UNITED STATES DEPARTMENT OF DEFENSE

FULL DEFENSE HEALTH BOARD VIRTUAL MEETING

Arlington, Virginia

Thursday, November 20, 2008

ANDERSON COURT REPORTING

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P R O C E E D I N G S

COL GIBSON: We'll go ahead and get started. I'll turn the meeting over to Doctor Poland, who's in Rochester at Mayo Clinic, he's the Board President; Doctor Poland.

DR. POLAND: Good morning, everybody. Roger, can I be heard well?

COL GIBSON: You certainly can be heard in the room.

DR. POLAND: Okay. I'd like to welcome everybody to this virtual or E-meeting of the Defense Health Board. While other Federal Advisory Committees have conducted meetings using web based technology and teleconference formats so that the public and members who couldn't physically attend are allowed to participate, this is a first for our Board. We intend to conduct the meeting as efficiently as possible. Bear with us if we have to work through any technical glitches during the proceedings.

We have four important topics on our agenda today that will require deliberation and

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decisions and discussion by the Core Board before their associates reports would be forwarded to the Department of Defense and made available to the public. Since DOD has requested three of the reports by the 1st of December, we will have to work hard to attempt to meet that request. I do want to mention that the room I guess has to physically be empty by 12:15; track the discussion and the time and keep things moving in a timely way.

So to get started, we'll need a designated federal official to call the meeting to order, which I believe is Ben Diniega. Ben, are you there?

DR. DINIEGA: I'm here, Greg. Good morning.

DR. POLAND: Good morning.

DR. DINIEGA: I'm here as the Senior Leadership in Health Affairs is - they're all involved with an off- site pertaining to the transition with the Undersecretary at Personnel

22 and Readiness. So there's a mandatory statement

1 to be read for the Board before we start the
2 meeting.
3 But it's always my pleasure to be
4 associated with the Defense Health Board, the old
5 AFEB. As the ultimate designated federal officer
6 for the Defense Health Board, a Federal Advisory
7 Committee, in a continuing, independent,
8 scientific advisory body to the Secretary of
9 Defense, via the Assistant Secretary of Defense
10 for Health Affairs and the Surgeons General of the
11 military departments, it's my pleasure to call
12 this meeting of the Defense Health Board to order.
13 DR. POLAND: Thank you, Ben, always a
14 pleasure, by the way. Ben and I have worked
15 together for well over a decade. Carrying on a
16 tradition of the Board which I hope will go on in
17 perpetuity, I would like to ask everybody to stand
18 for a minute of silence to, one, focus on the
19 reason for this Board and why we do what we do,
20 and to honor those that we're here to serve, the

men and women who are serving our country.

(Minute of silence.)

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DR. POLAND: May they and their families all be kept safe. So thank you. Since this is an Open Session, before we begin, I'd like to go around the table and the phone and have the Core Board and Subcommittee members introduce themselves. We'll start with those around the table at the meeting room in Crystal City and then move to the phone. Could we first have Core Board members introduce themselves, then Subcommittee members? Gail, can you go ahead and start?

DR. WILENSKY: Yes, I'll be glad to, Greg. This is Gail Wilensky and I'm with the Core Board of the Defense Health Board.

CDR FEEKS: Good morning; I'm Commander Ed Feeks, Preventative Medicine Officer at Headquarters Marine Corps.

DR. LEDNAR: Wayne Lednar, Global Chief Medical Officer for Dupont.

DR. CLEMENTS: John Clements, I'm the

Chair of Microbiology and Immunology at Tulane University School of Medicine in New Orleans.

DR. DUBOIS: Ray Dubois, Senior Advisor

at the Center for Strategic International Studies and a member of the NCR BRAC Subcommittee.

DR. MULLICK: Florabel Mullick, Director of the AFIB and Executive Secretary of the Subcommittee on Pathology and Laboratories of the Defense Health Board.

DR. ANDERSON: George Anderson, Subcommittee on Health Care Delivery, Executive Director of the Association of Military Surgeons of the United States.

DR. BLAZEK: I am Doctor Bill Blazek and I am at the Center for Clinical Bioethics at Georgetown University, and I am on the Medical Ethics Subcommittee.

DR. HALPERIN: Bill Halperin, I'm Chair of Preventative Medicine at the New Jersey Medical School in Newark, New Jersey, also Chair of Quantitative Methods at the School of Public

Health, same site.

CMS HOLLAND: I am Commander Major Retired Larry Holland, I am a Core Board member, and my role as I see it is to look out for our

service men and women and their families.

DR. POLAND: Amen.

DR. DINIEGA: Ben Diniega, Health Affairs, Acting DFO.

COL GIBSON: Colonel Roger Gibson, Executive Secretary. Doctor Poland, if it's okay, we'll go around the rest of the room. We've got another probably 20 or 25 people in the room.

DR. POLAND: That's good, and then we'll do the phone.

COL GIBSON: We'll introduce them and then turn it over to the phone.

DR. POLAND: Okay.

MR. GOULD: Philip Gould, Air Force Medical Support Agency.

COL MOTT: Colonel Bob Mott, Preventative Medicine Officer, Army Surgeon

General's Office.

MAJ WITH: Major Kathy With, Legal Counsel, Armed Forces Institute of Pathology.

CPT LARSON: Captain David Larson, I'm with the National Naval Medical Center, I'm the

Lab Director there.

COL BAKER: Colonel Tom Baker, I'm the Chief of the Integrated Department of Pathology at Walter Reed and National Navel Medical Center.

LT COL SILVER: Lieutenant Colonel Aaron Silver, Deputy Chief, Health Service Support Division, Joint Staff.

MR. BURY: Craig Bury, Senior Advisor, Information Manufacturing Company.

COL JEFTS: Colonel Barb Jefts, JTF CAPMED, Operations Directorate.

MR. RAYBOLD: Ridge Raybold, Armed Forces Institute of Pathology.

MR. PARRY: Michael Parry, Director of Operations for the American Registry of Pathology.

MAJ SESSIONS: Major Cecili Sessions, a

preventative medicine resident at --

MR. PEIPELMAN: Eric Peipelman, Armed Forces Institute of Pathology.

DR. WIENEKE: Doctor Jacqueline Wieneke, Department of ENT and Endocrine Pathology at the AFIP.

DR. MURPHY: Doctor Mark Murphy, Chief of Muscular Skeletal Radiology at the AFIP.

MR. JHA: Prakash Jha from Armed Forces - Pathology.

DR. SESTERHENN: Doctor Isabelle Sesterhenn, Chairman of the - Department, AFIP.

COL GIBSON: Doctor Poland, that finishes the room. Can we start with the Board? We're going to just do the Board members and Subcommittee members on the phone.

DR. POLAND: Okay.

COL GIBSON: We're recording the names. One of the things we have to do from the standpoint of a Federal Advisory Committee is capture the names of everyone who is in attendance

at a meeting, and that includes folks on the phone.

DR. POLAND: Okay.

COL GIBSON: But for the purposes of introductions, we'll just do introductions of the Board members and Core Board members that are on the phone.

DR. POLAND: Very good; my name is Greg Poland, I'm Professor of Medicine and Infectious Diseases at the Mayo Clinic in Rochester, Minnesota and current President of the Board. Are there Board members on the phone?

DR. KIZER: Yeah, this is Kenneth Kizer, I'm Chairman of the - Committee.

DR. PARISI: This is Joseph Parisi at Mayo Clinic; I'm a neuropathologist here at the clinic, and I'm a Core Board member and Chair of the Subcommittee on Pathology and Laboratory Services for the Defense Health Board.

COL GIBSON: Any other Board members on the phone at this time? I know that are several

that are joining us just a little later. Okay.

DR. POLAND: Okay. Since I can't be there in person and other members of the Board's Executive Council are there in Crystal City, along with a number of other Board members, I'd ask Doctor Wilensky, the incoming President, to run the meeting, because, you know, I won't be able to see people and run the meeting in a fissile way.

A reminder that we need to be out of the room by 12:15. Gail, would you mind going ahead and taking over the meeting physically from there?

DR. WILENSKY: Thank you, Greg, I'd be glad to do so.

DR. POLAND: Thank you.

DR. WILENSKY: I look forward to seeing you at our meeting next month.

DR. POLAND: Thank you.

DR. WILENSKY: Colonel Gibson has some administrative remarks before we begin the morning session; Colonel Gibson.

COL GIBSON: Thank you. I want to thank

Crystal City staff and our IT folks for all the work in putting this thing together. As you know, this is our first virtual meeting like this. I expected a few glitches and I've been pleasantly surprised at how few as we've gone through this.

Thanks to my staff, as well, and in particular to Ms. Jarrett in the corner. She's the one that really put this thing together and made it happen, so thank you very much.

As I mentioned, one of the requirements of holding a Federal Advisory Committee meeting is recording attendance, it's part of the federal statute. We have a sign-up sheet here that we're passing around the room to get everybody's name on, please fill that in. And if we have members of the media here, they should sign up on the media roster. And we are offering the opportunity for members of the public here in this room to provide testimony on any of the issues as we go forward, so we'll sign up for that, as well.

The meeting is being transcribed.

Please make sure you state your name before speaking so that our transcriptionist can capture the information. And this request also applies to individuals dialing in and accessing the slides on the web.

The next meeting, as Doctor Wilensky mentioned, is going to be the 15 and 16 of December at the Ronald Reagan Building and the International Trade Center here in Washington, D.C. There are a series of updates that the Board

will receive at that time, both in the area of health care delivery and protection issues. And we'll hear from senior leaders of the Department of Defense.

DR. WILENSKY: I'm going to begin now with the introduction of our speakers. Our first speaker this morning is Doctor William Halperin, who is currently serving as the Chair of the Department of Preventative Medicine at the New Jersey Medical School. As Chairman of the Military and Occupational and Environmental Health

and Medical Surveillance Subcommittee, he will provide the Subcommittee's external review of the risk assessment conducted by the Center for Health Prevention and Preventative Medicine in response to possible hexavalent chromium exposures at a water treatment facility in Iraq. Without further delay, I present Doctor Halperin.

DR. HALPERIN: Does anyone have a pointer perhaps? Okay, well, that's the first glitch of the morning, my fault for not bringing one. Well, thank you for the opportunity to make

this presentation. What you're going to be hearing about is a work in progress, and it's fairly fast moving, and I hope to - there we go, thank you very much. I hope to complete the presentation in about 20 minutes, leaving time for discussion.

I want to thank the Board members who have participated in this evaluation, who include John Herbold, Wayne Lednar, Jim Lockey, Tom Mason, and Alan Russell. This is a subset of the

Subcommittee, a subset defined by those of us who have security clearance, who are able to see the data on which this report is based. Could we have the next slide, please? First the charge, which came on October 6 from General Schoomaker, which is to review the Occupation and Environmental Health Assessment at Qarmat Ali Water Treatment Plant in Iraq that was done in 2003. Specifically, was the standard of practice for the investigation adequate? Are the reports of the - conclusions of the report as far as health valid?

To accomplish this, we had an initial

meeting of our Subcommittee on October 17 and planned for a site visit so that we could see the report and discuss this with CHPPM staff, which required a security clearance meeting which was held last week, November 12 and 13 in Arlington, Virginia, as I recall.

The report is quickly nearing completion, but it is not done yet, it's not been finalized by the Committee, and it's certainly not

been reviewed, so this is a progress report. Next slide, please.

I want to first put this into some perspective. You know, for two decades more I worked for Centers for Disease Control, really in various jobs, but always thought of myself as a field epidemiologist. There are arm chair epidemiologists and there are field epidemiologists. And field epidemiologists need to go into the field during an episode of something, with the idea of understanding what's going on and suggesting interventions, and coming out of that having controlled an epidemic, if you

will, or an exposure or whatever. And the slide that you see here is the first example of field epidemiology that society ever undertook, which was the investigation of cholera in London in about 1850 or '53, as I recall, by John Snow.

It was in a very hazardous situation that this epidemiology was done, with mortality rates in certain areas of London being very, very

substantial, unknown what the risks were to the investigators or the population, and the goal was to identify the exposures and to control those exposures to control health and to protect health in London.

This is the tradition I think with which we are now dealing with this CHPPM investigation. It is not arm chair epidemiology, it was field epidemiology. Next slide, please.

The site is in Basra, Iraq. It is an industrial site that produces industrial water for oil production. There is nothing potable water about this. This is water that is pumped into oil wells to produce oil. So first revelation, we're

not talking about potable water. This is a site that, I use the simple term ransacked. The condition of the site, we have no idea what the conditions were before the war. We know that the conditions that the site was found in were - there was disruption, buildings had been taken apart, there was definitely environmental contamination

with visible yellow contamination, turned out to be sodium chromate, which was used as a corrosion inhibitor in the water, so that you could keep pumping through these pipes and they didn't corrode and obstruct and so forth.

There was a continuous contractor presence at this site throughout successive cohorts of military who served as guards. So there's a continuous contractor who's working to get the site up and running, contracted to the U.S. government in some fashion, but there are successive cohorts, including the British first, then various National Guard units. So in the Roman sense of military cohorts, these are cohorts moving through this exposure environment. Next

slide, please.

I thought it would be valuable to show you where the site is, and since that information is classified, I went to Google to show you this information. So this is Kuwait. This is Iraq. There is a highway that takes you from Kuwait up

to Qarmat Ali, and I presume that Nahr in Aerobic probably means north, I presume. So this is Qarmat Ali, and it's valuable to have this perspective of where this plant really is. It's not out in the middle of the desert. Can we see the next slide?

This is closer, but I tell you, not the closest observation of the site that I can get down to house level, if you will. This is a closer view of Qarmat Ali, the river here with water channels going through. I could have gone back and forth and identified the site if I really knew what I was looking for.

It is an industrial site. This is the University of Basra. This is residential housing. This is in a peri- urban area. Next slide,

please.

This is the chronology of what happened back then. In the spring of 2003, after the initial war efforts, there was an effort to provide security at Qarmat Ali for the contractors

and for getting this site up and running as part of a project, I think it was called RIO, Restore Iraqi Oil Production.

In the summer of 2003, the contractor identified a hazard, it's a hazard identification in the risk assessment sense, and remediated by paving it over with asphalt and gravel, the hazard being contamination of the site with yellow pigment which was identified as dichromate. In 2003, U.S. soldiers observed the contractor staff in personal protective equipment. And any of you have worked - this has happened to me while serving with NIOSH, you're out of sight, and suddenly somebody comes with a whole level - different level of protection. And it is stimulating to everyone as far as, you know, who's right and if there is a right or who's appropriate

or whatever. But it did definitely stimulate questions, which went back to the health clinic.

Now, I apologize to those of you who know these terms much better than I, but I'm just

using them broadly. The question went from the soldiers themselves to the health clinic, which happened to be directed by a preventative medicine officer who had occupational health experience, and very quickly - after this there was a visit to the site, access to the site was restricted, this was on local initiative, there were health communication, it was called a town meeting, but this was really a town meeting of the DOD, not a town meeting of Basra, if you will.

On September 29, a CHPPM field investigation started. I don't mean it was initiated; they were on the ground in Iraq coming from the U.S. by September 29. That is - I almost wanted to characterize that, but I'm going to resist that. I'm just going to say that's a very few days. By October 17 there were personal protective equipment required. This is already

after the site had been restricted, so this was - if you were now going to go into this restricted site, you have to have PPE. And by October 30, a

field investigation was completed. So this is the chronology, the fast pace of this field investigation. This is shoe leather epidemiology happening fairly expeditiously. Next slide, please.

Now, in order to understand what they found, I mean I would simply have to talk about primary, secondary, and tertiary prevention, which we all know what that is and I'm not going to dwell on this. But I will now take this cascade of prevention and go the next step. Next slide, please.

So what do occupational field epidemiologists have in their back pocket that they can use, if you will, that is the equivalent of taking the pump off of - the handle off of a pump handle, as in John Snow? And it starts all the way at the beginning with design, if you will, which is a little irrelevant here. I mean the

industrial site was already in place. But it goes to issues of substitution and elimination,

engineering controls, environmental monitoring, and when each of these are instituted, there's always a fail safe, which is the one lower down the pike, if you will. So this is primary prevention, secondary prevention, and tertiary prevention, and there's this cascade of prevention. We have a great menu by which to choose to figure out what we can do to make things better.

Surveillance is not on this cascade because surveillance by itself does not prevent anything. Next slide. What surveillance is is the taking of information, the collection of information about any one of these things, its assessment, then feeding it back to change something higher in this cascade. So what surveillance is is a prevention feedback loop by which one takes information, analyzes it, and then decides things have to be done differently or things are happening just fine the way they are.

So that's the construct, it's field

epidemiology with the idea of, there's a cascade of prevention, what did they have available for them to do, how did they do it, et cetera, et cetera. Next slide, please. So let's start with exposure assessment, which is one of the elements. Well, the contractor had already identified the hazard and had identified elevated concentrations. They had moved on to encapsulation with asphalt and gravel, and samples that they took after the encapsulation showed minimal exposure to chrome 6. Chrome 6, by the way, is the major hazard that we're talking about. There are a few other issues here, but this is the major hazard. Chrome 6 has been associated with various health outcomes both in the short and the long term.

BRITFOR, apologies if this is not the appropriate name, a successive military cohort from UK obviously, also did exposure assessment and found minimal exposure to chrome 6. CHPPM then did a successive exposure assessment, at this point, in some instances having to dig through the

asphalt to see what was being encapsulated, if you will.

So CHPPM was there really after the encapsulation, and it found elevated chrome 6 in soil, particularly off site. And area samples and breathing zones found no chrome 6; that was because the soil samples were underneath the macadam, if you will, and the air breathing samples were in the environment after it was essentially remediated. So this is the sum of exposure assessment that was done, and it definitely identifies an exposure and identifies where it is and that there is a potential for exposure to people on the site. Next slide, please. So the next issue then is biological monitoring. So if there's an exposure, right, that's an exposure, but it's not a dose, so did anybody absorb anything, if you will.

And the issue here is to test for the presence of the toxin and biologic medium, which is urine, blood, breath, that's biological monitoring. And the choice of the test here was

appropriate. Now, I really have to beg your forgiveness for the last slide, but in the last few days I've not been able to find this in any text. So if I could have the next slide.

It's remarkable how these new systems can produce something that looks like it's handwritten, right. So, you know, you've got chromate in serum, you have chromate in urine, you have chromate in red blood cells, if you will. At the way left of the slide basically is - people have already been exposed. Exposure stops, right, then the question is, depending where you are going out to a month here at the far right, what will you find depending what medium you look in? Well, if you look in serum and urine and you find nothing, that's a false negative, right, because you wouldn't expect it a month later still to be there. But chrome attaches itself to red blood cells, red blood cells have a life span of approximately 120 days, if I'm still correct, if the AFIP will comment, thank you. So in a month, you know, 120 days divided by 30 is four. So we

should find three quarters of the level of chromate at a month in the red cells, et cetera.

So the medium that they used for biological monitoring in this instance was essentially blood chromate. We should have found something substantial if there was a substantial exposure, and that's the point of this curve. And the next slide, please, okay.

The result of the assessment was that of the many, many samples that were taken, essentially the biological monitoring showed that this was essentially in the range of non-occupationally exposed, not in the range of the occupationally exposed, not in the range of the excessively occupationally exposed.

So as a fail safe to, yes, there was exposure at the site, but the last cohort that was at the site, and that's important to say, and biological monitoring did not find levels that were excessive, alarming, et cetera, et cetera, no. Fail safe to biological monitoring is the issue of medical assessment, which is looking for

early signs and symptoms of disease, right. Well, that's done by a history and physical examination. And examples of things that could be found, I have seen these, some of these in practice, are chrome ulcers and perforations, impressive holes in peoples' fingers when they're involved in chrome plating and chrome has gotten into the skin, et cetera, et cetera, or the same kind of holes, but through the septum of the nose. And none of this was found or reported on medical examination, history, or from the soldiers at the site.

There were many more tests that were done, including assessment of respiratory irritation from a subjective point of view, and pulmonary function tests, and the respiratory irritation was high, but not high apparently for respiratory irritation complaints in Iraq in general. So there's some positives, but they're non- specific to this site. But there are some very key essentially pathoneumonic negatives here. So that's the medical assessment. Next slide, please.

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Then there's an epidemiologic assessment, that is, taking all of the clinical data that was collected. It's the assessment of that data vis-à-vis epidemiologic parameters, like how long was this person at the site, et cetera, et cetera. So as I reported before, the blood levels of chrome 6 were consistent with background, not with occupationally exposed, and there was no association essentially of the levels. Now, they were all low, but there are - some are higher in the low category, but they're all low, but there was no association of the level of exposure with such things as - level of chrome 6 in the blood with the length of exposure, et cetera. So the epidemiologic assessment is reassuring, if you will, as well. Next slide, please.

Now, the issue then is, you know, they're there to do something, they're there to protect health, you know, safety, health, et cetera, et cetera. So there are various issues that can be - should be considered.

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Control of exposure, which had been accomplished, site remediation, which had been accomplished, site access, which had been restricted, and medical care, which should be provided if there's, you know, there's a specific need above and beyond normal medical care. So these are some of the primary interventions that can be accomplished based on this field investigation. Next slide. Well, let's talk about health risk communication. The first one I mentioned that was done in the very early stages of the investigation, there were seven in total health risk communications to the various cohorts of military, to the current and the former units. So the results of the laboratory and the medical evaluations were incorporated into medical charts for the individual use by the soldier's medical care provider. So there was both feedback in general and also feedback in the medical context so that the information would be available in the chart. And that chart is available, my understanding, it's the chart I got when I left

the PHS. This is the one you put, you know, this is the record of your health and you carry it around, it's supposed to be in that chart for all of the soldiers. Next slide, please.

Now, the other issues being considered by the Committee, and you know, we're deliberating this and understand - we're essentially a week past collecting this data, so the Committee is chewing through the draft report, which was already written. And see, here's some of these issues. Next slide, please.

The full examinations that I've described and the biological monitoring, et cetera, was done on the cohort that was there at the time of the investigation, not the prior cohort. So we've got one National Guard unit that was thoroughly examined, not the prior National Guard units. So is it reasonable to go back or not go back and repeat this investigation with the prior groups? Well, that assumption, understanding the environment that this is being

done, this is not - this is war environment, lots

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of things to do, et cetera, et cetera.

One has to make an assumption based on what was found in this investigation for this group to decide whether it was reasonable to extrapolate the results to other groups or whether to go through the same process with all of the other groups, realizing that many of them are much farther out than 30 days from exposure. A decision was made, and that was essentially to extrapolate from this group, not to examine the other groups. Next issue, please.

Activism, there's probably a better term for this, but, you know, something needs to be said given that this is field investigation associated with intervention, that this investigation started locally, started in a very timely fashion, resulted in a rapid succession of interventions. In addition, the request to, you know, the home team, if you will, 6,000 miles away, resulted in a response team going to Iraq in

very short order and getting to work. So we are going to comment on the issue of activism. This

is the kind of thing that needs to be done when it needs to be done, not a year or years later. So the issue is, is the system, the SOP for the system set up such that they're in the field at the right time. And this is the data we've collected. I'm kind of signaling some of my thoughts on the appropriateness, but the report isn't done. Next comment.

Other issues in progress, access to industries specific experts. As somebody who worked for many years, really decades for the National Institute for Occupational Safety and Health, with a huge field team of industrial hygienists, et cetera, but a much huger array of industries that there are in this country and in other countries, the question always is, no generalist industrial hygienist can know all of them; at some point you have to find the people who really know each of these industries in very

much depth.

So the question is, is there ready

access to CHPPM to industry specific experts who

can be called up, that's in a non-technical - who

can be asked for their advice immediately, not

when papers are signed or classifications can be

offered and so forth. The next issue - and again,

I forgive this if it's somewhat alienating the

terms I've used, but I think there is an issue of

Silos versus Bridges. Various groups have

responsibilities for different - various public

health groups within the military have

responsibility for various groups, the Army for

the Army, the Navy for the Navy, the U.S. for the

U.S., the British for the British, somebody for

the civilians, et cetera, et cetera.

So the question is, what is the effect

of Silos and Bridges in this context of doing

rapid investigation when you have various groups

in the field and various public health groups are

related to them and there may not be communication

between them, or there may not even be contractual requirement for communication between them? So the issues of Silos and Bridges is an important one.

Classification is a real issue. Once something is classified, it's hard to review it with people who are unclassified, and I imagine it's hard to get people with general expertise from the civilian community involved in the classified episode. So there's a real issue of the effective classification of the investigation on the report, on the conduct of the report. Dissemination of results to similar sites, this is probably not the only industrial water treatment site in Iraq. Hazard recognition by field units, this is a really challenging issue. You cannot turn every worker in an industry into an expert on everything that might be hazardous to them. And it's particularly true of workers who may be going from industry to industry.

So how does one prepare the foot soldier

for recognition of the hazard so that they can immediately, the foot soldier or their field supervisor, so that they immediately know that there's a problem?

In this instance, remember, it was not

the foot soldier that recognized the problem, it was recognized by the prior contractor, if you will. So there is an issue of how does one prepare for hazard recognition by field units.

The other issue that we're going to think about is the number of available experts within CHPPM, that is, intox and epi and industrial hygiene, and what are the issues like career ladders that have some determination on the number and variety and depth of expertise that's available?

In this instance, you know, there was only requirement for one field investigation of - concurrently during a war scenario. There could be requirements for two or three or ten if you happen to be essentially in an industrial

environment. I mean if this were New Jersey, you know, you wouldn't go five miles, if you were going plant by plant by plant, before one would be overwhelmed by the details and intricacies of fairly arcane industrial processes. Next slide, please.

We have the two basic questions, did the investigation meet standard operating procedures for something like this? And we can compare this all the way back to John Snow. How does this essentially shape up, compare with how it would be done elsewhere, not some ideal, but how in reality this would be done within CDC or et cetera, et cetera, and we expect to have our conclusions on this really fairly soon.

And the other issue were the health conclusions appropriate that were made in the field? And we also will have our recommendations - our evaluation on this done fairly rapidly. And I think that should be the last slide, if I'm correct, yes, it is. Okay. Happy to take some

questions. And there - Wayne is here. Am I ignoring somebody else on the team? Okay. And there may be somebody on the phone who's also part of the team. And I have to explain that for the two days at the site, I think there were four of us who could be there - three of us who could be there for the entire two days, other people came

for a day and left, so if there's, you know, it's the usual thing, as far as responsibility for errors and whatever, I'm the constancy through this, so that's my fault if there are any errors. Thank you.

DR. WILENSKY: Thank you, Doctor Halperin, for that very interesting and informative presentation. At this time we will begin the question and answer session. For those members on the phone, if you would like to ask a question, please press star followed by the one on your telephone key pad. If you would like to withdraw your question, please press star followed by the two.

If you're using speaker equipment, you'll need to lift the handset before making your selection. Let's start with questions from those of you who are here at the table. And for those on site asking questions, you'll need to speak into the microphone, which we will share. Anyone have any question? Yes, Doctor Clements.

DR. CLEMENTS: John Clements; was there

any attempt to assess the health of the local population or inform the local population about potential health risk associated with the contamination of the site?

DR. HALPERIN: This gets back to the issue of Silos. In many ways, John, let me put my blinders on. We're evaluating the field investigation done by CHPPM for soldiers under the command of CHPPM. We're not evaluating the role of CHPPM vis-à-vis the contractors or the civilian site, right.

Now, that having been said, I know that the - I know because it's reported that the

contractors had health and safety personnel access. I do not know from the report what kind of information, evaluation, et cetera, was done for the civilian population.

There is commentary in the report of a civilian population being in the area outside the parameter fence, so that is a relevant question and gets to the issue of Silos and Bridges, et cetera. It also gets to the question of, as an

evaluation team having a true pictorial sense of where this is, which I think the Google maps are revealing.

If I've gotten the right Qarmat Ali, and you know, lots of ifs here, but - if I'm there, okay. So if I'm there, then there is a real sense that this is in a peri-urban area, the report does not address the exposure to - and understand, a lot of the variables are different, you know. It's time and concentration, so time and concentration for a civilian population could be quite different, time and concentration for

somebody on site. So a long winded answer, but the answer is, it's outside of the area of purview of CHPPM and this report, it does not mean it's not a relevant question.

DR. LEDNAR: This is Wayne Lednar. As part of the team that Doctor Halperin led, one of the observations was that, in trying to understand the event, there were these streams of information, Silos, if you like, that were inviolate, did not cross, were not shared, may

have been collected at the same time, or maybe even information that could help the military that was collected in advance of the military seeing a question that then needed to respond to.

So just from a protecting the health of the soldier point of view, one of the lessons learned of this I believe is to have a structure that supports the exchange of information that is helpful to understand the hazards at a site to which the military has an assigned mission so that that can be appropriately used to protect the

military. That did not appear to occur in this situation. So what could be, and we will have to understand more about this, but what could be potentially a solution to this root cause issue is a contractual sourcing solution, language written into DOD contracts for vendor support that specify when and how information that's relevant to protecting the health of the military can and will be provided, and that did not exist in 2003.

DR. WILENSKY: Any other?

DR. DUBOIS: Ray Dubois; Doctor, the

issue about similarly exposed with respect to the Guard units, I presume that when you use that term, you mean in terms of deployment period, in terms of length of time were similar between the various Guard units so that you could extrapolate?

DR. HALPERIN: Yes; I think - in thinking about the extrapolation issue, let me put this down here because I'm going to have to use my hands. The, you know, there's extrapolation to the soldiers who were in the Guard unit that was

investigated, if you will, who did not have laboratory tests done, so that's the first extrapolation. This extrapolation to two prior Guard units, if you will, and to the British, that's another extrapolation that should be considered, could be considered. Then there's the issue of, there are other industrial treatment water facilities that soldiers may be entering now or in the future, it's another extrapolation. There are a series of extrapolations, some which are of immediate concern and some of which are essentially for the point of view of preparation

for either future similar encounters. So there are a whole series of different kinds of extrapolations.

DR. DUBOIS: So you feel comfortable that your extrapolations with respect to length of exposure will withstand scrutiny?

DR. HALPERIN: The issue really here is, given that the prior Guard units at this facility, given similar circumstances that this Guard unit

had, a reasonable assessment I think was done that one could extrapolate to them. But if the circumstance is changing, I mean we've already heard questions about, you know, outside the fence is different from inside the fence, pre-incapsulation could be different than post-incapsulation and so forth. If the circumstances are the same, the extrapolation seems like a very reasonable thing to do. If the circumstances change, one has to be much more cautious.

DR. DUBOIS: Would you recommend testing the units that you're not testing?

DR. HALPERIN: Okay. This goes back to -- remember the hand drawn thing that I described? The length of time on that was a month, right, if you extrapolate that to four months, you should see no blood chromate. Even if there were elevated blood chromate, if you extrapolate that from four months to a year, or two years, five years, right, then your biological monitoring is

essentially worthless. It's going to be falsely negative - it's going to be negative, whether it's truly negative, false - it's going to be negative. You're just too far out to do any kind of biological monitoring.

The issue of dermal ulcers, chrome ulcers, and nasal perforation should have been picked up in the medical examinations, medical evaluations through the health risk assessment, et cetera, et cetera, of which a lot was done way back when, it should already have been done.

DR. DUBOIS: Not being a doctor --

DR. HALPERIN: Yes.

DR. DUBOIS: -- I would just suggest

that there's a political aspect of this. If I were a governor of the state of Indiana, my Guard unit, and they'd come back, and this assessment has now been done, I wonder whether those Guard members, when they came back and had their post-deployment physicals, were those post-deployment physicals focused on chromium fix,

red blood issue, et cetera, and if not, I think it makes some sense to at least recommend, even though time, X, months, years has taken place, because it's kind of saying to mom and dad of Sergeant Dubois, you know, we've done everything.

DR. HALPERIN: Yes; the question that's really being asked is - the mic, it's fine, okay. The question that's really being asked, I think, you know, it needs to be parsed a little bit. The history of what happened here, it's our understanding, is now in the medical records of all of the people, all of the U.S. soldiers who were there at that time.

So for the physician who is responsible for an individual, that they had an exposure, what

the level was, what the assessment was at the time, what the - it's all in the medical records, so that's on a one-on-one relationship with the physician and the individual, that's an accomplishment.

Now, the next question would be, is

there a reason for doing a population based assessment of these populations to see something, right? Well, there the issue is, well, what are you going to see and is what you see going to be indicative of a problem or indicative of a non-problem? So if you're five or six years after exposure, there's not going to be any evidence of chromium on board in any one of these potential tests. So essentially this would be not a valuable test to do at this point. One has the information about extrapolation, but studying this population biologically isn't going to contribute new information about their levels at the time back six years prior.

Now, in addition, you have information from the individuals about their symptoms at the

time that they were there. So, for example, did they have irritation, did they have respiratory irritation? That could be determined. But did they have nasal perforation or cutaneous ulcers and so forth? It should have been picked up by

this process long before now.

A doc who is asking - has a one-on-one relationship with those individuals, and it's in the chart, would be prompted to inquire, discuss, et cetera, et cetera. So I'm being long winded, but the real question is, these folks, in my opinion, deserve medical care. The value of an epidemiologic investigation at this point would be almost guaranteed to prove nothing, even if there had been an exposure, which is, by extrapolation, unlikely if the circumstances were the same. So I hope that answers your question.

DR. DUBOIS: It does; thank you very much. I know we only have one or two minutes left. I want to just give some context here and specifically in relationship to Doctor Halperin's questions and comments about Silos versus Bridges

and the similar hazards and similar site issues.

I was the Deputy Undersecretary of Defense for Installations and Environment and had responsibility for environment safety and

occupational health, and I had developed a relationship with all the combat and commanders, but specifically the CENTCOM commander with respect to environment issues, because there are a number of situations, in particular, when we went in to take over an air base that had been, for instance, a former Soviet air base, which was highly contaminated.

I got an intel report fairly quickly, and depending upon, and this is a Silo/Bridge issue, whichever military department had executive agency responsibility, I directed that military department to dispatch and deploy an environmental assessment team, such as the Army did with CHPPM. I can remember several examples in Afghanistan, Kajikstan to Tajikistan, and Iraq, where we did this. The policy issue is at the OSD level. And it is a matter of concern, was a matter of concern

to me, how quickly would I find out about these issues, and therefore, be able to direct an assessment or direct some kind of remediation if

necessary.

And I'll be glad to sit down with you, Doctor, afterwards to discuss sort of the food chain here, the chain of command, because we were very definitely aware of these issues a the OAD level, which is, you know, considerably distant from base X, forward operating base Y in Afghanistan, but it was an important development that we were aware of it and we took action.

COL GIBSON: Go ahead; we really need to move on.

CMS HOLLAND: This is Command Sergeant Major Retired Larry Holland. Thanks, Doctor Halperin, for your comments. I am still concerned that all of the National Guardsmen and maybe our brother, the British troops, some annotation, maybe once this report is finished, should go to their senior headquarters or Guard Bureau and make sure that we really have something on record for

these individuals in case something happens to them down the road and someone is not sure of,

Ray, what it is, because these National Guard units were not just from those states, they were scattered all over the United States, and catching up with all those troops I think would be a real tough situation.

DR. WILENSKY: I'd like to see whether there are any questions from people who are on the phone.

OPERATOR: Thank you. We do have a question from Doctor Tom Mason. Please go ahead with your question.

DR. WILENSKY: Okay. Can I ask, Doctor Mason, please keep your question short and the response equally short. Thank you.

DR. MASON: Thank you, Doctor Wilensky. I was serving on the Subcommittee with Doctor Halperin, and one of the issues that Command Sergeant Major just raised is consistent with one of our discussions, looking at post- deployment health assessments and looking for similarities or

dissimilarities between that which we got from

Indiana and may have from the other Guard units and potentially basically the parallel issue with regards to British forces. So I think that we should pay attention to what information is there, look for consistencies, and follow up on the Command Sergeant Major's recommendation, which I applaud.

DR. WILENSKY: Thank you. Any other comments or questions?

OPERATOR: We have no other questions through the audio participants.

DR. WILENSKY: If there is no disagreement or additional comments, the Core Board accepts Doctor Halperin's and the Occupational Environmental Health Subcommittee Report by consensus. Thank you very much.

Our second speaker this morning is Doctor Joseph Parisi, Professor of Laboratory Medicine and Pathology at the Mayo Clinic. As Chairman of the Scientific Advisory Board for Pathology and Laboratory Services, he will discuss

the draft report of the review of the Department of Defense Concept of Operations document for the establishment of the Joint Pathology Center.

DR. PARISI: Thank you very much, Doctor Wilensky. The Defense Health Board review of the documents that were provided and the presentation that was provided at the September meeting formed the basis of this report. Can I have the next slide, please?

The review panel was actually made up of the members of the Scientific Advisory Board for Pathology and Laboratory Services. The members are listed there, as well as selected members from the Defense Health Board Core and some selected Subcommittee members, and they are also listed on the Powerpoint slide. And I was the Chair of this session. Can I have the next slide, please?

The review process was related to the sequence that's shown on the screen. We initially had a question presented to the Board by Doctor Kelley back in June, and this was followed in September by a presentation at the Defense Health

Board meeting that was presented by Doctor Kelley and Colonel Baker.

We then had a teleconference with all the review panel members, as well as Doctor Kelley and other DOD officials on October 2nd. We provided a draft review document which went through several alliterations and was now just recently circulated to members of the Subcommittee and the entire Defense Health Board Core members. And, of course, today we're discussing this, and the intent then is to provide a revised report and submit this to Doctor Casscells and the DOD leadership in the near future. Can I have the next slide?

The public law, 110 to 181, specifies the establishment and maintenance of the Joint Pathology Center that should function as the reference center in pathology for the federal government. There was a clause in the law that also said if the President cannot determine that this would be established in the Department of Defense, then the JPC could be established

elsewhere. The law also details some of the activities of the Joint Pathology Center. Could I have the next slide, please?

And as a minimum, the law dictated - could you please go to the next slide? The Joint Pathology Center would provide a minimum - activities, diagnostic pathology and consultation services for - in medicine, dentistry, and veterinary pathology, pathology education to include graduate medical education, including residency and fellowship programs, and continuing medical education. I think I'm on the next slide, please, and that's slide number five. Can someone please advance - thank you.

So these are, again, the activities that were specified in the public law. Diagnostic pathology research and the maintenance and continued modernization of the tissue repository, and as a corollary to this, the utilization of the repository in conducting the activities that are detailed above. And we'll go through each one of these activities as we continue with the report.

The Board charge - could I have the next slide, please - was presented by Doctor Kelley, and there was a request that the panel review the Department of Defense Implementation Plan for the establishment of the JPC, that the Board review the Implementation Plan, and that we also comment on the plan's appropriateness and the feasibility within - for DOD within the context of the BRAC law, which is - which has been passed, as you well know.

The JPC Working Group was formed. Could I have the next slide, please? To come up with a concept of operations for this Joint Pathology Center. The vision of the - as presented by the Working Group, was to be the federal government's premier pathology reference center in support of the Military Health System, the DOD, and other federal agencies.

And the mission, I think these are both very important, concepts, the mission was that JPC will provide world class diagnostic subspecialty consultation, education, training, research, and

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the maintenance and modernization of the tissue repository in support of the mission of the Department of Defense and other federal agencies. So taking the Working Group findings, the concept of operations provided by the Working Group, and the presentations that were presented to the Board, we deliberated some of the details in the ConOps. If I could go to the next slide, please. So the review panel assessment then is, in conclusion actually, concurs with the vision and the mission as provided by the - provided in the documents and presentations by the Working Group.

The panel believes, however, that the Department of Defense needs to consider a number of other findings and recommendations as they develop a more strategic - more extensive Strategic Plan in the designing of the JPC.

There's a unanimous opinion that this is really a unique opportunity to develop a center of excellence. The panel recognizes the enormous contributions of the Department of Defense to medicine and the very important - and the

importance of continuing this legacy and providing world class pathology consultation, as well as research and educational opportunities. So we view this as an unequal opportunity, again, to design a very unique and important center. If you'd go to the next slide, please.

Some special attention - I'd like to now discuss in detail some of the findings of the panel and some of the recommendations that we'd like the Department of Defense to consider as they move forward with their Strategic Plan. First of all, regarding the clinical scope of service, the concept of operation provided diagnostic services to - was going to provide subspecialty diagnostic services, but these subspecialties were not specified, and the panel believes that this is a very important - this is very important to define as it will determine a variety of parameters in the design of the JPC, including staffing, cases that would be viewed there, et cetera. So subspecialty services need to be defined.

Also, the process of handling individual

cases, including the assession, the triage, the deposition, disposition, flow, reporting, and quality assurance of the - of cases, individual cases, needs to be refined.

The quality assurance is a very important piece of this. Since good medical treatment, as you know, requires an accurate tissue diagnosis, without a good diagnosis, treatment may be inappropriate or ineffective and may have medical legal implications, obviously, so this is a very important part of the clinical services that the JPC would provide.

We suggested in-theater support might be expanded to include the support of other diagnostic technologies that would service the soldier in combat. Also, we recognize the important need of interactions with other federal agencies, including the VA, NCI, Indian Health Services, CDC, NIH, the list could go on and on, but other federal agencies also ought to be considered in the scope of service of this JPC.

Also the names and interactions with the

Armed Forces Medical Examiner need to be considered as far as general pathology review of case material. The positioning of the JPC within the command structure generated considerable discussion among the panel.

The conclusion was that DOD was a logical choice for the location of the JPC, however, everyone - there was unanimous agreement by everyone that the JPC should be a high level and ideally an independent entity with high visibility within the leadership and not buried in a hospital Department of Pathology, where the priorities, the vision, mission and so on are considerably different. So we've got to emphasize that point.

We believe that the JPC would be best served at a higher level than what was presented in the ConOps. In support of this, if I can go to the next slide, please; in support of this, there should be a Board of Governors established that

would provide oversight. This should include federal agency representation, obviously, with

possible representation from civilian medicine and even industry. That, again, would provide active oversight and potential advocacy for funding should these become important issues. The development of performance metrics needs to be done, as well.

With further detail, the organizational structure, we believe that there ought to be periodic assessment of the resources as the workload and the activities of the JPC become better defined. And utilization of business principals and practices to increase cost efficiency ought to be employed, as well. Go to the next slide, please.

Regarding staffing, go to the next slide, please, it's very important that appropriate administrative and secretarial support be provided for the subspecialty pathology personnel. At Mayo, for example, each pathologist

has at least one secretary that's dedicated to doing the secretarial activities related to his or her workload, and many of us actually have even

more than one secretary that's responsible for our workload. Again, identification of the subspecialties needs to be defined. Also, the staffing by the JPC needs to be considered. For example, will this be made up more of senior or junior level pathologists, what will attract these pathologists to the JPC? Obviously, salary is an important consideration, and the salary at the GS-15 level is often times not competitive with the salaries in mainstream medicine.

More importantly than salary actually are probably the research and educational opportunities that the staff could engage in, and these are often times, again, more important to the individual staff member than salary issues. But, again, these staffing issues need to be better defined. We also would suggest that a full manpower allocation review be done based on a

viable business plan.

Regarding the workload, the workload that was provided to us in the documents included cases only from the Military Health Service and

the VA. However, if one agrees in principal that all federal agencies, that this is a national federal resource for all federal agencies, then the workload or potential work from other federal agencies needs to be determined and also be included in the workload.

Also, regarding individual cases, I think the case complexity is a very important piece of this that was not addressed. I suspect that the model that was presented was based more on a general pathology practice rather than a subspecialty pathology practice, where case complexity is very important and requires much more detail and time per case to perform.

So, for example, a general pathologist seeing any run of the mill surgicals, for example, hernia sacs and gall bladders, can process many of

these, while a pathologist that's dealing with a very unusual tumor or a complex neurodegenerative disease, for example, would require considerably more time per case. So, again, the case complexity needs to be part of the equation in

projecting realistic workload for the pathology staff. If I can go to the next slide, please.

The crown jewel in all of this, of course, is the tissue repository that resides at the AFIP currently. And I was delighted to learn of a new independent study by Asterand that provided a monetary value to the tissue repository, it's somewhere in the range of 3 to $3.6 billion. So this has enormous ramifications for potential use by industry, partnering with industry, partnering with academia in a research venue. It's very important to maintain and expand the tissue repository, and this requires active, committed professionals, both pathologists and support services, again, to maintain the repository. We also recommend that a process be

developed for access and usage of the material within the repository, and these processes also facilitate inner agency and civilian access to the materials. Go to the next slide, please.

Regarding research, go to the next slide, please, the panel recommends that a health

research management process be implemented, and this would include approving protocols, collaboration with other federal agencies, civilian academic centers, and even industry, and obviously that has the detail criteria for inclusion and protocol approval priorities need to be part of this process. If I can have the next slide, please.

The panel recognizes the vast educational and training opportunities that have been provided in the past by the Department of Defense for pathology, and we believe that these also need to be supported. The contributions by USUHS and the JPC need to be more clearly defined, and there need to be some recognition of pathology

training, subspecialty pathology training, and subspecialty pathology education that, again, has been provided in the past by the Department of Defense. In addition, we recognize that there are a broad spectrum of interest areas that have a major part of this being pathology, and this includes, for example, aviation, and accident

forensics, and investigation, and, of course, these need to be consistent with military treatment priorities and challenges as they evolve. So there needs to be obviously very flexible. But we believe that the educational and training component of this JPC is a very important one and one that should be continued.

Regarding the equipment and special design requirements, the Strategic Plan needs to address the design of state of the art laboratory and support services. This needs to provide high quality histology and immunohistic chemistry and even electron microscopy to provide the pathologists with appropriate material to

interpret. The design of the molecular laboratory is very important, and this is especially true as more molecular pros become available and advances in genomics and individualized medicine are made.

There was also a concern expressed by the separation of the JPC between Bethesda and Forest Glen campuses, and we - there is a sense that this was not ideal for work flow and for

communication between the two sites, so this also needs to be addressed in the Strategic Plan. What I'd like to now present are some of the final recommendations that the panel - that evolved from the panel's discussion. First of all, we believe that the Department of Defense has a unique opportunity to build a center of excellence. This obviously has to be within the constraints of the law, but it should meet the needs of all the federal agencies.

We also would like to emphasize that the JPC should be sufficiently flexible and adaptable since the needs will vary depending on health care

issues that potentially arise, so that this, obviously, to meet future requirements of the Department of Defense and other agencies, again, as they arise.

We also would like the Department of Defense to consider that all federal agencies have a piece of this or certainly can take advantage of the services provided by the JPC. Again, subspecialty areas need to be identified. Could I

have the next slide, please?

The organizational structures should be sufficiently flexible. There should also be collaborative relationships made between civilian entities and perhaps even industry. These can provide funding, streams of funding, but more importantly, increase intellectual and academic activity by the center. The education and training components need to be further developed. And, of course, all this should meet military health needs as things evolve. There should be a governance structure in place to ensure

stakeholder interest. The next slide, please.

Performance metrics should be developed and periodically reviewed. And we, as members of the Board, we like to be a part of this review process. There ought to be appropriate funding and resources allocated to ensure that the staff, space, and equipment, and facilities are sufficient to provide premier pathology services. And again, we view these as very important components of the Strategic Plan.

We recognize - could we go to the next slide, please? We recognize that the current budget that was presented may be inadequate for all the projected activities. However, we believe that the funding opportunities are available. Collaboration with other federal agencies is one place, but also partnering with civilian and industry also could provide funding sources. The tissue repository needs to be maintained and modernized, and all these will permit the JPC to thrive and meet its mission. Can you go to the

next slide, please? The tissue repository, again, is a national treasure, it's the crown jewel in this entire process, and every effort must be pursued to guarantee that the repository is preserved, modernized, and utilized appropriately.

The Defense Health Board also would like to review the Strategic Plan and we'd like to be involved early in the review process. Those are our major findings of the panel. I'd like to now open this up to discussion and any questions that might be available. Thank you.

DR. WILENSKY: In order - thank you very much, Doctor Parisi. In order not to get too much off of our schedule, I'm going to ask people to please keep their questions short and the responses equally short. We will use the same procedure we used before.

Those of you on the phone, if you'd like to ask a question, press star followed by one, and if you want to withdraw your question, press star followed by two. If you're using speaker

equipment, you'll need to lift the headset. Let me start with those of you who are in the room. Again, please keep your questions short and to the point. Ray.

DR. DUBOIS: Ray Dubois; Doctor, did the review panel reach any consensus with respect to the work flow considerations and the separation of assets between Bethesda and Forest Glen, i.e., should there not be a consolidation of the mission areas in one place?

DR. PARISI: I think ideally a consolidation would be best for work flow. It

often - it allows ready communication between the support services and the professional staff. So ideally a location that provides all those services in one unit would be ideal.

We thought that the separation of the assets between the two campuses actually was problematic. Even though there is a shuttle service available, it takes between 15 and 20 minutes to get things back and forth. But I know

from my own work on a daily basis, I often will walk downstairs to the technicians, you know, if there's a problem with a stain or if I need immunochemistry, that lab is only, you know, a floor away, the EM is up two floors, and so it's very - it makes the communication and the work flow much more efficient. And also, our secretaries are also on sight here right adjacent to our offices.

DR. WILENSKY: Any additional questions?

DR. POLAND: Gail, this is Greg Poland. Can you hear me?

DR. WILENSKY: Yes.

DR. POLAND: Just a quick thing. First, Joe, thank you, and to Wayne Lednar, who's there, too, for the tremendous amount of work that I know has gone into a large and difficult issue. One quick question for you, and it revolves around the tissue repository. I've had some interactions with them in the past.

Is there an existing or sort of

benchmark model that we don't have to go through today, but that could be proposed for how the utilization and access to that repository could occur?

DR. PARISI: I believe the current model at the Armed Forces Institute of Pathology actually works fairly well, Greg, works well. Again, there is this new report that was an assessment by this company called Asterand from Michigan, who reviewed the tissue repository in great detail and found that it was very viable and provided appropriate access to it and so on. The tissue certainly was very valuable. Maybe someone from AFIP would like to speak to that.

DR. POLAND: Not so much the mechanics of it, but just your general feeling that there is a benchmark way to do it.

DR. PARISI: I believe so, yes.

DR. POLAND: Thank you.

DR. WILENSKY: Are there any questions from members on the phone?

OPERATOR: Yes, we have a question from Kathy Slaunwhite. Please go ahead with your question.

MS. SLAUNWHITE: Thank you. Yes, it's Commander Kathy Slaunwhite from Canada here. Currently the Canadian Forces sends aviation incident or accident related specimens to AFIP for analysis. Under the proposed national structure, Joint Pathology Institute structure, is there any reason to be concerned that that continued access to sample analysis would be threatened or in jeopardy of being able to continue in its current manner?

DR. PARISI: Well, I would hope that it would continue. I would hate to see that go away,

because I think it provides a very important source of case material both intellectually, as well as providing a service to you folks.

MS. SLAUNWHITE: Yeah.

DR. PARISI: The plan as it was presented I don't think had any mention of that,

but that ought to be considered within the scope of service, I believe.

MS. SLAUNWHITE: Thank you.

DR. WILENSKY: Any other questions on the phone?

OPERATOR: We do not have any at this time.

DR. WILENSKY: Okay. The Board has received written statements regarding establishment of the Joint Pathology Center. These statements have been reviewed by the Executive Council and will be part of the formal meeting record. I understand there are members of the public who have registered present their comments on the JPC issue. I will ask Ms. Jarrett to assist us in having them come forward. Please

keep your statements as a summary statement to within two to three minutes.

COL GIBSON: Do we have members of the audience who would like to make a statement? We understood there were four.

DR. WILENSKY: If they're written, they're in the record.

COL GIBSON: If they're already written, they're already in the record. Okay, then fine.

DR. WILENSKY: Okay, thank you. If there are no additional comments, I would like to know whether among the Core Board members the Board is comfortable in receiving the JPC report by consensus. Okay, I'm getting nods of people around the room here. Is there anyone on the phone who is a Core Board member who is not comfortable with accepting the recommendations by consensus? In that case, please regard the report as being accepted by the Core Board, and thank you for all of your difficult work. I appreciate your activities. We are now going to take a short break. We will reconvene at 10:15. Thank you.

(Recess)

COL GIBSON: Okay, let's get started.

DR. WILENSKY: Doctor Poland will now cover the activities of the Defense Health Board's

Task Force reviewing the Department of Defense Biodefense Research Portfolio. This is a new question before the Board since the last formal meeting. We've been tasked to provide an external review of the Department's Biodefense Research Infrastructure and answer a series of questions relating to DOD's scientific and strategic investments. It's processes and procedures related to product development and licensure and to evaluate the scientific or strategic return on investment for previous and current research development, training, and education efforts. Doctor Poland, the floor is yours.

DR. POLAND: Thanks, Gail. If we can have the next slide. There seems to be a delay in how the slides come up.

OPERATOR: Pardon me, Doctor Poland. There is going to be a slight lag in the slides.

DR. POLAND: Okay, thank you. So just to reiterate, the Army Office of the Surgeon General, Major General Schoomaker requested that

the DHB address the three questions. And for simplicity, let me just characterize each one of them with a headline.

The first question revolves around need. Is there a national and strategic need for the military service departments to own and operate infrastructure in support of biodefense capabilities?

The second headline is translation. Are the current processes effective in transferring the results of basic research into advanced product development and licensure? And the third headline is sort of return on investment. Does the current system and processes provide a strategic return on investment for these efforts?

If I could have the next slide? I want to acknowledge and thank the Work Group members who have put a lot of time and effort into this. We had a teleconference on October 24, and then

meetings on November 7, November 19. And yesterday John Clements, who is there, and myself,

spent the day crawling in and out of a black hawk helicopter doing site visits to some of the biodefense assets.

So the Work Group members included myself, Wayne Lednar, Doctor Breidenbach, John Herbold, who has been with us before, John Clements, who's there with you, Frank Ennis, and Joe Silva. Next slide.

As I've mentioned, we've had four meetings, or really three meetings and a site visit thus far. The November 7 in person meeting allowed us to get briefings from DTRA, the JPEO, from each of the services involved, and the Office of the Special Assistant for Chem Biodefense.

Yesterday, as I mentioned, site visits were conducted to Edgewood Chemical and Biologic Center, Forest Glen, Rare and the United States Army Medical Research Institute for Infectious Diseases. Next slide. What I'm going to give you next is in the spirit of an interim report given

that all of our - all of the Subcommittee's

thinking hasn't yet been cohesively put together. As I mentioned, the site visits finished a mere 12 hours or so ago. But I can give you this much in the way of insight.

One is, we feel strongly that there's no dispute, that the DOD Biodefense Research Portfolio is both unique and necessary for DOD. There are a number of reasons for this, and the questions here seem to revolve around could another federal agency, for example, NIH or academia or industry do this. And, by the way, let me just mention that, because Bio Surety is in the title of the slide, the DSB, Defense Science Board, is actually examining the issues of Bio Surety.

We are focusing our comments on the three headlines that I mentioned. And given the very quick turnaround time for this, and I should mention, I previously served on an IOM committee that looked at similar questions related to broadly military infectious disease research, and

we spent over a year trying to come up with a reason to data driven conclusions, so this will be very high level. The reason that we think this is both necessary and needed by DOD is, there is a deterrent capability that would not be a feature of say academia or industry taking over this sort of capability. The other important thing, and we heard much in the way of testimony about this from those involved in responding to the anthrax letter attacks, by order, the responsiveness and turn on a dime capability of the military labs to respond to threats is not only sound, but as I say, was demonstrated in real time during the anthrax attacks.

We also heard quite clearly that laboratories in academic and industry are generally unwilling to engage in research that have very high levels of risk. In fact, there's only a few assets around the country where BSL-4 level research could be conducted, and for industry, where there's no profit motive for orphan vaccines, so, for example, vaccines against

special pathogens that are not going to provide a market for some public sector.

And the other thing which I had not realized was the particularly high demand for BSL-4 containment laboratories, especially for animal efficacy studies, and this revolves around the FDA's recent two animal rule for licensure of vaccines such as these that cannot be ethically tested in human populations. So not only does the military use this, but academic and industry are completely dependent on that DOD asset. Next slide. Our second preliminary conclusion is that the basic science research that we heard about is sound, but that there were barriers toward moving that or translating that into advanced product development and licensure.

Some of those include a fragmented organizational structure that strays away from the benchmark, what we felt was the benchmark, and that is industry best practices models.

There is not a single individual accountable and whose head is on the platter for

meeting timelines and translation, and in some cases, senior leadership that doesn't necessarily have vaccine development expertise and experience.

There are a number of complex management and oversight issues involving DTRA that we'll elaborate on in our report. We noticed a loss of intellectual capital due to difficulties inherent in transitioning junior level military personnel to higher level leadership positions and retaining qualified scientists along the lines that Joe was mentioning in terms of attracting top talent and retaining them. There are also, and this is a bit complex, but there are separate lines of funding for the different phases of, you know, pre-clinical research through clinical research and advanced development, and those come from different entities, and that collusion of facts is not amenable to project sustainability and to an acceleration of the process.

There was also the sense that the processes seem to be more concerned with inputs rather than outputs. One would think that the

sole focus might be on an output. We will have a vaccine against pathogen X in five years. That's not the sense that the Committee has, rather, it's a sense of, well, how many square feet do we have, what kind of funding do we have, those sorts of issues, sometimes politics, of course, too, and a complex and unwieldy table of organization that, in fact, is very difficult to get your hands around, and mostly unknowable even by those involved with it. Next slide.

There's some other issues, these include a lack of the level of communication. I shouldn't say lack of communication, it's lack of the depth of communication that should occur between responsibility - responsible entities. And a strong feeling that this should be very much a joint program. What we saw as a tendency, although there have been recent attempts at more communication, is that Army, Navy, and primarily those programs might have a lot of redundancy in overlap and that may or may not be even knowable by the individuals in those two different

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programs. There is now an integrated national portfolio which we thought was a very good start, but I think one of the things that will come out of our conclusions is, this really needs to be organized as a very joint program with a senior level experienced level highly accountable for the results of the program.

The TMTI is a novel experiment and has only been in place I think about a year and a half, two years, something like that, and those results need to be evaluated and if successful, generalized. This is sort of a pathway that's been developed to try to accelerate advanced development of products.

It is not clear that there are systematic, agreed upon, and explicit evaluation metrics to evaluate the different programs and the different phases that they are in, and that follows on to the ability to kill projects that might not be productive. It was not clear whether projects had been stopped, and if so, what criteria had been used. Next slide. So some of

our early recommendations are that, in the vain of productive biodefense research, our sense is that it will require centralization and joint programmatic planning, that the development of evaluation metrics was going to be important, that there be sustained and identifiable leader accountability, that there be realistic timelines and multi year funding rather than year at a time, and further collaboration. Next slide.

I might comment that when it gets to the ROI, we still have some work to do on that, but we very clearly heard the large number of patents that have been developed through this programs in the last three to five years, the amount of CREDA and collaborations that had occurred, publications that occurred, and even products that either had been licensed or at least passed and into the IND phase. So we did feel - we did have the gestalt that there has been an impressive return on investment, it's just been somewhat hard to quantitate that.

And then finally, I'll say that, again,

on a very short timeline here, what you have just heard will form the basis of a high level interim report that will be briefed to the service secretaries. And I think this date is correct that we have established December 3, 2008, in that. Next slide. And before I close on this, I would ask either Doctor Lednar or Doctor Clements, who have been particularly heavily involved in this, to add any comments. It's hard to capture the enormity of everything that we've heard in just a few slides and they may have some important insight.

DR. CLEMENTS: This is John Clements; thank you, Greg. By the way, how is your head?

DR. POLAND: A small head injury. For those in the audience, I skinned my head on the - climbing in the hatch of that black hawk on the second time, but I'm fine, thank you.

DR. CLEMENTS: We gave him a Purple Heart yesterday for his efforts. Just a couple of comments; one I think is particularly germane is

that our site visit yesterday was actually

conducted in conjunction with the General Officer Steering Committee visit to the sites. And Major General Robert Lennox and Major General William Rew were command officers on that visit and they have a report that is actually - it's not dove tailing this one, but it covers many of the same areas that we are covering, and they've offered to share their preliminary report with this Committee and should have it to us by Friday, and I think that should help inform us as we go forward in our discussions.

DR. POLAND: That would be wonderful, thank you, John.

DR. CLEMENTS: And I think that will be important for us. There were - the site visits yesterday I think were really complimentary to the discussions that we've been having, and the commands - each went to a great deal of trouble to lay out exactly what their programs were.

And I think that generally we came away

with very favorable impressions of the effort and the amount of attention to this particular

question, to these questions that we've been asked to address, and that will also help inform the discussions of the Committee.

But I think there are going to be some disagreements and I think we're going to need some time to discuss those. There were some variance at MMRC that I think we need to have a more full discussion about as we go forward. So I would reemphasize that we're still really at a - we're not at a - we're at the ultimate stage, we're not at the conclusion stage on the report yet.

DR. POLAND: Yeah; thank you, John. And I might just add a bit onto that, dove tailing to something Bill Halperin said about shoe leather epidemiologists versus arm chair. I was impressed once again and commend to any of the task forces working on important issues like this. The importance of actually seeing these sites and talking to the people involved, I find it's

impossible to really get the comprehensive view of that on paper, you've got to actually be on the ground to see it.

DR. WILENSKY: Thank you very much. We're going to begin the question and answer session using the same process that we have earlier. If anyone has just joined us telephonically, if you have a question, please press star followed by the one on your telephone key pad. If you'd like to withdraw your question, please press star followed by the two. Let me start with questions from those of you who are here at the hotel. Doctor Halperin.

DR. HALPERIN: Before there was Legionella, there was Legionnaires Disease. So my question is whether the effort that you're reviewing has to do with kind of proactive research that is contemplated or whether there's a reactive part, which is given the needs of either the military or even civilian population in identifying - newly identifying an agent, given an

epidemic. Is there a role for the function that you're reviewing in this, and is it responsive, does it have the response capability in that kind of a situation?

DR. POLAND: Those are excellent questions, Bill, let me try to briefly address them. In part, the answer to your question regarding new pathogens are more classified programs, so called Black Biology, and we are not reviewing those aspects, so we have concentrated on the non-classified, reserving the idea that, given the short time line, that we would take step one first and that those later steps would be the focus of more detailed discussions at a later time.

Nonetheless, they do recognize that, and yes, they do have that capability. Two of the sites in particular are unique in their ability to receive unknowns, that is, we don't know what this is, but it could be an extremely lethal agent, and they have the capabilities to deal with that and

genomics assets for pathogen sequencing and identification. You had a second I think sub-question buried in there, Bill; did I catch it?

DR. HALPERIN: No; I think you've

described that there's a capability for the unknown. The other question, which is a peripheral one is, there are arrangements for receiving these if they're let's say civilian or cooperation with CDC, et cetera?

DR. POLAND: Oh, yes, there are. And, in fact, just to give you one unclassified example, as part of the confusion and turmoil surrounding the initial anthrax attacks, and I can't remember the volume, but it was incredibly impressive ability for them to assist in the identification, testing of unknowns, et cetera, and they literally were able to turn that on a dime and devote those assets 24/7 to solving that issue and problem.

DR. WILENSKY: Any other questions?

DR. DUBOIS: This is Ray Dubois; did the Task Force consider, in your tic mark here on page four, at least on my page four, the sustained and identifiable leader accountability issue? As I remember, the question of who was in charge at OSD, was it PNR or AT&L, that is to say, was it

the Assistant Secretary of Defense for Health Affairs or was it the Assistant to the Secretary of Defense for Chemical Biological Radiological Matters?

DR. POLAND: So your question is, were we able to pin that down?

DR. DUBOIS: Well, I remember trying to adjudicate between those two gentleman, and I must confess, I don't know that I was very successful. And I can tell you, the Secretary of Defense wasn't very pleased. But nonetheless, did you look at it?

DR. POLAND: Not to that level of detail. And, in fact, just yesterday we got mailed an organizational chart. I'm aware it was

mailed, I haven't seen it yet. So I can't comment with that degree of granularity to your question. I can just generally say that as we went from site to site, it wasn't apparent even in the development of this that there's, you know, so to speak, a biodefense product development czar, whose, as I say, whose head is on the platter for

timelines, budgets, and return on investment metrics.

DR. DUBOIS: It would be nice if there was one.

DR. WILENSKY: The comment, if you didn't hear it was, it would be nice if there was one from Ray.

DR. POLAND: Yeah.

DR. WILENSKY: Are there other questions that people want to pose? Roger.

COL GIBSON: Yeah, this is Colonel Gibson. Just to add a little bit to this discussion, particularly with Doctor Halperin's comments, we have a bio - we're talking about here

a review of biodefense research. We also have a robust, non-biodefense infectious disease biological research program. MIDRP is an obvious example of Military Infectious Disease Research Program component. That wasn't part of this whole issue. The problem is, and this goes to the command and control and who's in charge, et cetera, is the missions of some of these

installations, some of these research facilities very much overlap.

DR. POLAND: Yes.

COL GIBSON: You've got USAMIIRED doing biological research and able to look at unknowns that may not be a biodefense issue and a biodefense mission, and in some cases it's the same people. So it adds to the confusion, et cetera, and I thought that was, you know -

DR. POLAND: Yeah, thank you, yeah. Just two other comments, one is, let me just say on a personal note, and, and I think reading the mindset of others on the Committee, we were very

impressed with the quality and the dedication of the people that we met and their local processes. But they are, to some degree, failed by a system that tolerates complexity and lack of accountability at a high - truly senior level champion that is sustained, not just, okay, there's a crisis right now, so I just wanted to make that point. The other is, I'd like Wayne, if he could, to just make a point that I thought was

a very insightful point that had, you know, we hadn't been very explicit about until he said it, and I thought really helped shape the complexion of our thinking. Wayne, if you'd make your point about the difference in BD research in sort of the civilian and industrial sector versus DOD.

DR. LEDNAR: Greg, can you give me just a little more of a mental jog?

DR. POLAND: It was the idea of deterrent rather than necessarily a product that would be used after an event.

DR. LEDNAR: My sense of - this is Wayne

Lednar. My sense of the - kind of the civilian activity is, it's kind of what we would call market focused.

DR. POLAND: Yeah.

DR. LEDNAR: There will be some understood need to which there is a research activity, product development, and fielding. So it tends to be kind of look in the rear view mirror at what you've recognized as the issue and then respond to it. It does not tend to be as

anticipatory, it doesn't tend to be as getting into the areas of uncertain science in a major way, and I think what distinguished some of the discussions that the Committee had with those who shared their experience and data were, they're always thinking about what's out over the horizon, they're thinking about how to leverage current capabilities to support troops in the field, to do it in a reality which is not a controlled laboratory setting, but rather the real world.

And these are not attributes that you

commonly see frequently in product development in the civilian sector, so these really are unique orientations inside DOD --

DR. POLAND: Yeah.

DR. LEDNAR: -- which are probably not buyable, if that's a word.

DR. POLAND: Good; thank you, Wayne.

DR. WILENSKY: Doctor Clements.

DR. CLEMENTS: Yeah, it's John Clements; and I'd like to make one follow on point on that, and that is that despite the fact that we talk of

these issues as if they're the same, there really is a difference between biologic warfare and biologic terrorism, and the mission of the military is primarily centered around biologic warfare. The nature of the threat is very much different, the agents are very much different, certainly the quality of the agent is very much different, and the concentration and dispersal issues are very much different.

And so it is difficult, even though you

may have an academic or industrial concern that could grow agent X and maybe do some stuff with it, to be able to design a defense parameter around that that can protect the war fighter is a very special skill set and it's going to be difficult to replicate that outside of the environment of people who understand the entire spectrum of possibilities. And so that gives this a very unique character. It's difficult to see how you could replicate that any place else.

DR. POLAND: Well said; thank you, John.

DR. WILENSKY: Are there any questions

from people who are on the phone? Heidi.

OPERATOR: We have no questions from the audio audience.

DR. WILENSKY: Great; if there is no disagreement or additional comments, the Core Board accepts Doctor Poland's presentation and the report in its current form by consensus.

DR. POLAND: Thank you.

DR. WILENSKY: Our last speaker for

today is Doctor Kenneth Kizer. He's Chairman of the Board of Medsphere Systems Corporation, the leading commercial provider of open source information technology for the health care industry.

Previously he served as Undersecretary of Health in the U.S. Department of Veteran's Affairs. He is currently the Chairman of the National Capital Regional Base Alignment and Closure, NCR-BRAC Advisory Panel, and will provide an update on its activities.

The group met earlier in the week in preparation to review the design and construction

issues regarding the new Walter Reed National Military Medical Center at Bethesda and the new community hospital at Fort Belvoir. Doctor Kizer, please begin.

DR. KIZER: Thank you, Gail. Good morning. If we could have the slides, the next one. This is going to be primarily about process. The deliberations of the group have not evolved to

the point where we actually have come to much in the way of any --

DR. WILENSKY: Ken, can you speak up?

DR. KIZER: Sure; is that better?

DR. WILENSKY: Yes, thank you.

DR. KIZER: Okay. Let me just repeat the couple points. What I'm going to say is mostly about process. The Committee has not moved forward enough in its work to really be at the point of coming to any conclusions, recognizing the short timeline we're on, we will be doing that shortly.

The first slide there just shows the Subcommittee membership and some of the subject

matter experts that were invited to participate in the meeting earlier this week. Monday and Tuesday were spent hearing a range of briefings and looking at architectural plans and a variety of other input on the - to try to help us answer the questions that were posed. The next slide.

Just in the way of background, as I say,

this has - to do with process. The group was convened only recently, had an initial meeting in August, and did some of the obligatory orientation and talked about some of the issues. The next slide.

Subsequent to that, the National Defense Authorization Act was passed, which included a requirement for an independent design review of the new Walter Reed National Military Medical Center, as well as the new hospital being constructed at Fort Belvoir. Just a little bit of a digression, in that legislative language, the term "world class" is used to describe these facilities, and, in essence, is put forth as a standard by which they will be designed and

constructed against.

In recent years, this - what was historically a marketing term, "world class", has been increasingly used in health care. Earlier this week I went to Google and looked up world class medical center and quickly was able to

identify at least 100 different medical centers that characterize themselves or their services they provide as world class.

This term has now made its way into at least two different federal laws as a standard, in this case, a standard against which over a billion dollars of public money is going to be spent building new hospitals. As was talked about earlier, it's also a standard against which the Joint Pathology Center will be held against and the services it provides.

However, there is no agreed upon meaning or objective and measurable way that this term has been defined by any authoritative or reputable entity. So with that as the background, turn to the next slide. The Committee has spent a fair

amount of its time actually focusing on trying to define what is world class, and recognizing that the law or the section that we're focused on here requires that we submit an opinion to the Secretary as to whether the design currently being

pursued and construction underway meets the goal of providing world class facilities, and if not, what should be done differently.

So we've, as I said, spent a fair amount of time deliberating that, augmented the Subcommittee with some architectural and patient representatives and other expertise to help look at the materials that were available. Next slide. Actually, I think that covers it; let's go to the next one, as well.

So after spending two days earlier this week looking at a range of background, I think we have started to form some impressions, although there are a number of areas where we have requested some additional data, and even since the Committee adjourned on Tuesday afternoon, some other areas have been identified that we probably

need to look at some additional information, as well. Hopefully we will get that in a timely manner, next slide, so that we can review it, have a chance to, next slide, discuss it with the idea

of having a draft report done in the first week of December to present to the full Board on December 15, after which we would hope to finalize it and submit it after the new year.

And with that, I think those are the main points I wanted to make, and I'll be happy to address any questions or hear comments.

DR. WILENSKY: Any questions that people have here first in the hotel?

COL GIBSON: Just to - this is Colonel Gibson. Just to add a little bit of context to this, and Doctor Kizer did carefully cover it, the NCR-BRAC Subcommittee of the Board was formed last - basically was put on the books last spring as a Subcommittee. From the Federal Advisory Committee Act standpoint, the only folks who can actually form a Subcommittee of a Federal Advisory Committee is the Board Chairman and the Board

itself.

So we started that process way ahead, starting having meetings regarding NCR-BRAC, and

design and construction was only one of the multitude of issues that that Subcommittee will deal with. After that happened, we - Congress passed the law requiring this external group. The Department and the Defense Health Board agreed that, with augmentation, as Doctor Kizer said, the NCR-BRAC Subcommittee could serve as this external group as long as they meet all of the federal requirements for Sunshine Act and Federal Advisory Committee Act. So that's how we're operating. The reason we're briefing this today when it isn't a final product yet is because one of the requirements is to update the Board and deliberate these issues in Open Session before a report can go final to the Department of Defense.

In this case, the law specifically outlined folks who - types of people that needed to be on the Subcommittee or on the panel and specifically dates when the report has to be to

the Secretary of Defense, January 14, thus the rapidity or the speed with which we're dealing

with this issue.

DR. KIZER: Thanks, Doctor.

DR. LEDNAR: This is Wayne Lednar; I don't know whether this issue or this question is in scope for the group that's deliberating, but I think it has facility and capability implications. If we think about how the Department of Defense and its medical treatment response has supported Iraq and Afghanistan, it has acquired really unique capabilities, for example, in the care of the amputee. And as we think about capability that's been developed, we certainly wouldn't want to see that atrophy in the future. At the same time, we do not want to see a high volume of patients needing this care, but we need to sustain that capability in some way. Some of that is facility, some of that is expertise of its providers. And as we're thinking about supporting the military in the future, how do we keep that capability, size it to current need, yet have an

ability to scale it rapidly if the need should

occur again in the future?

DR. KIZER: Well, I think that's a great question. It's a little bit outside of the scope of this immediate report, but I think it's within the purview of where we anticipate the discussion going in the future. And it also brings up somewhat of a nuance in that world class as a term has been described or has been used to describe both specific types of health care, and in this case you're referring to complicated wound care, as well as facilities.

And the standard or the metrics by which one might objectively and measurably look at that standard are different for the two. And so I do anticipate that we are going to have to weigh in on both what might be considered a world class medical center, which is required by this report as far as design and construction, but also what does it mean to provide world class care in whatever area. And in doing that, I think that sets the stage for how one maintains, or at least

may help provide some guidance on how one maintains those skills and expertise on an ongoing basis.

DR. WILENSKY: Ken, let me just clarify. Will there be an explicit discussion of the issue that you've raised? What is it that you, as a Subcommittee, we, as a Core Board, accept as appropriate to the term world class medical care?

DR. KIZER: In our report, there will be a substantive discussion of that issue.

DR. WILENSKY: Great.

DR. KIZER: And it is, for example, on what is a world class medical center, there are at least 11 different domains with a menu attendant to each as to how we are thinking about that.

DR. WILENSKY: Ray, did you have a comment?

DR. DUBOIS: This is Ray Dubois; as Doctor Kizer said, we intend to define world class as it pertains to the Walter Reed National Military Medical Center. And there will be an appendix listing the domains and certain criteria

that we believe to be applicable. To the issue also which is a part of this that Doctor Lednar raised, considerable discussion Monday/Tuesday on - under the term or under the rubric flexibility was ensued, and that included scalability, it included expansion, it included also alliances outside of the Walter Reed National Military Medical Center with other medical centers within the military, the Veteran's Administration, and the so called non-government or private sector hospitals and medical centers and other centers of excellence.

So it was very robust, and several of us were there, discussion over a two day period, and one which we hope will yield both a satisfactory answer to the Congress based on their charge, as well as to the military community as a whole.

DR. HALPERIN: Bill Halperin; I want to say this, it may be superfluous, but soldiers are a distinct occupational work force, and essentially given the ebb and flow of wars, the issue that Wayne and you are describing is the

issue of how to deal with surge and surge capacity. And it's - to think of world class at a static point in time and not think about surge is - I mean nobody would do that rationally. So the issue is that outside of the military, probably the issues of occupational injury dwarf the number of military injuries. So in thinking about how to keep a military specialized unit in, you know, the optimal treatment, let's say the amputations, one, I would hope, would think about the other work force, which is the civilian occupational work force that in many ways different agents, but they end up with the same sorts of amputations, trauma, et cetera.

And I don't know that anybody has really thought of emphasizing, giving sort of the same kind of optimal care to the civilian occupational injured who are, in many ways, so parallel, but in many ways are so distinctly different because they're not soldiers.

DR. KIZER: Well, actually, let me just comment on that. I wouldn't characterize your

comment as superfluous, but more as reinforcing to some of the discussion that was had. And the very explicit discussion was held, can you have a world class medical center or a world class military medical center that does not first meet the criteria being a world class medical center, and so there is some tiering and there are additional issues that are specific to being a military medical center, including the one you just identified as far as surge capacity, that go beyond what may be required, or at least add a different dimension to what may be required for a civilian hospital to meet the requirement of being "world class."

CMS HOLLAND: Sir, this is Command Sergeant Major Retired Larry Holland; besides the amputee area, you know, we have some great research and a lot of good work going on in the burn centers and other specialties that we have that have very come a long way that, you're exactly right, that we can help the civilian community, but I would really like to see us reach

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out to our brothers and sisters who are the same individuals that are going to the VA, and a lot of their facilities do not match up as I'm seeing now as a retiree with some of the centers that I had the privilege of using.

So as you and your group goes through here, I would like to see us reaching across the aisle, per se, to try to help the VA and - because you're caring for the same service men and women that you served the first time, sir.

DR. KIZER: Well, I think, again, your comment is reinforcing to some of the discussion that was had, in the sense that while the task that we have, and the assignment is quite specific and defined in law, there is at least some belief that what comes out of this effort may be used more broadly than the specific assignment and may well be used in the future as the yardstick or measure by which other federal facilities of whatever type may be held against. And so we're cognizant that this may have broader application than just the two facilities that are requested in

the legislation.

COL GIBSON: This is Colonel Gibson; exactly right, Doctor Kizer. To put it in context, this charge that Doctor Lednar mentioned and Command Sergeant Major Holland and Doctor Halperin transcends just this question, but it is perfectly aligned with the mission of the Defense Health Board's Health Care Delivery Subcommittee, it's aligned under the NCR-BRAC Subcommittee, and it is certainly part of the overall charter of the Defense Health Board.

So we have ample opportunities across the entire spectrum of the Board to engage in this issue of flexibility and adaptability and extrapolation of this issue to the entire MHS and beyond.

DR. WILENSKY: Any further comments? Heidi, any comments from the phone, any questions?

DR. BREIDENBACH: Yes, I have a question. This is Doctor Breidenbach. Doctor Kizer, one of the things that world class hospitals carry out is clinical research. Have

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you looked at the issues of how the military deals with clinical research and active duty military? Is that an issue which needs to be addressed or do you think that's not a problem?

DR. KIZER: Well, the - that is one of the specific domains, if you will, by which we think characterizes a world class medical center. The sheer volume of information that we need to look at to answer the specific charge of the legislative language here has been focused on the design and construction plans and at least some tentative look at the operational plans of the two facilities.

And while we're cognizant that there are a whole host of other issues such as you have identified that need to be looked at, we just haven't gotten there. But we certainly are mindful that this is something that ultimately, if this issue is worked through in more detail, probably does need to be looked at.

DR. BREIDENBACH: Thank you.

22 MR. JHA: Doctor Kizer, this is Prakash

1 from AFIP. Since you are trying to define the
2 definition of world class and it has clear
3 implication of the JPC, as a member of AFIP, we
4 have been recognized for a century as world class.
5 Do you think - will it be a good case study or a
6 model to understand what exactly is both
7 structurally and functionally the definition of a
8 world class entity be?
9 DR. KIZER: Well, I think some of the
10 things that have historically characterized the
11 AFIP as the leadership role that it has had are
12 some of the same types criteria that are being
13 looked at in our definition and how we expect to
14 characterize it. I would say that certainly what
15 was world class 100 years ago or even ten years
16 ago is probably significantly - in some ways
17 significantly different than what would be
18 considered world class in the 21st century.
19 So I think that we're looking through
20 the lens of today and in the future, which

incorporates many of the things that historically have fit that bill. But also, there's, again,

some differences between a world class service, which I think is more along the lines of what AFIP's role has been, than a medical center, which does have different design and construction issues that wouldn't apply necessarily to a service or a care process.

DR. WILENSKY: Any other comments?

OPERATOR: We have no questions from the audio side.

COL GIBSON: Okay. This is just as - Doctor Breidenbach is a new member of the Board, he's going to be serving, and you can give us a bit about your background, if you're still there, sir.

DR. BREIDENBACH: Yes.

COL GIBSON: He's going to be a member of the DHB's Task Force on Health Research. Doctor Breidenbach.

DR. BREIDENBACH: Yes; hello, everyone,

Warren Breidenbach, Louisville, Kentucky, University of Louisville. My background is plastic surgery, specifically reconstructive

microsurgery.

DR. WILENSKY: Great; we're glad to have you part of this group. We look forward to seeing you.

DR. BREIDENBACH: Thank you.

DR. WILENSKY: Any further questions? Ken, we recognize the importance of what you're doing and what it means to this specific construction, but other hospital construction in DOD, and we will look forward to hearing more about it at our December 15 and 16 meeting. Doctor Poland, can I ask you to provide some final comments?

DR. POLAND: Yes, thank you, Gail, and thank you for being there at the physical meeting and running it, much appreciated. I do want to - I don't want to rush through this last part, I want to pause a moment for something very

important, and that is, as some of you, but many of you may not know, Colonel Gibson will be retiring, and the plan is that we'll make some more formal comments at our next Open meeting, but

because he will not be in uniform at that meeting, I wanted to make a couple of comments.

The first, Roger, and I mean these in a heartfelt way, you have been an extraordinarily skilled leader and administrator. And it reminds me of the statement once made that he "performed the commonplace under uncommonplace conditions", and that really relates to, and some of the newer members of the Board may not realize this, the Board has gone from a couple of handfuls of individuals to a quintupling when you actually look at the number of people involved, well over 100. There is not certainly a week, much less a day that doesn't go by when there isn't a teleconference, an in person meeting, a site visit, et cetera, and Roger and his staff have, with extraordinarily - touch, organized and

carried all of that out, it's truly remarkable. I think it's more than obvious, Roger is also a patriot, and I want to commend his service in that regard, and an incredibly skilled facilitator and hard worker.

I want to paraphrase, if I might, and it's because I'm a fan of the Greek antiquities and of ancient Greece, Steven Pressfield wrote a book called Gates of Fire, which is sort of historical fiction that was made popular in the movie 300, when the 300 fought against the Army of Persia, which was 10,000 in number, and during that battle, one person survived, which happened to be a slave who was captured by the Persians, and he's interviewed by the king of the Persians, who's trying to understand what a king really is, and let me paraphrase, a leader.

So in that vain, let me characterize Roger and my time with him this way, using Steven Pressfield's words; "I will tell His Majesty what a leader is. A leader does not dine while his men

go hungry, nor sleep when they stand at watch upon the wall. A leader earns the love of their constituents by the sweat of his own back and the pains he endures for their sake." And there's some literal part of that there, right, Roger? "That which comprises the harshest burden, a

leader lifts first and sets down last. A leader does not require service to those he leads, but provides it to them. He serves them, not they him." And that, to me, characterizes to the endth degree the quality of Roger's leadership.

And I just want to commend that, Roger, and on a personal note, it's a wonderful thing to call you a friend, and I hope that through all of our years of working and retirement into the future, we will always be in communication because I have admired you as an individual and certainly your skills to turn around an organization like the AFEB into what is now the DHB is truly a remarkable feat, so thank you very much, Roger.

DR. WILENSKY: Fortunately, although he

is retiring from the military formerly, we are not letting him escape from providing --

DR. POLAND: That's right.

DR. WILENSKY: And so he will continue with us in his civilian capacity, which is very important for me going forward. It is I think important, helpful that, although new to the

Defense Health Board, not new to working with Colonel Gibson. He was, of course, the person that we had contact with in the Task Force for the future of military health care that I co-chaired along with General Corley, and was also our federally designated official on the trip to Qatar, Iraq, and Langstool that General Corley and I did in August of 2007, so we are delighted, all of us on the Defense Health Board, Roger, that you'll continue working with us.

DR. POLAND: Yeah, wonderful. So unless any member has other business to present to the Board, we'll conclude our meeting. I look forward to seeing all of you at our next Open meeting on

December 15 and 16 at the Ronald Reagan Building and International Trade Center in Washington, D.C. And Colonel Diniega, could I ask you to adjourn the Board's business, please?

COL GIBSON: You're not going to give me a chance to comment?

DR. POLAND: Roger, please, yes, sorry.

COL GIBSON: This was a surprise, I

didn't expect anybody to talk about this, we were trying to get this meeting done virtually, and it's been a little hectic to get it all - all the pieces together. I would like the Board members to stick around for just a couple seconds afterwards to get a little feedback from you on this type of process for me. That said, I can't do this job without staff, and I have absolutely great, great staff. They have pulled together things and really committed themselves to it. I also can't do it without you. Keep in mind, I get paid to do this job.

I don't know whether I'm a patriot or

not, but the folks around this table and the members of the Board are true patriots. This is not their day job, this is what they do in their spare time for free for the service members, because that's the audience, that's who we're here for, is to take care of those guys and gals and do it right. And politics aside, you know, we honor them. So thanks for the words, thanks for the applause, and more to follow, I hope.

DR. POLAND: Thank you, Roger. Ben.

DR. DINIEGA: Before we adjourn, I'd like to just remind people who are interested in attending Roger's retirement ceremonies, there's a luncheon on December 5 and a retirement ceremony that afternoon. And on behalf of the Department, I'd like to just express the Department's appreciation for all the hard work in a multitude of issues that the MHS has brought forward to the DHB, and thanks for the Subcommittee's hard work also. So I declare the meeting over.

(Whereupon, at 11:19 a.m., the

PROCEEDINGS were adjourned.)

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