UNITED STATES DEPARTMENT OF DEFENSE

DEFENSE HEALTH BOARD MEETING

DAY 2

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P R O C E E D I N G S

DR. POLAND: Good morning, everybody. The agenda has been slightly altered, primarily because the Deployment Health Research Center, External Review, and Health Implications for Prisoners of War was accomplished yesterday. So we're going to follow our current agenda down to 11:00, and then the Board will go into an Executive Session.

So we have a lot to do today, this morning, so we'll get started. Ms. Embrey, could I ask you to call the meeting to order, please?

MS. EMBREY: Absolutely, my pleasure. As the designated federal official for the Defense Health Board, a Federal Advisory Committee and a continuing independent scientific advisory body to the Secretary of Defense and to -- via the Assistant Secretary of Defense for Health Affairs, and the Surgeon Generals of each of the military departments, I hereby call this meeting of the Defense Health Board to order.

DR. POLAND: Thank you; and again,

carrying on the tradition of our Board, if I could ask everybody to stand for a moment of silence to honor our service men and women.

(Moment of silence.)

DR. POLAND: Thank you all very much. Since this is an Open Session, as we did yesterday, I'd like to go around the table, have the Board and distinguished guests introduce themselves. And one other comment is to any members of the public that would like to make statements during the session today, and I believe we have some regarding at least two of our agenda items. Could I ask you to please register or sign in with Lisa, who I gather is probably out at the table. Okay.

Oliver, if you could raise your hand, too. She's also available to assist you. So maybe, if we could, I'll go the opposite way today, start with Colonel Gibson, and have people introduce themselves.

COLONEL GIBSON: Colonel Roger Gibson, I'm the Executive Secretary for the Defense Health

Board.

MR. UNTERMEYER: I'm Chase Untermeyer, a private business man in Houston.

MR. O'LEARY: Dennis O'Leary, President of Emeritus, The Joint Commission.

DR. PARKINSON: Dr.Mike Parkinson, I'm the President of the American College of Preventative Medicine.

DR. PARISI: Dr.Joe Parisi from Mayo Clinic, I'm a neuro pathologist, and also Chair of the Subcommittee and Pathology and Laboratory Services for the DHB.

DR. ERDTMAN: Good morning, I'm Rick Erdtman, the Director of the Board on Military and Veterans Health at the Institute of Medicine.

DR. SHAMOO: Adil Shamoo, Professor and former Chair, University of Maryland School of Medicine, I'm Bioethisist.

DR. HALPERIN: Bill Halperin, Chair, Preventive Medicine, New Jersey Medical School, Newark.

DR. KELLY: Jim Kelly, Neurologist at

the University of Colorado and Chair of the Traumatic Brain Injury External Advisory Subcommittee.

DR. BLAZEK: I'm Dr.Bill Blazek, I'm a -- at Georgetown University in the Center for Clinical Bioethics, and I'll be in the Subcommittee on Medical Ethics, Health Care Ethics, thank you.

DR. MULLICK: I'm Dr.Florabel Mullick, Director of the Armed Forces Institute of Pathology, and also Executive Secretary of the Scientific Advisory Board for Pathology and Laboratory of the Defense Health Board.

COMMANDER SLAUNWHITE: I'm Commander Cathy Slaunwhite, a Canadian Forces Medical Officer in a liaison role at the Canadian Embassy in Washington, D.C.

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

CAPTAIN NAITO: Captain Neil Naito, Director of Public Health, Navy Medicine.

COLONEL MOTT: Colonel Bob Mott, Preventative Medicine, Officer at the Army Surgeon General's Office.

LT. COLONEL BLEDSOE: Yolanda Bledsoe, Health Service Support Division at the Joint Staff.

LT. COLONEL GOULD: Phil Gould, Air Force Medical Operations Agency.

CAPTAIN COWAN: Group Captain Alan Cowan, I'm the British Liaison Officer to the Office of the Assistant Secretary of Defense for Health Affairs, Forced Health Protection and Readiness. Try saying that if you had a drink. I'm also the British Liaison Officer to the Veteran's Administration.

DR. KAPLAN: Good morning; I'm Ed Kaplan, Professor of Pediatrics, University of Minnesota Medical School.

DR. MILLER: I'm Mark Miller, Director for Research at the International Center at the NIH.

DR. BLAZER: I'm Dan Blazer,

Psychiatrist at Duke, Epidemiologist, as well.

DR. GARDNER: I'm Pierce Gardner, I am a Professor of Medicine in Public Health at the University of New York at Stony Brook.

DR. OXMAN: I'm Mike Oxman, Professor of Medicine and Pathology at the University of California San Diego, and an ID doc and virologist.

DR. BENJAMIN: Good morning; my name is Richardean Benjamin, I'm the Chair of the School of Nursing at Old Dominion University in Norfolk, Virginia.

DR. LaNOUE: And I'm Alcid LaNoue, DR., Orthopedic Surgeon, former Army Surgeon General, retired since '96, special interest in amputations.

DR. SILVA: Joseph Silva, Professor of Internal Medicine, Infectious Diseases, and Dean Emeritus, University of California, Davis School of Medicine.

DR. WALKER: David Walker, Chair of Pathology at the University of Texas Medical

Branch and Executive Director of the Center for Biodefense and Emerging Infectious Diseases in Galveston.

DR. DETRE: Thomas Detre, Professor of Psychiatry and former Senior Vice Chancellor for Health Sciences, University of Pittsburgh.

DR. CERTAIN: Robert Certain, retired Air Force Chaplain, Episcopal Priest serving in Marietta, Georgia.

DR. KELLEY: Joe Kelley, Deputy Assistant Secretary for Clinical and Program Policy.

DR. LUEPKER: Yes, I'm Russell Luepker and I'm a Professor of Epidemiology and Medicine at the University of Minnesota.

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

DR. WILENSKY: Gail Wilensky, Economist, Senior Fellow at Project Hope.

MS. EMBREY: Ellen Embrey, Designated Federal Official.

DR. POLAND: Greg Poland, Professor of

Medicine and Infectious Diseases at Mayo Medical School in Rochester, Minnesota.

MR. DINIEGA: Ben Diniega, Health Policy, Analyst, Health Affairs.

DR. CAMERON: Dr.Daniel Cameron, I'm an Internist in private practice, Epidemiologist, and also from the University of Minnesota, and I'll be talking about Lyme Disease today.

MS. JOVANOVIC: Olivera Jovanovic, Support Staff, Defense Health Board.

MS. BADER: Sarah Bader, Defense Health Board Support Staff.

MS. BASU: Sandra Basu, writer with U.S. Medicine.

MR. CAMPBELL: Joe Campbell, UK -- Office of the Army Surgeon General.

MR. DRABEL: Ray Drabel, Armed Forces Institute of Pathology.

MR. PERRY: Michael Perry, Director of Operations for the American Registry of Pathology.

MS. STOMBLER: Robin Stombler with Auburn Health Strategies.

DR. LIPSITZ: Robert Lipsitz, Preventative Medicine Physician.

DR. MOORE: Thomas Moore, Preventative Medicine, Resident, Uniformed Services University.

DR. BELLAN: Chris Bellan, Preventative Medicine, Resident, Uniformed Services.

MR. BAKER: Tom Baker, I'm the Chief of the Integrated Department of Pathology at Walter Reed Army Medical Center and National Naval Medical Center.

MR. LARSON: David Larson, I'm the Lab Director at the National Naval Medical Center and I'm the Specialty Leader for Pathology for the Navy.

MS. GERZ: Martha Gerz, Joint Task Force, CapMed, Clinical Operations.

MS. JEFFS: Barb Jeffs, JTF, CapMed, Health Care Delivery Operations.

MR. CARNE: Bill Carne, Department of Public Health at Brook City Base, Texas.

MR. DEALE: Tim Deale, Deputy Chief at NSA Medical Center.

MR. THOMPSON: Donald Thompson, I'm at the Defense Department, Office of the Inspector General.

MR. LAUDER: Dave Lauder, Neonatologist, Director of Medical Operation Policy, Air Force Surgeon General.

MR. WEBB: Mark Webb, Army Surgeon General's Office.

MR. BERNETT: Dan Bernett, Program Director at the General Preventative Medicine Residency at USUHS.

DR. POLAND: Colonel Gibson has some administrative remarks before we begin our first morning session.

COLONEL GIBSON: I want to thank the staff here at the Sheraton Crystal City Hotel for helping with the arrangements for the meeting. And thank you to all of our speakers for all the hard work in putting together the briefings and getting them in on time, on schedule.

Also, thanks to my staff, the Defense Health Board Support Staff, for all of the travel

arrangements and all of the other business that needs to be done to carry on one of these meetings. I also particularly want to thank Ms. Ward, who's back at our office doing the rest of the administration while we're gone, particular with the subcommittee meetings coming up.

Those of you not sitting at the tables, we have handouts that are outside, we'll also be passing out those to the members as needed. Restrooms are located out the door, to the left, and down the hall. This is an open meeting of the Defense Health Board. By Federal Advisory Committee rules, we would very much appreciate if you'd sign in for this. We need to account for everybody who attends the meeting and ensure that that goes into the record for the General Services Administration. Because it's an open meeting, we're transcribing the entire meeting, so please introduce yourself when you speak, speak clear so our transcriptionist can capture everything accurately.

Refreshments are available for this

morning's session, again, to the left, down the hall, and go around the corner, you'll find them there.

We have CME credits for this meeting. The paperwork is either outside on the table, and for the Board members, it's in your books. Lisa can help you with the administration of those. Please turn those in before you leave today. Thank you.

The next meeting of the Defense Health Board will be December, tentatively the 11th and 12th. We may have to adjust that slightly, a day either way, we'll let everybody know, post it on our web site, as well as send an email to the Board members so they know when it is. And the topics will be related to subcommittee updates, draft recommendations and new business before the Board at that time. The meeting is tentatively scheduled for the Air Force Academy in Colorado Springs.

DR. POLAND: Thank you. Our first speaker today is Colonel Thomas Baker of Walter

Reed Army Medical Center, who will provide an update on the Joint Pathology Center. Selected members of the Defense Health Board will review the Department's Draft Implementation Plan regarding the establishment of the GAPC and provide comment and recommendations. Colonel Baker's slides are under Tab 9, I believe, yes, Tab 9. We have, I think, 30 minutes scheduled for this.

DR. KELLEY: And Doc Poland, just a few introductory comments, a follow-up from the last meeting as Dr.Baker is getting ready; we asked the Board to review a strategic plan for a Joint Pathology Center, and this comes after the direction under the BRAC law for the dis-establishment of the AFIP, and then the last National Defense Authorization Act, which instructed the President to form a Joint Pathology Center within the Department of Defense unless it could not, and then it was to form that Joint Pathology Center under one of the other federal agencies if it could not be done in the Department

of Defense. And so at the last meeting, I briefly presented the process, where we went from a large number, six or eight different options, how we came down to three, which ended up with a discussion with this proposal. You can just bring up Dr.Baker's slide, that's fine. And now that has been turned over to the Joint -- to the Joint Task Force to develop an implementation plan, and this is the opportunity to review that implementation plan for comments.

The decisions, we've already made the decision that it could be done in the Department of Defense, and so that was the first decision; then the second decision was how, or the structure, and that's going to be described here in the implementation plan.

COLONEL BAKER: Thank you, sir. I appreciate the opportunity to come and brief this concept of operations. And this is a -- I believe the entire Board has a copy of our Concept of Operations. And this is kind of a big picture look at our proposal for the Joint Pathology

Center, as well as kind of a big picture implementation plan. And as Dr.Kelley noted, this is the purpose of the brief, so I won't go through this. And then Dr.Kelley also talked a little bit about the background. Under BRAC 2005, the Armed Forces Institute of Pathology was directed to be dis-established, except for several components, one of them being the Tissue Repository, which is germane to this conversation. Under the National Defense Authorization Act of 2008, as Dr.Kelley noted, I directed the President to establish a Joint Pathology Center with four components.

One component is consultation, including medical, dental, and veterinary services; the second component is research; third component is education, including graduate medical education and continuing medical education; and the fourth component is maintenance and modernization of the Tissue Repository, which is currently owned by the Armed Forces Institute of Pathology.

And, of course, at the Working Group, eight courses of action, as Dr.Kelley noted, were

reviewed, carefully vetted, and the proposal was for the one that was presented by the Joint Task Force, CapMed. And so at that point then, we started developing our Concept of Operations based on what we had briefed -- we put in our course of action for the Joint Pathology Center Working Group.

The vision of the Joint Pathology Center is to serve as the federal government's premier pathology reference center supporting the Military Health System and other federal agencies. The mission is that the Joint Pathology Center will provide world class diagnostic subspecialty pathology consultation, education, training, research, and maintenance and modernization of the Tissue Repository in support of the mission of the DOD and other federal agencies.

Under our Concept of Operations, as we noted, the Joint Pathology Center will be under the Joint Task Force, and it will actually be a part of their premier medical center, the Walter Reed National Military Medical Center. The Joint

Pathology Center will be under the -- for command and control, be under the Department of Pathology in Walter Reed National Military Medical Center.

This is our organizational structure there. And you'll see that -- if you look at the bottom there, you'll see that we actually cover all the things that we require. Our diagnostic service, which is in the middle there, is basically our consultative service. The Tissue Repositories we talked about. In addition, in support of our Diagnostic Service, our Concept of Operation includes standing up a state-of-the-art Molecular Pathology Lab to support that Diagnostic Service. Research and education, then, of course, all the support pieces that go with that, are noted on the right. And you'll see on the left, there's actually two things which we'll touch on very briefly. Under BRAC law, we're required to stand up a Pathology Program Management Office, and we'll talk a little bit about that shortly.

And then under BRAC law, we're required to retain the -- it's the DOD Tumor Registry

System called ACTUR. And so we -- those will actually be two things within the Joint Pathology Center, as well.

The functions of the Joint Pathology Center will be to provide subspecialty pathology service, specifically subspecialty pathology consultation to general pathologists within -- at outlying medical treatment facilities. They'll also support the Armed Forces Medical Examiner for consultation, as well as the Centers of Excellence within DOD.

And they'll do that by employing state-of-the-art interpretative technology. As we talked about, the Molecular Pathology Lab will support that, as well as a robust immunohistochemistry section, and immunoflorescence section, as well. As we talked about, under BRAC law, we're required to operate a Pathology Program Management Office. And what this office will do is, it will actually administer and provide quality assurance oversight for contracts for outside consultative services,

to basically provide outside consultative services for anything that's beyond the scope of the Joint Pathology Center.

We envision our Joint Pathology Center; the way we have it proposed is that we should be able to meet about 80 percent of the Department of Defense's consultative needs in terms of pathology. The other 20 percent or cases that are just deemed too difficult for the Joint Pathology Center will basically go out through the Program Management Office to select world experts as needed for consultation.

Under the NDA 2008, they actually specifically state that we provide veterinary and oral pathology consultative services, and, of course, we've got that worked into our plan. Here in the National Capital Region, there is a Veterinary Pathology Residency Program within DOD, as well as an Oral Pathology Residency Program, and we're working with them to basically provide the consultative services required under NDA 2008.

And as required under NDA 2008, the

Joint Pathology Center, under our proposal, we will operate the world renowned Tissue Repository. As most of you probably know, this is one of the largest, most expansive tissue repositories in the world, and we'll operate that with several different facets. Number one, the Tissue Repository will be used for -- to support our pathology consultative service with prior case material, you know, being able to compare it with current ongoing cases.

We're also going to open it up to other medical treatment facilities for clinical care, so that they'll have opportunity to look at cases that were submitted to the AFIP or to the Joint Pathology Center and are now in the Repository.

If they're seeing a patient, for example, at William Beaumont in El Paso, Texas, and they need to see what the prior breast biopsy or liver biopsy or whatever looked like, that opportunity will be available.

In addition, I think equally as important is that the Tissue Repository will --

there's so much material in here and so much opportunity for utilizing that for research. Our goal is to open that up and basically make that material accessible for research within DOD and the federal government. So that would be pretty much the entire repository of archive tissue. The Joint Pathology Center is a part of the new Walter Reed National Military Medical Center. Since it's a part of the Department of Pathology, it will be an integral part of our Pathology Residency Program at Walter Reed. So they'll provide military medical education there. In addition, it'll be a participating institution for the other five DOD pathology programs and other federal institution pathology programs, so that training will be provided there.

In addition to graduate medical education, we're looking at partnering with USUHS, collaborating with USUHS to provide a robust online continuing medical education program for pathologists and other providers within the federal government.

And we think that one of the opportunities there is for us to provide continuing medical education for our folks that are deployed. We have physicians that are deployed who don't have some of the opportunities that we do state side for medical education.

And then we talked about the research aspects, you know, the opportunity, especially using the repository for research and opening that up to the DOD and the other federal agencies for research, so that's also one of the key functions that we're looking at with the Joint Pathology Center. Under our Concept of Operations, within the Joint Task Force, we're looking at a personnel requirement of 81 people, of which 79 of those will be civilian, and in terms of pathologists, that will be 25 total pathologists, of which 23 will be working within the consultative or diagnostic service, and one position for the Chief or the Director, and then a molecular pathologist working in the Molecular Laboratory. The rest of that is support.

Our work load here is based on the AFIP work load for the last three years. So we estimate that we would see about 24,000 consultative cases per year. In terms of facility requirements, the majority of the Joint Pathology Center would be housed at Forest Glen Annex, the Forest Glen Campus up in Maryland. And actually, that's a mistake on the slide, it's actually 54,500 square feet that we have up there that currently houses the AFIP Tissue Repository and is slated for renovation with MedCom dollars, Army MedCom dollars, to support the Repository.

Looking at that, we feel that we'll be able to easily fit in there our consultative service, as well as our Molecular Pathology Lab, in addition to the Repository that's there. The administrative services, for example, the PMO Office, as well as other admin support, will be on the Bethesda Campus. Our equipment and initial start-up costs, and this is a rough estimate, about $3 million, and this is above and beyond the money that the Army Medical Command has slated for

renovation of the two buildings on the Forest Glen Campus, so this is above and beyond that. And like I said, this is a rough estimate which we'll refine as we move on in this process.

Our estimated annual operating expenses are about $14.1 million. And once again, this will be refined as we move on with the process and see where we need to be at a later date.

Our key assumption is that this will be program funding, it'll be through the Defense Health Program. The VA currently provides significant financial support to the AFIP, and one of our key assumptions is that the VA will continue this historical level of financial support for the Joint Pathology Center.

And as good stewards of tax payer's money, one of the things that we're looking at and we're going to look at very, very closely is, what equipment can we use from the AFIP. They have a lot of good state-of-the-art equipment, especially in the Molecular Lab and with all the microscopes and everything, and we'll look at that all very

carefully and see what we can actually reuse. And once again, as good stewards, we've been looking very carefully at what efficiencies we can gain. With this being under the Walter Reed National Military Medical Center, we feel that there's actually significant opportunity for us to consolidate specific administrative services, that is, histology services, transcription, and other administrative services.

And at this point, we're actually looking at at least a $700,000 reduction in the total cost of this as a result of these gained efficiencies.

We also think that especially with the repository material, we have an outstanding opportunity to collaborate with other federal agencies for research, and education, as well. So we will be looking at that very, very closely. But we feel this is one of our prime opportunities with the Joint Pathology Center.

In terms of the way forward, as we move through our careful vetting process of our Concept

of Operations, we will ultimately like to, of course, gain approval of our Concept of Operations and then develop an implementation plan. And this implementation plan will be a very -- actually a very detailed implementation plan with implementation teams consisting of subject matter experts, both at the AFIP and within DOD and presumably other subject matter experts to look at all the details that we need to do to this to make sure that we do it right. That will be -- include equipment, personnel that will be looking very carefully at the Molecular Pathology Lab, the Consultative Service, what do we really need, what exactly do we need to provide, and so on.

So this is actually one of the key points to our way forward, is to have a very good implementation plan that covers all the issues that we need to look at. And as we look at our implementation plan, that will help us refine our program requirements and really boil it down to what is it that we actually need to do to do the business of the Joint Pathology Center.

We will, of course, ensure strategic communication with our stakeholders, the VA, the AFIP, the medical treatment facilities that would be using our services, USUHS, so all the stakeholders, and we're actually already starting that process.

Next, of course, we want to complete the facility's renovation and finalize our equipment acquisition strategy, keeping in mind that we're looking at getting a lot of the equipment from the AFIP if it meets our needs, so we're going to look at that very carefully. And since there's 79 civilian positions within the Joint Pathology Center, these positions will be filled under the rules of the Civilian Personnel System within the Joint Task Force CapMed. So whatever their process is for that, this will be within that process.

And, of course, we want to synchronize the transition with Walter Reed as it closes the old Walter Reed, as well as BRAC transition here in the National Capital Region. And we want to

make sure that we stand up the Joint Pathology Center, as the AFIP standing down, to ensure that whatever services are going to -- at the AFIP that we will also have at the Joint Pathology Center, that we'll ensure that we'll be able to transition these so that there's not a lull in consultative services for the Department of Defense. What are your questions?

DR. POLAND: I'm sure there will be comments or questions that the Board has. Joe, Dr.Parisi.

DR. PARISI: Thank you, Colonel Baker, for your presentation. I only recently had an opportunity to review the Powerpoint and your Concept of Operations, so my comments are relatively incomplete and preliminary at this point. I thought it was very important for the Defense Health Board to be reminded of the details of the Defense Authorization Act of 2008 that directed the President to establish the JPC, and I asked Olivera to reproduce that, and you have a copy of it here. And I think it recognizes -- I

think the law clearly directs that the JPC should function as the reference center in pathology for the federal government, so it's establishing a very high bar here.

It also recognizes the enormous contributions that the AFIP has made over the years, which I think have been, to a large part, under recognized, but it also suggests that maybe the AFIP is a good model or at least a potential model for this new Joint Pathology Center of Excellence.

The law also provided, and I'm not sure where we are with this, to be honest with you, but it provided for the option of it not to be located in DOD. And I think, having this Joint Pathology Center or the reincarnated AFIP or something similar to it in DOD is problematic, and I think that's been a major thorn in the evolution of AFIP. It seems to me that, historically, it made sense to have it under Department of Defense when it was established as a medical museum in 1862. As the AFIP evolved, the functions became much

greater and much more complex, much more collaboration without world, and it's taken on a new flavor as it's become the -- as it was recognized as the Center of Excellence for Pathology throughout the world actually.

So I'm not sure it really belongs in the Department of Defense. One of the problems with having it under DOD is that it has to be militarily relevant. And we heard that all the time when I was on the staff, when I was a staff person there, there was -- everything we do has to be militarily relevant. Well, how do you define that? If you define it medical care in the big sense, then everything we do is medically relevant. If you're talking about the field soldier, then it's very limited.

And again, historically it made sense, but the way pathology is practiced at the Institute, and the variety of cases it's seen, it's not necessarily exactly one to one militarily relevant.

So because it's under Department of

Defense, it's historically under scrutiny by the Surgeons Generals periodically, and they've always looked for it to cut costs. If you look at the big picture of things, and I was surprised yesterday at the numbers we were presented with, $44 billion a year for health care, only six percent of that goes to this subgroup that's called, what was it called here, Consolidated Health Support, six percent of the budget went to Consolidated Health Support, and of that, less than one-half of one percent funds the entire AFIP. So I mean you're talking about peanuts here in the big picture of things.

That's not to say you -- I mean we have to be physically responsible, but this is a very small number, and you're getting a lot of bang for your dollar, I think here. So the money issue is a problem, and I fully recognize that. On the other hand, I think a function of our government, and this is me talking, a function of the government is to preserve things that are good for mankind, good for science, good for society, and

good for the common good basically.

And it seems like we ought to be able to find a place that would fund AFIP or fund this Joint Pathology Center and make the bar very, very high. I think -- I commend you for your plan, but I think having it as a part of a medical center, Department of Pathology, lessens its impact and its stature. And I think there are some -- at least philosophically, I think there are different approaches that you might take to -- if you're really serious about making this a Center of Excellence, my feeling is it should really be a free standing entity or attached to some other federal agency, that's my take on it anyway.

And then I've got a whole bunch of specifics that are more, you know, the devil is in the details, and I've got a whole bunch of detailed questions that I could ask, too, but maybe other people would like to chime in at this point.

DR. POLAND: Let me get Wayne, and then Mike.

DR. LEDNAR: Wayne Lednar; as General Kelley said, it's really been looked at that the mission of AFIP can be done by DOD, if I heard you correctly, sir, and, in fact, over the years has been in DOD. So clearly we have a history of performance that, you know, has been performed within the structure of DOD.

I guess the question I have, and I'm going to be sort of looking towards Ms. Embrey as I ask this question, but as a federal government premier resource, and that's bigger than DOD, and we have the Tissue Repository, which is a unique resource, and we have important health questions that need to be addressed for DOD, this is a research question, how do we take proposals to utilize the Tissue Repository, for example, and reconcile them against the entire DOD health research agenda that this is a priority, it is military relevant, it is a good and appropriate use of this precious resource, and that there's some rationalization before the Tissue Repository begins to be depleted? I'm not sure who is the

best to respond to that.

COLONEL BAKER: Well, if I could answer that, just a couple points here. We do need -- and the devil is in the details in how do we do that and how do we do that, so that, you know, it works properly and truly supports research within DOD and the federal government.

As a part of a -- the fact that it's, you know, it's now going to be a living repository, meaning we're still going to have active contribution and material to the repository, I think one of our roles in the Joint Pathology Center is to ensure that it doesn't get depleted and that we reconstitute it with material available from active consultative cases and potentially other sources within DOD, including tissue blocks before they get, you know, routinely disposed at other places. I think we have a lot of opportunity to ensure that we're not going to just deplete the Tissue Repository, but that it'll grow and actually be maintained as a vibrant Tissue Repository for research purposes.

MS. EMBREY: And Joe Kelley may want to add to this, but, you know, the fact that the Center is being located in Bethesda, on the Bethesda Campus right across from NIH is not accidental. It is a rich resource, not only for the military, but for the country, and it has a history of -- its relationship with, you know, this kind of research where it's needed. And since it will be a Center of Excellence for Pathology, it will be both military relevant, as well as connected to the research that's going on elsewhere. So I'm very confident that it's being positioned in the right place.

DR. POLAND: Let me get Dr.Parkinson. He was -- Joe, did --

DR. PARISI: Isn't it going to be at Forest Glen? I thought that's what I just heard.

COLONEL BAKER: Yes, sir.

MS. EMBREY: Oh, I thought it was at --

COLONEL BAKER: Yeah, I'm sorry, it'll be a part of the Walter Reed National Military Medical Center, but the Tissue Repository is

currently up at Forest Glen and that's where it'll remain and that's where the Consultative Service and the Molecular Pathology Lab will be.

DR. PARISI: So it's going to be physically separated from Bethesda is my point?

COLONEL BAKER: Well, it'll be physically separated by a few miles, yes, sir.

DR. POLAND: Dr.Parkinson.

DR. PARKINSON: Yes, Mike Parkinson. Well, again, just to -- maybe everybody else on the Board understands this and I wasn't awake in the first 15 minutes, but the statute, which did, as Dr.Parisi mentioned, allow the possibility of making this truly a federal agency, supporting the federal government and other things nationally, the 180 days has passed.

The Department has determined, i.e., the President has determined that this will remain within the Department. So, to me, the challenge now is how to make it actually not only survive, but thrive to meet the mission of what is in the statute, which is to be a meaningful federal

agency to serve Americans, vice DOD with a tin cup going around and hoping somebody reimburses you. So the biggest direct care systems in this country are the Veteran's Health Care System, you've got some degree of money, and I guess it's not specified how much that is, so the first question is, is that adequate, and if not, how do we use some strategy and tactics to increase the reimbursement.

Number two is, obviously, although they have less of a footprint, is the, you know, the Public Health Service, which is AHECS and its region, I mean its community health center platforms, the Indian Health Service, where are those subspecialty pathology dollars going now.

When I see a complex case at the Indian Health Service in Santa Fe, and it goes to the University of Mexico, those dollars have got to be coming back. If there's a subspecialty, hematology consultation, you should be having an effected business model that makes it attractive to send that FedEx or whatever you do to get to

AFIP, so start moving out. In other words, and I think the leadership of the Department needs to sit down with all of the other federal agencies and say this is the premier center for subspecialty consultation, 23,000 is not enough, it should be 35, 45, 50, I don't know what it is, but at a time when both presidential candidates are talking about getting more money out of my tax payer dollars, we need to start thinking a little bit more like Quest Diagnostics, which says, no, we have a competitive way to do this, and run the risk of saying, well, the federal government shouldn't be in trying to attract business.

I mean this is as much of an opportunity. Now, it does mean that there's got to be some heavy lifting even beyond the E-ring of the Pentagon to say, what are we going to do to make the government, when it does do special services, that are not either volume intensity enough such that Johns Hopkins can't do it or do it as well as this place, how do we do that?

So I think there's a good news and bad

news story. I mean the historical ways that Dr.Parisi of the AFIP and what it did, it truly is at a time -- read the Wall Street Journal today, what we're doing in advanced genomics and the other ways we're trying to understand etiology of cancers, I mean all the Tissue Repository, the people you've got at AFIP have got to be part of the national understanding, and without a robust advanced pathology platform in the country, but we've got to get out and market it, we've got to have a strategic plan. I'd love for the DHP to come back and say, okay, that's a great thing in terms of bricks and mortar and budget in terms of version 1.0, what is your strategy to get the VA, IHS, PHS, FDA, you know, maybe it's already there, maybe it's all that volume of effective work that's come your way, but if not, what's the plan to come back to DHB and make this thing a realty so that there are people clamoring for your services rather than being treated.

Unfortunately, it's kind of this, well, it's not really relevant to Iraq today, which I

agree, it's not the right question.

DR. POLAND: Mike, and then Joe.

DR. OXMAN: I may also have been asleep a little bit and may not have heard correctly, but I think the independence of the Center is very important, and it's very important that both intellectually and budgetarily it isn't submerged in an individual pathology department where it may or may not prosper and may or may not lose its identity. And so I'd like to hear about the governance of the entity and how it will be independent of the USUHS Pathology Department.

COLONEL BAKER: The Walter Reed Pathology Department, it won't be a part of USUHS, it'll actually be a part of the Walter Reed National Military Medical Center, Department of Pathology. It will be one of the services based on our Concept of Operations, it will be one of the services under the Department of Pathology, but it'll be not only physically separate, but in terms of pathology staff and what they do, they'll also be functionally separate.

DR. OXMAN: Does that mean that there will be any sort of independent board of overseers who will be able to keep its independence and make sure that it has broader representation than just Walter Reed?

COLONEL BAKER: Well, I think that -- there's a lot of opportunity there to look at that, I would agree with you. And one of the things that we've talked about is, for example, having a board made up, you know, of at least the pathology consultants for the military services and the VA. But there's probably opportunity to look at that. And I agree, that's something that we do need to look at.

DR. POLAND: Joe.

DR. SILVA: Joe Silva; just a technical question. On these consultations --

COLONEL BAKER: Yes.

DR. SILVA: -- 24,000 per year, what percent are outside DOD, and can you contrast that say ten years ago with the AFIP? How much of a subspecialty external DOD consultation do they

have now versus the past?

COLONEL BAKER: Well, sir, I can answer about where these numbers came from. We actually subtracted out the civilian consultations from this, so this number does not include -- this is DOD and the VA in terms of consultative material. And Dr.Mullick can correct me if I'm wrong, but I believe the civilian consults comprise about 33 percent -- 34 percent of the total work load. She could probably comment on that a lot better than I could.

DR. MULLICK: The evidence work load for civilian, military, and VA has been around 50,000, up and down a little bit. In the last couple of years, because of the BRAC and the feeling that AFIP cannot do the consults because they are winding down and people are leaving -- which is incorrect, the consults have gone down. It has to remain at 34 or 35,000. So the number that Dr.Baker calculated is eliminating all the civilian consultations and I guess other related agencies and giving -- presenting only the

military and the smaller percentage of VA cases.

DR. POLAND: We need to wrap up in a minute or two here. But Wayne and then Joe, I mean Russ, sorry.

DR. LEDNAR: Wayne Lednar; I realize as part of BRAC, there's clearly some expectations, call it institutional blocking and tackling, but I have an operational question, and that is, how this move, how this change is better, better for DOD, better for the federal government, and can you share with us how those who are served by the AFIP and these 35 to 50,000 consultations per year, what their sense was as you developed this Concept of Operations, and then as you put together this plan, how this addresses some of those concerns from those the Military Health System request in particular?

COLONEL BAKER: Yes, sir, I can actually comment on the Military Health System, the concerns of the Military Health System. Losing the -- the AFIP provides, you know, a lot of great services for the Military Health System. And as a

general surgical pathologist, you know, I still practice, the AFIP provided invaluable consultation during my 20 years, and that's one of the biggest things that we lost, with the AFIP going away under BRAC.

The process that was put into place with the AFIP and being dis-established, the Program Management Office process of basically sending out consultations to whatever consultants had contracts we saw as potentially problematic in that we did not -- we benefit from one stop shopping, knowing that our cases, you know, especially the military relevant ones, they're going to be seen by ID, by -- by, you know, so on and so on, so that was one of the things that we feared losing with going with, you know, basically sending out all of our cases.

And I think with, you know, looking at the key components of the NDA 2008, and our Joint Pathology Concept of Operations, we're going to be able to bring a large part of that consultation back into DOD, ensure that it's one stop shopping,

ensure that we're able to track military relevant things, you know, such as, you know, if there's any, you know, new infectious disease, things like that, you know, that come out of that, we'll have that opportunity to do that as a one stop shop. So I think from a consultative standpoint, this will greatly benefit, significantly benefit the DOD and the VA.

DR. POLAND: Dr.Luepker, do you want to make a comment?

DR. LUEPKER: Yes, Russell Luepker, two quick questions about money directly and indirectly. BRAC, as I understood it, was a cost -- partly driven by cost saving issues. I'm curious how this new plan plays out in terms of overall costs or cost savings. The second, and I'm not sure I tracked the whole thing here, but there's discussion about -- it sounds like fee for service in the rest of the world, in the non-governmental world, and having done some of that as a government agency, it's tricky business, and one -- one needs a business plan to do this,

and maybe you're doing it already and making money hand over fist, but if you're not, you ought to think about it a lot.

COLONEL BAKER: I'm sorry, sir, I was concentrating on your last question there.

DR. LUEPKER: How is this going to save money under BRAC?

COLONEL BAKER: Yes, sir, sorry about that. Well, a couple things; I mean when we put together our plan, we were looking at, number one, what were some of the funding that was already out there as a result of BRAC. For example, our Pathology Management Office process is slated for somewhere in the neighborhood about $7 million. The VA contributes a portion. The Repository, since it is required to be maintained under modernized -- maintained and modernized under BRAC law, there's money that goes with that. So right there, there's about $12 billion plus that are going for -- that are already there to provide those services that we're going to basically be -- maintain after BRAC. So, you know, I think in

terms of looking at the total cost, you have to kind of look at the fact that there's $12 million right there that was already kind of slotted to provide those services. So now we're looking at the quality of the care that we're bringing back in, which is that one stop shop, you know, having, you know, cases being able to be looked at by infectious disease, hematology, by GI or whatever in the course of getting an appropriate consult that really serves our needs.

DR. KELLEY: If I might add just a little bit on that.

DR. POLAND: Briefly.

DR. KELLEY: I think there's three pieces, we just mentioned one, for the funding. The PMO was also included in the BRAC law, so it was funded before. And then the BRAC law assumed that all of the consults would be going down to the civilian community and would have to be paid for, and the ones that are brought back, that funding is there, too. So there's three pieces of funding. The question about in DOD, as

Dr.Parkinson said, that decision has been made, that it could be, it was directed to be done in DOD unless it could not be done in DOD, and the decision was made that it could be. This is a way it could be done, so therefore, it could be done, and it will be done in DOD. And --

DR. POLAND: Okay.

DR. KELLEY: -- one other aspect of law that hasn't been mentioned is that it has to follow the BRAC law, and so we can't ignore anything that's directed in the BRAC law, and that's both in the BRAC law and in the NDA that establishes the Joint Pathology Center.

DR. POLAND: Thank you for that clarification. Let me wrap things up here. The JPC issue, as I see it, involves technical aspects associated with the pathology services, issues associated with establishing a Center of Excellence in the NCR, and issues associated with health care delivery as they relate to the support of the Military Health System and DOD.

As a way to deal with this, what I would

like is Representation of the Health Care Delivery Subcommittee, the NCR BRAC Advisory Panel, and the Scientific Advisory Board for Pathology and Laboratory Services, all parts of our group, to review that plan. In specific, Dr.Parisi I think could take the lead on that, and other members of the Pathology Group should also participate, since the input of those individuals I think is key. Since it will involve the NCR, I hope Dr.Kizer, Mr. DuBois, and Dr.Carlton would also be involved. And from a Health Delivery standpoint, I'd like General Anderson, Dr.Kokulis, and Dr. Lednar to be a part of the group.

The Department needs to have an answer, as I understand it, by October, so I think a way forward here is one to review the written plan, now that we have it. Joe, for your group and the group of individuals I mentioned, to independently develop questions and comments that you would have about that, and if you can, to meet as a group within the next ten days, given the timeline that we have, within the next couple of weeks, and

expect the DOD Work Group members to be available to discuss specifics of it; does that sound acceptable, Joe?

DR. KELLEY: We'll certainly work on it.

DR. PARISI: Maybe we can do it by phone conference, at least --

DR. POLAND: Yeah, I think you may well to facilitate it. Go ahead.

DR. PARISI: But I think there are several issues that we need to talk about.

DR. POLAND: Yeah, you need to dig into. Okay, thanks.

DR. PARISI: So just -- it is part of the -- that's a closed issue, and it's -- go anywhere else.

DR. POLAND: Dr.Kelley, is that correct?

DR. KELLEY: I think that's correct. I do not foresee it going anywhere else. I mean the -- I think that the decision has been made.

DR. POLAND: Okay.

DR. MULLICK: Can I ask just quickly; I think it was -- I don't think it was Dr.Parisi,

but somebody mentioned that the President had approved this JPC and DOD -- I was not aware of that. Has it gone to the President and been approved by the President? I thought I heard -- I think Dr.--

DR. POLAND: He didn't return my call, so I --

DR. PARKINSON: No, that was just a turn of phrase, because when the Department, acting on behalf of the President, as in the statute, so I think the Department, from General Kelley, has said we can't make a compelling argument, nor should we make a compelling argument based on the Department's decision, i.e., quotes the President, I mean that's all.

DR. MULLICK: Oh, okay.

DR. PARKINSON: I was just --

DR. MULLICK: I've been following it.

DR. PARKINSON: I'm sure it didn't go to the White House.

DR. MULLICK: Following closely then the process, and I remember all of Dr.Kelley's

documents, each one of them, and there is a series of things, you know, and I didn't think the President had been in the loop yet, but --

DR. POLAND: Okay. Thank you very much. I think we need to move on.

DR. PARKINSON: Okay. Thank you, sir.

COLONEL GIBSON: The Defense Health Board staff will support you as far as a physical meeting as soon as we possibly can and any teleconferences that you want to put together.

DR. POLAND: Okay. We've got two new questions to come before the Board, one regarding Chronic -- Syndrome and the other on autism and applied behavioral analysis therapy. After we work through these questions, there will be an opportunity for anyone who wants to to make a public statement. In order to do that, if you have not done so, register on the sign-in sheet with Lisa Jarrett right outside the room. Written statements are also welcome and will be reviewed by the Board. So the next speaker then is Deputy Assistant Secretary of Defense for Clinical

Programs and Policy, Dr.Joseph Kelley, who will provide an update regarding a question that was recently brought to the Board concerning the use of therapy for Lyme Disease. You can find the presentation slides, as well as a copy of the question under Tab 10 in your notebook. And we have set aside 15 minutes for this on the agenda. Dr.Kelley.

DR. KELLEY: And what I think I'll do, sir, is that, I will just introduce it, and if you could push the first slide. There have been a large number -- a small number of prominent cases of Lyme Disease, and there has been some discussion, there's been some discussion in the open press about the appropriate diagnosis and the appropriate treatment both for acute, but more discussion in terms of chronic Lyme Disease, in making the diagnosis, and how that should be in.

We would like to ask the Board to review the diagnosis and treatment of Lyme Disease and provide us some advice on how that should be implemented in DOD. And I think that we can --

you have the slides that I put out, and I think we have a follow-on presentation, which I think we should just go to right away.

DR. POLAND: Thank you. Then we'll move right on to Lieutenant Commander Todd Gleeson from the Infectious Disease Department of the National Naval Medical Center, who will brief the Board on clinical issues regarding Lyme Disease within DOD. His presentation is also under Tab 10.

DR. GLEESON: I appreciate everyone's time for this important topic, and I appreciate representation from ILADS, as well. So recently there have been some issues, some key issues raised in the diagnosis and management of Lyme Disease, and I think the main issues are in the diagnosis of infection with Borrelia burgdorferi. There is incomplete, not 100 percent sensitivity of the screening test, and so the main argument, main concern of most people is, are we missing cases, are we missing the diagnosis in our patients.

And then recently the Attorney General

of Connecticut brought up a lawsuit against the IDSA, Infectious Diseases Society of America, stating that their guidelines then withheld by preventing insurance payments, withheld needed therapy from a lot of patients with the diagnosis of Chronic Lyme Disease, and that's still an ongoing process. In general, there are two camps of thought, IDSA versus ILADS, International Lyme and Associated Diseases Society guidelines.

The reason that I'm presenting is just to provide information on how we, Infectious Diseases military physicians, diagnose and management Lyme Disease. Some background; there are multiple diagnostic methods that we use. First of all, with the erythema migrans rash, which I'll show you, that's diagnostic in and of itself. We do not recommend confirmatory testing with blood testing later, we diagnose and we just treat.

Currently the CDC and the IDSA recommend a two tier testing system where we do a screening ELISA to detect antibody, but then a confirmatory

western blot if that ELISA is positive or not completely negative. There are other tests that we have, there's PCR, which we can do PCR on the blood in patients, and up to 65 percent of patients with multiple EM rash, they'll have a positive PCR. And in patients with a single EM rash, 45 percent of those patients will have a positive PCR in blood. And we also do multiple lumbar punctures in our patients and look for Lyme involvement of the CNS. And we really have a large training component. For example, I just went down to Pax River, Branch Medical Clinic in the Navy, and gave a Lyme update and tick borne diseases talk, and this is what I teach at the National Naval Medical Center, and Walter Reed, as well.

In the New England Journal article -- of Internal Medicine, you'll see that it's not that always classic target rash, it's, in fact, 59 percent of presenting Lyme Disease with rash, you have a homogenous erythema, and then you might have central erythema, and the classic bulls eye

rash is only seen in nine percent of patients, and this is where one potential miss of Lyme Disease patients occurs, it's misdiagnosed as cellulites and not treated with Doxycycline. But with education, and with seeing these patients back, we do get the diagnosis.

So the two tier testing, screening with the ELISA is insensitive in the first two weeks of infection. By four weeks of infection, sensitivity is maximized. And again, if it's positive or indeterment, I would do a western blot for both IGM and IGG, and we use CDC criteria for interpretation. We use only FDA approved testing at the National Naval Medical Center. We do use an ELISA that we do in-house, and we sent our western blots out to Quest. And at Walter Reed they use a different ELISA in-house. They also do their western blots in-house. The sensitivity and specificity of our screening tests are about the same. They, at their max performance, it's 86 percent sensitive, but remember, that's not 100 percent, which drives a lot of the argument here.

A lot of providers in D.C., where our patients go if they're unhappy with MTF care and they want a second opinion, and I've spoken to at least three of these physicians in the area, National Integrated Health is one clinic, and they often send their tests to IGeneX in San Antonio, I'm sorry, Palo Alto, California, I've spoken to that lab, as well. They're not FDA approved, and they say that they do not need to go after FDA approval, they have internal validation assays only.

But what's really important is that when I see these patients eight months into their care by providers in the D.C. area who claim Lyme specialty, they've been paying out of pocket, not for the pharmaceuticals. They can take a paper prescription to our pharmacies and get that filled. It's mostly in paying for the lab testing, as well as the provider visits. It drives the Lyme wars. And this is -- by the previous President of ILADS, in that, since we have such miserable sensitivity of our testing,

which he claims 56 percent, we're missing a lot of patients, and they go across our desk without getting a diagnosis. Really, in the first two weeks, certainly the sensitivity can be that poor. It's improved to 81 to 86 percent by three to four weeks.

This is what we use at NNMC, and you'll see that in this study they used positive sera early -- in early convalescent disease and then early neurologic disease. And the sensitivity is on the right, and you'll see that the best it does is 81 percent.

You know, we won't hide the fact that our screening test is not 100 percent sensitive, as we want in a screening test. We'll talk about that in a bit.

Treatment durations for Lyme Disease, that is on behalf of the Infectious Diseases Society of America, in terms of their guidelines, I'm not a representative specifically, but I am a member of IDSA, the treatment durations are well studied, and we in the military ID, Internal

Medicine, Family Practice, generally follow these guidelines, but it is our choice. The ILADS guidelines are discussed frequently in our ID conferences, and we necessarily need to know what those guidelines are, because our patients that come to us generally give us a copy of those guidelines, as well as other web sites. These are the guidelines we use, and again, these are under re- review. Presently, in May, 2008, the Attorney General of Connecticut made a statement that the outcome of their lawsuit is that there will be, without conflicts, a board to review these guidelines in terms of the evidence.

Corroborating kind of the IDSA guidelines, but I will admit that there was one member of the IDSA Board on this Board of the American Academy of Neurology Review of treating Lyme in the central nervous system. In Europe, for example, Doxycycline alone for ten days -- 14 days, is adequate for treating CNS disease.

However, in North America, we only have Burgdorferi borrelia, they have many other species

over there, so it's not exactly commensurate data.

However, the American Academy of Neurology also feel that for treatment of central nervous system disease, 28 days of intravenous Ceftriaxone is adequate, and even 14, 21, or 28 days, but beyond that is not needed. And this is what we generally use. There are many different stages of Lyme Disease, where if we, for example, have a tick bite, we can give one dose of 200 milligrams of Doxycycline if it's an Ixodes tick within 72 hours, and within at least 36 hours of attachment. But if you have erythema migrans, you can give 14 days of therapy with Doxycycline, for example, or Amoxicillin. And then if you have more invasive advanced disease, the regimens generally become IV and longer, up to 28 days.

And again, we do -- and we are conversant with the ILADS guidelines, both in ID, as well as in internal medicine at Bethesda and Walter Reed. In general, if you look at Lyme Disease patients, up to 13 percent of them in well designed prospective studies will develop a

symptom complex of fatigue, difficulty concentrating, aches, pains, headaches. This is defined by this group mostly as a chronic Lyme Disease diagnosis, and they postulate that this is due to ongoing infection, relapsed infection, refractory infection.

The IDSA standpoint is that there are no viable borrelia organisms left in the body and it's not a persistent infection, which does not require more antibiotics. And the statement then is, there is a post- Lyme Disease syndrome in the IDSA guidelines explained where the symptoms, if they -- if the duration is greater than six months after your Lyme Disease diagnosis, then you have a diagnosis of post-Lyme Disease syndrome. Recently, and I actually give a copy of this article in the New England Journal to my patients when I see them in consult usually well into this process, there's a critical appraisal of chronic Lyme Disease, and again, these authors redefine and say there's a post-Lyme Disease syndrome for sure, but there's not chronic infection that

requires more antibiotics.

I just picked two cases that I saw in clinic, and we see this very frequently, I see about two patients per week in consultation for Lyme or chronic Lyme Disease. This was a 35 year old pilot, came to me with fatigue, difficulty concentrating, and headaches three times per week responsive to Tylenol. His Lyme ELISA was negative at Pax River. But recently his daughter, two years old, was recently hospitalized for Lyme arthritis and had a definite diagnosis by blood tests, and this was a major stressor.

He took his whole family to our MTF and felt that he was blown off, and then wanted further evaluation with the National Integrated Health. Also went to a Lyme specialist in Connecticut, drove his whole family up there. At Bethesda, our two tier testing was negative. In fact, I sent a western blot despite a negative screening test, and that was also negative. And the provider at NIH, the other NIH, sent blood to IGenex, and that was indeterminate. But he wrote

prescriptions and set a peer trial therapy to see if his symptoms get better. And so by the time I saw him, he had had over eight months of Amoxicillin and Azithromycin, which was filled at our pharmacies.

This just puts, in my opinion, the patient at risk for selection of organisms such as Strepneumo, as well as C-Dif infection, Claust -- infection, certainly in this age of Super C-Dif, as well. And we have a lot of data on chronic Azithromycin usually into a lot of resistance, for example, in our H-pleurigastritus.

Clinical case two, I use this to show that we are not draconian with the IDSA guidelines. This was a 41 year old male, active duty, '05, in the Army, had a tick bite a long time ago, in 2004, was given empiric therapy for two weeks, never had a rash. He was evaluated by a neurology in December, '04; his Lyme testing was negative, including his CSF testing, and they still gave him some Doxycycline for 30 days.

In 2006, his Lyme serologies were again

negative. He saw the civilian provider in Fairfax, Virginia, who sent IGeneX testing to California, which was positive, recommended six months or more of IV Ceftriaxone with symptom scores monthly to see if the symptoms were getting better as the objective end point. Saw Walter Reed, repeatedly negative testing, however, we said it's not unreasonable to give intravenous Ceftriaxone to this patient, we have not yet explained his neurologic symptoms, and his antibody response back in 2004 may have been abrogated by the Doxycycline that he was given, which is a true statement. But beyond that, 28 days is not substantiated by the literature. So he did get that therapy and was still upset with not getting more than a month of Ceftriaxone.

So up to 25 percent of patients will experience fatigue or muscle aches after antibiotics, and over time, most of them do return to normal. But if you have persistent symptoms beyond six months, this is where a post-Lyme Disease syndrome, in our opinion, is the

diagnosis.

So up to 13 percent in well designed prospective studies will have subjective symptoms of unknown cause. Fatigue and headache is part of that. In some studies, these symptoms occur in the general population, up to ten percent. So it's not known if there is specifically an increased risk of these symptoms after Lyme Disease. Most of these studies never had a control group to show whether this was higher than the general population or not. And most of our position on prolonged IV or pelotherapy is unreasonable.

It was in 2001, in the New England Journal, and they had 78 patients who were positive for Lyme Disease on testing, 51 patients who are negative on testing, they all had at least some objective data of having maybe the EM rash of Lyme Disease or other objective data, which a physician said that they probably had Lyme Disease, and they were given either one month of IV Ceftriaxone with two months of oral

Doxycycline, or they actually got a pic line, identical appearing intravenous and then oral placebos.

And in general, they found no significant differences in the scores between those who got those antibiotics and those who got the placebo. So there does not seem to be a positive effect, a durable effect of antibiotic therapy in these patients with this diagnosis of post-Lyme Disease syndrome. So our policy recommendations are to continue to use the IDSA guidelines. We are waiting as a community, as ID community, for this re-review of the guidelines based on the lawsuit by the Attorney General of Connecticut, and I think a lot of information will come at that point. I don't know the date that that will come about, but I expect it within the calendar year.

So in conclusion, although the sensitivity of our tests are not 100 percent, we use more data than just that test. And we also teach that, look, our sensitivity of our testing

is, at best, 81 percent. So we do treat patients empirically if we think that they were exposed and they have a symptom complex of Lyme Disease.

We ID specialists and the MTF's are available 24 hours a day for consultation, and we do consults on many, many of these patients. And in our opinion, we think the ILADS guidelines, which recommend prolonged antibiotics, often IV with its associated problems, and potential iatrogenic harm to our patients, is not what we endorse at the present time. Any questions?

DR. POLAND: We'll make a few comments here. The plan will be, of course, for the Infectious Diseases Control Subcommittee to dig into this. I would like to ask the help of a few additional people based on their expertise in this; one is Dr.Parisi, because of his expertise in neuropathology, Dr.Reddick, and General Anderson. And what we'll do is meet, come up with our recommendations, and bring those back to the Board for vetting, so that would be the process. Questions or comments, though? Ed.

DR. KAPLAN: Kaplan; could you tell me, maybe I missed it, the burden of disease?

DR. GLEESON: So I think recently, a look at the data for the past 365 days was 3,700 cases of Lyme Disease diagnosed and treated and MTF's in Army, Navy, and Air Force.

DR. KAPLAN: -- annually?

DR. GLEESON: Annually, yes, sir.

DR. POLAND: Dr.Oxman.

DR. OXMAN: Dr.Oxman; I'd just like to make a comment, and maybe it's, again, my slow hearing this morning, but prolonged IV antibiotic therapy, in addition to the risk of selecting for resistant organisms and colitis, there's an enormous risk of super infection with staphylococcal endocarditis, and so I think that in the absence of good justification, the use of long term IV antibiotics is something that we should consider as an additional risk, and a risk of potentially fatal complications.

DR. POLAND: Dr.Miller.

DR. MILLER: I always like the term

idiopathic, where the patient has pathology, and the DR.s are usually idiots in not knowing what's going on. And in this particular case, there's a lot of other controversies, and medicine is -- what is the diagnosis in the end, and what do these patients actually have. What is the gold standard actually that's being used in terms of defining the sensitivity and specificity of these tests?

DR. GLEESON: Yes, sir; so these are not only erythema migrans positive patients, but Borrelia burgdorferi cultured from these patients, either from the EM rash or blood.

DR. MILLER: So the culture results are that high, higher than the other confirmatory tests?

DR. GLEESON: Well, what they have done is, they've taken those patients that they're able to culture Borrelia from, and truly PCR is more sensitive, so if you have an EM rash, single EM rash, you can get PCR from the blood, detect its DNA in 45 percent. If you have multiple EM rashes

from the spirochetemia, you can see it in 65 percent. But the cultures are probably 20 percent lower than PCR in terms of growing it. So once we get a subset of patients from which we actually grew Borrelia, then we actually run our serologic assays on those patients or use that as the gold standard.

DR. POLAND: Dr.Gardner.

DR. GARDNER: Pierce Gardner; yeah, but in your slide, you showed that only nine percent of what you're regarding as a rash, I think that you were including -- actually had classic EM. So presumably that's your -- that should be your gold standard, because the others have other set of possibilities that will cloud the issue.

And it's the fundamental issue, of course, that the epidemiologists would like to make a tight diagnosis that they could account the real, real, real cases, and the clinician faced with patients with wide symptoms would like to fit as much as they possibly could into a diagnosis of Lyme Disease, and until there really is a gold

standard test that one can really rely on, and we haven't ever got there, it's going to become a clinical opinion in which I had to write an editorial about this, I said uncertainty breeds strong despaired opinions, and that will, in fact, it'll be a who shouts the loudest and gets the most attention until we can actually find the gold standard to us, and we are -- we haven't made much progress in the last few years.

DR. POLAND: Dr.Walker.

DR. WALKER: The serologic tests may have better sensitivity than we believe. There are patients with erythema migrans, particularly in the Southern United States, that are associated with the -- bites that do not transmit Borrelia burgdorferi. So there are patients you can see are erythema migrans, and it's really -- it doesn't indicate that the Lyme Disease serology is incorrect.

And I'll also tell you that -- because I'm an expert in a couple of other infectious diseases, like Rocky Mountain Spotted Fever and --

infections, I am approached almost every week by patients who claim to have chronic Rocky Mountain Spotted Fever and chronic humanmonisiactripiosis, neither of which has got any evidence for there being a chronic form of the disease.

DR. POLAND: Okay, thank you. Okay. We have opportunity now for open discussion and comments from the audience. Ms. Jarrett will assist us in having members of the public who have registered. Do we have any, Lisa?

MS. JARRETT: Yes; we have two public comments regarding the Lyme Disease.

DR. POLAND: Okay. Sorry, go ahead.

MS. JARRETT: The first one being Dr.Daniel Cameron.

DR. POLAND: Okay. Dr.Cameron, are you -- please take the microphone. I'll ask each of you to please keep your statement under five minutes, if you can, so that we can get through all that we have to do. And, Dr.Cameron, could you just introduce yourself again, please, for the Board?

DR. CAMERON: Okay. I'm Dr.Daniel Cameron, I have been in private practice in Mt. Kisco, New York since the late '80's. And to speak at this body where evidenced based medicine is such a premium, I was heartened when Dr. Steer described neurologic Lyme as memory and concentration problems, irritability, sleep disturbance in 1990, and Dr. Fallon described all kinds of emotional issues that were originally diagnosed as psychiatric disease.

There were several publications in the early '90's. What was -- what I found, since I'm an internist in primary care, is that I was disappointed when the IDSA took an evidenced based medicine approach, put a panel of 12 people together in 2000, and concluded that there was no such thing as chronic Lyme as a distinct diagnostic entity. So it doesn't fit very well with my practice and the patients, and so I put together a panel that looked at the evidence and published that evidenced based guidelines, reaching significantly different conclusions.

And so in the packet that I have before you, I wanted to at least have it in a folder, those guidelines, so that a good read between what that ILADS panel came up with and what you read on IDSA is appropriate.

What happened next is that in 2006, the IDSA came up with another panel, it came up with much more of an elaboration on this whole chronic Lyme, post-Lyme Disease syndrome type thing, and so in my comments under the issue and discussion is that there were three conclusions that were so different between the IDSA and ILADS.

One is that chronic Lyme Disease does not exist. And so there are very few real good epidemiology studies. I'm an epidemiologist at the master's level from the University of Minnesota, so I dusted off my degree from the '70's, looked at the data, and the surveillance definition for the CDC doesn't look for chronic Lyme or post-Lyme, so there's very few numbers as to how many people are sick. The slide you saw earlier with about ten percent -- 13 percent

treatment failure, that was of EM rashes, where they meet entrance criteria, they're identified, they're treated decisively in a clinical trial. But if you do a nice case control or cohort study, you find that 34 to 62 percent of people are sick on long term follow-up, so there were 34 percent sick in a Massachusetts cohort with arthritis, recurrent -- neurocognitive impairment, and neuropathy, and 62 percent of a cohort in Westchester County, this was 3.2 years later. So one was six, one was 3.2 years, showing that on long term follow-up, these people are sick.

Also, the Klempner Study, even though they don't talk about it, they were sick for an average of 4.7 years before they even got in the study. So you're dealing with a particularly sick population. Even Dr.Fallon's study at Columbia, they were sick for nine years on average before they got in that study. So it shows at least there are people out there sick.

The second difference is that Lyme Disease is nothing more than aches and pains of

daily living, which was talked about at the slide earlier, that there are people with aches and pains. But if you look at -- and there's a paper in here that's published, 22 different independent carefully designed measures, from the short term, 36, the fatigue severity scale, the fibromyalgia severity scale, all of them show they're as bad as fibromyalgic chronic fatigue patients, worse than diabetes, worse than heart attack, and every one of those measures in there shows that these people are severe, they're far from the normal aches and pains of daily living.

So that doesn't mean I always have the right answer for how to treat in my practice, but at least they're sick.

Also, there's an economic study that showed that these people were costing 16,199 a year, and 95 percent of that were not the DR.s, there were indirect costs and non- medical costs and productivity costs.

And the third difference is that there's no credible evidence that antibiotic treatment is

effective. If you look at the actual trials, the four NIH sponsored trials, the biggest problem is, they were sick for 4.7 years in the Klempner Study, nine in Fallon, and with that type of data base, that's like a post traumatic stress disorder patient, they're often much more difficult to treat than one therapeutic modality, and we're finding in ILADS those cases that got talked about on these slides earlier are going to take more than an antibiotic, they're going to take some dietary changes, some counseling, some rehab to really get that quality of life back up. So what happened in the rest of the discussion is that the Attorney General, you know, because you always wonder what does an Attorney General have to do with evidenced based medicine, and they didn't look at every detail of the medicine, all they did was say, well, how come the ILADS perspectives and how come some of the DR.s weren't included the process, why isn't there a dialogue, why did it come to these kind of extreme conclusions, and so why don't they get a review of the data.

Now, this is just the infectious diseases side of America, which has had great progress over the years, great promise, it's just that we need some dialogue. So hopefully we'll move it away from the Attorney General, back into an evidenced based medicine structure.

So what I wanted to do is recommend that instead of just the IDSA position is that we include actual dialogue and include some of the things ILADS has been doing, some of the things we've been doing with the most complicated patients, and these are the ones that are talked about. So just to close up, I just wanted to show you what's in the packet, is that if you look at the packet, you know, as I said, I list -- I included the ILADS guidelines. Sometimes when you read the guidelines, nothing says that everybody has to have IV therapy for prolonged -- for months and years; I go to IV ten percent of the time, even under my most complicated patients, so it's -- it often lays out the problems in the guidelines.

If one goes to the -- the second submission is that clinical trials validate the severity of persistent Lyme Disease symptoms. This paper just got accepted for publication. But the most important thing is that table one, which is page eight of that document, it lists all 22 standardized instruments, and it shows not only what the cases are, but the controls, the text talks about how sick they are versus normal populations.

The next submission, you know, everybody would wish to have a nice economic paper, how much does it cost to have a Lyme patient. This went -- this is a study by a CDC author, where they went to Maryland, which is this area, looked at data bases of people who were seen by DR.s in Maryland, and they found that 95 percent of the costs were not DR.s, because most of them weren't really being treated. And the reason I included that is, if we go to the last figure three, you don't have to actually page through it, it's just that if you get treated for Lyme early, it's 1,300 a year,

late is 16,000 a year. And the last two things that are included is a generalized liability paper talking about what's really wrong with making too much of the NIH trials; 4.7 years is hard to generalize.

A research letter that talks about specific cases of people who had delayed treatment. There's an initiative by ILADS, it's to treat people early, treat more than 30 days if you need to treat based on judgment, treat longer than 30 if you need to, and that's captured in a prevent chronic Lyme Disease type paper.

And so what that is is that we always practice primary care, I mean primary prevention is to prevent the tick and a rash from getting in trouble. Tertiary prevention is like how to deal with the sickest of all Lyme patients or sickest of all heart patients, but we never get around to secondary prevention, which is how do you prevent these complicated patients. And so what I want to do is, I included the Attorney General piece, but I rushed through it, and I appreciate the -- just

letting this information get out, so when it goes to Committee, they can look at this kind of evidence and include it when they weigh all of those factors.

DR. POLAND: Thank you, Dr.Cameron. I believe, Mike, did you have a question?

DR. OXMAN: Yeah, one question; how do your patients differ from patients with "chronic fatigue syndrome"?

DR. CAMERON: In my practice, I find that the list of symptoms of chronic fatigue, fibromyalgia, look exactly the same. And I agree with Dr.Dante from Boston, who had some dollars from one of the Gulf War syndrome, the Gulf War syndrome also looks the same, so it's -- anybody that I treat longer than 30 days or 60 days ends up having to see lots of specialists to look at different views and different perspective. But if you just study the symptoms, no difference.

DR. POLAND: Okay. Lisa, I think you said we had another speaker?

MS. JARRETT: Yes, sir.

DR. POLAND: Is that speaker here?

MS. JARRETT: Yes; it's Commander Lipsitz.

DR. POLAND: Would you also introduce yourself and keep your statement to five minutes?

DR. LIPSITZ: Sure; good morning, everybody. My name is Commander Rob Lipsitz, and I'm a family physician, as well as a preventative medicine physician who's actually pretty knowledgeable in Lyme Disease based on my training. Well, my grand knowledge did not prevent me from being hospitalized this month at Naval Hospital Bethesda for Lyme Disease.

So when I found out the Defense Health Board was meeting, I thought it would be a good opportunity to come and listen to the up-to-date information as it's being presented. I just wanted to ensure that the Board, when they are discussing this topic, is aware of patient perspective.

Now, I'm a physician, and as the adage goes, the provider that treats himself has a fool

for a patient. And I thought I had an intravirus syndrome, and I was getting sicker and sicker and couldn't understand why.

And I walked into the neurology clinic, where they promptly admitted me for rule out -- syndrome, but fortunately they had a high clinical index suspicion, something I do not have, and they drew antibody titers for Lyme Disease, which turned out to be positive, and they started me quickly on treatment, and I approved, and here I am today. So I think one of the important things to remember with Lyme Disease is to have a high clinical index of suspicion for the disease. Certainly I had risk factors. They asked me, you know, are you a runner, do you go in Rock Creek Park, are you active, I do all those things, so that's probably how I acquired the illness.

So here's a physician that did not think he had Lyme Disease and thought that would be way out there, but the providers actually did have a high clinical index, and they found it and treated it. So please make sure your providers are aware

that in areas high risk, or even in lesser risk, that they are considering Lyme Disease in their differential diagnosis. That's all I had, thank you.

DR. POLAND: Thank you, and we're glad for your recovery. Thank you all for your comments. Again, I would reiterate that any written statements are welcome and will also be reviewed by the Board. I neglected to mention one other individual that I would like to help us with this issue, and that's Dr.Shamoo, although has he left here? He may have stepped out for a moment. Colonel Gibson, did you want to make a comment?

COLONEL GIBSON: Yeah; we received written statements from ILADS, and those will be posted on the GSA web site as part of the federal record. We'll post most of that right away, put it up almost immediately after this meeting. Part of it contained telephone numbers and email addresses. We'll have to do a Privacy Act review on those before they go up to make sure that we're not violating anybody's privacy. After that, they

may end up redacting those phone numbers, et cetera, and then the substance of the rest of it will go up.

DR. POLAND: Lisa, are there any other --

MS. JARRETT: No, sir, no, not for the Lyme.

DR. POLAND: No, okay. Dr.Parkinson, did you register?

DR. PARKINSON: I rarely register on anything. But, no, thank you, Dr.Poland. Just a thought, and it's a little -- this issue is an example of what I see in expanding -- rapidly expanding scope of the DHB. I mean this has been an interesting meeting for me. And in light of the Connecticut Attorney General's frank lawsuit against a specialty society that -- and I'm now the president of a specialty society, I know many of you are involved in both organized medicine and things like that, it has the potential to have an extremely chilling effect on the potential for expert opinion groups that issue recommendations.

And as an aside, as the DHB goes forward, and it looks like the frequency and visibility of these types of issues may be coming before the Board, I think it's important for the Board members to understand any potential liability issues, real or perceived, around statements of the DHB.

Again, we've been doing this for years, under the rubric of the AFEB for things that are DOD specific, we have a public web site, our information and recommendation is available. As we apparently move to 150 individuals under the DHB, with a wide variety of issues, in this contentious area, I don't think we have to look any further than our binder to see what's going on out there vis-à-vis the Connecticut Attorney General. So just aside, maybe it's taken care of, but it rings little distal alarm bells for me perhaps.

DR. POLAND: Dr.Silva.

DR. SILVA: Joe Silva; I shared with the Subcommittee when we started the dig in this issue that this is an enlarging process, I agree with

Dr.Parkinson. I used to chair for the California Medical Association, a committee on scientific affairs, and we used to analyze all kinds of policies like this. Within a few years we had to close down the committee in the process. Lawyers beat the tar out of us, the CMA had its coiffeurs paid out for groups that had a specific issue. So this is a hot button, and I could probably name another seven or eight that are just coming over the hill. So we need to be on guard and we need to know what our legal rights are, because we can -- our body could be manipulated in ways that we not -- may not foresee right now. Thank you.

DR. POLAND: Okay. We're going to take about a five to ten minute break and then reconvene, if we can, try to keep it in the five minute range.

(Recess)

DR. POLAND: Okay. If members will take their seats. We're running about 15 minutes behind here. Our next speaker this morning is Captain Robert DeMartino, who is Director of the

Behavioral Medicine Division within the Office of the Chief Medical Officer in TRICARE Management Activity. He'll provide a brief on a question that was recently brought to the Board regarding the issue of autism and applied behavioral analysis. His presentation and slides are under Tab 11. And we have scheduled 15 minutes for this presentation.

CAPTAIN DeMARTINO: Good morning; my name is Captain Robert DeMartino, I'm with the Office of the Chief Medical Officer. I'm with the U.S. Public Health Service and have been working on issues related to autism now for maybe about two years, one and a half, two years, in a variety of different ways.

First, I would just like to -- I'm not sure how familiar people are with the disorder. It is a disorder in which no cause has been found. In fact, if you have been watching the news recently, you'll have seen that, once again, the implication that vaccines are somehow responsible has been sort of refuted once again in another

meta-analysis. That's been happening several times, but there has been, over the years, a number of people who have been very invested in that as a cause, but so far it hasn't come through. But, of course, there's nothing really else to pin our hopes on just yet, although there's a lot of work being done.

So Autism Spectrum Disorders, which were sort of -- sort of comprise several disorders, including autism as been described over a number of years, and added to that were a couple of other disorders, Retts Disorder, Childhood Disintegrative Disorder, Pervasive Development Disorder, are not otherwise specified. These all fall within the DSM, the Diagnostic Statistical Manual from the American Psychiatric Association. So when we're talking about -- I'm talking about ASD sort of as a group, but remember, certainly there's no one cause for the disorders in this group, I mean nobody is even suggesting that.

In addition, there's -- there are not even -- the symptomatology sort of only -- in some

ways only marginally overlaps, so it's a bit of a grab bag of groups. But the reality is that between autism, Autistic Disorder, and Pervasive Developmental Disorder not otherwise specified, that makes up really a big portion as far as prevalence for these disorders.

So when it's serious, it's apparent by age two, often diagnosed somewhere in the three to five. That number has been coming down over years. And even the expression of the symptoms is very variable.

The other disorder that I forgot to mention that's in this group is Asperger's Disorder, which, again, has some overlapping symptoms with Autistic Disorder, but generally is less serious, someone has generally much more ability to lead an active life and participate in activities and schooling, education. The core deficits of ASD, communication, social skills, deficits, and these repetitive behaviors which are sort of the hallmark, I think what people sort of recognize as autism, but not necessarily prevalent

to a large degree in every child with autism. Certainly that's not necessarily a big component of Asperger's Disorder, for instance. But when we talk about the core deficits, we're talking for the group of illnesses as a whole.

This slide and the next two are just meant to show that in the absence of a causality, and in the absence of really a definitive means of addressing the symptomatology, in other words, something that clearly works in a large proportion of patients, reliably, there have certainly emerged a number of interventions over time related to this.

I would say that the majority of them have never really been examined to any great degree. A couple have been examined to a great degree, some with better results and some with definitively, this doesn't work. For instance, sensory integration therapy has been, after a number of studies, shown not to really provide a clinically significant difference in symptoms. But this was just to show all the things that have

sort of emerged over time, whether it's things like chelation, vitamin therapies, secretin, anti-fungals, all of these have been -- at one point or another as sort of, you know, the fix for the symptoms, but unfortunately, that never has proven true.

The therapies shown at the bottom are, as you know, they're not just for autism, they're used in all kinds of varieties of conditions and have proven to have some good effects in a limited number of deficits, sort of a small number, but generally not the kinds of deficits that really cause the problems for children for autism, the communication disorders, which really -- and some of the cognitive problems.

Again, as I said, these next two are just -- really just to give you a sense about all the different things that have, you know, between holding therapy and craniosacral therapy, I mean just there's -- I mean it's not hard to find them. If you type in Google, I mean people who are -- conform to these and want to practice them will

pop up, for better or worse.

On the other hand, comprehensive programs, of which there are much fewer, are generally collectic programs put together by people who have a lot of experience in the field and have sort of put together what they think makes developmentally and -- the most sense. And one thing characteristic of all these, most of them, in one way or another, use ABA, Applied Behavioral Analysis, as a -- intervention approach somewhere within there, some more, to a greater degree, and others to a much lesser degree. But all of these use that one way or another.

Some of them are much better known than others. TEACCH is well known; I think North Carolina has incorporated that as the intervention that they use, you know, state-wide, for instance, and RDI has more recently been sort of been talked about quite a bit more. Some of them have been studied better than others.

So ABA, when we talk about ABA, we're talking about something that came out of

essentially operant conditioning. Skenarian conditioning, which essentially uses rewards and punishments to effect change. In fact, the Lovaas who did this sort of seminal studies in the '70's and '80's on ABA sort of really used punishment, actual physical punishment initially to get his change, and he sort of -- great effects. Of course, that sort of became impossible to do over time, and the punishments are more, you know, withdrawing things that are wanted. But, in essence, it's operant conditioning, and it can -- it's evolved over time, it's I think become more subtle, more nuanced over the years, and there's been quite a bit of work in studying ABA. One of the biggest problems has been the, you know, the fidelity to certain models and whether the studies have been done with, you know, with -- well controlled and using good control groups, things like that.

So the published studies that were reviewed most recently and most comprehensibly by the Institute of Medicine that was in the early

part of this decade essentially sort of said, listen, you know, we don't -- I mean there's no definitive number, we don't know that this absolutely works, this one doesn't work, but their sense was that more ABA was better than less ABA, for the most part, and that the only study that sort of gave a number was the earlier Lovaas studies, in which he used 40 hours of treatment in a treatment week, and he got good results.

So that is sort of what got carried over into the IOM report. And although they said, essentially, sort of over 25 seem to make the most sense, and less than that, there wasn't evidence that there was going to be a good effect using intensive ABA, intensive meaning anything that you're doing, you know, 20 or more hours a week is pretty intensive, certainly. And I put this up just sort of to get a clarification, because ABA is really sort of a method of doing something, it uses operant conditioning, but the way it gets implemented, you know, looks like a lot of different things. It just -- sometimes it looks

like sitting across a desk, giving jelly beans, sometimes it's happening in an actual environment, and it has to do with giving, withdrawing, things that the child identifies as what they want, and using those as your rewards and punishment, so it doesn't always look the same, and there -- and a lot of these kinds of methods have different names, so there's lots of techniques that are associated with ABA.

But at its core, the most important thing is that ABA is built on a -- sort of a scientific foundation of doing an analysis first of behavior, applying -- and the analysis sort of says what happened before the behavior that you want or don't want, what can you do to change that, I mean -- and then there's a feedback loop.

So it's, again, built on operant conditioning. The methodology of ABA is founded in some pretty solid, you know, it has solid foundations. And as I mentioned before, because it's a, you know, it's not a fixed intervention, it's used -- in lots of different things, so in

all those comprehensive, it's used in one way or the other, they don't always look the same, and in many other interventions sometimes these kinds of methods and techniques are used, as well. And over time, they've been used for a variety of things. I mean essentially anything in which you want to change behavior, whether it's a speaking behavior or a physical behavior or anything other kind of behavior can -- is subject to operant conditioning, and we've known that for decades.

So it's not -- I don't think anyone will be surprised to know that, you know, learning to learn, communication, social skills, health care, academics, all those have been subject to operant conditioning with the expectation that the foundations of ABA are solid and they can produce change.

And I don't think that when you look through the literature, that you find studies on every single one of these that would really feel, you know, strongly convincing of a use. But there is certainly a large body of literature at this

point, because a lot of these have been studied in one way or another. So the issue is that the -- Lovaas studies in the late '80's was a relatively small study in which he assigned two groups to a 40 hour treatment group, and one with ten hours or so of treatment, and in that sense, he initially sort of described it as random, but, you know, in review over the years, it's been pretty clear that that wasn't really a random assignment at all.

Now, his -- the people he worked with redid those studies over time and sort of followed up on them with some mixed results. And, you know, this has sort of left, you know, a little bit of an uncertain foundation about, you know, where ABA is. I mean certainly people feel very, very strongly about this, very strongly that ABA is the only, at this point, definitive evidenced based treatment for ABA.

And I think that it's sort of hard to argue, because really nothing else of any significance has emerged as being -- unless you count pharmaceuticals that can dampen certain

kinds of behaviors, but if we exclude that, then there's really nothing else.

At the same time, when we think about -- certainly in TRICARE, when we think about the kinds of interventions that we're going to support, our judgment generally has to be, is it safe and is it effective, and that's -- and we keep a high bar for the very reason that making sure that our beneficiaries get safe and effective treatment is much more -- it tends to be more important in the medical sphere. Now, ABA has always -- has been generally sort of conducted in the educational environs, in schools, with the idea mostly because this is done with very young children, we're talking about the three to six or seven, not much pass that, with the intent of getting them into school, into normal classes, if possible, but at least able to learn, able to integrate into their -- with their peers and move on from there.

And so I think that one of the big issues that we're interested in is knowing about,

you know, what do we have now, now that many years have passed even since the IOM earlier in the decade, a number of years have passed since then, maybe with another eye looking back to see what we know about ABA, what we can find out, what the literature has to tell us about the short term effects, about the long term effects, because, in essence, I mean this is really one of the more important things to know, is whether the interventions that are happening in the three to six year old range have -- I mean that would certainly be important, if that -- if the gains that are touted as being made during that time are lost, you know, that's a serious problem, so that's another important question. And what does the literature indicate about the intensity and duration of care that's beneficial, because I think that's one of the most contentious issues. I mean how much good ABA, if ABA is effective, how much good ABA is necessary, for how many years, how many hours in a week, what does the literature tell us about that, you know, to achieve short

term and long term effects.

And I can tell you that the literature is, you know, has a strong push towards one way of thinking about that, but it remains reasonably murky, murky enough to I think justify a question of this sort to the Board.

So just to wrap up implications; so, by law, ABA is -- it's not a benefit under our basic TRICARE program, so it's not considered a medical intervention, it's considered an educational intervention that we have incorporated into a special kind of a benefit, a special benefit that sort of runs along side of the general medical benefit, it's under a special program called the ECHO Program, and it's really the only non-medical intervention for autism that we -- except for, as I say, occupational speech therapy that we cover. And if we had -- in general it's sort of thought that if we apply the same sort of rules that we apply for a medical treatment, whether it be a pharmaceutical treatment or a surgical intervention or something like that, if we applied

the same kinds of standards to ABA, it probably wouldn't reach the standards necessary to say, hey, this is an effective medical intervention, it probably would never get up to that. But we don't consider it a medical intervention, we consider it an educational intervention. So that's the -- I guess -- I don't think I have anything else, do I, no.

DR. POLAND: Thank you. I'd like to begin open discussion, first with members of the Board, and I think we do have at least one person -- public comment that's registered. Dr.Blazer, do you have a comment?

DR. BLAZER: Yes; this is Dan Blazer. I'll begin with a couple of statements. One is, I am not an expert in this area. I actually work in the other half of the life cycle, so I do not know this area well at all. What I do know is that the struggle that these families go through is profound, and I just want to be sure we understand that this is extremely difficult for families to manage. And I suspect many people around this

table have known families, if not their families themselves, who have had to deal with these problems. Having said that, what I do know from the field of psychiatry at least is that this is probably the hottest topic in the entire field of psychiatry at the present time, as far as I know. Certainly it's, from what I can tell, is the hottest topic from the National Institute of Mental Health. This is dominating research, it's dominating trying to understand what the proper therapy should be, et cetera.

And I guess, recognizing the charge to the Board, I just think it's important for us to be very cognizant that the people sitting around this table may not be the best individuals to answer that question. And if there were no individuals trying to answer this question, that would be one thing. If, in fact, there are a lot of very bright people trying to address these issues, I think that puts it in a somewhat different perspective. So I just want to kind of get that out.

My bottom line is, let's not try to get ahead of the curve on this one too far. I recognize the distinction between educational and therapeutic from the perspective of ECHO, but what I would note is that when you look at it as a mental health professional, those two things are not separated, they're part of the same. The idea is, how do you help these kids to get better, that's the goal, and there are a lot of people trying to figure that out.

DR. POLAND: Dr.Parkinson, and then Dr.Shamoo, and then Dr.Kaplan.

DR. PARKINSON: Well, Mike Parkinson; every major health insurance plan, where I've spent the last number of years of my life, has their coverage policy decision and the process. I will tell you, as anything but evidenced based, despite what the five major carriers will tell you that they maintain.

In reality, they're all hampered by a flawed medical model that says that -- I mean and you said it directly, nothing personal, but

education is not therapy. I mean education is therapy when 80 percent of all disease, illness, injury, and death is relating to behavior. So we are saddled in DOD, as we are in the private sector, by a broken paradigm along the lines that Dr.Blazer just said.

Having said that, just so I understand the process, the way the DOD works now, if I have a child with autism, I automatically qualify for ECHO designation, and then as a result of ECHO designation, I then have access to an educational program which the Department has removed from the usual coverage policy decision versus, you know, usual care versus "investigational", which is what would occur at any health plan. It's deemed investigational because we don't have the criteria, therefore, it's not covered. So the ECHO program and the autism within the ECHO allows TRICARE to kind of say that's a different benefit, but we're not going to subject it to the usual TRICARE coverage policy decisions; is that clear, is that -- I'm trying to piece it together and I

want to make sure I have that right.

DR. BLAZER: Well, you sort of have several different issues there. Congress mandated a program separate from the medical program that would cover children with certain severe illnesses and provide services and other things, other kinds of --

DR. PARKINSON: Right.

DR. BLAZER: -- that aren't offered in the medical benefit.

DR. PARKINSON: Okay. And the ECHO is that program?

DR. BLAZER: Yes; and it used to be called something else --

DR. PARKINSON: Okay.

DR. BLAZER: -- now it's called ECHO.

DR. PARKINSON: So in a way, the question is kind of the wrong question as it's framed by the Department, I think. The question is, is there evidence that ABA is effective to relieve pain, suffering, coping for families going forward as opposed to using medical effectiveness

criteria, which we would do for a health benefit plan.

If you've already got the ECHO designation, and the Board can add value to saying is the ABA a good thing to have to help families cope, muddling that up a little bit with a medical evidence criteria used for health benefit, which is what we would do in Blue Cross or what we would do in a traditional plan, say no, it doesn't meet the way we do health benefits design.

So I'm just -- as the Board goes forward, it seems like Dr.Blazer's approach to this is, how can we help these families vice muddling it up with does it meet scientific criteria or not, because it clearly doesn't, I mean it would be investigational IND you know, whatever you would call it, if it went to Aetna United, so the other piece of that obviously is, how do all the major health plans, and there are only five of them anymore that exist, how do they all treat ABA therapy, that's for the Committee's work, but is it deemed investigational by Blue

Cross Blue Shield Association and their clinical policy committee, those would be useful pieces of data. But it seems to me we're mixing the two in the question, and we may not need to have to do that to get to the outcome that Dr.Blazer is talking about.

DR. BLAZER: I'd just like to respond to that slightly, because I think -- I mean no one is denying that there aren't -- we shouldn't be doing things that would be benefit -- that would benefit the families of this, and to that end, there are certainly other things, families have access to care, and there are other benefits that would do that.

So I mean certainly it's not all the eggs are in this one basket, and I don't think anyone is sort of suggesting that, you know, ABA is the only way that we sort of approach families, you know, it's the only thing that we have right now that has risen to any level in which, you know, we can feel comfortable.

But, you know, if you look at the kinds

of things that parents want and would ask for, not for having some standards, and we would be covering hyperbaric oxygen therapy, we would be carrying chelation, we would be covering, you know, a whole variety of things that families feel are important to do. And our job is to say, listen, you know, we know that this is -- that the situation is very, very difficult, but there are certain things that we feel we can't do for the safety of everybody, even if you feel very strongly that this is something that you want.

DR. PARKINSON: Well, if I may just ask one other clarification, because this is all just clarification for the Board's work, it says that the Department has launched a demonstration project, so did you describe the demonstration project in terms of who it is, the evaluation criteria, or is this the process you want the Board to help design a demonstration project?

DR. BLAZER: No; there's a demonstration that's existing right now.

DR. PARKINSON: Did you present that?

DR. BLAZER: No, I did not.

DR. PARKINSON: Is that relevant to the Board's work?

DR. BLAZER: I don't think so.

DR. PARKINSON: It would be my first gut reaction.

DR. POLAND: Yeah, I think it would be. Mike, I would share that opinion. But --

DR. BLAZER: Because it's not a demonstration program to test the effectiveness of an intervention, it's a service model demonstration.

COLONEL GIBSON: Can I -- this was a presentation of a question to the Defense Health Board for getting that early on briefing background or explaining the details of what we're approaching. We have lots and lots of subcommittees, we have a Psychological Health Subcommittee. I would expect, and I assume that Dr.Poland will say I'm assigning it to the Psychological Health Subcommittee, we'll bring in experts, et cetera. So does the full core Board

need every detail today?

DR. POLAND: But I think your question, anything that's being done in this regard would be of relevance to that subcommittee. Dr.Shamoo, you had a comment?

DR. SHAMOO: Yeah; a question and some comments. Thank you for your presentation, a nice job. As you well know, autism is a whole spectrum, God knows how many diseases, and it's -- ten years ago I became involved in looking at the literature. I couldn't believe that there were full professors giving conference talks which was based on no science, but making conclusions nevertheless. It's the worst field in terms of quackery. And even NIH has fell into that quackery by supporting a clinical trial with no basis and fact to reach that level of a clinical trial on chelation therapy. And it was shocking to me that someone who's been editor and founder of a journal called Accountability in Research.

So having said that, the ABA, it's really like fate. Have you seen the people who

practice ABA? It's not like this may work only with -- you said a spectrum with one-tenth of the spectrum of 1/50th of the spectrum, they think it should work with everything, and they are very religious about it almost.

When you try to fund them through the name ABA, what you are doing, you are encouraging that modality of treatment for the whole spectrum. You yourself said very well that ABA is really behavioral mod. And why can't you just fund them through generalized behavioral modification so people will not be pushed into falling into one modality which the data are really are not there yet?

DR. POLAND: Thank you. There was another comment, I think. Ed, and then Mark.

DR. KAPLAN: No, there was a comment, I was raising my hand, but my question has been asked by the previous -- has been answered by the previous discussion.

DR. POLAND: Dr.Miller.

DR. MILLER: Mine is also a comment.

I'm not going to comment whether or not ABA has any therapeutic effects or not. I think this whole field is a -- process and I'm not convinced actually that it necessarily is or isn't.

However, I think it's important to also recognize that if these patients are receiving up to 35 to 40 hours of therapy, there's a social benefit to that, too, potentially a social benefit that no one can deny that these families suffer from the psychological aspect of dealing for the entire family, and 35 to 40 hours of relief, to a certain extent, of having extra help and support by the therapy itself is something that we should at least acknowledge is potentially important, although it might not be therapeutic, it's a relief for the family overall and that whole psychosocial structure.

DR. POLAND: Thank you. Bill.

DR. HALPERIN: This is also a comment about the complexity of this issue. One of the other commissions I sit on is the Mandated Health Benefits Commission for the State of New Jersey,

where any legislation that's going to increase the coverage of -- insurance coverage, as we've just heard from Mike, has to go through this commission. And I'd say about half of the states now have such commissions.

And the decisions are a combination, a loose, non-formulated combination of evidence, of thoughts about social benefits, about what's it going to do to the cost of health insurance and denial of other people.

So the issue is whether -- much of the decision about whether TRICARE will offer this may be decided by the states, whether they include it as a mandated benefit if TRICARE is going to be operating in those states, which gets into all sorts of interesting issues of which trumps which, a federal system, a state system, et cetera. So it's just an issue to consider, but the decision may be made by the state commissions.

DR. POLAND: That's a good point. Okay, thank you. We're running about 30 minutes behind here, and I do want to leave time -- I do want to

leave time for -- we have Lisa, one speaker from the public?

MS. JARRETT: Yes; Ms. Karen Driscoll. She is an autism parent and military wife.

DR. POLAND: Thank you. Please, yes, go ahead and take the podium. And, again, if you can keep your comments to under five minutes.

MS. DRISCOLL: Thank you. Good morning, my name is Karen Driscoll, I'm a Marine Corps wife and parent of a young child with autism. And I think it's imperative I bring to you today the parent family perspective about this devastating medical disability.

Dr.Parkinson, you raised some excellent questions that I think really focus on the impact of our military families. Currently, I know you had a question about the ECHO program. Currently, the ECHO program has segregated ABA therapy out of the TRICARE Basic program, and it's available for children with severe disabilities.

But what that does require is that a parent must enroll their child into this program.

So it's not a guarantee that all children with an autism spectrum diagnosis actually receive ABA therapy, and many children have been denied. It's up to the discussion of the various managed care support contractors, and there's been relatively inconsistent application of this policy across the three regions. So I want to highlight that to you. And further, what the ECHO program then does is, it places a limitation, a financial cap on a child's treatment program. And so -- and that current cap is at $2,500 a month.

And if we look at prescribed level of care for these patients, for example, a two year old with a diagnosis of severe autism will go and see a developmental pediatrician, and our medical physicians are prescribing this care to our families. They are telling families, you need to be doing this for you child, and I'm telling you, you need 35 to 40 hours a week.

Under the current autism demonstration project to enhance access to care for our military families, that's going to provide about ten hours

a week. So the limitations of the current ECHO program are inadequate to meet prescribed level of care, and so families are going into significant debt, my family being one of them.

But what that really says is that for our younger families and enlisted families, most often these children go without. Now, in some geographic regions, many families are lucky to perhaps get intervention services through the school district or the local state Medicaid run program. But given the mobile nature of a military family, inconsistent access to services is a major problem. For example, when I left Camp Pendleton, California, and moved to Quantico, Virginia, I had a wonderful therapeutic program offered part-time in the school, and they also funded my home therapy treatment program.

My son was getting the recommended standard of care 25 hours a week, which is outlined as policy by the American Academy of Pediatrics, as well as the National Academy of Sciences with its National Research Counsel Report

from 2001, minimum 25 hours a week upon diagnosis.

So by segregating autism treatment out of the TRICARE Basic program into an ECHO program, it's causing delays and denial of services, and it puts a financial cap on a child's prescribed treatment plan, and a financial cap that does not even meet the minimum recommended standard of care from the American Academy of Pediatrics.

Now, I want to highlight a very important quote from the American Academy of Pediatrics 2007 Report. "The effectiveness of ABA based intervention in Autism Spectrum Disorders has been well documented with five decades of research by using single subject methodology and in controlled studies of comprehensive early intensive behavior intervention programs in university and community settings." The American Academy of Pediatrics is telling physicians and families ABA is safe and effective, and we're recommending early and intensive use.

Now, much focus has been placed on early diagnosis, rightfully so, because the earlier we

catch autism, the more malleable a child's brain would be, and the more effective they would respond to a treatment program.

But early diagnosis is only good when treatment is received. And we will look at the issues our military families experience; access to care, and funding for treatment are our two main barriers.

So when we look at how do we develop a comprehensive treatment program for this patient population, we need to focus on delivering that service to our families. When we're living in rural military communities where access to intensive therapeutic programs may not be available through the school district, or military families are hitting bottom of wait list to bottom of wait list at every single duty station, effectively never getting intensive intervention. So the key issues when we look at treating this patient population would be, how do we get access to prescribed level of care. Now, is ABA the only way to go? Now, I can only speak to that

experience because my son has responded tremendously to ABA therapy at a significant financial cost to my family. But I believe there are effective treatment programs, and Dr. DeMartino did a wonderful job outlining the other intervention programs which fall under that behavior intervention category.

I believe the way the medical field is emerging is that recommend ABA therapy; if it's not proven to be effective for your child, go and explore these other behavior intervention methods that have shown some level of efficacy.

But I believe ABA has met the standard of medical necessity. It's safe, it's effective, and it is now the standard of care within the medical community. It's supported by the National Institute of Mental Health, American Academy of Neurology, American Academy of Pediatrics, National Academy of Sciences. At what point do we say this overwhelming body of science and data is adequate enough to provide access to prescribed level of care for these patients? Now, one of the

things I'm going to be submitting to you today through, I gave a copy to Lisa, is an opinion letter provided to the Armed Services Committee signed by various subject matter experts from across the country. Most notably, we have the signature of Dr.Christine Plesha Johnson. She's the co- author of the 2007 American Academy of Pediatric Support, and Dr.Pauline Filipek, as well as a separate letter prepared by Dr.Gina Green. She's one of the leading autism research experts in the field today.

I hope you consider the information provided in those letters with serious weight versus the opinion that ABA is special education. And I think it's very important that you recognize ABA, as Dr.DeMartino outlined, behavior analysis, it is not special education. We may be teaching our children skills, but we're developing these skills so that these children may live independently, and we're providing these skills so that their overall quality of life is greatly improved.

And, Dr.Parkinson, you raised another great question earlier, and recently the Journal of the American Academy of Adolescent Psychiatry in 2006 concluded that ABA therapy has been proven effective at improving mental health of all family members. And so, if I may, I just want to provide a wonderful example of that. I have three children, my oldest has autism. At age one, my daughter was afraid of her big brother. Because a child of autism doesn't often recognize that he has an impact on other people around him, he's not cognizant of the social skills that are necessary to have a proper conversation. My son tends to yell.

And so, as you can imagine, the strain on a family when an infant is afraid of being in the same room as her older brother, it hurts me, it hurts my son, it hurts my daughter. And so recognizing that important trouble, our therapist was able to develop a treatment, or rather a program we could work on as a family unit, and she would help us through this to create, modify a

child's environment to create positive social interactions between my daughter and her brother.

And we're also working on teaching my son skills to modulate his voice, teaching social skills, that's just one typical example, but it's a wonderful example on how ABA can improve the mental health of the family.

One last thing I do think it's important you understand is, there are now eight states that mandate coverage of autism treatment as medically necessary, including speech therapy, physical therapy, occupational therapy, and applied behavior analysis. Twenty more states have bills pending on the exact same thing. So there are now many regions of the country where civilian coverage of applied behavior analysis and autism treatment is better than TRICARE. This is a readiness issue, this is a retention issue. And I'll provide this information to Lisa before I leave.

DR. POLAND: Thank you.

MS. DRISCALL: I have one quick

important information to share. A recent FOIA request has outlined that the autism incident rate in the military is every one in 88 children. That is active duty service members. Every one in 88 has a child diagnosed with autism. We need to get in front of this. We need to treat these children and provide them with the intensive services they require so that they can lead happy, healthy, and independent lives. I appreciate your leadership and your openness to hear our comments today. Thank you.

DR. POLAND: Thank you for coming. My plan here is, first of all, to reiterate that any written comments would be gladly received by the Board and reviewed. And as Colonel Gibson suggested, we're going to be assigning this topic to the Psychological Health External Advisory Subcommittee, who will meet and deliberate the issue and bring back their recommendations to the full Board for a discussion in open session. I would like to ask them to please take under consideration Dr.Blazer's recommendation, that we

be sure that that is adequately staffed with subject matter experts in this particular area, so thank you for that.

We're going to move on to new Board business. Tab 14 of your meeting binders has the DHB by-laws, as well as four recently signed memoranda requesting the Board establish task forces to address various issues, and I'll just run through those.

One is a recent request to the Board by Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, Ms. Embrey, regarding setting up the task force in order to review and provide recommendations on the manner by which DOD should maintain funding and clinical competency within amputee care centers in the post-conflict setting, in addition to determining the most appropriate infrastructure for providing such care.

Obviously, we would expect contributions from everyone on the panel on the care of individuals with amputation and functional limb

loss. But I would also like to ask the following people on the Task Force to include members of the NCR BRAC Advisory Panel and Health Care Delivery Subcommittee, Dr.Parkinson, Dr.Lednar, Dr. Kokulis, Mr. Tobey, Mr. DuBois, and Dr.Kizer. I'd also like to ask Dr.Butler from the Trauma and Injury Subcommittee to be a part of this group. And before I move on to that, Lieutenant General LaNoue is also here and a part of that. General LaNoue, would you like to make any comments?

GENERAL LaNOUE: I'm General LaNoue; I have a unique experience in this in that in 1964, when the first bombing took place in Vietnam and we had our first amputee casualties being shipped back to Texas, I happened to be there in the residency program, and we were suddenly overwhelmed with numbers of amputees that nobody present had been experienced with, and it presented a new problem.

I went off -- after a year I went off to Vietnam and then came back to Valley Forge and we continued to have large numbers of amputees. And

while I was assigned at Valley Forge General Hospital, nobody there knew how to take care of young, agile, robust adults who happened to be missing a leg. And the policy at the time was to ship them off to the VA, and I was ordered to do their boards. Now, I'd have the family in their weeping because they would visit the VA and they would find people my age and older, alcoholics, drug abusers, and they wanted to be taken are of by their own, they wanted to be with their own team, they wanted to be identified either as an Army or Marine or a Sailor or Airman, and feel that they're getting that support.

I might say that one of the casualties was a young officer by the name of Fred Franks, who's now the Chairman of our Board, and an amputee, who through a more mature version of our program that I happened to institute, was able to return to duty and not feel that he was required to sell pencils on a corner some place, which some of our patients did, too.

And as I reviewed the history of it and

then watched the end of the Vietnam War and watched Valley Forge Hospital close, and then I moved whatever I could to Walter Reed because I happened to be assigned there to try to reinvigorate the amputee program, there were no longer anymore casualties coming in.

So the history is that with every war, we have certain categories of patients, amputees and limb loss, functional limb loss being one of them, not the only one. The first group of patients come in and people say, what do we do now, and they get very bad care. When I was Deputy Surgeon General, I got a call from a Texas billionaire with funny looking ears, and he had somebody from his community who needed specialized amputee care, and the hospital didn't know what to do with him.

Right now we've got the most effective, the most sophisticated, the best that's ever been done in the history of science, and I'm positive it's going to disintegrate as this war ends. I hope the war ends. But who's going to tell me

that there's not going to be another war and we don't go through the same cycle again.

The politics this time was different than the last time. The politics this time said we owe these men and women a return to normal life and normal capability. They didn't say that when I was doing it. I was almost court marshaled for keeping patients under my care against orders, because the families really wanted to be cared for by us, and that will happen again. Whether it's a war with Russia or Ossetia or wherever we might go the next time around, there will be another war, we will have the need, and we need a bridge to maintain our capability. I don't know what that bridge is, but we need to look for it.

DR. POLAND: Thank you, and a good set up for why this is such an important issue for this subcommittee. I would also like to ask that the clinical and program policy, as well as FHP and R provide experts to contribute strategic input to this question. The services and TRICARE Management Activity should also designate a

representative to assist the panel, including TMA budget representatives. And I would also ask that the Department of Veteran Affairs be involved in the Task Force deliberations, and perhaps we can get a -- the Task Force can provide a brief to us at our next full Board meeting in December.

In addition to the memorandum requiring sustainment of clinical competency and funding for amputee and functional limb loss patient care, there are also three memoranda signed by the Assistant Secretary of Defense for Health Affairs, Dr.Casscells, which requests the Board establish three additional Task Force.

One is a Task Force on nutrition, which will be established in order to provide a review of DOD initiatives pertaining to nutrition and health promotion within contingency environments and offer policy and research recommendations which address various nutritional issues with the goal of optimizing physical and mental performance of service members, especially during combat and within military training environments. The idea

is that this Task Force would specifically focus on the nutritional composition of diets, use of dietary supplements, the impact of nutrition on immune status and performance, and current research within the Department concerning enhanced diets for service members.

Another Task Force will assess the scope and structure of DOD health related research in order to provide the Department with recommendations regarding enhancing and improving health research to make it more efficient and effective while maintaining alignment with the Department's vision and priorities. The Deployment Health Research External visit highlighted the need for something like this.

Of particular focus that has come up is the review of regenerative medicine research and best practices. Current research efforts within the Department require streamlining and coordination since various departmental agencies conduct research which covers a very broad scope, relies on multiple funding streams, and is carried

out in concert with academic institutions, consortia, and other research entitles. As a result, there's a critical need to mitigate and resolve the difficulties which stem from those complexities and exacerbate the identification and resolution of any health research gaps.

Finally, an additional Task Force that's been requested is to assess the scope and structure of DOD medical stability operations, including the review of education and training of relief providers. Lessons learned from events such as Hurricane Katrina illustrated the urgent need for the Department's involvement in stability operations and disaster response.

DOD doctrine has recently been amended to characterize stability operations as a core competency of the U.S. Military and equivalent with combat operations. The Task Force will specifically focus on addressing metrics, contingency planning, and logistics of integrating medical stability assistance across all departmental activities and should consider

communication, outreach, and coordination efforts -- aspects of such efforts.

Dr.Casscells will be nominating members to serve on these Task Forces. Core Board members who wish to serve on these Task Forces may do so, as well. In addition, subcommittee members who have particular interest in any of these are eligible to participate, so please let us know if you are -- have interest there. There's also been a Work Group on Information Management and Information Technology developed under the Health Care Delivery Subcommittee, which will examine issues pertaining to Information Management and Information Technology infrastructure, as well as that interface between DOD and DBA.

So any particular questions about any of those task forces or aspects? If not, then I think we will adjourn the Board and go into Executive Session. Ms. Embrey, can you adjourn the Board's business meeting, please?

MS. EMBREY: My pleasure; this meeting of the Defense Health Board is adjourned. Thank

you for your work and thank you for coming.

(Whereupon, at 11:54 a.m., the PROCEEDINGS were adjourned.)

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CERTIFICATE OF NOTARY PUBLIC

I, Carleton J. Anderson, III do hereby certify that the forgoing electronic file when originally transmitted was reduced to text at my direction; that said transcript is a true record of the proceedings therein referenced; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and, furthermore, that I am neither a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

/s/Carleton J. Anderson, III
Notary Public # 351998
in and for the Commonwealth of Virginia

My Commission Expires:
November 30, 2008