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P R O C E E D I N G S

(7:30 a.m.)

WALTER R. DOWDLE, PRESIDENT, AFEB

PRESIDENT DOWDLE: Good morning. I'd like to start off by thanking our host. I see someone is coming in, but I don't see our host here anymore. I would like to say that we've been shown outstanding hospitality here, and not only did we see some fabulous hardware yesterday, but also had the opportunity to have a very instructive day reviewing the training exercises that were going on.

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So, again, to those at Camp Pendleton and those who have been so helpful in setting up this for us, we very much appreciate it, so thank you very much.

Okay. We have a very tight schedule this morning, and we will have to be through here by 10:15. We have a number of people who are depending on that time in order to make their airplanes, so we need to move along, and so the speakers please note, if they can stick to their time, and not only that, allow a little time for discussion, we'd really appreciate it. A reminder, once

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again, to announce your name. If you have questions, or comments are made during the session this morning, please state your name.

So why don't we go ahead and get started, then, and we'll start with Colonel Falkenheimer.

//

SHERRY FALKENHEIMER, OFFICE OF THE ASSISTANT

SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

MS. FALKENHEIMER: Good morning. This morning I'd like to give you a brief presentation of a DoD

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directive entitled "DoD Immunization Program for Biological Warfare." This is an attempt to address some problems that we found during Desert Storm, that we did not have a policy in place that would assure that our soldiers were immunized, in advance of deployment, against biological warfare agents, and it was intended to complement the directive that Doctor Parkinson talked about yesterday, on immunization against -- and I brought this to the Board mainly because the Board -- thank you.

It covers three main areas, provides both

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policy, responsibility and procedures, for vaccination as well as research development, acquisition of vaccines, and stockpiling of vaccines. I'm only going to talk in detail about the vaccination provisions, which are the ones that will primarily involve the Board.

Just briefly, the research development and acquisition provision mainly states that it is DoD policy to integrate and prioritize research to develop new and better vaccines against these agents, and they will be prioritized somewhat along the lines you'll see when I

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speaking about prioritization of the biological warfare threat, and it also states that it's DoD policy to develop a capability to acquire and stockpile vaccine against these agents, in sufficient quantities to protect the program force against biological warfare agents.

The vaccine policy basically says that we will immunize our forces against validated BW threats, which I'll explain in a moment, for which suitable vaccines are available. As many of you know, we don't have vaccines against all of these agents, and some of them are in early

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development, and that we'll do it in sufficient time for forces to have immunity before they arrive in the theater.

In other words, we don't want to have to be immunizing people once they're in the theater, like we did during Desert Storm.

These are the definitions of how we determine a high-threat area, and a validated BW threat, like other threats, it's primarily a line decision, in this case by the Chairman of the Joint Chiefs of Staff, and he has the types of input he has in other operational decisions.

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When determining the threat, he'll get information from the intelligence community, the defense intelligence agency, and also, for each theater, the theater commander, what's called the Unified Commander in Chief, will prioritize the threat in his theater, and provide that to the Chairman, and the Chairman will try to get the big picture, and prioritize it worldwide.

A validated threat is basically done the same way, with input from the Chiefs of Staff of the services, and that provides us the targets against which we need to

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develop, acquire vaccines, immunize people, and who will be immunized.

It states that personnel assigned to high-threat areas, as defined by the previous provision I mentioned, personnel who are predesignated for crisis response; these are the initial forces that go within hours of a problem in the world, and also personnel that will be in the planning to go, as follow-on forces.

Now, it only requires that they be immunized in time to have adequate protection before they get the

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theater, so late follow-on forces would not necessarily be immunized in peacetime, if we had sufficient time after the beginning of a contingency to immunize them in the States, or wherever they are before they go, and the policy does allow the Chairman of the Joint Chiefs of Staff to make exceptions to these provisions, where he feels it's necessary.

The final slide, this is where the AFEB comes in, the procedures for the immunization program. Basically, after the first two things are done that I had

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mentioned first, the theaters telling the Chairman of the Joint Chiefs of Staff how they perceive the prioritized threat to their theater, the Chairman consulting with his advisors, and developing a worldwide prioritized threat.

They'll forward that to the executive agent, which is the Army. The Army is the DoD executive agent for biological and chemical warfare defense, and then, within 30 days, the Army is to consult with the other services, and with the Armed Forces Epidemiological Board, and recommend what they believe are suitable vaccines and

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protocols to protect against the agents in the prioritized threat, and that will be forwarded to the Assistant Secretary of Defense for Health Affairs, who will make the decision on which protocols and vaccines to implement, and direct that the services begin that implementation.

Some of the vaccines, as you know, are still in investigation, on new drugs, and they'll be used under appropriate FDA provisions, or other legal provisions, such as we had during wartime, during Desert Storm.

That's all I have. I just wanted to familiarize

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the Board with this rule. I'd be glad to answer any questions.

LOU KULLER, UNIVERSITY OF PITTSBURGH

MR. KULLER: Doctor Kuller. Could you tell us what's been the tick-borne encephalitis in former Yugoslavia, and the Board, I know, was briefed about a year ago on the issue of tick-borne encephalitis vaccines and the problems that were occurring. Has anything happened since then?

MS. FALKENHEIMER: I can't comment on that.

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It's not in the biological warfare threat area. I don't know if any of the services have any follow-up on --

MR. KULLER: The Board was presented with information concerning potential risks of tick-borne encephalitis in Bosnia, and the concern about the availability of the vaccine, considering that there might be some deployment of troops at some time, and I was just wondering, considering what we've just heard, is there any follow-up or anything happening?

RICK ERDTMANN, OFFICE OF THE SURGEON GENERAL

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MR. ERDTMANN: This is Colonel Erdtmann speaking. I think there's somewhat of a separation between the natural biologic threats and the BW threats, and there is an intent to use the TBE vaccine, which is still under I and D, to certain forces that would be deployed over there, under certain conditions, at certain times of the year, but you're limiting this discussion just to BW threat agents?

MS. FALKENHEIMER: Yes, and, as I mentioned, this policy only deals with biological warfare threats.

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It's not intended to impact the endemic disease immunization regulation that Doctor Parkinson talked about, and I don't have any information on how many people we may have immunized against tick-borne encephalitis.

STEPHEN O. CUNNION, UNITED STATES NAVY

MR. CUNNION: Captain Cunnion. As far as I know, there's no reports of any cases coming out of any of the UN forces in Yugoslavia.

MIKE PARKINSON, UNITED STATES AIR FORCE

MR. PARKINSON: Doctor Parkinson. We have an

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air-transportable hospital over in, I believe it's Sagreb, right now, and we have not used TBE vaccine in those personnel.

PRESIDENT DOWDLE: Yes, Doctor Gwaltney.

JACK GWALTNEY, UNIVERSITY OF VIRGINIA

MR. GWALTNEY: Has the Board been involved in this in the past? In other words, what was the previous procedures for making these decisions, and are there classified issues involved with this?

MS. FALKENHEIMER: Yes, there are.

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MR. GWALTNEY: For example, were people immunized in the Gulf War for certain things, and so forth?

MS. FALKENHEIMER: Yes. There has been press about this issue and the Gulf War, but some of the information remains classified, and I think it would unclassified to say that the Board did have a role in confirming the recommendations that were made during Desert Storm, that they were reasonable and appropriate.

MR. GWALTNEY: Well, how does this change that?

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MS. FALKENHEIMER: It basically sets in a policy that that's how we'll do it. During the Gulf War, we had no policy, so we were kind of making it up as we went along, trying to figure out the best way to make recommendations, and have them acceptable to our leadership.

PRESIDENT DOWDLE: This is Walter Dowdle. Are then we to assume that there will be an annual review with the Board?

MS. FALKENHEIMER: Yes, that's the intent, that

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each year the threat will be looked at again. The first year will obviously be the most difficult time, but it will probably need to be slightly revised, as the threat changes over time.

PRESIDENT DOWDLE: But, I mean, before the Board, will the Board be briefed annually?

MS. FALKENHEIMER: Yes, sir. It may not be the whole Board. It could be the infectious disease subcommittee, or whoever you think is appropriate, and security clearances will be required for the threat

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briefing.

PRESIDENT DOWDLE: Okay. Doctor Perrotta.

DENNIS PERROTTA, TEXAS STATE HEALTH DEPARTMENT

MR. PERROTTA: I'll be the first to show my ignorance, and perhaps if a list of BW threats could be provided to us somewhere down the line, before we are requested, because I quite honestly don't know.

MS. FALKENHEIMER: That's what would be done, sir, but that list is classified. There is information from courses at Usamred (phonetic) of some of the things

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that we are concerned about. It's well known that anthrax, for example, is a biological warfare threat, and botulinum toxin. There are quite a range of them, but when you see the actual threat list, what countries we think have what, and what priorities our flight leadership give to each one, which they think are most likely to have an impact on the force, and be the biggest threat, that we'll have to do in a classified mechanism.

PRESIDENT DOWDLE: Okay. Other questions? Yes, Doctor Allen.

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JIM ALLEN, AMERICAN MEDICAL ASSOCIATION

MR. ALLEN: Jim Allen. I think it would extremely useful for the Board, at some point, to have a review of what happened, for example, with the decision-making process on anthrax vaccine in the Gulf War, because I know that that was a difficult one. You already intimated, which I wasn't aware, that there hadn't been a policy in place, which I guess is what contributed to the difficulty.

MS. FALKENHEIMER: Well, there were some general

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statements in the old immunization regulations that provided that it could be done, but there was nothing specific.

DR. ALLEN: I think, given the recent fairly significant changeover in the composition of the Board, it would be very useful to have a review at some point of what happened, exactly.

PRESIDENT DOWDLE: Okay. Doctor Ascher.

MIKE ASCHER, VIRUS LAB, STATE OF CALIFORNIA

MR. ASCHER: This is not a mysterious area. The

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list is very short, we heard it, which has, in other words, agents that are validated for which there are vaccines, but I guess the point is that there's no way to adapt that to future threats or newly identified threats, or how that is going to work, and this is a policy to do that. There's nothing mysterious; four agents that are really --

MS. FALKENHEIMER: I'll say that it's really a much longer list, but which ones --

MR. ASCHER: But not that we have vaccines.

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MS. FALKENHEIMER: -- leadership feels we should immunize against -- we have current vaccines.

MR. ASCHER: Yeah, it's a short list.

MS. FALKENHEIMER: But there are a fair number of investigational vaccines.

PRESIDENT DOWDLE: Well, clearly this is going to be one of the items that will be taken up in more depth in further meetings of the Board.

MS. FALKENHEIMER: If you'd like a briefing during the Washington meeting, that might be a good time,

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because it would probably be easier to arrange classified facilities.

PRESIDENT DOWDLE: Doctor Kuller.

MR. KULLER: Is there a similar activity with regards to chemical warfare, and issues related to the detection and issues related to the chemical -- that might be used?

MS. FALKENHEIMER: There's a program to protect our people against a chemical threat. That was recognized as a serious threat quite some time ago, really, at least

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10 or 15 years ago, and there are current provisions, particularly in the medical area. We had a presentation to the Board that was in place during Desert Storm on what we had, and it was basically drugs that we provided the troops, either for prophylaxis or use after exposure to nerve agents, and then skin decontamination for mustard.

There's really no specific treatment for mustard. We did field granulocyte colony stimulating factor (phonetic) under R and D, in case we needed it for bone marrow suppression, for mustard exposure during the

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Gulf War, but we're much more up-to-date on having things fielded, having policy in place, having people trained in the chemical area, than biological. It was more recently recognized as a serious threat.

PRESIDENT DOWDLE: Okay. Thank you, Colonel Falkenheimer. We must move on. You're going to be hearing more about this in the future.

Next is the pneumonia outbreak at Wilford Hall.
Doctor Schillinger?

DOCTOR SCHILLINGER, WILFORD HALL MEDICAL CENTER

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MS. SCHILLINGER: Good morning, everybody. In the next several minutes I will present the results of an investigation of an outbreak of pneumonia which occurred between July and November amongst staff at the Wilford Hall Medical Center on Lackland Air Force Base in San Antonio, Texas.

I would like to start by acknowledging my co-investigators, particularly Doctor Matt Dolan of the Wilford Hall Medical Center on Lackland Air Force Base, Doctor Benjamin Schwartz of the Childhood and Respiratory

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Diseases branch of the CDC and Prevention, and Doctor Deborah Talkington of the Respiratory Diseases Lab at CDC.

Next slide.

In the second week of August 1993, mid-summer, in Texas, 14 employees of the Internal Medicine Outpatient Department at Wilford Hall developed radiographically demonstrated pneumonia. Five people required hospitalization, one in the intensive care unit.

All persons described a characteristic clinical syndrome of fever, headache, and severe myalgias, with the

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onset of cough several days into the course of illness. The etiology of the outbreak was unknown. Bacterial and viral culture of sputum and serologic tests for Legionella, Mycoplasma (IgM), Chlamydia pneumoniae, Adenovirus, Respiratory Sensitia (phonetic) virus, parainfluenza, and Influenza A and B were negative.

Cases of pneumonia continued among members of the Internal Medical Department in the latter half of August, and at the end of August members of the Childhood and Respiratory Diseases branch of the CDC were invited to

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investigate the etiology of the outbreak, determine risk factors for infection, and to develop and evaluate prevention measures.

A passive pneumonia reporting system was implemented in early August at Wilford Hall Medical Center. Physicians in the Emergency Department and Primary Care Clinic were instructed to notify Doctor Dolan of all patients seen at these two sites with pneumonia. Active case finding was initiated in early September. Screening questionnaires soliciting respiratory and

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systemic symptoms were distributed to residents and staff, nurses and technicians within 11 hospital departments. Hospital employees visiting the Primary Care Clinic were also asked to complete a screening questionnaire.

Because a number of internal medicine physicians had been ill, we were concerned about the possibility of doctor-to-patient transmission. To investigate this possibility, a medical record review was performed for patients discharged from medicine wards during August. In addition, patients diagnosed with pneumonia were referred

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to us by physicians who had cared for these patients, and who were themselves ill. Next slide.

We defined a definite case of outbreak-associated illness as chest x-ray-documented pneumonia occurring in a hospital employee or their contact between July 1st and November, in the absence of a known etiologic agent. A "probable" case was defined by the occurrence of three concurrent symptoms, cough, fever and myalgias in the same population, and a "possible" case was the occurrence of two of these three symptoms.

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We identified 45 definite, 88 probable and 107 possible cases among hospital employees. Fifty-one percent of those who had chest x-rays performed showed an infiltrate. In all, six people required hospitalization; there were no deaths. Next slide.

This slide shows definite and probable cases plotted against time. The peak of the outbreak occurred in mid-August, and primarily included persons who worked in the Internal Medicine Department, shown here in red.

During September, October and November, most

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case patients worked in other areas of the hospital. The attack rate among employees of the Internal Medicine Outpatient Department was 26 percent. There was an attack rate of 43 percent for internal medicine residents of all three years. Physicians in the Psychiatry and Pediatrics departments had attack rates of 20 and 15 percent, respectively. Outside these departments the attack rate was lower. A review of medical records did not show any evidence of spread to hospitalized patients.

Whenever possible, we obtained acute and

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convalescent sera specimens from persons meeting the case definition. For those definite and probably cases with ongoing respiratory signs, we obtained nasopharyngeal swab specimens, which were sent in transport media to CDC for culture and antigen detection. Acute and convalescent serum specimens from early case patients were evaluated for etiology.

Seven individuals with chest x-ray-documented pneumonia were tested by complement fixation for IgM and IgG antibody to mycoplasma. Four of seven showed a

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fourfold rise in titer, and the remaining three case patients had a convalescent titer of at least one to 64. Next slide.

In order to determine which mycoplasma species caused infection, immunoblotting techniques were applied to these sera. This slide shows five pairs of sera, labeled "TX" for Texas, and "A" and "C" for acute and convalescent specimens. Lane 13, which is the second from the right, is a *Mycoplasma pneumoniae* control serum. Essentially, the black bands represent antibodies, and

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lane 13 shows two prominent *Mycoplasma pneumoniae* antibodies, and if you look at the difference between the A, or acute, and C, or convalescent titers, you can see that there's a difference in the intensity of the band, representing intercurrent infection with *Mycoplasma pneumoniae*. Immunoblotting techniques also demonstrated the absence of *Mycoplasma genitalium* and *Mycoplasma fermentans* species.

Twenty of 42 nasopharyngeal specimens grew an arginine utilizing mycoplasma species, which was later

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identified as *Mycoplasma salivarium*, a commensal organism. No other *Mycoplasma* species was isolated. Serologic evaluation on the first 14 sets of paired sera included tests for a wide range of respiratory pathogens. These tests were all negative. Next slide.

This slide summarizes the results of serologic testings on case patients in the outbreak. Thirty-three percent of definite cases with convalescent specimens showed a fourfold rise in titer, and 70 percent had a convalescent titer of greater than or equal to one to 64.

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Definite cases, those with chest x-ray-documented pneumonia, were significantly more like than probable or possible cases to show a fourfold rise in titer. There was no difference in the proportion of definite, probable and possible cases with negative results. Next slide.

We next conducted a matched case control study to determine risk factors for infection, and to more accurately characterize the clinical manifestations of disease. Forty-five definite and probable cases with onset of illness between July 15th and September 15th were

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matched with controls by department of employment and occupation. Cases and controls were questioned about activities and exposures for the four weeks before the matched case's onset of illness. Descriptive analysis included three additional unmatched cases. Next slide.

Case patients in the case control study described a distinctive clinical syndrome. In addition to the symptoms cough, fever, and myalgias, which served as one of the sets of entry criteria for the case control study, 75 percent of patients reported headache, 55

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percent reported the illness as having an abrupt onset, and 40 percent described rigors. The abrupt onset and rigors make this clinical syndrome notably different from the usual presentation of mycoplasma illness.

If hospitalization is considered as an indicator of the severity of illness, acuity appeared highest in the second week of August, when four of the six patients requiring hospitalization became ill. In all, 84 days of work were lost among case patients, with 1.7 days of work lost, on average. Notably, 41 percent of cases worked

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throughout their illness. Next slide.

We compared exposures of case patients and controls to identify risk factors for infection. Analysis of the matched case control study revealed that attendance at internal medicine noon conference on one of two days at the end of July was associated with developing disease. Internal medicine noon conference is a daily conference which is attended solely by physicians, almost exclusively those in the internal medicine department.

We asked all study participants if they ever

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attended noon conference. Of the 32 people that attended these conferences at any time, we obtained detailed information on specific conference attendance, using a calendar with a medical topic and patient presented at each conference. Twelve of 17 cases, or 71 percent, attended conferences on July 28th or 29th, compare with two of 15 controls. No other day, for two weeks on either side of this two-day period, was associated with an increased risk for illness.

The two conferences in question were

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approximately 14 days before the peak of the outbreak in mid-August, consistent with the incubation period for mycoplasma. Although this was a significant risk factor, it does not explain all the cases. It is likely, therefore, that these two noon conferences served as a single-source exposure for a number of internal medicine physicians, but the disease was also transmitted on a person-to-person basis.

There was no risk associated with time spent working with internal medicine physicians, frequency of

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attending conferences with internal medicine physicians,
frequency of attendance of morning report or noon
conference, or taking overnight calls in the hospital.
Next slide.

We also evaluated the impact of antibiotic
treatment on the duration of clinical illness. For case
patients treated with a macrolide or tetracycline
antibiotic within one week of onset of symptoms, seen here
on the left, the mean duration of symptoms was shorter
than that for individuals treated with an inappropriate

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antibiotic, seen in the right-hand lane. For example, people treated with an effective antibiotic had fever for a mean duration of 4.5 days, as compared to 12.6 days for those treated with an ineffective antibiotic. These data support the notion that early recognition and appropriate antibiotic therapy for mycoplasma disease can shorten the clinical course and limit morbidity.

Among those who were treated with an effective antibiotic from the outset of their treatment course, those who were treated with Azithromycin had significantly

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shorter duration of symptoms than those treated with either erythromycin or doxycycline. However, several apparent relapses following treatment were observed in this group, making it difficult to reach a conclusions regarding Azithromycin's efficacy. Next slide.

In order to investigate preventive measures, we designed a prospective double-blind placebo trial to study the use of doxycycline as a prophylaxis for mycoplasma disease. Three hundred and forty-six people were enrolled in the trial. Two hundred and thirty-two received

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doxycycline, 100 milligrams twice a day for 14 days, and 114 received placebo, dosed the same way. Study patients were interviewed at intervals of two, four, and six weeks after starting the treatment/placebo regimen, and were questioned about respiratory and constitutional symptoms, as well as possible side effects of the medication.

We defined an illness event as the simultaneous occurrence in a study patient of any two of seven symptoms: cough, fever, myalgias, headache, sore throat, sinus pain, and ear pain. With the exception of headache

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in conjunction with sinus pain, and fever in conjunction with sore throat, any combination of these symptoms was accepted as constituting possible mycoplasma illness. Study patients reporting these symptoms were asked to have blood drawn for serologic testing. Next slide.

Preliminary analysis of data from the doxycycline prophylaxis trial suggests that treatment with doxycycline conferred protection against the manifestation of respiratory and constitutional symptoms associated with mycoplasma disease. Twelve of 232 people on doxycycline

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developed symptoms classified as an illness event, compared to 15 of 114 on placebo. This affords a protective efficacy of 61 percent, with confidence limits of 19 to 81 percent. Analysis of the serologic results from this trial are pending.

Analysis of adverse events associated with treatment has not yet been done. However, during the course of the study, one individual developed severe esophagitis, and was removed from the trial. He was later determined to be on doxycycline.

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Although additional analysis is ongoing, we would suggest the following conclusions. Data from our case control study suggests that a single-source exposure contributed to the explosive nature of the outbreak among internal medicine physicians. In contrast to the classical description of mycoplasma, abrupt onset and rigors can be a manifestation of mycoplasma disease. Early treatment with a macrolide or tetracycline antibiotic shortened the duration of respiratory and constitutional symptoms. Treatment with Azithromycin

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resulted in earlier resolution of symptoms when compared to other macrolides and doxycycline.

Preliminary analysis of data from the doxycycline prophylaxis study suggests that a 14-day course of doxycycline may prevent the development of clinical disease in the setting of a mycoplasma outbreak.

The potential availability of an effective prevention measure underscores the importance of early detection of a mycoplasma etiology.

Any questions at all?

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PRESIDENT DOWDLE: Thank you very much, Doctor Schillinger. I think that this points out, once again, that over the past few years we've seen some very successful studies between CDC and the Department of Defense, and various of the branches, and I think this was another very good one. I can't imagine that there won't be quite a few questions, particularly from a few here that have had some experience in this area. Doctor Ascher?

MR. ASCHER: This certainly presented very

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typically for Cue fever (phonetic), a common source that has been reported around the country, and you didn't look at that early on, apparently. We don't think that's what it is, but exposure to a pregnant sheep in a surgical amphitheater would give you almost the same story; a little less cough, but abrupt onset. Did you look at Cue fever?

MS. SCHILLINGER: Titers for -- were done at -- but not at CDC.

MR. ASCHER: I mean, that's something that would

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have come to mind immediately. The question of serology, for those of us that think about it, is not very hard. This is sort of soft results, and you've got a mycoplasma, but it's a cross-reactive something, probably.

MS. SCHILLINGER: You mean you don't feel that it's pneumoniae?

MR. ASCHER: They're not very hard serologies, and blots are flaky.

PRESIDENT DOWDLE: Doctor Gwaltney?

MR. GWALTNEY: Well, I'm totally convinced that

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this is a classic common-source outbreak of *Mycoplasma pneumoniae*, I think. I don't know why you didn't grow it.

I don't know what was going on with the culture methods, but I think you did a beautiful job, epidemiologically, a textbook job of working up this epidemic. There have been other common-source outbreaks of mycoplasma, one in a dental clinic, associated with a dental drill and other things like that.

In the big picture, I guess the question is how much mycoplasma do you have at Wilford Hall, and is it

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seasonal, because that would influence whether preventive measures, antibiotics or whatever, would really be worth doing. In some parts of the country, it used to be felt that it was not seasonal, like in Seattle and areas like that; it seemed to be around all the time. Most of the time, in the United States, it comes in epidemics that last for several months, a half-a-year, and then it goes out of the community, and I really am not up to date on what the current thinking is, or what your experience has been at Wilford Hall, and if you have that information.

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Also, there is a mycoplasma vaccine that was being developed, that was tested in thousands of people at Parris Island in the past, and I don't know what's happened with that, either.

MS. SCHILLINGER: With respect to Wilford Hall, I'm from the CDC, and I don't know a great deal about the history of mycoplasma at Wilford Hall. We did look at individuals between the ages of 13 and 35 discharged from the hospital, and the discharge diagnosis etiology pneumonia of unspecified etiology, as a crude measure of

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what may have been *Mycoplasma pneumoniae*, and this particular year, 1993, for the period between July and October, actually the proportions made of that population was smaller than in previous years, so this epidemic would not have been picked up by that method.

I believe, actually, the crosdantics (phonetic) lab, they have been at Wilford Hall or on Lackland. That article is written between individuals at UBA and Wilford Hall, but I don't know much about the history of Wilford Hall.

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With regards to the vaccine, I've seen several of those articles, and it looks like shortly after '66 or '67 work on that sort of dropped off, and I think there was some suggestion that individuals vaccinated and thereafter closed to mycoplasma developed more severe disease than individuals who had not. There was one article suggesting that, and I don't know if that is what led to the loss of interest.

UNIDENTIFIED SPEAKER: Do you have any anecdotal information about what happened at that noon conference?

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Was a patient presented, or some of the staffers know to be ill at the time of the conference?

MS. SCHILLINGER: I don't believe any of the individuals that were there were known to be ill at that time. It's kind of funny: the topic presented on July 28th was "Acute Respiratory Failure," and -- no, there was someone there, and certainly they may or may not --

UNIDENTIFIED SPEAKER: Have you gotten together -- a core look at the --

MS. SCHILLINGER: Not that we could discern.

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The -- social events, and there had been no social gatherings. This occurred about six weeks into the residency year, and so we've looked very closely at the period around the end of residency and the beginning of the -- class, to see if -- gathering, and no one acknowledged any gathering that was --

PRESIDENT DOWDLE: Doctor Poland.

GREG POLAND, MAYO CLINIC

MR. POLAND: Were there any differences in any sphere between the patients who had confirmatory

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serologies and the patients who did not?

MS. SCHILLINGER: Not on an array of 10 respiratory symptoms that we looked at, in terms of duration and presence of that -- I believe for sinus pain and chest pain there was a difference between definite and probable and possible cases. I should add, too, that probable and possible cases were designated as such by the symptoms they had, and the absence of positive x-ray includes many people who had never had a chest x-ray, and if they had, they may have been grouped as definite

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grouping, so that may be why there's not much of a distinction between those three groups.

PRESIDENT DOWDLE: Okay. Thank you very much; appreciate it, very nicely done. Yes.

MATT DOLAN, WILFORD HALL MEDICAL CENTER

MR. DOLAN: Matt Dolan, Wilford Hall. Let me just add a couple of things specific to the hospital there. As far as looking at Cue fever, we had been worried about that earlier, because there was a specific room that seemed to be associated with the outbreak of

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disease, and we were worried that there may have been an animal that had given birth in the air supply, or something like that. It turned out that there actually is no air supply to the room, so that was out, and serologies were done on maybe the first 30 or 40 patients that came down with this, and they were uniformly negative.

Regarding incidence of mycoplasma among employees in the hospital, we looked back over the past year-and-a-half or two years, as far as admission diagnosis of pneumonia. There was a seasonal peak in the

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wintertime, of pneumonia hospitalizations, but that peak seemed to be mostly attributed to pneumococcal disease, and the other, which looked like mycoplasma, seemed to be pretty much flat throughout the year, without a seasonal peak.

PRESIDENT DOWDLE: Thank you. That's helpful. Okay. We need to move on, then, to acute respiratory disease problems, TB testing, Captain Ledbetter and Commander Gray. Is Commander Gray giving -- all right. Good morning.

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GREG GRAY, NAVAL HEALTH RESEARCH CENTER

MR. GRAY: I'd like to say that we have done some recent studies, I guess 1989, not too recent. We looked at a random selection of 200 Marine recruits after 11 weeks of training, and found, by serologic test, which is more specific than the CS and Eliza (phonetic) -- excuse me, I'm sorry; it was CS. We found about a five percent seroconversion rate. Captain Edmonson, who is a pulmonologist at the hospital here in San Diego, at the main hospital, also additionally explained about 20,

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overall, of the pneumonias that were admitted, about 1989, due to mycoplasma, among recruits at the Naval Training Center, so we think it's one of our prime etiologies, but how much is there, and if it's seasonal, we really can't answer that.

I want to talk to you today about a study that Doctor Ed Gastaldo has performed at Parris Island, which is the Marine Corps recruit camp on the East Coast, regarding skin testing antigens, and also discuss some of the other respiratory disease threats that we're facing.

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Next slide.

All Navy and Marine Corps recruits receive a tuberculin skin test early in their training. We use the Mantoux intradermal method, and give patients with 10 millimeters or greater induration six months of INH prophylaxis. In 1991 and 1992, the branch clinic at Parris Island used a Scalvo tuberculin antigen, manufactured in Italy. In November 1992, this product was recalled, and the Navy was supplied with Aplisol, a Parke-Davis product. After the conversion to this new antigen,

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Commander Gastaldo noted a 1,500 percent increase in the prevalence of positivity, over a two-month period.

Commander Gastaldo was alarmed, but not sure if he had an antigen problem or if the difference in positivity percentages was true. He and Commander Gil Potter of the Navy Environmental Health Center contacted various state and federal experts, and found that there were numerous reports of potency differences among the three available products. As compared to a research study of 2,400 Navy and Marine Corps recruits in 1990, with the

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Connaught antigen, Scalvo's product identified a low prevalence, and the Parke-Davis product was more in line with the expected prevalence of about 25 cases, or positive tests, per 1,000 recruits.

Commander Gastaldo designed a clinical trial of both the Connaught and Parke-Davis antigens, both of which were available to Navy and Marine Corps centers. The study was double-blinded. Each volunteer received both skin tests, one test per arm. The antigens were randomized to the right and left arms. After insuring the

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same amount of antigen caused the same amount of cutaneous bleb, the skin tests were read 48 hours later, by different readers, using the pen-and-ink and caliper methods.

Commander Gastaldo screened over 1,200 recruit volunteers over a period of several weeks. One hundred and fifty of these recruits had an induration of one millimeter or more on at least one arm. The mean indurations of these 150 volunteers differed for the two products. Controlling for the variability caused by

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individual readers, or application to the right or left arm, the differences between the two antigens could not be explained by chance alone. For the Navy's cut point of 10 millimeters in induration, the Aplisol, as compared to Tubersol, would have classified eight more subjects as having had a positive screen test. This is about an eight percent difference of the positives.

To the individual, this would mean a chest x-ray, clinical exam, and a minimum of six medical visits to monitor six months of INH therapy. Extrapolating this to

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the entire Navy, 160,000 new recruits each year, this difference would mean an additional 1,066 recruits each year would receive prophylaxis. These recruits would tally 6,400 additional patient encounters. Next slide.

Our early conclusion is that there appears to be a difference in antigen potency between the two FDA-approved products that the Navy uses. This difference may merit an examination of U.S. standards for tuberculin production. At present, we understand that lots of antigen are compared with an FDA standard in mouse models.

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With the present epidemic of tuberculosis in the United States, the potency problem may be an important issue in tuberculosis control.

This week, the Board has heard two presentations already regarding epidemics of bacterial respiratory disease among military personnel. Before I introduce our third speaker on the subject, I just want to remind the Board that, in addition to pneumonia epidemics, we have epidemics of other organisms, including Strep pyogenes, which causes acute rheumatic fever, and sever Strep

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pyogenes infection, such as toxic shock-like syndrome.

Next slide.

 These problems are likely to increase, as the pathogens develop resistance to our empiric therapies. Here you see erythromycin resistance among Strep pyogenes isolates. Our chief intervention in these epidemics has been benzathine penicillin G. Streptococcus pneumoniae is already commonly resistant in the United States. The prevalence of penicillin resistance in the Navy is unknown, but we know that we have had several penicillin-

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resistant isolates here in San Diego County.

It has been predicted that soon Strep pyogenes will also develop penicillin resistance. This is frightening, because we have no good alternative prophylaxis to benzathine, and should these resistant and virulent pathogens become entrenched in our training populations, we may suffer epidemics such as those seen during World War II, when acute rheumatic fever and pneumonia caused tens of thousands of hospitalizations.

We must develop surveillance strategies to

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detect drug-resistance to high-risk pathogens. We know we have a problem in San Diego, but we don't know of its magnitude, because we don't have the resources to investigate.

We must develop prophylactic medications as an alternate to penicillin. We need safe, broad-spectrum, and long-acting substitutes to use as interventive tools for future epidemics. We have permission to test Azithromycin, which would we think would be a good solution, but again we don't have the resources.

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At this time, I'd like to introduce Captain Reynolds, who is a pulmonary specialist and head of internal medicine at Camp Pendleton. He has worked in the hospital since 1986, and followed the annual pneumonia epidemic since '89. Better than anyone else in the Navy, Captain Reynolds knows the Camp Pendleton patients and their clinical picture, which is very confusing.

CAPTAIN REYNOLDS, CAMP PENDLETON

MR. REYNOLDS: I'm a clinician, and, as clinicians are wont to do, I'll probably make some

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statements that are unfettered by any scientific fact.

My real purpose for being here is to acquaint you with an epidemic, which we believe to be of historic proportions, and to enlist your aid and support in obtaining the resources to deal effectively with the epidemic. The epidemic started in 1989, at an area of the base that's northeast of here, about 45 minutes. It is where the Marine combat training takes place, and there is also a school of infantry and an infantry training battalion there.

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It's very rigorous training. I don't know how much you know about it. I don't know if Captain Ledbetter described the conditions out there, yesterday, but it's fairly rigorous training. There are probably over 3,000 personnel who are at risk. Two weeks of that training takes place in the field, and the only shelter is shelter halves, and the recruits sleep in sleeping bags on the ground.

That kind of training has been going on for several years, but in 1989 it became reorganized as Marine

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combat training, and in that year there were 124 pneumonia cases reported and documented. Eighty-eight percent of those were noted radiographically to have airspace infiltrates. Seventeen percent of the pneumonia cases were bacteremic, and had positive blood cultures for *Strep pneumoniae*, and when serotyping was done on these isolates, 89 percent of them were from a common isolate or a common serotype, that is, serotype one.

There was a lot of morbidity and toxicity associated with the pneumonias. There was a 99 percent

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rate of empyema in these pneumonias, and over half of those ultimately required decortication, so it was a fairly significant source of morbidity, and rather frightening at the time. Next slide.

It was decided to give pneumococcal vaccine, which was done, and after the administration of the vaccine the number of cases declined dramatically. However, in the following years, the number of pneumonias have appeared to remain high. Next slide, please.

Because of the continued increased number of

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pneumonia cases, a decision was made that, in order to do appropriate surveillance and to collect microbiologic data, that we would admit all active duty pneumonia cases to the hospital, and so most of this data that is presented is data acquired during these hospital admissions.

What we saw was a rather constant rate of pneumonias that really didn't vary a whole lot, except during the summer, and, as you can see, there's a little dip in May, June, July and August, but, outside of that,

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the numbers of cases of pneumonia remained constant, from October of '90 to December of '93. That means that we had approximately 100 to 150 cases of pneumonia each year, and at this moment over 805 patients have been surveyed for the presence of pneumonia.

As the epidemic persisted, there were some changes that we noted, just in the clinical presentation.

As time went on, there was a lot less morbidity, toxicity and complications, and fewer sterile site isolates were obtained, which has caused us a great deal of difficulty

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in trying to identify, at this point, a specific etiologic agent.

Also, we noticed that there were more pneumonias identified for the 31 area. Now, the 31 area is an area where Marine recruits from MCRD come up here for a month, for weapons training, and again there is a fair amount of field activity in this particular months of weapons training, while they're here. Next slide, please.

Unfortunately, this doesn't project very well, but let me just make the point that I've tried to make on

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the previous slide, that we will have more and more difficulty obtaining sterile site isolates. The first circle up there, in the yellow, the yellow pie, that represents blood cultures positive for *Strep pneumoniae*, and that was the first year, the '89-90 epidemic, and you can see that it's a fairly sizeable proportion of the total isolates.

However, the next year, in '91, the rate of blood cultures dropped from approximately 20 percent to nine percent, and the year following that, it went down to

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one to two percent, so it was a major problem for us, in assisting identification of a specific etiologic agent. Next slide, please.

 This is data, recent data, from 1993, and it's not inclusive of all the cases we've had since January of '93, but you can see that the incidence is fairly generous, approximately 30 per 1,000, and if you look at the incidence of community-acquired pneumonias and some of the references in the literature, you can see this is manifold higher than one would expect to encounter.

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The following data you have to take with a grain of salt. I have attempted to make the point that these continue to be most likely Strep pneumoniae, but I really don't have any scientific to support that. I tried to review all the x-rays, and the hypothesis is that, if these x-rays continue to be airspace in character, and in my opinion they have been, that perhaps that would give some support to the fact that this is Strep pneumoniae, since airspace pneumonia is commonly associated with bacteria, and we know from biologic surveys of community-

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acquired pneumonia that *Strep pneumoniae* is still the number one cause.

This slide shows the results of an analysis of x-rays showing airspace infiltrates over all the sites, and you can see that in the 52 area there is 64 percent. The percentage of airspace pneumonias in the pneumonias from there is 64 percent, and significantly different from the other areas. Next slide, please.

This slide summarize the x-ray data, of the x-rays I divided up into three main categories, that is,

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airspace, interstitial, and finally indeterminate or bronchopneumonias, and again my theory kind of breaks down here, because if you look at it within the sites, if you look at the types of pneumonia within the sites, there is really no significant difference between the three. Well, I got the 52 area, the 31 area, and all of the areas on base, and there are 14 other areas on base, but you can see that my hypothesis sort of breaks down here, but still there are more airspace pneumonias coming from the 52 area. Next slide.

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This shows some of the same data. Next slide. I want to show you this, real quick. Rick, can we show this one overhead? This is some of the raw data, and a lot of the conclusions are confounded by the fact that there are a significant percentage of x-rays that I have not reviewed. As you can see, there are 33 from other areas, of x-rays that so far I've not been able to locate or review, so a lot of the data is confounded by missing data points.

You can see, from January '93 to now, there have

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been 307 patients entered into the pneumonia surveillance study. Now, not all those had pneumonia. Some of them, a significant number, had normal chest x-rays, as you can see, so not all those are pneumonias, but even given that, I think that the numbers of cases of pneumonia are striking, and, you know, again, I think historically this is a huge pneumonia epidemic. Can you lift it up some, now?

This is the percentage of total pneumonia cases by site, and again you can see that it's the 52 area where

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the pneumonia is primarily centered, with 60 percent of the cases coming from there.

We've been hampered in our efforts to put an end to this epidemic, by no resources. We have tried many approaches, without success. My feeling as a clinician, and knowing the history of the epidemic, and seeing the clinical presentations, I still feel that Strep pneumoniae is the most likely agent, but I have really no data to support that, other than my own clinical suspicions, and knowledge of some of the data from 1989, which showed, I

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think more convincingly, that it was Strep pneumoniae.

 This year, we've had, from the period of January of '93 to the present, we've only had seven sterile site isolates. One of those was spinal fluid from a patient who had Strep pyogenes, a pleural pulmonary infection, and there was a Strep pyogenes isolated from the pleural fluid of another individual with Strep pyogenes empyema. There were five isolates of Strep pneumoniae. Only three of those actually came from the 52 area, and they were all different serotypes.

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So there's really no basis for us to design an intervention in the epidemic. I'm very concerned, as a clinician, knowing the morbidity of this epidemic in the past, if we don't act in some fashion, one, either to design a study to determine the actual etiologic agent, or the other option would be, I think, to act on a clinical hunch, and give pneumococcal vaccine, but the people who have the wherewithal to give us the money for the pneumococcal vaccine are a little bit loathe to invest that kind of money in that sort of mass intervention,

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without better knowledge that it would work, and who can blame them?

On the other hand, we are hampered by lack of funding for the necessary science to come up with an answer that would satisfy them, so we are in a classic Catch-22 situation here, and the reason I am before you is to make a plea for your support, in helping us obtain the necessary resources.

PRESIDENT DOWDLE: Yes, Captain Ledbetter.

CATHERINE LEDBETTER

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MS. LEDBETTER: Captain Ledbetter, NEPME5. One of the comments I failed to make yesterday was that the pneumococcal isolates from the 52 area were all vaccine-preventable. They were serotypes that are covered by the vaccine, and I think that's worth knowing; we have been lucky that way.

We have not been quite as lucky this year, if luck indeed is what it takes, but if you'll recall the dramatic drop with the intervention in 1992, we haven't seen quite that dramatic drop this time. Our intervention

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has been a little bit slower kicking in this time this time, but we've had five more pneumonia cases from the 52 area in the last two-week reporting period, and it's down from the 14 and the 10 range, but it's still not down to where we'd like to see it. So there have been five, even though we are beginning our intervention there. Thank you.

PRESIDENT DOWDLE: It's very difficult, of course, for this Board to have any influence on resources. That has not been a strong point of ours. However, I

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will say that the Board would be very glad, I'm sure, I think I can speak for the Board, by saying that if we had a formal question on this to the Board, regarding strategy, we would certainly be very glad to respond, and I'm sure it would be helpful.

Doctor Kuller.

MR. KULLER: I'm still a bit confused. As I understand it, you don't give pneumococcal vaccine at the present time, even to the troops that are going into area 52?

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MR. REYNOLDS: Well, we've done it on an intermittent kind of basis. We've done up this intense surveillance, and when we get anxious that there's going to be a peak, then we tend to intervene, and pneumovax is only given here by the MCRD now, but we don't give it regularly. We don't have the money to do it, you know, on a constant and continuous basis.

MR. KULLER: From a clinical perspective, though, your own perspective, if you had the money and could give the vaccine, would you give the vaccine?

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MR. REYNOLDS: I would recommend that it be done, yes. I mean, I think we need to either design a study that identifies the agent, so that we can give a logical intervention that would be expected to work, or we play a hunch, a clinical hunch, based on data in the past, that pneumococcal vaccine will work, but we're doing neither now, and we're continuing to see large numbers of pneumonia, and my feeling is we need to do something.

PRESIDENT DOWDLE: Yes, Doctor Schaffner.

BILL SCHAFFNER, VANDERBILT UNIVERSITY

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MR. SCHAFFNER: Well, we've heard two fascinating presentations this morning, so let me separate first the apple from the orange, and go back to the Tubersol/Aplisol prospective study. The difference between those two skin test antigens has, as was said, been noted by others, and is causing all kinds of mischief, as people all over the country are trying to cope with the increased concern about tuberculosis.

I have not seen another clear prospective study in which the two agents were actually tested

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simultaneously, in the same population, in a population of this size. It's really important that that information be brought together and published, and brought to the attention of the Food and Drug Administration.

The FDA has been notified about this discrepancy by others, and I don't know that very much is being done at the present time. I'm happy to help in any regard there, because I think that's a real finding, and it's an important one.

Apropos my comments about the occurrence of

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pneumonia at Camp Pendleton, we're putting labels on it, and I think we've got cart before the horse. We're calling it an epidemic, and we're calling it, putatively, pneumococcal, and certainly there are bits and smidgeons of evidence suggesting that. As a new member of the Board, I want information.

If Camp Pendleton were the state of Tennessee, and this kind of circumstance were happening in one community, I guess after local folks tried to deal with it, and were left with the kind of conundrum that you

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have, some phone calls would be made, and I would think that the State Health Department would be able to respond with some sort of epidemic assistance, and, if the State Health Department couldn't manage it, there would be another phone call made to the CDC, and perhaps some sort of epidemic aid would be arranged, so that the parameters of the problem could be defined, and some epidemiologic analysis performed, which, with all due respect to the obvious efforts of the clinician, usually add things to the information already provided. I don't know what the

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resources in the military are, so I'd love to know what happens, under circumstances like that.

MR. CUNNION: This was addressed to me, and I took it up to the Navy R and D Center, which took it over to the Joint Services ASRAM (phonetic) Committee, and they said it was nice, but there wasn't any money in the budget for respiratory disease research. So we took it to the Marine Corps, and the Marine Corps can only fund medical research that has to do with equipment; that's according to the regulations. They can test new military equipment

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that has to do with medical, but they can't fund pure medical research, so that was out.

We went to the clinical investigation people, and they didn't have the money. We were asking for a minimum of \$40,000 to start a surveillance program, and we just went around and around. Everybody was passing the buck. Actually, one time the R and D says, "Well, make it into a half-million-dollar research protocol, then you have a chance." We tried that, and that didn't work, either. So we've been spinning our wheels on this. We

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just can't get anybody to pay attention.

PRESIDENT DOWDLE: Why is this a research program? Why is there research?

MR. CUNNION: Surveillance, this is the problem. The clinical people say it's research, the research says it's not research, so the trouble with surveillance is that no one is willing to pay for it. The R and D community is not willing to pay for it, because they claim it's not research. The clinical community says it is research, and they won't pay for it.

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MR. REYNOLDS: I can't tell you how penny wise and pound foolish that is, because the numbers of pneumonias admitted to Camp Pendleton, over the years since 1989, if you cost that out in terms of hospital days, that's an incredible amount of money. Also, there are economic impacts that is directed towards the people operating the training out of the 52 area. When they lose somebody from training, and have to start them over again because they were admitted to the hospital, that's an expensive proposition as well.

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You know, I understand that there are various different pots of money, and it's hard to get all those pots together, but we do have a major problem, and I agree that we need help from a scientific and epidemiologic standpoint, to help us design an appropriate intervention.

PRESIDENT DOWDLE: There are some other questions around here, very quickly. Doctor Gwaltney.

MR. GWALTNEY: I think you're doing an excellent job in your surveillance, even though you're only a doctor, a treating doctor, or whatever you said, but I

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disagree with one thing that you did say, which is really not correct. It is not an agent. There's no place on earth where one agent or group of agents causes pneumonia.

What you've got is a situation where, continuously, you're having rhinovirus infections, coronavirus (phonetic) infections. They're coming through this population all the time. Superimposed on top of that is influenza, respiratory sensitia virus, mycoplasma, and, in addition, then you've got the bacterial causes of pneumonia.

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The epidemic you had of type one pneumococcal pneumonia is unusual. It's really quite an unusual episode. I don't think you've had that since then. Your data show you, unless your labs quit being able to grow pneumococci, or you're not collecting your specimens right, I'd believe what your data is showing you. That came through there, that was an episode; it could come back.

What you need is what we used to have, which was called a commission on acute respiratory disease, which

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capitalized the research and preventive efforts at a level that was commensurate with the difficulty of the problem, and unfortunately you're one of the few places, as I understand, in the military, where pneumonia is a major problem at this time, and if other bases were having it, I think they'd pay you some attention.

MR. REYNOLDS: The serological testing during '89, that is, the first year of the epidemic, did show a trend toward increased paraflu (phonetic) on the serology, so your first point, about maybe there is no one single

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etiologic agent, is well taken. One of my theories as to why the sterile site isolates have dropped off is that, as I told you before, we have a really intense program of surveillance here now, and everybody, all the providers, are very attuned to the pneumonia problem, and they are very cooperative in getting chest x-rays on people they suspect pneumonia as part of their diagnosis.

So we get these patients much earlier than in 1989 and '90, and they get admitted, and they get an antibiotic therapy very early in their course, whereas, in

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1989 and '90, we saw people who were well into their illness before we were able to treat them, and therefore I think we had a little easier time getting sterile site isolates, because they were sicker. Their organism load was higher, and the chance of getting documented bacteremia was better.

That is a theory that I've used to explain why the drop in the isolates, but I must agree with you, that I have also suspicions that maybe it's not the same epidemic that it was in 1989, that there's other causes.

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PRESIDENT DOWDLE: Okay.

MR. ASCHER: I'm confused. The resistance to administer pneumococcal vaccine is based on the --

MR. REYNOLDS: Financial, basically.

MR. ASCHER: Well, you know, the principle of the vaccine, based on its polyvalency, is that this is part of the overall picture, as Doctor Gwaltney says. Pneumococci are in this package of all the pneumonias. It's the most severe one, that has the worst complications. It's preventable. It's justified. You

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can't necessarily justify it on how many sterile site isolates you got, or showing epidemics, which may or may not occur from time to time, but it's preventable, so if you ask the Board, do we recommend pneumococcal vaccine at this point, the answer will be yes.

PRESIDENT DOWDLE: Captain Ledbetter.

MS. LEDBETTER: Captain Ledbetter. Just a quick comment. We did bring this question before the Board a couple years ago, when the Board composition was different, and the response we got at that time was, "Get

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us more information. We don't have enough information to recommend pneumococcal vaccine." We feel very strongly that we can't get the information. Commander Gray, among others, has designed a study that would give us answers, but we truly can't seem to find funding.

We have made the steps and tried to these things. We've got a surveillance team who does very aggressive surveillance for these people. We stack up our numbers, we look at 805 cases, and we say, "Oh, my God." But yes, we're very happy to have the support to say, "Go

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ahead and use pneumococcal vaccine," because that's been a problem in the past. Thank you.

PRESIDENT DOWDLE: Captain Cunnion, your presentation is going to have a bearing on this; right?

MR. CUNNION: Yeah, I have a letter here which Commander Gray --

PRESIDENT DOWDLE: Before I call on you, I wonder if I could ask Doctor Benenson if he would like to make a comment. You've been awfully quiet this morning; a little institutional memory, here.

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BUD BENENSON, SAN DIEGO

MR. BENENSON: Well, there are several things. First of all, Jack, I think, will back me, that the whole mycoplasma business was first presented to the world at a meeting of the AFEB. Monroe Eaton used Al Koons' (phonetic) techniques of fluorescent antibody detection, so that the mycoplasmal problem originated in your group.

As far as the pneumonia here is concerned, I think this does provide an inordinately good opportunity to answer questions. Now, one of the things, my

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inclination at the moment would not be to give vaccine to all recruits coming. They're not recruits; they've gone through their -- half of them have. That's one of the limits that was not presented, and that is that, the area 52, these are recruits. They have completed their recruit training period, and then they go into this very arduous hardening phase. I think the Commandant of the Marine Corps at that time believed that every Marine should be a Superman, and this was the training to expose to it.

I do think there was some environmental factors

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that were disclosed in the original episode, and that goes all the way back to World War I experience, and that is respiratory diseases are transmitted very effectively during the sleeping hours, if respiratory tracts are close to one another, and there was a correlation between distance between the nose and throat of the two people in a pup tent, and whether or not they got the disease. Am I correct in that?

UNIDENTIFIED SPEAKER: That's correct, and intervention was taken.

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MS. LEDBETTER: Basically, it's head to toe now, instead of head to head.

MR. BENENSON: Right. So there is an environmental factor here. Now, the issue of vaccine, I think this situation provides an excellent opportunity to answer the question, and that is not to vaccinate everybody, but do a study on whether a vaccine is effective. Give vaccine to half of them, and a placebo to the other half. Now this becomes a research project, and I think it has to go through all sorts of Navy and

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Department of Defense approval phenomena, but Jack is right.

 This is a situation in which respiratory illnesses are being transmitted from one person to another, and I originally had said, "Look at the environmental situation." I say it again, and I think we can answer it, whether the pneumococcal vaccine will give protection, and is it worth doing? To give it to everyone answers no question at all. Is that what you want?

PRESIDENT DOWDLE: Thank you, Bud; appreciate

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that.

MR. GRAY: Commander Gray. I just want to say that we have proposed a clinical trial with several arms, including the pneumococcal vaccine and a placebo, erythromycin and benzathine. We've received the necessary waiver for I and D, and we're all ready to; we just don't have the resources. So our hope is today that you folks will agree with us, and the question that we're proposing, and endorse doing such studies to solve, or at least attempt to solve, this problem. It's going to be dynamic.

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I mean, each year the etiologic agents are going to change, so what we really need is a broad-spectrum intervention.

PRESIDENT DOWDLE: Okay. Thank you. Let's now turn to Captain Cunnion.

MR. CUNNION: Okay. I think everyone has it. It's labeled "Draft"; it wasn't meant to be. I faxed this over earlier last week, and then I took off for Lunar New Year, and then Friday had to -- so I never got a clean copy sent, or I thought I was going to bring one.

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I would like to raise the question that Doctor Gray is proposing here, on the first page. Considering the history of past morbidity and mortality that bacterial respiratory pathogens have cause among military populations, and the recent emergence of new bacterial threats having epidemic potential, would the Armed Forces Epidemiological recommend that, A, the services conduct surveillance for new bacterial respiratory disease threats, and recognized bacterial respiratory disease threats which are now antibiotic-resistant or have

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increase in virulence among high-risk active duty population; B, the services conduct clinical research trials of prophylactic agents, alternatives to benzathine penicillin G, among high-risk active duty populations?

The following pages are background of some history and some attempts to get funding, even outside the military, including NIH and CBC.

PRESIDENT DOWDLE: Okay. Further discussion?

MR. KULLER: It seems like there are two problems here. One of them is an acute problem, which is

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a recurrent ongoing epidemic, and what should be done to basically -- seat-of-the-pants approach, you might say, to reduce the likelihood of severe morbidity occurring. It seems to me that that's a question of what's the public health direction to go. The second one is really a very important research question, and that seems to be how to deal with the problem, and try to have a better understanding.

I guess the two are linked through the idea of doing trials, but it seems to me that there are two

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problems here. One of them is a very acute problem, and fortunately there's been no fatalities, but I presume if we -- and maybe you could say it's a sad commentary on life, that if there had been a fatality there wouldn't be a problem, because the money would have been available to solve it, but it's a sad commentary the way we do things.

You have to wait until you have a disaster before you have any help.

So I think that we have two problems here, and I'm not sure whether we can put them both together, or

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whether they're two separate issues.

MR. ASCHER: The point being, from Doctor Gwaltney's comment, that if you eliminate the pneumococcal threat, you still have a hell of a problem of respiratory disease in these people. That's the point, and it really is that.

PRESIDENT DOWDLE: Doctor Gwaltney.

MR. GWALTNEY: And it's very hard, in such a complicated problem, to really understand. What about adenovirus? Do these people get adenovirus vaccine? Have

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they been vaccinated? I mean, there are all kinds of things you need to know, before you really can make recommendations, in terms of interventions that you hope would be effective.

PRESIDENT DOWDLE: Okay. Yes, Doctor Poland.

MR. POLAND: For that reason, why limit it to bacterial respiratory disease threats? There are reasons to think that there are other organisms, and even effective interventions for those other organisms, if we knew they existed.

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PRESIDENT DOWDLE: Okay. Yes, Doctor Perrotta.

MR. PERROTTA: I was just going to say that letter A looks very much like -- pathogens that CDC is bringing up, and I would agree with Doctor Poland. Why limit it just to bacterial? That, perhaps, helps separate, as Doctor Kuller said, the local problem versus the larger problem. Maybe the local problem is a bacterial one, although -- plenty of discussion as to -- may not be that, as well.

PRESIDENT DOWDLE: Okay. Doctor Chin.

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JIM CHIN, SCHOOL OF PUBLIC HEALTH, UC BERKELEY

MR. CHIN: I see no problem to the Board saying, "Yes" to the following of those questions, but my question really is, then, what happens after that, because things just go on and on.

MR. CUNNION: The point of this is that, if the Board says, "Yes," because this is -- well, I hope it doesn't go this far, but we had the same problem with JE vaccine. In 1988 the Board recommended the use of JE vaccine, and we couldn't sell, so we had two vegetables in

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the Marine Corps, two years ago, and then we instantly got the money, and now the program is in effect, from now on, but I hope it doesn't go that far, but we are laying the groundwork so, if this doesn't work, and we use the JE as an example of what happened in the past, maybe we can move it before we have disasters.

MR. ASCHER: You know, penny wise and pound foolish. Early antibiotic treatment and hospitalization of pneumonia is not cheaper than vaccine. It essentially comes out of two different pockets here; that's one of our

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biggest problems.

PRESIDENT DOWDLE: What I would suggest that we do is take this issue up in the executive session. There are two questions, now, that we need to take up. So let's move on, then, to the Persian Gulf update. We've already had some discussion of this, early on, and Captain Berg, some of the work that's been ongoing with Captain Berg and the Navy Reserves.

WILLIAM S. BERG, UNITED STATES NAVY

MR. BERG: Thank you very much; I appreciate it.

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Good morning. My name is Bill Berg, from Preventive Medicine Group Two. I think this report has become superfluous, because we have the answer in the Sun. This is germ warfare using a mutant strain of influenza, which is going to be worse than AIDS, according to a WHO spokesman, and there are government warehouses for thousands of people, and it's all in here, and I'll let you read afterwards.

At the last meeting, I reported the results of our visit to two detachments of CB Battalion 24, those in

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Asheville, North Carolina, and Columbus, Georgia. That was from a year ago, 1992. This past fall and this month we revisited those two units, and we also went to two additional ones. Next slide, please.

The units that we visited are Asheville, number 1324, where we were able to interview 95 percent of the veterans; Columbus, number 1624, where we were able to interview 70 percent; and more recently Atlanta, Georgia, 1124, where the participation dropped off to 46 percent. Doctor Hayashi (phonetic), the head of my epidemiology

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department, is down in Knoxville, interviewing detachment 624, and the participation has gotten up to 56 percent. One of the things that we are running into, at least in this battalion, people are dropping out of the reserves, and they're very difficult to have access to. Next slide, please.

This is from the Asheville detachment, the 10 most common symptoms as of last November. The order has shifted around somewhat, but I think what may be encouraging is that, this column here, a number of the

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veterans reporting those symptoms have gotten better, and a number of them have reported that the symptoms have gone away altogether. Next slide, please.

If we look at the specific diagnoses of this group, 34 percent have a verified diagnosis. We asked them, "What illness do you have?," and then we went and looked at the medical records to try to verify this. A little under half, 10 out of 21, have a psychiatric illness. There are some diagnoses that are being attributed to Persian Gulf illness. We found two of

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those, a cancer of prostate and a case of hyperthyroidism.

Both of those had been detected a year earlier. We knew about those. No cases of hepatitis or HTLV-1, although very few of them were actually tested for it.

Ten veterans had 11 psychiatric diagnoses. Interestingly, two of them had post-traumatic stress disorder. Four of them had an adjustment disorder. All of these were seen by a psychiatrist, who made the diagnosis. Now, he wasn't strictly going by the DSM, we know, because, for example, adjustment disorder is only

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good for six months, and you have to -- something else.

Our psychiatric consultants tell us that some psychiatrists are very fussy about how they diagnosis post-traumatic stress disorders, and others just sort of eyeball it, and say, "Yeah, that was it," but I think the take-home message is that, at least in this group, there is a certain amount of psychiatric morbidity. The chronic fatigue syndrome, we knew about a year ago. Next slide.

Cardiovascular, gastrointestinal, ENT, nothing here that really stands out. This is a somewhat older

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group. What is interesting, in all of the detachments so far, there has been a certain amount of sinus infection reported. I don't know whether that has anything to do with Persian Gulf, or whether it's just a handy diagnosis.

The individual with the heart valve replacement, you'll recall, had endocarditis during Desert Storm. Next slide.

Genitourinary, musculoskeletal, endocrine, again a potpourri of diagnoses, nothing that really stands out.

The herniated disk, again we knew about that last year. He became symptomatic after return, but was certainly

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doing a lot of physical labor during Desert Storm that could have contributed to this. Next slide, please.

Okay. Now we have shifted to the Columbus detachment, 1624. We were able to interview 70 percent of those. A number of them have dropped out. We tried to contact them, the 12 who would no longer drill and the four who were pending, but things are not looking very optimistic for follow-up, and, as you can see, one of them died.

This is a very unique group. It does not

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hesitate to talk to the media. You have seen many of these people on CNN and elsewhere. They are quite frank, saying that they use the media to advance their cause. They are now beginning to think that the media is using them a little bit.

There is extensive networking, not just among themselves but nationwide. I talked to one of these individuals, who said, "You asked us about cancer cases. Why, in the space of a week I was able to talk to 300 veterans who have cancer, cancer of the brain, cancer of

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the pancreas, cancer of the kidney." It's easy; there's cancer everywhere. We'll get into a little bit of what may be going on here, I think, later.

All of them are convinced that they were subjected to chemical warfare, and many of them have really strongly bought into a conspiracy theory that the government is covering this up, and that our visit down there was part of the coverup, to sort of whitewash all of this, and this is Eric Hoffer's (phonetic) true believer sort of mentality: "Yes, there was chemical warfare

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there."

Further exacerbating the situation is a physician they have access to, who has told them, "You were subjected to chemical warfare, and this is why you are sick." He has told them, "You were infected with HTLV-1, and this is going to cause cancer, and you've given it to your wives, and they're going to get cancer."

The sad fact of this is that all of the HTLV-1 tests were really negative or at worst indeterminate. Next slide.

These are some of the diagnoses. The Persian

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Gulf syndrome was made by the physician I just talked about. He has no diagnostic criteria for this; it's just, "You're sick, and you were in the Persian Gulf." We'll get into some of the others in a little bit more detail. The dermatological, there was one sort of nondescript, not very impressive rash that the dermatologist couldn't give a label to, and a couple of cases of tinea pedis.

The non-Hodgkin's lymphoma, we knew about a year ago. This is important, because the dogma among this group is that the VA made this diagnosis, but did not tell

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him. It was a little bit more complicated than that, but, adding to the HTLV, the one situation, a lot of the veterans in this group and elsewhere are convinced that somewhere in the VA record is a cancer diagnosis with their name on it; they've just not been told yet.

A lot of these people have garden variety lymph adenopathy. The doctors in the area are not convinced by it, but one of the reservists was able to talk to a doctor, and convinced him to do a biopsy, and came back reactive hyperplasia, which is hardly surprising, but I

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think this is part of what's going on. People are confusing adenopathy with diagnosed cancer. Next slide, please.

Gastrointestinal, pulmonary, musculoskeletal; the pulmonary cases are all smokers, not surprisingly. There are 12 gastrointestinal diagnoses, but one individual accounted for five of those, and one for three of them. Next slide.

Okay. This is detachment 1124 in Columbus, that we just interviewed about three weeks ago, four weeks ago.

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Relatively low turnout here, 46 percent, came to the drill weekend, that we were able to interview.

UNIDENTIFIED SPEAKER: Not Columbus.

MR. BERG: I'm sorry, Atlanta. Yeah, 1124 is Atlanta. Thank you, Steve. This has some interesting characteristics. This group does not talk among itself, and we sent the chief petty officer down, and he was disgusted, because the senior enlisted people in the group were not looking out for the junior enlisted people, and the feeling is that, had they had more of a lookout for

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the people, and encouraged more group talking and getting together, some of these illnesses might not have been there.

The group basically took off for three months after they came back, and did not drill. My own feeling is that this could have been detrimental, based upon some of the other people we've talked to, and my experience at the Center for Prisoner of War Studies. I think the last thing we want to do is bring people back from a very intense emotional experience, and then just let them go

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their own way, without some sort of depressurizing.

Interestingly, they are different from the other detachments, where there's an awareness of the VA registry, but many people are saying, "I don't want to have anything to do with the VA." Many of these individuals were not even aware of the VA registry. Next slide. That's just the symptoms, just for information. Next slide.

One psychiatric diagnosis. This was an individual who came back from Desert Storm to find his

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wife had been having an affair. There was a divorce, a custody battle. He was railroaded out of his job, he filed for bankruptcy. So, not surprisingly, he was depressed.

The other diagnoses are, again, a mixture of things. The polymyositis is interesting. I don't know whether that has anything to do with Desert Storm. The diarrheic individual has been worked up; no etiology. We again have two sinus infections, and no cancer cases. Next slide.

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I just talked to Doctor Hayashi, who is down in Knoxville. About 46 percent of the individuals have medical diagnoses there. Again, it is a hodgepodge of things. Interestingly, there is one individual with focal nephrosclerosis, and three individuals with sinus infection; no psychiatric diagnoses, no cancer.

MR. SCHAFFNER: Bill, excuse me. The person with polymyositis, is that a biopsy-proven diagnosis, do you know, or is that a clinical impression?

MR. BERG: That's a clinical impression, not a

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biopsy.

Okay. What we are doing might be sort of micro-epidemiology. This is not the sort of study that needs to be done, but we're responding to requests from the Surgeon General and Congress and DoD, to sort of find out what's really going on there, as opposed to what CNN is saying, so the conclusions are fairly tentative.

One of the things that's hindering us is that there is no standard evaluation for these individuals, and so, even though we may not have much hepatitis, many of

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them were never tested for it, for an example.

There's also a lot of variation from detachment to detachment. We went down thinking that they were all going to be the same, and they're not. The attitudes towards the whole process and their experience varies quite a bit.

A minority have been given some sort of psychiatric diagnosis. So far, all of them that have seen a psychiatrist have a psychiatric diagnosis, but there are two caveats for this. First, of all, there are a number

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of individuals whose evaluation is pending, and we have to go back to see what the result of that is. The second caveat is that all of these, except for the individual at Atlanta, are from Asheville.

The next point, a large number of them are symptomatic. Many of them have more than 10 symptoms that they rate as significant, but, in contrast, there's very little work time lost, so they're hanging in there and continuing to work. Another caveat here, though, is that these people, by and large, work in the construction

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trade. They have little in the way of sick leave, and for many of them a day off from work is a day without a paycheck.

Fear of cancer is common. My sense, without a control group or an extensive evaluation, is that the medical diagnoses are about what you would expect in this group. This group is about 10 years older than the active duty group. The mean is about 39, and many of them are in their 50s. Next slide.

I'm going to change gears a little bit here.

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Task forces and working groups and coordinating bodies are proliferating in the beltway like mushrooms after a rain, and I'm on some of them. One of the questions that comes up is, "What is the Armed Forces Epidemiological Board doing?," and I volunteer that the Board is aware of it, they're aware of the study that the Army did on the 123rd RCOM (phonetic), and so one, and stressing, of course, that I'm not a spokesman for the Board, but I think it would be useful to present to you who the four major players are.

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The first one is the Defense Science Board Task Force on Gulf War Chemical and Biological Exposure. This was an attempt to bring in outside experts, very credible, to look at the CW question, and hopefully say, "There's no evidence of this," and lay this to rest. Whether it will work out that remains to be seen. The chairman of this is Doctor Joshua Lederberg. The charter has expanded to include all health effects, and they are in the process of reviewing all of the data that is available. This science board is to terminate somewhere in the summer, after

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issuing a report.

The second group is the Institute of Medicine/National Academy of Sciences, which has chartered a committee to review the health consequences of service during the Persian Gulf War. They are primarily focusing on the VA registry and the DoD registry and other data, first of all to look at the adequacy of the registry and make recommendations, and second to make recommendations for additional epidemiological studies that need to be done. This committee will be in existence for five years,

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and issue an annual report.

The next two are sort of coordinating bodies. The Persian Gulf Veterans' Coordinating Board is a tri-agency, the departments of Veterans Affairs, Defense, and Health and Human Services, chaired by the VA. This is mostly to make sure the left hand and the right hand are talking to each other, and nothing gets lost between the cracks in the government bureaucracy.

Finally, the fourth group, paralleling the Persian Gulf Veterans' Coordinating Board, is the Gulf War

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Veterans' Health Matter Steering Committee, which is an intra-DoD body, looking at much the same sort of thing, and coordinating it.

So those are the four players, and of course within each of them there are committees and subcommittees, ad nauseam. That concludes my remarks. If there are any questions, I would be happy to answer them.

Post-traumatic stress disorder, particularly out of Vietnam, but there haven't been any that really looked at symptoms. The symptoms of post-traumatic stress

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disorder are more geared towards anxiety and startle reactions and so on. The symptoms that we're seeing here are more suggestive of, to me, if anything, of depressive symptoms, and the psychiatrists tell us there's sort of a distinction between anxiety and post-traumatic stress disorder, and depressive symptomatology, so we really have not seen this in other groups, but nobody has really looked at it, at that particular level.

PRESIDENT DOWDLE: Yes.

MR. FLETCHER: Doctor Gerald Fletcher. I have

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really enjoyed this. I think a lot of this, in the older population, probably had many preexisting problems. Do you have much data on the past history of these people, like emphysema, hypertension? These are preexisting problems, I'm sure.

MR. BERG: We have tried to exclude the ones that were clearly preexisting, but yes, a number of them had preexisting hypertension and high cholesterol. None of them were terribly sick, because they are in the reserves, and there's a certain variation. You can have

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high blood pressure and be on medicine, and so on. Anyone with significant illness, by and large, would be dropped out of the reserves. This is not entirely -- there were certainly people we got over there, and found simply not fit.

PRESIDENT DOWDLE: Colonel Parkinson.

MR. PARKINSON: I just wanted to reflect on something, a conversation that Doctor Ascher and I had yesterday, while we covered the 30 miles back and forth between the three sites, at the medical school training

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site, and that is to look at this phenomenon as perhaps reflective of a totally new way the DoD is doing business, in the total force concept. To my knowledge, Desert Shield/Desert Storm represents the first time that we massively mobilized reservists, in the numbers, and with the speed and rapidity, unlike previous efforts.

I think, as we move towards a total force, looking at the preparation of individuals, both physically and emotionally and socially, pre- and post-deployment, I think this may be a good event, although it's coming to us

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in a medical guise, medical complaints, because, for a lot of reasons, those are more socially acceptable, perhaps, than other ways of expressing stress and coping mechanisms.

That's not to say that we don't have to investigate it thoroughly, but unfortunately we're now well beyond the case of -- well downstream of doing what we should have done in the first place, is detecting whether or not we truly had a case. This was an outbreak. We never defined if we had a case, and now we're

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downstream with committees, and with investigations, and with physical examinations, without defining the case up front.

More importantly, what's the phenomena that we're really describing here? I think it has a lot to do with our use of the reserve forces, the disproportionate reporting of reporting of the syndrome in the reservists versus the active duty, and that's not meant to sound pejorative, but as a phenomena we need to study systematically.

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PRESIDENT DOWDLE: Doctor Ascher.

MR. ASCHER: I want to enlarge on that a little bit, and Bill and I had a conversation at lunch as well. Make sure that everyone understands that reservists do not have health benefits in our present system, and the amount of time that they're supported after demobilization is how long?

MR. BERG: Basically, until they are demobilized. There is a physical exam, and if there's any illness or medical problem they are retained on active

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duty.

MR. ASCHER: What rang a bell was your comment of the fact that they really don't have a process to sort of transition them back, with the support, and I think that is the symptom that Doctor Tomlinson talks about, where the people are brought back, and just dumped back onto the civilian sector, with no support, no access to health care. Even if they have headaches for a while, they don't have any access to get treated; it's not in the system. They have to go through the VA, and they have to

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activate all sorts of pathways that are just not there.

So I think, as we hear, and I'm in this as well, as we add more of the support in the reserves, we have to develop a system to carry the reserves back into society in a more organized way.

Now, being personally in a unit that was mobilized as a surprise, we were not prepared, because the plans for the mobilization did not include our unit. It was changed at the last minute, so this was clearly a new thing, but it was also a surprise, and my unit did very

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poorly. They were supposed to go over; they didn't. They came back, they got stuck in Colorado, and it was just all the usual things, but we haven't gone and asked them questions. Many of them are angry; I know that.

PRESIDENT DOWDLE: Other comments?

CAPTAIN ARTHUR, UNITED STATES MARINE CORPS

MR. ARTHUR: I'm Captain Arthur, from Marine Corps Headquarters, Director of Medical Programs. There is one way a reservist can retain their ability to seek medical care, and that's through the VA, if they get a

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diagnosis that is service-related or service-aggravated to a significant extent while they were on active duty. They can get treatment for that ailment through the VA, but not get global health care through the VA.

Another factor with the CB units is often they don't go through basic training. They don't go through boot camp. They are construction workers who have a union card, and are accepted in their profession as builders or heavy equipment operators, and they come on active duty without really going through the usual boot camp, and the

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boot camp offers the young sailor or Marine an introduction to the armed forces that these folks haven't had. They didn't anticipate that they would go to war. They didn't anticipate the conditions; they'd never been in the conditions. They'd never been in the arduous field conditions, so I think they were set up to not be adjusted to them as well as the regular active duty, or other reservists who have gone through boot camp. Thank you.

PRESIDENT DOWDLE: Any other comments? Doctor Harlan.

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MR. HARLAN: Harlan. The Veterans' Administration has now given a diagnosis, so that people can present themselves, and be seen, and be evaluated, and that diagnosis allows them to also receive treatment benefits, and the other things that come along with having a diagnosis.

MR. ASCHER: But if they had six months of access to military medicine on the way back out to civilian life, they can get their headaches and their stiff necks and their tummy aches cared for, in a way that

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would transition them, and they wouldn't have to get a label of some VA diagnosis, which is a nightmare.

MR. HARLAN: Well, I think the real problem is the VA only in the past, I think it's two or three months, has actually given this label, that allows them to come in, and allows them to come in with complaints, and to be evaluated, so they went approximately what, a year-and-a-half, I guess, before they had the opportunity to do that, and it was grudgingly given as well, so that, to these individuals, no one appears to have been particularly

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interested in what happened to them. Neither the armed forces were interested, nor the Veterans Administration. The Veterans Administration belatedly is interested. So I think there's a great deal of anger and hostility.

MR. BERG: If I may make one small addition, I'm not sure the VA has actually made a diagnosis. I think what has happened is that any Persian Gulf veteran who is ill, and feels that it was due to that, can come in and get evaluated and treated for it. I don't think there's any sort of diagnosis yet, and this is important, because

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there's lots of loose talk about Persian Gulf Syndrome, and similar things. There's no diagnosis anywhere of this syndrome. Doctor Sanford is working on an operational diagnosis that will probably be geared more towards compensation and disability pension purposes than any sort of clinical diagnosis.

PRESIDENT DOWDLE: Thank you. As we discussed yesterday, it's not too clear, exactly, what the Board might do, particularly with all the other commissions that we've got going and all the other groups. However, we

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would certainly be glad to do whatever might prove to be useful. We'd certainly be glad to do that, but I'm not sure that we would want to jump in and start something that's totally redundant.

Okay. We have come to the end of the agenda this morning, and it's now time for the executive session of the Board, and I should point out that the executive session, of course, is open, for those of you who would like to stay. What I would suggest is that we take about three minutes, no more than that. We've got to get back

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here and get started, so take a couple minutes; be right back.

(Whereupon, a brief recess was taken.)

(Executive session.)

PRESIDENT DOWDLE: Can we reconvene, please? Okay. There's two questions that have come before the Board, and I guess we might say a question that -- I'm not sure it has formally come before the Board yet, but certainly one that we are well aware of, so we need to deal with those, and then there are a few other issues

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that we need to take up, as well.

First, I'd like to ask Mike if anything should be brought up in the way of announcements, and then if you'd say a few words about the questions, and then I would suggest that in dealing with the questions I'd like to ask Lou Kuller to take the initiative here, because obviously he's the one that's actually dealing with them, and so -- appreciate it. Mike?

MIKE PETERSON, EXECUTIVE SECRETARY, AFEB

MR. PETERSON: Probably one thing we need to

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consider, and I need to give you some background on, is, as we've transitioned into an entirely new Board membership, one of the things we have not done as a Board, that we need to do sometime in the very near future, is appoint chairpersons of each of the subcommittees; that's disease control, health maintenance, and environmental quality.

According to that AFEB charter, that is supposed to be done on an appointment basis, by the President of the Board, and so we can either take volunteers, or you

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can leave it to Doctor Kuller and I, or however you feel it should be done, but according to the charter it's supposed to be done by appointment by the President of the Board. So you might want to just give that a thought for a minute, and let me just review the questions, then I'll come back to that.

The last question, actually the first question we heard about, was relative to the formation of a subgroup to address the area of injury, morbidity and mortality in the military, and we certainly heard data,

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and have heard in the past, relative to that subject, and the importance of it. Bruce Jones has given me a copy of some topics. I have, I think, the only copy right now. I'll make this available to you. You got an overhead board?

UNIDENTIFIED SPEAKER: He's going to pass them out.

MR. PETERSON: Okay. He's going to pass them out. You might want to take a quick look at this. The question for the Board, though, is, specifically, "Should

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we form a subcommittee on a continuing basis, to address injury, morbidity and mortality in the military, providing advice and consent on an -- basis?" So that's the question to the Board, and I think, based on the data at this point, I think it's probably fair to ask whether the Board feels that such a subcommittee be formed.

I don't think there's probably much need for much discussion. Maybe we ought to take a show of hands.

All those in favor?

UNIDENTIFIED SPEAKER: This is injury following

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Bruce's board definition.

MR. PETERSON: Again, I think, once the subcommittee is formed, our purpose is to do this under the broad umbrella of the AFEB, and what we probably ought to do at this point, since the Board has formally voted to form the subcommittee, is maybe ask for a show of hands of Board members who would like to serve in that capacity, as members of this subgroup. Doctor Hansen.

Okay. So we have Doctor Perrotta, Doctor Hansen, and Doctor Karol. What I will do now is work with

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Bruce Jones and other DoD representatives, and come up with some additional members to the subgroup, who will represent expertise outside of the AFEB, but will represent expertise in this particular area in the United States, and they will make up the rest of the membership, and then I'll kind of turn the thing back over to Bruce Jones as the DoD liaison, and let him decide where to go from there.

I would ask all the Board members, in particular those who volunteered to be on the subgroup, to take a

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look at this. This is kind of an idea sheet, maybe a starting point. It certainly can be expanded, if you desire. Lou?

MR. KULLER: I was wondering, if this is essentially, as I see it, all issues related to surveillance, is there some interest in the Board also looking in terms of what to do about some of the injury problems? I mean, you presented some interesting problems. This seems to be focused primarily on improving surveillance, but not about any kind of implementation of

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preventive approaches.

MR. ERDTMANN: I certainly think there is lots of room for suggestions on specific preventive approaches.

It seemed to me that the broader, more important issue right now is establishing the foundation for ongoing injury prevention and control, which really means getting a good, sound basis in surveillance, that can be used for prioritizing programs and research priorities, but I didn't mean to exclude specific issues, but I thought that the generic issues were more important at this time than

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the specific issues.

PRESIDENT DOWDLE: Okay. Well, since you have the floor, why don't you go ahead and go into the second question, and did you have additional comments on the second question?

MR. PETERSON: No. The only thing I want to point out, maybe when -- get back the appointment of chairpersons.

MR. KULLER: I think the second question that we have today that was presented is really very broad, and I

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think it's also two specific questions. I think, from the viewpoint of the Board, perhaps, the most pressing question that we really need to deal with is the problem as it exists right now at Camp Pendleton. It seems to me that this is a very substantial problem that we heard about, and the Board needs, I think, in response to this, to at least be able to deal with that particular problem immediately, or at least in the immediacy, at least with some recommendations that we heard.

I think the second question is certainly the

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broader issue of respiratory disease, but I think that there is a really very substantial problem right now, and so I would think that the first thing the Board really should think about or do is perhaps look at a group within the Board, to make some fairly immediate recommendations, and to deal with Camp Pendleton, the pneumonia problem at Camp Pendleton, and the respiratory disease problem there, and then, secondarily, somewhat more leisurely, perhaps, deal with the issue of acute respiratory disease, and how to deal with this.

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The respiratory disease problem has come before the Board repeatedly, in the sense of the fact that there is clearly lack of interest and lack of funding of respiratory disease issues within DoD, as well as within the federal bureaucracy, but I think the first problem is a very serious one, and one that we really need to deal with very quickly, and be able to at least make recommendations that may help the people at Camp Pendleton or people within the branches of the services, to respond to this acute problem.

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MR. ASCHER: On the procedural side, if we get around the issue of being asked questions and responding, in the past, and in fact in recent history, the Board, or a subset of the Board, has served as ad hoc committees. We reviewed the HIV vaccine. There's sort of a standing tradition of doing a little recatsial (phonetic) work. Are you suggesting, or I will, that the service ask for a subset of individuals to serve as an ad hoc committee to review the problem, and sort of outside of the normal channels, and make recommendations, just as consultants to

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them? Is that appropriate?

MR. KULLER: Well, I think that that would be appropriate. In reading this over, it's obvious that there are two questions here.

MR. ASCHER: No, I'm talking about the first issue, only, the acute problem, to actually ask some people to go and help them with the acute problem.

MR. KULLER: Clyde Deese (phonetic) has conducted clinical research trials of prophylactic agents in a high-risk active duty personnel, and I think that

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that's, besides clinical trials, really needs to deal with the problem in these high-risk populations, but I would agree with you, so I'd appreciate any comments from any of the --

MR. PETERSON: Well, there may already be a mechanism within the Board, and that's what I addressed initially, and that's the disease control subcommittee.

MR. ASCHER: That would be the ad hoc committee.

MR. PETERSON: And I guess we're talking about the same thing, so it seems to me that's almost a natural

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way to do it, and kind of falls back on --

MR. KULLER: I think we should set a time frame, at least. I would like to see us perhaps make sure that the other Board members get some kind of a report back, within a relatively short period of time.

MR. ALLEN: How have the subcommittees worked in the past? Do we actually physically travel and get together, or is it primarily through mailing materials and conference telephone calls?

UNIDENTIFIED SPEAKER: All of the above.

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MR. PETERSON: Yes. Sometimes, for example during a two-day meeting, if the question is addressed on the first day of the meeting, sometimes the subcommittee will meet in the evening before the second day, and come up some type of a draft response to questions. That's one way to do it. In this case, the question, because of timing and so forth, and snowstorms and everything, didn't get addressed until the second day. Your suggestions, any one of those can be done, depending on to what degree the subcommittee chairperson and members need to have, in

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terms of time to take a look at the issue, and how much time they need to come up --

PRESIDENT DOWDLE: See, had this worked right, it would have been much simpler. There would have been a meeting last night, and then that subcommittee would have presented to the Board today, and then we would have gotten feedback on it, and the thinking process would have been quite different. That's the ideal way in which you want to use it.

MR. ASCHER: And for the big question, that's

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fine, but I'm saying for the short term problem, their epidemic in progress, could we just give them the hammer they need, by three or four of us taking phone calls, and you go back to your people and saying, "The ad hoc committee, or the subcommittee, said, 'Do it?'"

MR. PETERSON: Let me make a suggestion, maybe, just as a straw man (phonetic), and the way to do this is, the disease control subcommittee members, once a chairman is appointed, maybe can do that today, since we have the need to do it, and the chairman take the responsibility to

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canvass the members of the disease control subcommittee, and come up with a proposed response that then, through my office, can be circulated to the rest of the Board members, and probably within a period, I would think, of a couple of weeks, we should be able to get something back in writing, at least to the first part of the question, to the Navy, and therefore use the disease subcontrol (phonetic) through the chairman, and back to me as the executive secretary, to circulate to the Board members for comment and consent, and I think in a reasonable period of

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time have a response back to the Navy, at least to the first part.

MR. KULLER: That would be excellent --

MR. PETERSON: I guess the key to that suggestion, then, is the chairman of the disease control subcommittee. I'm not sure if everybody even knows for sure who the -- I think I've circulated this in the past, but let me just read it real quickly, since we're talking about the disease control subcommittee. It's Doctors Allen, Ascher, Bagby, Chin, Gwaltney, Poland, Schaffner,

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and Stevens. It's a large subcommittee; those are the members.

So I don't know how you want to work, but, like I say, by charter, that's your decision, to appoint. If you want to be more democratic, and say, "Do we have a volunteer?," maybe you can do it that way, but I guess we need to come up with somebody.

Mike, you want to do that?

MR. ASCHER: I nominate Doctor Chin.

MR. CHIN: I have to decline, because I'm not

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going to be around, periodically.

MR. ASCHER: For the record, the first part of the question is not this; it's Doctor Kuller's first part.

MR. KULLER: Right. I think my feeling is you could deal with the second part by the next meeting, and get us a report by the next meeting, on what we should do about the respiratory disease problem. I think the first part should be resolved very quickly by the committee, and then the channels that were just reported, and at least go on record by the Board of what the recommendations were,

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based on the information we heard today.

MR. PETERSON: So, for the record, then, I guess, Mike, it's understood that you're going to do both parts of the question, but in the order of importance?

MR. ASCHER: Yes.

MR. PETERSON: Okay. I guess the only other piece of business I have, since we're talking about chairman, this might be a good way to go ahead and get the other two chairpersons for the other two subcommittees, so let me read those to the members. Health maintenance is

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Doctors Fletcher, Hansen, and Doctor Sell. Doctor Kuller was a member, but by virtue of being President now we'll take him off, so I guess we're looking again for a volunteer appointee.

MR. GWALTNEY: I'll be on it.

MR. PETERSON: Okay. Doctor Gwaltney. Okay. And the other subcommittee is environmental quality, and that's Doctors Karol, Liu, Lucker (phonetic), Perrotta, and Schottenfeld (phonetic), so we have two out of --

UNIDENTIFIED SPEAKER: It's the last person to

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push back.

UNIDENTIFIED SPEAKER: There's two that aren't here.

UNIDENTIFIED SPEAKER: Doctor Perrotta volunteered.

UNIDENTIFIED SPEAKER: I thought I heard that, also.

UNIDENTIFIED SPEAKER: Loud and clear.

UNIDENTIFIED SPEAKER: I was going to ask you if you could be one of them.

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UNIDENTIFIED SPEAKER: I'm on more than one committee.

MR. KULLER: Where is the --

UNIDENTIFIED SPEAKER: Totally new committee for the accident surveillance, or is this going to come under --

MR. PETERSON: No, this is going to be a subgroup. The terminology gets a little murky here. On paper, we have three subcommittees, in our charter, and what we're talking about is forming a subgroup, much like

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the subgroup that we've already formed for HIV behavioral change, and for alcohol morbidity and mortality.

MR. KULLER: I'm wondering whether the other groups don't have much to do, whether the environmental quality group could not start out the accident surveillance -- at least as a starting point.

MR. PETERSON: Okay. Well, we did ask for some volunteers for that subgroup.

MR. KULLER: Okay.

MR. PETERSON: And we had Doctor -- but that

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broke down, and actually they represent two of those people -- represent -- so I think we're set. We have environmental quality representation on the subgroup --

MR. KULLER: I think one thing that I think would be useful for the Board, perhaps at our next meeting, might be to go over the minutes of the last four or five Board meetings, and perhaps get an update of what happened, I think, for a lot of people who don't have a memory of the last couple of years on the Board, or two or three years. It might be useful to just see what was

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presented to the Board over the last few years, and actually what's still current, what has happened, and what other issues that are background, what we've done over the past few years.

PRESIDENT DOWDLE: I might comment on this, as well. I think during the last two years, I think for those of you who have been around and associated with the Board for quite some time, you've seen some enormous changes in composition. You've certainly see changes in the Board in the number of people that have now been

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appointed. So, in a sense, you see, with Bill Harlan -- essentially an entirely new Board from four years ago.

I'm very pleased to have been associated with this evolution of the Board. I would hope that we can get some of the old-timers back on, after they've had the two-year lapse, to bring a little more institutional memory back to the Board, but I am extremely pleased, and I think we've got a Board now of sufficient size and sufficient quality to really deal with most of the issues that the services might wish to present to us.

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So I would hope, having made all these changes in position, the Board to be now available and ready, that the services indeed utilize the Board more, think of the wider ranges of issues that could be addressed, and also I would hope that the Board could be a little more assertive, to be honest. I mean, I think that there is room for that, and, as we've talked about this before, that there is no reason why we can't also bring up issues within the Board, and can't also initiate things here. We don't have to wait entirely for questions.

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It becomes a little more delicate, obviously, and certainly we can work with the services in posing whatever questions are needed, but it can be done, and I would hope that you don't feel constrained by just waiting on questions themselves.

So I do think you're certainly ready, and I think that a great deal of credit here goes to Mike. Mike has worked very hard, and I think Mike has done a very good job.

Before I get too far into a swan song, let me

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just ask the preventive medicine officers if they have any comments that they would like to make.

MR. CUNNION: Captain Cunnion, the Navy. I agree with your comments. I would like to see the Board more active. I think our problem is that we get bogged down with a lot of daily crisis management, and sometimes don't have a chance to step back and see a bigger picture, which you folks can see, and I would encourage that the Board come up with questions, and ask us, and go for it like that.

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We definitely have benefitted in the past from the Board's questions we've raised to the Board and their answers, because we occasionally need a hammer to hit our folks with, and the Board is definitely a very good hammer. Sometimes, like in the JE case a little bit late, but hopefully we can, by using that experience, show that the Board can predict these things, and you'd better listen to the Board, because if you don't we're going to be in trouble. So hopefully I would like to see a little more interactiveness, on both sides of the fence.

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MR. ERDTMANN: Colonel Erdtmann. I would certainly echo Steve's comments. I see the changing face of the AFEB as a positive thing, and I think the opportunities to bring some of the former members back is also a possibility that I would support, for the continuity issue that you mentioned.

I would have no problem whatsoever with the issue of the AFEB asking questions to the services about how we do business, to perhaps get us thinking more about possible questions. We would then ask you back. So I

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certainly wouldn't feel threatened, from the Army perspective, of having that happen. It has not happened very much in the past, and I would encourage it.

We can still, if we don't have good answers for that, maybe that actually will generate the need for us to do some more work, to get better answers for you, and then to move forward with the issue.

My last comment would be that I personally am sorry to see you leave. Your leadership has obviously had a major impact for this whole process, and I wish you well

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in your next role, whatever that happens to be. Give us your phone number, for two years from now.

PRESIDENT DOWDLE: Mike.

MR. PETERSON: Just very briefly, I want to echo both Captain Cunnion's and Colonel Erdtmann's comments on your leadership, Doctor Dowdle.

Two observations. One is, in your role as new Board members, I think there's an increasing need, certainly from my little cubicle of the world, to know you on a personal basis, and hope that we can have dialogue

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between meetings. It has been invaluable, for example, conversations in support that I've received from Doctor Fletcher, regarding a very controversial fitness assessment program, and I think that type of availability, and in like ways, if you know of things in the services, programs that could be of use to you, in your academic or practice circles, use us as well. It should be a bilateral and usually a beneficial relationship. Anything that is a good relationship has that give and take to it, and that occurs largely outside the context of these

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meetings.

Secondly is to just say that we may be in a very new era in DoD Health Affairs, and, without jinxing him, I hope that Steven Joseph's confirmation goes smoothly.

He's a denominator public health person, for many of you who know him, and it may be an opportunity, putting on my political hat, for some high-level contact, and Mike has already talked about this, between the AFEB and DoD Health Affairs, at a level and with a sensitivity that perhaps, while there somewhat before, has never been there to this

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degree, and I think that that should be explored explicitly, early on in the -- assuming that he gets confirmed, I'm looking forward to that very much.

Thirdly is something that Rick and I have talked about, and it's really broadening the scope, if you will, a little bit beyond the historical, even the areas that are represented now by membership on the Board, and that is the role of preventive medicine in epidemiology and health care. We're more and more convinced in the Air Force that the cornerstone of managed care is prevention

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and epidemiology, and I think, in the circles in which you all work, that if there's a way in which we can even bring you some controversial things like PSA screening programs, or, you know, those types of issues which, quite frankly, are going to be bottom-line issues for our medical commanders, that we can show that the AFEB and preventive community is uniquely positioned to contribute to the dialogue. I think that will be a very convincing way to get questions asked of the AFEB, and vice versa. I don't see anyone, really, right now doing that function within

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DoD.

PRESIDENT DOWDLE: Steve?

MR. CUNNION: May I ask one interjection here?

One of the first things the Board can do for us, and Bruce Jones brought it up earlier and stuff, the problem we've all faced, since we'll all been in preventive medicine, is that we have no outpatient database, and the DoD spent millions of dollars producing a CHCS (phonetic) program for outpatient database, and didn't even include diagnosis, so, I mean, we're still fighting an uphill

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battle in the bureaucracy, to be able to collect information to be able to use for health care.

MR. KULLER: I think this is why it's important to go back over previous meetings of the Board, because we spent a whole Board meeting dealing with the problems of surveillance of clinical data that could be useful for preventive medicine and epidemiology, and it was an extremely interesting meeting, but obviously nothing came from it, so if we at least go back and see what the Board talked about the last time, three years ago, about this,

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or two years ago, at least we can start from that point and go forward, rather than start all over again.

PRESIDENT DOWDLE: The other thing, of course, that we set out to do a couple of years ago, was to give the new Board and the new people coming on an orientation to the services, and I think that's been extremely successful. It hasn't been without its cost, of course, in that it's taken up time from the Board. I mean, obviously, we spent half-a-day yesterday, and we spent half-a-day at most of the last four meetings that we've

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had, but I think that's been extremely useful. Now essentially all branches of the service now have been involved, and had briefings, orientations, and I would say that we certainly ended up in a very good one, and we would once again like to thank our hosts, and particularly Captain Ledbetter. Please pass on our thanks to all of the staff here who have done such a great job in providing us the type of experience that we needed, so thank you very much.

MS. LEDBETTER: I will, sir.

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MR. KULLER: We'd like to thank you for your leadership over these years, and especially during this transition. Without you, I'm sure this transition may not have worked. The Board has really come around very nicely, I think, and we all really appreciate it, the work you've done for the Board in the past few years, in making sure of the transition, which is smooth. I'm rather surprised how smooth it's been, given the turnover of number of people, and different focus, et cetera, but it's your leadership that's made it possible, so thank you, and

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we all wish you well.

PRESIDENT DOWDLE: Thank you, but we also have another. We also need to thank Bill Harlan. Bill has worked very hard for the Board over a number of years, and Bill has been given some very difficult assignments, and Bill, we appreciate how much you've done, and you will find quite a few things about Bill, if you go back into the previous -- so thanks again.

So, Lou, I don't have a gavel -- a hammer.

MR. CHIN: Before we leave, Mike, there were a

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couple of questions that were raised to the Board in between the meetings, one on HIV and one on lead. What happened to those? Are we ever going to hear anything about them?

MR. PETERSON: What was done with those questions, then, they were the types of questions that didn't require a specific answer. They were more questions addressed for advice. The advice was provided, verbatim, back to those who asked the question. That's another way the Board can do business, so there was no

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need to go back to the rest of the members of the Board for a census, or a straw man. The information that was provided by --

UNIDENTIFIED SPEAKER: I would just also like to say thank you to Walter, Bill.

PRESIDENT DOWDLE: I would like to see though, I mean, I would like to make certain that all of the Board members have a chance to make any comments that they would like to make, or ask any questions, before we get away. We've got just a few more minutes.

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MR. FLETCHER: Let me make one comment. I've really enjoyed talking to Mike Cloud (phonetic), the exercise testing standard physician at the Air Force. I think this is important, that we move along here to find some standard type of exercise -- involve the other branches. Actually, some of the runs and so forth I believe are dangerous to a degree, and I think we need to have a standard, simple, submaphical (phonetic) way to look at people's level of physical conditioning.

I think actually this can move on. A lot of the

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things that we've talked about, there is some soft data that healthy, well-conditioned people do have less infection and things of this type, and I think moving on in this two-and-a-half population here in the military, that we can really provoke some prevention in many other areas, so I think we have sort of a launching board with proper fitness assessment, and we can move on and standardize that through a series of meetings. I think it would be very, very helpful.

MR. ASCHER: I'll speak to process as well, as

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their whole business. As I mentioned, several of us did sit on the vaccine advisory, about a year ago, for Don Burke (phonetic), on the microgenesis product issue, and what's interesting is that that deliberation was never mentioned in any of the subsequent press, and in fact it was never even indicated what our recommendation was, and it wasn't done officially, and I think we have to think about that as an issue.

It might have been the better way to do it, it might not be, but we've got Persian Gulf War in the same

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way. Are we going to have quiet deliberations, where nothing ever gets transmitted, but we were very smart and nobody knew it, or, you know, are we going to look foolish? I don't know, but I'm thinking that we ought to worry about that ad hoc process, and make sure it gets connected with the official mechanism, and maybe Doctor Joseph could be made aware of the fact that that's a useful mechanism, and, had that come out earlier, it might have solved the problem, and not have four reviews, and consensus conferences and God knows what, about that

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vaccine.

PRESIDENT DOWDLE: John?

MR. GWALTNEY: At the last meeting there was raised the possibility that the adenovirus vaccine supply might not remain available. Has that problem been solved, do you know?

PRESIDENT DOWDLE: Would anybody like to speak to the adenovirus vaccine? What I had heard after that, in my inquiries, that there was another batch, in fact, that was being made. That other batch was supposed to be

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lasting five to seven years, or something like that, but I think there's a real question about what happens after that. Rick, you may know something about that.

MR. ERDTMANN: Sir, unfortunately I don't have any new information on that. I was not at Fort Bragg, and I was not aware that that was brought up as an issue.

PRESIDENT DOWDLE: But, I mean, clearly that's something that the Board needs to give time, so that's what I had that for. Barbara?

MS. HANSEN: It's been great knowing you; can't

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wait to see you back in two years.

PRESIDENT DOWDLE: No comments on me. Okay.
Thank you very, very much. It has indeed been a real
pleasure, and I wish you all the luck in the world.

(Whereupon, at 10:01 a.m., the above-entitled
matter was adjourned.)