  
15 obtained from a trainee and the blood specimen is  
16 incubated overnight in this reagent-coated tube.  
17 Then that blood specimen is centrifuged to  
18 separate the plasma product. The plasma then is  
19 transported to our lab at Brooks for that assay.  
20 Whatever is left over is stored for future  
21 studies. So that's generally what happens to each  
22 blood specimen.

1                   So in the study itself, the Basic Military  
2                   Trainees (BMTs) will be enrolled, informed consent. So if  
3                   they decide not to enroll in the study, that's fine, they'll  
4                   still get the skin test like everybody will. That's the  
5                   standard practice now, and the results will be  
6                   obtained from that and treatment will be guided by  
7                   the results of that test.

8                   Those who decide to enroll in the study,  
9                   they'll get an additional 3 cc of blood collected  
10                  at a blood draw that's already done for other  
11                  purposes anyway, and then that little blood  
12                  specimen will be processed like I described. All  
13                  the treatment will be, treatment decisions will  
14                  depend on that tuberculin skin test.

15                  Yes, ma'am?

16                  MS. EMBREY: As part of the informed  
17                  consent on the blood, I mean, since we're drawing  
18                  it for other purposes, are you adding the fact  
19                  that this might be, if they agree, be included in  
20                  this trial? Because one of our issues has been,  
21                  you know, making sure people understand what we're  
22                  doing with their blood or we're not doing with

1 their blood.

2 COL. NEVILLE: Right. The informed  
3 consent is specific to inclusion in this study,  
4 and the other blood, screening for HIV and so  
5 forth, that's the standard thing now. That  
6 doesn't require informed consent.

7 MS. EMBREY: I understand, but if you're  
8 including it, because we have an asterisk saying  
9 it's being drawn for other purposes, is there an  
10 additional notification as part of your consent  
11 for this study?

12 COL. NEVILLE: Yes, yes.

13 COL. GIBSON: A follow-on to that. You  
14 just mentioned that you're going to be storing  
15 that blood for future use. Is that part of the  
16 consent document as well?

17 COL. NEVILLE: I'm sure it is, but I can  
18 find out. I'm sure it is.

19 COL. GIBSON: Okay. Thank you.

20 COL. NEVILLE: So later on in the basic  
21 training time line they are offered an opportunity  
22 to donate blood. So those who do choose to -- who

1 don't want to donate blood, their part of the  
2 study is done. Those who do donate blood  
3 voluntarily, and some of them do, are offered  
4 enrollment in the study.

5 Those who are in the study, have been  
6 enrolled in the study voluntarily and donate  
7 blood, they will also have blood drawn again at  
8 that time when they donate blood, and another Tuberculin  
9 Skin Test (TST) placed to compare the different -- the  
10 test/retest validation. And within the laboratory at AFIOH  
11 10 percent of them will be tested again, just to  
12 validate the test.

13 So this summarizes. Our hope is to get  
14 2,400 trainees to volunteer at the beginning, and  
15 we estimate about 1,000 at the end of their  
16 training time will be in the test.

17 So this is a short list of other issues  
18 to be considered, as far as study impact, the time  
19 of day that the specimen is collected, variations  
20 in the duration time of incubation, the time  
21 between blood collection and centrifugation and so  
22 forth, holding time in the lab until the Enzyme Linked

1 Immunosorbent Assay (ELISA) test is performed.

2 And this is the list of participants in  
3 the study, who are collaborating there. AFRL, the  
4 Air Force Research Laboratory, the CDC of course,  
5 the AFIOH laboratory, and Air Education & Training Command  
6 (AETC) is the last one.

7 And I believe that's all I have. Are there any  
8 questions?

9 DR. POLAND: Actually one question we were just  
10 discussing is the time line on this. When are you thinking  
11 that the validation studies and all would be done and you  
12 would have results?

13 COL. NEVILLE: We were planning to start this  
14 coming October, next month. There has been a little bit of  
15 delay, I understand, a little delay with the CDC, but that  
16 has been resolved, I understand, so October we should start.

17 DR. POLAND: And the process is how  
18 long?

19 COL. NEVILLE: About 10 months total,  
20 assuming they capture enough volunteers from the  
21 BMT population.

22 DR. POLAND: And so for this sort of

1 enhanced assay, what actually is the sensitivity  
2 and specificity, at least in the early part of the  
3 studies?

4 COL. NEVILLE: The sensitivity is--

5 DR. POLAND: You mentioned that it's  
6 better by some percent compared to the old one,  
7 but--

8 COL. NEVILLE: Compared to the TST.

9 DR. POLAND: Okay, so we don't know  
10 until the study is done, or--

11 COLONEL NEVILLE: Well, yes. There's  
12 not a real good gold standard, so for this study  
13 and others that have been reported, the true "no  
14 disease" really depends on their history and their  
15 risk factors and so forth. So using that as the  
16 true negative --

17 COL. GIBSON: I guess I've turned it  
18 slightly. The sensitivity and specificity test  
19 for this QuantiFERON Gold methodology has been  
20 done several times, done by the company, done by  
21 others. The issue in my mind is not testing that.  
22 The issue is how you value your population, your

1 prevalence of disease. Therein lies the reason  
2 for doing this sort of study.

3 And the most important reason in my view  
4 is the feasibility study, understanding how it's  
5 going to work in this population, given these  
6 laboratory resources and all of the other things  
7 that are germane to this.

8 The Board has recommended in the past  
9 that DOD consider moving to QuantiFERON. The  
10 hold-up has been lab. This test, the QuantiFERON  
11 Gold, is tough to do. It takes a lot of  
12 laboratory personnel to put the little drops in  
13 the tubes at specific hours, etcetera.

14 This thing is an enhanced product, so it  
15 would be very --

16 COL. NEVILLE: We have automated a lot  
17 of those logistical problems. And the fact that  
18 we can store that specimen for two months, up to  
19 two months, that makes the logistics of doing this  
20 thing much easier, and particularly sending it to  
21 a central lab which has that automated process.

22 DR. POLAND: Well, it does make it

1 simpler and it doesn't. I mean, at the recruit  
2 training level you can have your answer in two  
3 days or two months, so you wouldn't actually want  
4 to take advantage of the two-month --

5 COL. NEVILLE: Right, right. It's an  
6 outlying crisis, perhaps, if there's an issue or  
7 an outbreak, or overseas somewhere.

8 DR. POLAND: Yes. I mean, we could  
9 right now calculate the positive and negative  
10 predictive value, since we've got -- if we take  
11 TST as the gold standard, you know the incidence,  
12 so if we knew the sensitivity and specificity we  
13 could understand that.

14 Pierce?

15 DR. GARDNER: Just a clarification. I  
16 sat through a discussion a couple of weeks ago in  
17 which the concern was the timing logistics. And I  
18 guess in the previous iteration you had only a  
19 matter of hours to process the specimen, so  
20 actually now you can keep it for weeks and months.  
21 Is that what I understand?

22 COL. NEVILLE: That's right.

1 DR. GARDNER: So that changes the whole  
2 dynamics, at least what the lab has to do.

3 COL. NEVILLE: Right. It's incubated  
4 overnight, for 12 hours, 12 to 18 hours, and then  
5 once that lab has refrigerated it, you can keep it  
6 for at least two months or a little longer.

7 DR. GARNER: That will change the --  
8 there are only a couple of labs around the country  
9 who have been willing to try to set this up as a  
10 service, clinical, just because of those  
11 logistics. And this will change the whole  
12 dynamics, I think, nationwide, if that holds up.

13 DR. MILLER: In your study population,  
14 are you stratifying on the basis of foreign or  
15 domestic/foreign BCG vaccination?

16 COL. NEVILLE: No. The manufacturer, in  
17 their studies, indicate that prior history of BCG  
18 vaccination doesn't -- in other words, that alone  
19 won't trigger a positive test.

20 DR. LUEPKER: Thank you. Russell  
21 Luepker. You know, you say you're collecting  
22 2,400 cases, and maybe I didn't hear it. What is

1 the incidence of a positive test in this  
2 population?

3 COL. NEVILLE: It fluctuates some. I'm  
4 not sure if it's reproduced there. Around 1.8  
5 percent I believe is the mean --

6 DR. LUEPKER: One to 2 percent. Thank  
7 you.

8 COL. NEVILLE: I do have one in here  
9 about the specificity and sensitivity. Depending  
10 on the population, the sensitivity was 89 percent  
11 and the specificity was 96 to 98 percent.

12 COL. GIBSON: Specificity should be --  
13 it shouldn't vary much in population, but I think  
14 there are values and risks based on prevalence and  
15 specificity.

16 DR. PARKINSON: Thanks, Jim. That was  
17 very good. Clearly the value of this to the  
18 military is training time. That is the sole  
19 currency that commanders at basic training care  
20 about.

21 And to Ms. Embrey's question, I  
22 hopefully won't have to wait for subsequent

1 analysis of what is a high level, comprehensive  
2 economic analysis of "as is" versus "to be."  
3 Because I think if you had to be a betting person,  
4 you know, with numbers like that on  
5 sensitivity/specificity and the current hassle  
6 factors of a test that is notoriously -- it is the  
7 50-year-old story about TSTs, and this may be a  
8 very good solution.

9           So I hope some bright people down at San  
10 Antonio, and places perhaps like the  
11 Pharmacoeconomic Center right across town, could  
12 put together a very high level economic analysis  
13 that would be ready to go at such time that you  
14 get the clinical outcomes of the study, because I  
15 think it could be very -- so often I think the  
16 medics bring them things that's just a burden.  
17 This might actually be something that could be a  
18 time and hassle saver that would be a real asset,  
19 potentially, depending on what you find.

20           COL. NEVILLE: And not just the BMTs but  
21 anybody.

22           DR. PARKINSON: Oh, yes.

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1 COL. GIBSON: Just a tag on to Mike's  
2 comments. You and I actually experienced this.

3 We had multiple pseudo outbreaks, pseudo  
4 epidemics of tuberculosis that we ended up going  
5 out and evaluating and dealing with the public  
6 affairs issues associated with that, that  
7 QuantiFERON Gold would be helpful in simply  
8 misreading of TSTs.

9 I have a question: Is QuantiFERON Gold  
10 FDA-approved?

11 COL. NEVILLE: Gold is. Gold In-Tube is  
12 not yet, but apparently Australia does it. It's  
13 not approved yet here in the U.S.

14 COL. GIBSON: What was the time line  
15 that the company gave last time for approval in  
16 the United States.

17 COL. NEVILLE: I don't know.

18 COL. GIBSON: Thank you.

19 DR. POLAND: Okay. Thank you very much.

20 (Applause)

21 DR. POLAND: Lieutenant Colonel Wayne  
22 Hachey from the Office of the Deputy Assistant

1 Secretary of Defense for Force Health Protection  
2 and Readiness was to give us an update on pandemic  
3 influenza. Unfortunately, his grandmother died,  
4 and he is away today, although may join us  
5 tomorrow.

6 So what I will do is briefly, as an FYI,  
7 go over the recommendations from the Select  
8 Subcommittee on Pandemic Preparedness. This is  
9 typical of and actually codified in terms of how  
10 the Board works. So the subcommittees, when they  
11 come up with recommendations, are to bring those  
12 back for the knowledge of the rest of the Board.

13 So to tell you briefly what has been  
14 involved -- and I would be remiss if I didn't  
15 thank the other subcommittee members who have been  
16 involved: Greg Gray, who is now retired off the  
17 Board, Ed Kaplan, Mike Oxman, Joe Silva, Pierce  
18 Gardner, Frank Ennis, Walter Dowdle, and Roger  
19 have put an enormous number of hours and energy  
20 into this.

21 We had a face-to-face meeting at the  
22 Pentagon last January, I think it was, with the

1 military Surgeons General. We have had, for  
2 months running, a weekly about one hour  
3 teleconference. We have been at briefings and got  
4 a full series of briefings from personnel from the  
5 National Institutes of Health (NIH), CDC, National Vaccine  
6 Program Office (NVPO), FDA, DOD, and others. In June, I  
7 think it was, we had a full day meeting with Secretary  
8 Winkenwerder, Tony Fauci, representatives from FDA and DOD  
9 and numerous other organizations.

10 All of this has culminated in five  
11 series of publications or documents that are  
12 behind Tab 5, and we have come up with  
13 recommendations for pandemic preparedness, a  
14 document on recommendations for the use pandemic  
15 influenza vaccine, recommendations regarding the  
16 use of masks during an influenza pandemic, the  
17 role of children in the epidemiology of influenza,  
18 and then representing sort of the idea of  
19 developing a playbook of comprehensive responses,  
20 we developed 10 pandemic influenza scenarios.

21 These were sent to Dr. Winkenwerder in  
22 mid-July. I'll just take you briefly through them

1 and give you the sense of sort of what they mean  
2 in terms of general recommendations.

3 The first was that DOD be a full and  
4 active partner with NIH, CDC, and the FDA in the  
5 national effort to respond to the pandemic or  
6 avian influenza threat. We suggested developing  
7 and funding and sustaining a Pandemic Influenza/Avian  
8 Influenza (PI/AI) research and development focus, so  
9 that DOD would be seen as a credible partner at the  
10 table with these interagency meetings, and also noted  
11 that historically that had been the case, and in fact  
12 I would say DOD actually led the national efforts in  
13 the past.

14 We also talked about developing a PI/AI  
15 clinical case definition, so that all the services  
16 would be on the same page in terms of reporting,  
17 and that that definition be consistent with that  
18 devised by WHO and CDC.

19 We made a point to talk about ensuring  
20 uniformity of key points in the PI planning  
21 process across the services, for example, by what  
22 mechanisms would diagnostic specimens be

1 collected, transported, evaluated, and results  
2 reported? Clarifying and indeed strengthening the  
3 role of existing DOD diagnostic laboratories of  
4 excellence. Clarifying the who, how, where, and  
5 when for priority with vaccines and antivirals.  
6 The playbook idea for comprehensive responses to  
7 an AI or PI threat.

8 We also suggested developing a -- we  
9 called it a comprehensive and informed procurement  
10 business model for decisions regarding acquisition  
11 of pandemic vaccines and antivirals, and in  
12 specific pointed out the value of a rolling  
13 inventory model that would allow limited purchase  
14 of the current vaccine. And there is so much flux  
15 in the vaccine development field, and of course no  
16 one knows what the eventual strain will be, that  
17 you wouldn't want to buy all you need for the next  
18 five years type thing.

19 Going on, then, let's see. What else  
20 was different here? In terms of antivirals, we  
21 again had basically the same sort of  
22 recommendations regarding antivirals. In

1 particular we were a little more specific with  
2 some studies that might be of interest.

3 One is that there is no other viral or  
4 other disease where you see the rapid development  
5 of quasi-species or of antibiotic or antiviral  
6 pressure, where we use a single drug.

7 For example, let's use TB as a model,  
8 since we just talked about it. We would never  
9 treat TB with a single drug.

10 And given the resistance potential for  
11 influenza, it sort of doesn't make sense in some  
12 ways that we use a single drug. In fact, that may  
13 provide the pressure for it to evolve toward  
14 resistance. So we talked about so-called two hit  
15 studies and studies regarding higher doses for  
16 longer periods of time.

17 We've also talked a lot about planning  
18 for and stockpiling more than one neuraminidase  
19 inhibitor. We had some surveillance  
20 recommendations in regards of capabilities,  
21 particularly for some areas where there might be  
22 some gaps. We heard Ann talk about some of those,

1 Africa in particular, the Middle East, and to a  
2 lesser extent, South America.

3 We talked about DOD playing a greater  
4 role in collecting H5 and other isolate data. We  
5 then went on some outbreak response  
6 recommendations, including development of  
7 stockpiles, surge capacity, new models of PI  
8 response.

9 I have not yet been successful, but I  
10 have at least placed calls to two of last year's  
11 Nobel prize winners in economics who have  
12 successfully -- in fact, in the past have  
13 partnered with DOD, I believe, in using game and  
14 chaos theory to make -- to develop scenarios and  
15 make optimal recommendations where you have  
16 multiple intermingled variables that are  
17 continuously changing and unpredictable, so it  
18 seems that there might be actually something to  
19 gain out of that.

20 A response plan for pediatric  
21 beneficiaries and the need for that to be  
22 developed. The need to pre-position antibiotics,

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1       beside rapid diagnostic tests, masks, etcetera.  
2       Development and approval of local installation  
3       plans for how they might carry out isolation and  
4       quarantine.

5               So that's sort of a high level overview  
6       of the recommendations that we had. We also had  
7       recommendations regarding the use of pandemic  
8       influenza vaccine, and key among those  
9       recommendations was that only FDA-approved  
10      vaccines be considered for administration to DOD  
11      personnel in the absence of an immediate threat,  
12      which would be evidence of sustained human-to-  
13      human transmission. And then a series of  
14      recommendations regarding the use of pandemic  
15      vaccines.

16             I think I'll stop there and ask if there  
17      are questions from the Board. Ms. Embrey, did you  
18      want to make comments?

19             MS. EMBREY: Do you know whether or not  
20      Wayne is going to give his presentation tomorrow?  
21      Because if he isn't, you know, he works for me,  
22      and I can certainly fill in the gaps if you need

1 me to.

2 COL. GIBSON: Dr. Hachey plans on being  
3 here tomorrow. We'll just have to wait and see.  
4 This came up suddenly. I got an e-mail from him  
5 on Sunday night saying that this happened. So  
6 we'll hope he will be here. If not --

7 MS. EMBREY: If not, I will pitch-hit  
8 for him, because unfortunately I am intimately  
9 familiar with the department. And on behalf of  
10 the department, I seriously appreciate the hours  
11 that you have put into assisting us and advising  
12 us.

13 You must know that your guidance and  
14 recommendation has significantly influenced how we  
15 have shaped our planning and policy guidance to  
16 the department in this arena. For fiscal reasons,  
17 we may not be able to do everything, but I think  
18 the spirit and intent of your recommendations have  
19 been embraced and are in the process if not  
20 already have been implemented. So I'd like to  
21 thank you officially, on behalf of the department,  
22 for your continuing assistance in this particular

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1 endeavor.

2 DR. POLAND: We have felt that those  
3 recommendations really were appreciated, and to  
4 have all of the very senior leadership in a room  
5 for eight hours to go through this was probably  
6 unprecedented.

7 Comments or questions from the Board?  
8 Please.

9 DR. McNEILL: Mills McNeill. I'm sure I  
10 speak for the entire Board when we thank all of  
11 the committee who have worked on this, and I think  
12 that everything that has been done will serve as a  
13 good foundation for whatever virus may become the  
14 agent of interest.

15 However, having said that, it does  
16 appear that the highly pathogenic H5N1 avian  
17 strain is not behaving in the manner that had been  
18 predicted, based on the failure of this virus to  
19 be carried along the migratory bird routes. It  
20 does not seem to have demonstrated a propensity at  
21 this point in time to become an effective human  
22 virus.

1                   And I'm wondering if in this national  
2                   environment, where it seems a lot of other  
3                   government planning is driven by hysteria, if we  
4                   may not need to take one step back and develop  
5                   some good planning for how do we develop plans  
6                   based on good science, which I think that this  
7                   forum could do now, but then be able to continue  
8                   the momentum that I think we all agree is  
9                   necessary when the public attention or the  
10                  attention of the scientific community may become  
11                  diverted somewhere else. And I think this  
12                  may be where the interest and emphasis could  
13                  lie right now. This is more of a comment than a  
14                  question, but I would appreciate your thoughts.

15                  DR. POLAND: A couple of thoughts. You  
16                  make some good points there. One is that the  
17                  final chapters of this virus haven't been written  
18                  yet. It's an unusual virus, emerging in '97, and  
19                  then we see nothing for six years until 2003, when  
20                  everybody sort of thought this is off the plate  
21                  and we don't have to worry about it anymore.

22                  I think what it does do, as you're

1 suggesting, though, is that it informs pandemic  
2 planning which needed to take place and is going  
3 to occur, sometime, somewhere, with some strain.

4 And I think there is a certain economy  
5 that allows this to integrate with our biodefense  
6 efforts for whatever pathogen or virus would be  
7 "de jour," of the day.

8 MS. EMBREY: I could comment on that, as  
9 well. In fact, yesterday the Department of Health  
10 and Human Services held a Conference on Bioshield,  
11 and brought together all of the manufacturers,  
12 private industry, as well as the federal  
13 government, to talk about biological defense  
14 strategies and how we would address the  
15 manufacturing communities to engage on  
16 countermeasures across the whole biological threat  
17 spectrum, not just pandemic influenza but others.

18 And one of the, I think, interesting  
19 outcomes, there was -- Secretary Levitt was there.  
20 We had the White House, the Homeland Security  
21 Council, represented by Dr. Benkaya, who advises  
22 the President on bio threats. And his comment to

1 the crowd was essentially what we are learning as  
2 part of the outcome of doing this national  
3 preparedness for infectious disease is that we  
4 need to take our lessons learned about this  
5 layered community approach, and to take a very  
6 strong look at how our current public health  
7 infrastructure needs to adapt and change for this  
8 and future infectious disease threats.

9           And so I think there is an obvious  
10 lesson learned. Even if this pandemic doesn't  
11 occur, there will be some other, and we need to  
12 look at this as an all-hazard approach and to take  
13 some of these important initiatives for this  
14 effort and apply it to our capacity and  
15 infrastructure nationwide.

16           DR. POLAND: Wayne? Then we'll go right  
17 down the line.

18           DR. LEDNAR: Wayne Lednar, Kodak. I  
19 just share our experience inside of a corporation,  
20 global, multinational thinking about this. What  
21 we found early on in our discussions was that  
22 there was a perception by the line, if you like,

1 "This is a medical issue.

2 Fix it." Obviously this is much more  
3 than a health issue.

4 And my suggestion would be in the  
5 scenarios to make it clear that there are certain  
6 aspects of the military that have responsibility  
7 to answer questions based on this context. Some  
8 of them will be the mission- critical impacts on  
9 the line of the scenario, and what's the  
10 continuity of operations issues to anticipate, to  
11 work through. As the pandemic occurs and it  
12 produces morbidity and mortality in the fighting  
13 force, then how do you rapidly regain your  
14 operational capacity? And how do you flex your  
15 military units to shore up weak points in a unit  
16 that's just getting really hit?

17 Operational issue. The other circle  
18 that we found really important to sign up and get  
19 committed is a whole collection of what we call  
20 work force support functions. Some of it is  
21 medical, and some of the issues about antivirals  
22 and respirators and gowns and quarantine and

1 restriction of movement.

2 Some of it is human resource policies.

3 In countries where there are approaches to support  
4 child care, the fact that child care centers and  
5 schools will be closed in advance of the pandemic,  
6 how are we going to keep the business operating  
7 when people cannot appear for work because of  
8 family responsibilities?

9 The whole information systems and  
10 information technology support, vastly overplayed  
11 how remote telecommuting is going to be an  
12 effective filling in the gaps. It will not be  
13 effective. That's the judgment of our Information System  
14 (IS) and Information Technology (IT) folks.

15 So all of these kind of dimensions,  
16 purchasing, health safety and environment safety  
17 risk profiles, all need to be sort of brought  
18 together along with the mission critical, and I  
19 think unless it's clear in the scenarios that this  
20 is a context, now let's talk about each of the,  
21 really the questions for impact need to be, it  
22 could easily get missed that, you know, "The Assistant

1 Secretary of Defense (ASD), Health Affairs will take care of  
2 this for the department."

3 DR. POLAND: Let me ask General Col to  
4 comment on that specific point.

5 MGEN. COL: I think that that very much  
6 was the opinion early on, this is a  
7 medical issue, but let us fix it. I think that we  
8 have migrated, and Health Affairs, the surgeon or  
9 the medical community is not the lead. It is the  
10 operations community that's the lead, and so they  
11 are the planners. Sure, we're involved in every  
12 step of the plan, but they are the ones who have  
13 the lead. And in the medical community we pushed  
14 that so it didn't become an isolated medical  
15 issue. And so I think that we have addressed  
16 that.

17 One of the things that I have noticed  
18 some progress as I have been involved in a number  
19 of these discussions is, originally everyone  
20 predicted the pandemic was going to affect so much  
21 of the population and affect all of the  
22 infrastructure that you mentioned, except for

1 their own.

2 Yes, and so I think that that has also  
3 progressed, and so now people say, "Well, if  
4 there's a 30 percent attack rate, my people are  
5 going to have a 30 percent attack rate, too, so  
6 what are we going to do to get around that?" Not  
7 all of those plans are done, but at least it is  
8 now being considered.

9 DR. LEDNAR: But what is slowly also  
10 beginning to emerge out of the ground fog on this  
11 issue is interest in those who are looking at  
12 financial viability of organizations, and the  
13 extent to which they are not preparing is being  
14 judged by the investment community as a  
15 vulnerability. And what's quite possible in the  
16 future is that stock price will be affected by  
17 ineffective pandemic planning.

18 DR. POLAND: I might point that what is  
19 interesting, Harvard Business Review devoted an  
20 entire section to business planning for pandemic  
21 influenza.

22 Colonel Gibson also wants to make some

1 comments.

2 COL. GIBSON: Just one comment on the  
3 scenario. As we started developing these  
4 scenarios, as the group was working on them, they  
5 kept trying to write the solutions, and the whole  
6 idea was to lay the scenarios out, give them to  
7 DOD, let DOD work on a solution so that it could  
8 be multifactorial. Dr. Oxman, who is not here,  
9 kept saying, you know, here is a scenario and here  
10 is a solution for DOD. That's not what we were  
11 intending in the long run. Let DOD work this  
12 through.

13 DR. POLAND: Which was atypical because,  
14 as you know, Mike is a very shy, retiring --

15 Pierce, did you have a comment?

16 DR. GARDNER: I just wanted to make a  
17 comment about AFEB in general. We wonder  
18 sometimes what happens after we make  
19 recommendations. And I think the July 15th  
20 meeting was a very important meeting, and one of  
21 the recommendations that was followed through on  
22 and enacted was really opening up the cooperation

1 between the labs to submit and make accessible the  
2 genetic analysis of the isolates in a way that's  
3 fostering advancement in the field. So I think we  
4 get a small pat on the back for adding an oar to  
5 that movement at a time that seemed to be  
6 important.

7 DR. SHAMOO: Dr. Lednar reminded me that  
8 in order to be comprehensive -- and this is just a  
9 side issue, and then I'm going to talk about my  
10 primary concern -- that the disability community  
11 in the country will react differently to a  
12 pandemic, because their communication  
13 ability, their physical mobility, their mental  
14 status, all affect them very differently.

15 And it's a very large, if you consider  
16 all the disabilities, and the pandemic is not only  
17 going to be concentrated on one part, so you're  
18 talking about around 20 percent of the population  
19 is going to be disabled. You can't just tell  
20 them, "Okay, now leave this place." You need  
21 transportation, communication, etcetera. Since we  
22 are very comprehensive, I wonder if that should be

1 included in the thinking process.

2 And you triggered my mind because my son  
3 actually had an MBA project on what do you do, in  
4 a case of an emergency, for the disabled community  
5 in a State, for example? That was his project,  
6 and that's what reminded me of it.

7 But in case of a pandemic and the use of  
8 vaccines, this is really going to be -- and I'm  
9 not opposing it -- I'm just saying this is going  
10 to be really an uncontrolled or semi- controlled  
11 clinical trial of the whole population. Are we  
12 thinking of collecting information and clinical  
13 data at every stage of the way? Because that  
14 would be such an important piece of information  
15 for subsequent pandemics.

16 DR. POLAND: You mean like safety and  
17 efficacy data?

18 DR. SHAMOO: Everything. Even blood  
19 tests, everything, yes. I mean, you're talking  
20 about hundreds of thousands, now, of subjects,  
21 basically. We're giving them vaccine, and we are  
22 not going through anywhere near what a controlled

1 clinical trial is.

2 This is a clinical trial. You're giving  
3 them vaccine which has not been tested at such a  
4 large scale. It has never been tested in true  
5 clinical trial, or approved, maybe, even.

6 DR. POLAND: Well, and that was one of  
7 the first recommendations, was that the vaccine  
8 used would be an FDA-approved vaccine.

9 DR. SHAMOO: Yes, I realize that, but in  
10 a pandemic were you have 50,000 deaths, I think  
11 that will be softened.

12 DR. POLAND: Yes, it could well be, and  
13 then there are mechanisms like --

14 DR. SHAMOO: That's right. So this  
15 isn't a controlled clinical trial, and all I'm  
16 saying is we need to plan, since we're being  
17 comprehensive, to collect the data, because it's  
18 going to be a very important piece of data for  
19 subsequent generations.

20 DR. POLAND: True. Bill?

21 DR. HALPERIN: I just would reflect that  
22 we meet, that is, representatives of my Department

1 of Preventive Medicine in the School of Public  
2 Health meet periodically, a couple of times a  
3 month, with a local health department in a large  
4 metropolitan area.

5 And, you know, where the word "military"  
6 comes up fairly frequently is where we speculate,  
7 given a pandemic situation, depletion of local  
8 infrastructure, problems with food supply,  
9 etcetera, there is this -- you know, the only  
10 positive thing that's said is, "Well, then there  
11 is the capacity of the military." And, you know,  
12 I think it's--

13 MS. EMBREY: Thirty percent of our  
14 people will be affected, too.

15 DR. HALPERIN: I'm sorry?

16 MS. EMBREY: Thirty percent of our  
17 people will be affected, too.

18 DR. HALPERIN: Yes. And maybe the  
19 rationale, the optimistic rationale, it shouldn't  
20 be that optimistic, but one of the scenarios you  
21 would hope is, in the dire situation, as described  
22 in "The Great Epidemic" recently, is what that

1 relationship is going to be like. How is one  
2 going to cope, really, through the worst of days?

3 DR. POLAND: We don't have an answer to  
4 that, Bill.

5 DR. HALPERIN: Yes, I know.

6 DR. POLAND: But an interesting thing  
7 about the federal plan to me, or among the most  
8 interesting things about the federal plan is the  
9 explicitness of what they can't do, and what  
10 states and locals are responsible for.

11 MS. EMBREY: I think it's important,  
12 too, the Department of Defense has its own role in  
13 contributing to the overall national plan which  
14 addresses some of those issues. And Northern  
15 Command domestically has the responsibility for  
16 marshaling available forces to provide support to  
17 civil authorities here in the U.S., and their plan  
18 is explicit about how they are going to approach  
19 doing that with available resources.

20 But the DOD, like every other agency,  
21 has to have a plan for how they're going to  
22 address and deal with their population at risk.

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1                   And with your guidance we've really  
2 beefed up our Public Health Emergency Officer's  
3 role, expanded our training opportunities, put new  
4 principles in place for our disease surveillance  
5 capacity, and alerting and reporting mechanisms.

6                   We have, we really do -- we are limited  
7 by the amount of prevention tools that are  
8 available to us, so it becomes a public health  
9 education process.

10                  And the national plan, and the President  
11 has been unequivocal about his objective to ensure  
12 that the federal government, in its expert  
13 guidance to the country, be consistent in its  
14 educational message to the community, that you  
15 don't have this CNN effect where any expert with  
16 an epidemiological background can stand up in  
17 front of a TV and say, "This is what you should  
18 do," and it's all different.

19                  The objective here is to have  
20 evidence-based, good educational material out  
21 there for widest distribution, consistent across  
22 the country. And so that sort of limits DOD, who

1 likes to lean forward in its messaging to a more  
2 broader audience (?). And I think, you know, we  
3 have benefitted from your forward thinking, more  
4 so than any other federal agency, so kudos to you  
5 and kudos to us.

6 But that's our plan, and NORTHCOM really  
7 is seriously evaluating those surge requirements.  
8 And I think we have a representative from NORTHCOM  
9 here.

10 DR. POLAND: Did you want to make a  
11 comment? How many white horses do you have?

12 SPEAKER: Two. I would just reiterate  
13 what Ms. Embrey said.

14 MGEN. COL: In answer to your question,  
15 too, one of the things that the national plan  
16 really tried to stress is that we're not going to  
17 be able to push the national response on DOD,  
18 because of worldwide commitments and also because  
19 if it's a pandemic, there is a national response  
20 and we could expect, all over the country, people  
21 asking for the same resources. And so that's part

1 of the thinking process of going there. The  
2 military will be prepared to help out, but they  
3 cannot respond in a similar way to coming into a  
4 disaster that's localized as opposed to something  
5 that's global, national in areas.

6 DR. POLAND: Mike?

7 DR. PARKINSON: Yes. Parkinson, with  
8 Lumenos. We get a lot of requests from companies,  
9 as a large health insurance plan, about what  
10 should we do, where do we go? And of course  
11 there's any number of consultants who charge a lot  
12 of money out there in the private world to do  
13 these things.

14 I guess for members of the committee,  
15 having spent all the time that you did in looking  
16 at national plans versus others, are there aspects  
17 of this report of the DOD, in nuance or in  
18 substance, which are different, in that you would  
19 go back to your health department, the Advisory  
20 Committee, and say, "You know, something that  
21 you're really not putting enough attention to  
22 is..."?

1                   And an area I'll just throw up in my  
2                   cursory reading, re-reading of the  
3                   recommendations, is the whole role of children and  
4                   the connection with schools. And what seems to be  
5                   kind of a little mushy -- yes, maybe you close  
6                   them early -- it would seem like there might be  
7                   something in there that might be a little more  
8                   epidemiologic or quantitative, that might be  
9                   better guidance for a typical community to do.

10                   And so, broad general question, is there  
11                   anything different in this report?

12                   DR. POLAND: Yes, Mike.

13                   DR. PARKINSON: Second, what are the  
14                   things we should take back home to our other  
15                   organizations that all of us here represent? And,  
16                   third, what about the pediatric piece?

17                   DR. POLAND: Yes. You're absolutely  
18                   right, Mike. An example would be, in the  
19                   pediatric piece, the school issue. There is a  
20                   body of work that's been done, modeling work  
21                   that's been done by the NIH, that was in fact the  
22                   last briefing that the Board actually had, that

1 was very illuminating, I guess is the word I would  
2 put on it. Not all of that is open for public  
3 consumption, although they are working toward  
4 publishing the models. And that will be a very  
5 important piece, and I suspect, based on what we  
6 heard, will change the thinking of a lot of public  
7 health departments.

8           The other one that I can think of right  
9 offhand is the idea of stockpiling more than one  
10 neuraminidase inhibitor, and the thought that  
11 under certain scenarios it might make sense -- and  
12 these are very limited infection sort of scenarios  
13 -- to use more than one drug. So that was a  
14 little different in terms of a stockpiling and  
15 resourcing plan.

16           DR. McNEILL: Just one more comment. I  
17 think as far as describing how mature planning has  
18 evolved at the State level for this -- and I  
19 certainly agree with everything that's been said  
20 about the DOD not becoming the lead agency for the  
21 national response, there's no way -- but thanks to  
22 the public health preparedness cooperative

1 agreement with the CDC, and the funding that's  
2 coming into the States, we are definitely adopting  
3 our present programs, and it's demonstrated in the  
4 Hurricane Katrina response. We sent something  
5 like 20 people five years ago to hurricane  
6 response. We sent 1,400 to Hurricane Katrina from  
7 our Mississippi Department of Health.

8           With the planning that has gone into the  
9 strategic national stockpile, planning for staged  
10 distribution and so forth, all of these kinds of  
11 processes lend themselves immediately to pandemic  
12 influenza response. So I think the good news is  
13 the national planning that has occurred since  
14 9/11, with the infrastructure that is in place at  
15 local and State levels. Plus the fact that I pray  
16 the federal government will make it very plain to  
17 the States that there is not going to be the  
18 response that might ordinarily be coming, the same  
19 response to a hurricane or a tornado, because  
20 you've got so much to do that it sort of  
21 overwhelms the ability of the federal resources in  
22 these.

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1                   So I think, again, we are headed in the  
2 right direction both nationally, and I think at  
3 the State level a lot of good work is being done,  
4 and I agree with the team members. And as you  
5 say, Dr. Poland, if it's not H5N1, there will be  
6 another one down the pike where we have to be  
7 ready.

8                   DR. POLAND: Okay. Thank you, and thank  
9 you to our committee members who have put so much  
10 time into this.

11                   Roger has a few announcements, and then  
12 I'll dismiss us.

13                   COL. GIBSON: Working lunch here for the  
14 Board members, the liaison officers, the  
15 distinguished guests, and the speakers. The rest  
16 of you, there is, as I mentioned, the Officers' Club is  
17 across the way and there are restaurants off base.

18                   If this is your last day, if you're not  
19 going to be here tomorrow, pick up your CME.

20                   See Karen about the attestation  
21 statements. And we're still missing five menus.  
22 Try to get those to Karen here very quickly, so we

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1 can call the restaurant and they can be prepared  
2 for us tonight. That's it for me.

3 DR. POLAND: Okay, so we will dismiss  
4 for lunch. For those of you that want to be on  
5 the tour, we'll reconvene at 1330 right in front  
6 of this building, so 1:30 sharp for the tour.

7 (Whereupon, at 12:35 p.m., the  
8 PROCEEDINGS were adjourned.)

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