U.S. DEPARTMENT OF VETERANS AFFAIRS RESEARCH PROGRAMS

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BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

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U.S. DEPARTMENT OF VETERANS AFFAIRS RESEARCH PROGRAMS

THURSDAY, OCTOBER 4, 2007

U. S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:02 a.m., in Room 334, Cannon House Office Building, Hon. Michael Michaud [Chairman of the Subcommittee] presiding.

Present: Representatives Michaud, Snyder, Miller, and Brown of South Carolina.

OPENING STATEMENT OF CHAIRMAN MICHAUD

Mr. MICHAUD. The Subcommittee on Health will come to order. I would like to thank everyone for coming here today.

At this hearing, we will examine the U.S. Department of Veterans Affairs (VA) Research Program. Research is one of the core missions of the Veterans Health Administration (VHA). VA is unique in that it has the capability to provide clinical services and conduct research within the same organization.

As a result, the VA has done ground-breaking research on topics ranging from post traumatic stress disorder (PTSD), prosthetics, smoking cessation, and treatment of heart disease.

The purpose of this hearing is to examine VA research programs, particularly in light of the current conflict. As we all know, Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) have presented us with some new challenges in caring for and treating injured soldiers.

In recent years, we have seen a dramatic increase in the number of returning veterans with conditions such as post traumatic stress disorder, traumatic brain injury (TBI), and traumatic amputation. These conflicts have produced nearly 28,000 severely injured veterans, over 700 of which have had traumatic amputations.

It is vital that VA continue to push the edge of research in order to provide these brave men and women with the most up-to-date care available whether they need prosthetics, pain management, eye care, or any number of other services.

It is also important that VA work in collaboration with the U.S. Department of Defense (DoD), academic partners, and other public and private entities to leverage their resources and knowledge and to produce the best possible results out of their research.

I would like to send a special welcome to one of our witnesses today. On June 21, 2003, Major David Rozelle was leading a convoy

west of Baghdad when his vehicle struck a land mine which resulted in the loss of his right foot.

After spending 8 months recovering at Fort Carson, Colorado, Major Rozelle returned to Iraq as a troop commander conducting operations in Baghdad and Tel Afar. He was the first troop commander to redeploy in the same battlefield as an amputee in recent military history.

Major Rozelle is currently serving as an Administrative Officer at the Military Advanced Training Center (MATC) at Walter Reed Army Medical Center. Drawing on his personal and professional experience, Major Rozelle helped plan and design this brand new facility using the most state-of-the-art research available.

I would like to welcome you, Major.

Continuing research is vital to improving healthcare, saving lives, and improving the quality of life for our sick and injured.

I look forward to hearing from our witnesses today about what VA is doing and what VA should be doing to advance that core mission, research.

I would now like to recognize a good colleague and friend, Ranking Member Miller, for an opening statement.

[The prepared statement of Chairman Michaud appears on p. 28.]

OPENING STATEMENT OF HON. JEFF MILLER

Mr. MILLER. Thank you very much, Mr. Chairman.

We all know that research is necessary to generate new knowledge and achieve both scientific and clinical excellence. VA is world renowned for its medical research. VA's Research Program has a strong history of success and is credited with pioneering life-saving therapies and treatments that have improved healthcare not only for veterans, but for patients as a whole.

This year, for example, the first vaccine for shingles was approved as a result of VA research.

Modern molecular medicine and rapidly advancing medical technology make a strong research enterprise more important to veterans now more so than ever.

As we map out the future of VA and the research that they do, we must work to ensure that the VA's goals are aligned with the special healthcare needs of both our new generation of veterans from the Global War on Terror and our older veterans of previous wars.

Recognizing the value of VA research, we must also be aware that nothing is more important than translating research from the bench to the bedside.

I am pleased to see that we will hear from the Administrative Officer from the Military Advanced Training Center and have the opportunity to discuss collaborative efforts on Federal research for the benefit of our military and veterans.

Mr. Chairman, I appreciate the opportunity to participate in this hearing today and yield back the balance of my time.

[The prepared statement of Congressman Miller appears on p. 28.]

Mr. MICHAUD. I thank the gentleman.

On our first panel today is Dr. John Feussner, who is Professor and Chairman of the Department of Medicine, Medical University of South Carolina in Charleston, South Carolina. He is testifying on behalf of Friends of VA Medical Care and Research (FOVA).

Major Rozelle, who is the Administrative Officer from the Military Advanced Training Center (MATC) at Walter Reed Army Medical Center.

And Dr. Mark Lema, who is Chair of the Department of Anesthesiology, who is testifying today on behalf of the Pain Care Coalition (PCC).

So I would like to start off first with Dr. Feussner.

STATEMENTS JOHN R. FEUSSNER, M.D., MPH, PROFESSOR AND CHAIRMAN, DEPARTMENT OF MEDICINE, MEDICAL UNIVERSITY OF SOUTH CAROLINA, CHARLESTON, SC, AND VOLUNTEER STAFF PHYSICIAN, RALPH H. JOHNSON VETERANS AFFAIRS MEDICAL CENTER, ON BEHALF OF FRIENDS OF VA MEDICAL CARE AND HEALTH RESEARCH; MAJOR DAVID ROZELLE, ADMINISTRATIVE OFFICER, MILITARY ADVANCED TRAINING CENTER, WALTER REED ARMY MEDICAL CENTER, DEPARTMENT OF THE ARMY, U.S. DEPARTMENT OF DEFENSE; AND MARK J. LEMA, M.D., PH.D., CHAIR, DEPARTMENT OF ANESTHESIOLOGY, CRITICAL CARE AND PAIN MEDICINE, ROSWELL PARK CANCER INSTITUTE, BUFFALO, NY, AND PROFESSOR AND CHAIR, DEPARTMENT OF ANESTHESIOLOGY, UNIVERSITY OF BUFFALO, STATE UNIVERSITY OF NEW YORK, SCHOOL OF MEDICINE AND BIOMEDICAL SCIENCES, AND PRESIDENT, AMERICAN SOCIETY OF ANESTHESIOLOGISTS, ON BEHALF OF PAIN CARE COALITION

STATEMENT OF JOHN R. FEUSSNER, M.D., MPH

Dr. FEUSSNER. Good morning, Mr. Chairman, other Members of the Committee. My name is John Feussner.

As you alluded to, I am Professor and Chairman of the Department of Medicine at the Medical University of South Carolina in Charleston. I am also a volunteer staff physician at the Ralph Johnson VA Medical Center in Charleston. Previously I served VA in Washington, D.C., as its Chief Research and Development Officer from 1996 to 2002.

I would be remiss if I did not thank the Committee straight away for its support of VA research as evidenced by your recommendation for a $480 million appropriation for fiscal year 2008.

As you already stated, VA research is one of the Nation's premier biomedical research programs attracting high caliber clinicians who both do research and deliver medical care in VA's healthcare facilities. These physician researchers represent a scarce national resource and one that VA has sustained over several decades.

Recall also that the VA Research Program is an intramural program, only supporting physician researchers and other scientists who are VA employees. These investigators are at the forefront of research that impacts newly returning veterans from Iraq and Afghanistan, especially concerning traumatic blast injuries, burns, and post traumatic stress disorder.

And as it has done historically, VA is taking the lead on research issues affecting aging veterans who constitute the largest portion of veterans seeking treatment in the VA health system.

The VA research enterprise continues to be veteran centric focusing its resources on illnesses either unique to or highly prevalent among veterans. The support and commitment for VA research from this Subcommittee really is the good news.

However, and there are always many howevers, the current $480 million appropriation only provides a starting point for a more sustained future investment. New funding is necessary not only to sustain current research but to fund new research initiatives, to support career development for new physicians and other scientists, and to improve VA's aging research infrastructure.

New funding can enhance research in such areas as traumatic brain injury, the effects of limb loss from our recent military conflicts and on the physical and psychological well-being of veterans.

Because of past severe budget constraints, even approved and meritorious, VA research projects were either underfunded at a low dollar amount or unfunded entirely in part because of the inflationary and other escalating costs of doing high-quality research.

The FOVA Coalition encourages Congress to consider an orderly and predictable growth strategy for the VA research budget for the foreseeable future. Otherwise, gains made by this current Congressional appropriation may be lost without adequate attention paid to the future year research expenditures.

However, even with sustained growth, Congress must begin to invest in VA's aging research infrastructure. In 2001, the VA research evaluation project assessed the state of the research infrastructure by surveying sites on the quality of the physical infrastructure, the organizational structure supporting research, and the availability of state-of-the-art research equipment.

We estimated then that a dedicated funding allocation of approximately $40 million per year would be necessary to maintain and upgrade VA research facilities. Unfortunately, the events of September 11, 2001, intervened and attention to this crucial need for VA research waned.

We all applaud the Committee's recommendation for a $15 million construction funding stream for VA research facilities in its views and estimates for the 2008 fiscal year budget. This is certainly a very, very positive first step.

However, at least $45 million needs to be allocated for research facilities improvement under this minor construction account each year for the foreseeable future. Such an annual allocation could improve VA's research infrastructure in as many as a dozen facilities each year.

Finally, I would like to leave the Committee with several thoughts. First, our sincere gratitude for your support of this critical national resource, the VA Research Program.

Second, please consider a strategic commitment to sustain this growth for the foreseeable future so that present gains are simultaneously sustained.

And, finally, embrace the challenge and commitment to make the quality of VA research infrastructure match the quality of VA researchers. We should not expect world-class physicians and sci-

entists to work in deteriorating research facilities. VA cannot afford to lose its best and brightest in this way.

Again, Mr. Chairman, Members of the Committee, thank you for the opportunity to present FOVA's views on the Research Program. I will make every effort to answer your questions.

[The prepared statement of Dr. Feussner appears on p. 29.]

Mr. MICHAUD. Thank you very much.

Major Rozelle.

STATEMENT OF MAJOR DAVID ROZELLE

Major ROZELLE. Chairman Michaud and Congressman Miller, thank you for inviting me to participate in this hearing alongside my colleagues from the Department of Veterans Affairs.

I am Major David Rozelle, an Armor Officer and Administrative Officer of the Military Advanced Training Center or MATC at Walter Reed Medical Center.

I am excited to talk to you today about the use of advanced technology at the MATC and at the Center for the Intrepid, CFI, at Brooke Army Medical Center in San Antonio, Texas.

The openings of the CFI on the 29th of January 2007, and the MATC on September 13th, 2007, demonstrate the tremendous support of American people for our wounded warriors. These facilities are symbolic of the significant advances that are being made in the care provided to our courageous servicemembers.

Within the walls of the MATC, one recent patient described it as where the magic happens. It is a mix of technology and philosophy that allows our warriors to return to a lifetime of the highest physical activity, psychological and emotional function. Each servicemember is treated as a tactical athlete bringing the latest advances in sports medicine to bear.

Within the walls of the MATC, there is a multidisciplinary health professional team that works together to seamlessly bring the patient from recently wounded status to return to warrior status. This team includes representatives from the Veterans Benefits Administration, the VA social workers, and VA vocation, education, and rehabilitation counselors.

While the team includes those thought to be part of the traditional rehab team, the physical therapists, occupational therapists, physiatrists, and nurse case managers, it also includes psychological liaison providers, biomechanics, the patients, and the patient's family, among others.

The facilities boast many state-of-the-art capabilities. These capabilities include the firearms training simulator which includes a Blue Tooth technology which replicates the weight, feel, and responsiveness of the actual weapons, an M16, M14, rifles, and the nine millimeter pistol.

Also included is one of the most sophisticated gait labs in the world with a 23 camera capture system, a dual force plate treadmill, and six force plates in the floor to analyze gait patterns for adjustments to both prosthetics and for treatment plans.

The best example of both centers' one-of-a-kind capability would be the computer-assisted rehabilitation environment or CAREN system. Imagine a helicopter simulator and replace the helicopter with a platform placed in front of a virtual reality screen.

Imbedded in this is a treadmill with dual force plates underneath the treadmill.

There are a number of scenarios that patients react to as part of the therapy and the future programming capabilities are indeed limitless.

The facility offers a variety of opportunities which include a climbing wall, tread wall, an indoor walking and running track with a static harness system called the solo step. This support system frees the therapist to watch the patient and to make immediate corrections to their gait and patients the freedom of walking on their own.

The elevating parallel bars were developed specifically for our military amputee population. This allows the patients to train for community obstacles that they frequently encounter such as sloping streets, sidewalks, or ramps.

Technology has played a significant role in prosthetic restoration. New methods of measurement have resulted in more efficient methods of measuring the servicemember's amputated limb with better precision, efficiency, and quality.

These methods include the computer-aided design, computer-aided manufacturing, or CAD CAM, the optical digitizing and stereo lithography where CT scans are digitized and used to print an accurate three-dimensional model of the residual limb including existing heterotrophic ossification.

The program pioneered and implemented the concept of early custom postoperative prostheses and coupled for the first time with a policy of utilizing externally powered prostheses components.

Under this philosophy, the prosthetic sockets are rapidly produced with extremely durable and temporary materials and are coupled with the most technologically advanced components.

The patient receives multiple and frequent sockets to accommodate the volume and shape changes common during the early postoperative phases.

The use of myoelectric upper prosthetic components instead of body powered components places much less stress on the residual limb and permits the patient to begin to train much earlier in the rehabilitation process.

The innovative use of current state-of-the-art technology has attracted many manufacturers to our program who are seeking to provide new technology to program prior to release to the general population.

The resulting collaboration between the DoD and the Veterans Health Administration is ongoing and has already led to several significant successful projects. Among these is the development of the VA/DoD clinical practice guidelines (CPG) for patient care. The CPG sets in place the clinical pathway for both pre- and post-amputation patient care.

Additionally, partnership between the DoD experts and industry recently resulted in the development of the newest generation of sea leg, which is a microprocessor controlled prosthetic and even allows instantaneous adjustment to variable walking speeds for amputees.

As of September 2007, there have been 700 servicemembers who have sustained a major limb amputation in support of the Global

War on Terror. Twenty-three percent of these individuals have lost an upper limb and over 20 percent have lost more than one limb. Nearly 90 percent of these servicemembers have been under the age of 35 and as a result, have unique psychosocial needs and generally seek to return to a more active lifestyle than older individuals.

Additionally, the majority of combat-related amputations do not occur in isolation. Over 50 percent have documented traumatic brain injury, some with vision and/or hearing loss, and many have significant remote fractures and significant soft tissue wounds, others with comorbid paralysis from peripheral nerve injury or central cord injury, and nearly all with contaminated wounds requiring frequent surgical wash-outs and extensive antibiotic use.

These complex medical, surgical, and rehabilitative challenges require unique approach treatment and warrant dedicated research programs to optimize care.

The advanced training centers have proven to be an ideal setting for training and advanced techniques related to amputee care and prosthetics.

In addition to VA/DoD Clinical Rotation Program, we have held a number of courses attended by military therapists, Veterans Affairs therapists, and prosthetists from around the country.

One example of our collaborative efforts was a recent conference that brought together internationally recognized experts in amputee care from the DoD, VA, and academia to outline state-of-the-art care and set a road map for future research needed for this population.

The findings of this conference are scheduled to be published in a textbook which will be disseminated internationally.

The combination of advanced technologies, innovative clinical practices, caring providers, and an amazing group of warriors in transition with strength and courage to seek the high ground and continuing to move forward has led to revolutionary changes in our understanding of capabilities of individuals with limb loss.

I thank you for inviting me to talk to you today about the capabilities and the magic at the Military Advanced Training Center at Walter Reed and the Center for the Intrepid.

Your continued support for our wounded, ill, and injured is very much appreciated by the soldiers and staff at Walter Reed and throughout the Army.

[The prepared statement of Major Rozelle appears on p. 31.]

Mr. MICHAUD. Thank you very much, Major.

Doctor Lema.

STATEMENT OF MARK J. LEMA, M.D., PH.D.

Dr. LEMA. Mr. Chairman, Congressman Miller, my name is Dr. Mark Lema. I Chair the Department of Anesthesiology, Critical Care and Pain Medicine at the University at Buffalo and the Roswell Park Cancer Institute.

Today I represent the Pain Care Coalition, a national advocacy effort of the American Academy of Pain Medicine, the American Pain Society, the American Headache Society, and the American Society of Anesthesiologists or ASA. I currently serve as President of the ASA and I am also a pain physician.

Collectively the PCC represents over 50,000 physicians, clinicians, researchers, and educators who serve in leading clinical roles in the specialized field of pain management. Some of these specialists work in the VA healthcare systems and others are involved in collaborative relationships with research and clinical care programs through the VA system.

Briefly, I would like to discuss the complex problem of pain, especially for the men and women of our military. While we have made great advances, much more research needs to be done.

Mr. Chairman, pain is a very large public health problem in this country. Over 80 percent of patients seeking a doctor have pain as their primary complaint. The pain problem is even more prevalent in our military and veteran populations.

If miners, movers, and construction workers suffer low back pain from heavy lifting, imagine the toll on the spine of those active combat duty soldiers in full battle gear.

If truckers develop back pain from long hauls, imagine the toll of those soldiers inside armored vehicles going long distances on poor or nonexistent roads.

If life's daily stresses serve as triggers for those suffering migraine headaches, imagine the impact of battlefield conditions on the military personnel's stress.

Over 90 percent of the severely injured veterans enrolled in the VA polytrauma centers are suffering from chronic pain with most of these veterans having pain at more than one site. Eighty-five percent have traumatic brain injury.

As professionals in the pain care field, we must ensure that the brave military men and women who serve or have served our country get the very best care in pain management possible. However, many of these injuries have no cure.

I applaud the VA for its leadership in focusing resources on the assessment and treatment of pain. We are particularly supportive of the national pain management strategy initiated in November 1998. There is still much work to be done.

The Pain Care Coalition believes VA's pain research effort can and must be significantly enhanced. We urge this Subcommittee to develop targeted legislation with three basic components.

First, Congress should require VA to establish a focused research and training program directed at both acute and chronic pain within its medical and prosthetic research programs at VA headquarters.

Second, Congress should authorize, and VA should designate, cooperative centers throughout the country for research and education on pain.

Third, Congress should authorize these newly created pain research centers to compete on an equal basis with other priority research areas.

Mr. Chairman and Members of this Subcommittee, pain is often characterized as the invisible disease. Unlike cancer, diabetes, and heart disease, there are no reliable tests to confirm the presence and severity of pain. But that is no excuse for letting research efforts lag behind those of other VA research priorities.

In closing, I would like to quote U.S. Army Deputy Surgeon General, Joseph G. Webb, Jr. In October 2005, he said, "Wounded sol-

diers in Iraq and Afghanistan benefit from receiving some of the most advanced technologies and techniques in medicine today. The benefits of advanced pain management are improved postoperative outcomes and the potential to eliminate chronic pain, particularly in amputees."

Mr. Chairman and Members of this Subcommittee, please help ensure adequate funding for pain management research. We must join together so that our brave men and women returning from combat continue to receive the best care possible by developing cures for traumatic, painful conditions.

Thank you. I would be glad to answer any questions.

[The prepared statement of Dr. Lema appears on p. 34.]

Mr. MICHAUD. Thank you very much. And we thank the other two panelists also.

A couple of questions. Major, my first question will be to you. You have played a very large role in the design process at MATC. Could you give us a brief description of how the MATC was designed with the wounded warrior in mind and what are the lessons that we and VA might be able to learn from that process?

Major ROZELLE. Well, I think the key, Mr. Chairman, was that we got together the entire team, so we looked at this center and who was going to be in it first. And then we went to those agencies. Rather than letting engineers design it for us, we brought a team together to say what do we need.

We were then able to sit down and review through a number of different sets and see what space we needed and what was required based on what the Health Facility and Planning Agency would allow us to have space-wise. And we continued to reconfigure it in the process.

Another successful approach we used with the Military Advanced Training Center was we did what is called a design build. Basically we were able to sit down as a team with the engineers that were designing it for us as they did their 10, 30, 50, 75, and 90 percent drawings and continue to make adjustments based off our teamwork where we would get together and virtually walk through the building and continue to do business.

We actually continued to make changes in design to include walls and room space and room function up until the 90 percent. It was a very successful tool rather than walking into a building that was designed by someone else and then having to occupy and then make changes.

There were two systems that we actually had to build the building around. One is the gait lab that I talked about specifically because it required an isolated slab. That is something you cannot post engineer into a building. The second, of course, would be the computer-assisted rehab environment, the CAREN, which is the simulation room. It is another isolated slab and literally had to have the building built around it.

And to answer your second question, how can we move forward on this, we continue to get our teams together to look at the future of the Walter Reed at Bethesda, for instance. Everything from our building will be moved from MATC to Bethesda. That is a very unique characteristic.

And then, of course, when it is at Bethesda, we will be able to test it and it will be tested and we can make changes as we move forward.

We would like to think that our building is the model that people already have come to study on what does this advanced facility look like and are very proud of it.

Mr. MICHAUD. Thank you very much. That was very helpful.

Dr. Feussner, as you know, there are going to be several new VA hospitals built over the next few years. As the VA moves forward with these new hospitals, what type of infrastructure would you like them to consider incorporating into these facilities in order to support research activities?

Dr. FEUSSNER. Well, with new hospitals, we are beyond the point of any remodeling issues. So new hospitals should be built with new research facilities.

I think you know, you were in the building in Charleston, the Strom Thurmond Medical Research Building in Charleston, which was a joint venture between the Federal Government, State government in South Carolina, and the Medical University, it is state-of-the-art research facility, about 120,000 square feet.

The kind of collaboration and integration of research disciplines that the Major has referred to occur commonly in these state-of-the-art facilities. And the price back when our facility was built in 1996, the price was about $45 million. It is probably substantially more than that, but also substantially less than building a brand new hospital facility. It would be unfortunate if the building of hospitals, if it did not occur simultaneously with the build-out of new research facilities.

Mr. MICHAUD. Thank you.

Another question for the Major. You have worked hard when you look at the collaboration with VA on patient care. Can you go in a little more detail about the collaboration between DoD and VA in your facilities in terms of patient care, resources, and research?

Major ROZELLE. Well, Mr. Chairman, specifically to integrating the VA into our building, now we for the first time have all three offices represented within our building. The idea is that this seamless transition should occur at the building. And we are very proud to have them there inside our walls. And that is a large step forward from where we were when I was injured in 2003.

As far as collaborative research, it seems that we at least quarterly have either training or conference where we bring together our partners which we consider VA to be one and, of course, academia another where we reach out and bring people together whether it is something simple as, you know, say, a running clinic where we bring in whether it is VA prosthetists or therapists in to observe this young special population on these very unique prostheses or whether it is a conference where we are getting together to write textbooks.

And we continue to look at the future of, you know, specifically gait analysis and the future protocols that will come out of that room are endless as well as the CAREN system, you know, another great collaborative opportunity for DoD and VA to work together.

Mr. MICHAUD. Thank you very much.

My last question is for Dr. Lema. You talked about amputees' experience with phantom limb and stump pains. Can you be more specific as to what these pains are and do you think part of it is because of where the joints are for these limbs? Is that part of the reason—we just really have not done enough research in that particular area?

Dr. LEMA. Thank you, Mr. Chairman.

Phantom limb pain is a very complex pain problem because it is a central pain problem. The brain is actually wired to understand that it has fingers regardless of whether fingers develop. And, likewise, when an organ such as an arm or a leg is removed, the body still has imprinted in the brain the capability of sensing the nerve fibers that would have gone to that area but were avulsed during the trauma.

So that is how pain can often be recognized by a person who no longer has a limb. And oftentimes a person will remember the last thing before the nerve has been destroyed. So many times, it is a painful avulsion and that could be the last thing that our military personnel remember.

So there are number of different phantom limb pains, three in particular. One is through chronic disease which is actually different than phantom limb pain from traumatic avulsion. In other words, losing a limb as a result of a blast.

And, finally, there is also stump pain and stump pain oftentimes can be a result of poor surgical technique in a controlled environment or the inability to actually approximate avulsed tissue because of the blast. And that puts stress and strain on the blood vessels and the nerves as the surgeons try and approximate the skin around the stump. And, of course, anytime pressure is placed on the prosthetic device, intense pain can be experienced by the patient.

So we are talking about all of those. But in particular, we are talking about coordinating pain management into these areas to the point where you recognize that pain management is a discreet entity.

Currently if you look at all of the programs that the VA has and you envision each one of those programs as a pebble in a bowl, pain medicine is the water that touches all of those pebbles. We would like to make it a discreet entity so that it does not lose its focus when the other research efforts are being focused, as the Major said, on very important advances in prosthetic therapy.

Mr. MICHAUD. Great. Thank you very much.

Mr. Miller.

Mr. MILLER. Continuing with the pain issue, in the research that VA is doing now with returning veterans from OEF/OIF, is that research that can be utilized with older veterans? Or are some of these issues more directly related to new wounds or issues that we are seeing in the battlefield today?

Dr. LEMA. Your best chance of success is usually addressing pain aggressively at the first opportunity. Oftentimes effectively treating acute pain will prevent the changes that actually go on. These are changes that actually occur in nerve cell remodeling. In other words, the nerves change their personalities. And oftentimes, once that happens, it is more difficult to treat.

So people who have actually had chronic pain that is more long-standing have to actually undergo different types of treatment that is oftentimes more difficult.

We have an opportunity with this war to address the transition between the effectiveness of what we see in our military hospitals to then what we see for our veterans around the country. We believe that that transition is not as seamless as it could be and especially in the area of pain medicine where 90 percent have unrelieved pain. It is incapacitating.

Imagine if you had a headache right now, you could not focus on this hearing. But imagine if that headache persisted every day of your life. How would you be able to function as a normal human being? And that is what we are trying to address.

Mr. MILLER. Major, when the MATC was being designed and built, was cost an issue or were you hopefully provided an opportunity to put in there what you needed?

Major ROZELLE. Well, the cost is always a consideration, Congressman. But, you know, we had guidelines for the building. You know, we had $10 million to spend on the facility. But I never felt limited. I never felt strapped by that amount. If I needed something, I knew that I could go back and request it. So thank you for that.

But also, you know, we had great support within the Department of Defense as well. We had lots of visitors who came and said what else can we put into the facility. And after a tour, they realized that we pretty much had put everything in there that we needed.

So we would never turn down money certainly, but we had enough for the mission and we actually ended up coming in under budget. So we are very proud of that. The $10 million was the right amount for that facility.

Mr. MILLER. You may have already addressed this in your testimony, but as far as replicating the MATC around the country, is it being done? Where is it being done? Others obviously are looking to what you are doing; what does the future hold?

Major ROZELLE. Well, sir, you know, I think that we have had a lot of visitors from around the world. You know, we looked to our partners in this war. We had the Canadians come take a look at what we are doing. The Israelis are interested in what we are doing.

The Colombians have also come and taken a close look at, you know, treating our soldiers together, you know, the idea that we have clinically proven that, you know, if you have a peer group, people heal better together. And, you know, that is something that is unique to what we are doing. You know, when you are newly injured and you spread those units across the country, they are finding themselves healing by themselves.

So this package that we have created is certainly exportable, but we also do not want to say we should build a Center of Excellence or ten more Centers of Excellence across the country. We are satisfied with what we have now.

Mr. MILLER. That is all, Mr. Chairman.

Mr. MICHAUD. Mr. Brown.

OPENING STATEMENT OF HON. HENRY E. BROWN, JR.

Mr. BROWN OF SOUTH CAROLINA. Thank you, Mr. Chairman. And I am sorry I was late. I had to be in a markup in another Committee.

But it is a real pleasure to welcome my good friend from Charleston, Dr. Feussner, and we are grateful for his involvement in healthcare delivery not only just in the private sector in Charleston but also in the VA community.

And, of course, you know we have been working with you, Mr. Chairman, and other Members of the Committee to try to explore some areas of possibility that we might be able to share some of the research and some of the expertise that we find between the VA and the Medical University.

And we are grateful that you would come. You know, we have been on the cutting edge, I guess, of the Strom Thurmond Gazes, you know, Heart Research Center. And as we do, I guess, an expansion program there at the Medical University that, you know, it gives us more opportunity to combine some of our resources between the VA and the Medical University.

So we are grateful to have you here today. I am sorry I missed your testimony, but I am sorry I missed the testimony of the rest of you gentlemen, too. But, anyway, thank you.

It is a concerted effort that we are trying to combine as many of the resources of the taxpayers' dollars to not have duplications but to find the best of both worlds and combine those, you know, intellectual capitals to try to be sure that our young men and women that are coming back from harm's way in terrible physical condition, that their needs will be met.

And I think it is absolutely a great idea that when those guys come back, they need the, I guess, support of their group. And so I think being in a group kind of a setting gives a little more of, I think, encouragement in their healing process.

But it has been a real pleasure, Mr. Chairman, to serve on this Committee to try to find and meet the needs of our veterans. And we are grateful for the Charleston model as we try to not only save the taxpayers money but to bring the best, brightest minds together to be sure that we have a broad front to attack the needs of our veterans.

And thank you, John, for being here.

Dr. FEUSSNER. Thank you, Congressman Brown.

Mr. MICHAUD. Thank you once again. I would like to thank the panel for your outstanding testimony this morning and look forward to working with you.

And it goes without saying, Major, we really appreciate all that you have given to this great Nation of ours. We are all extremely proud of you and the other men and women who proudly wear the uniform of the United States. So thank you very much.

Major ROZELLE. It is an honor. Thank you.

Mr. MICHAUD. This panel is dismissed, and we will set up for our second panel.

I would like to welcome the second panel here: Dr. Tom Zampieri, who is the Director of Government Relations for the Blinded Veterans Association (BVA); Carl Blake, who is the National Legislative Director for the Paralyzed Veterans of America

(PVA); and Joy Ilem, who is the Assistant National Legislative Director for the Disabled American Veterans (DAV).

I would like to thank all three of you for joining us today. And we will start with Dr. Zampieri and work down. Thank you.

STATEMENTS OF THOMAS ZAMPIERI, PH.D., DIRECTOR OF GOVERNMENT RELATIONS, BLINDED VETERANS ASSOCIATION; CARL BLAKE, NATIONAL LEGISLATIVE DIRECTOR, PARALYZED VETERANS OF AMERICA; AND JOY J. ILEM, ASSISTANT NATIONAL LEGISLATIVE DIRECTOR, DISABLED AMERICAN VETERANS

STATEMENT OF THOMAS ZAMPIERI, PH.D.

Mr. ZAMPIERI. Chairman Michaud and Ranking Member Miller and Members of the House Veterans' Affairs Subcommittee on Health, on behalf of the Blinded Veterans Association, we thank you for this opportunity to present our testimony today on important research programs.

BVA is the only Congressionally chartered veteran service organization exclusively dedicated to serving the needs of our Nation's blinded veterans and their families. And we have worked for over 62 years with the VA closely in developing special rehabilitative programs, both outpatient and inpatient rehabilitative programs for our Nation's blinded veterans.

Our testimony includes a great deal of data and statistics that hopefully will not overwhelm anybody, but I thought it was important that people understand that the prevalence and the incidence of blindness and low vision in the United States is one out of every 28 Americans over the age of 40, which amounts to 3.3 million Americans are either blind or have low vision.

This figure is from 2004 and when broken down, it separates to 2.3 million with low vision and about a million who are legally blind. However, each year, 200,000 more Americans develop age-related macular degeneration, which is the most common cause of blindness in our older veterans over age 65. Diabetic retinopathy is another frequent cause of blindness in younger veterans between the ages of 40 and 65.

The take-away from some of this is that the employment rate of those individuals of working age between age 19 and age 65 who have a vision-related disability remains still only at half of the nondisabled workforce, 38 percent, and that figure is at the end of a lot of the other employment data that I put in there.

And I think that is a statement on the importance of research in regards to not only medical research but advanced prosthetic devices and new technologies to assist individuals in their recovery from vision loss and being able to enter the workforce.

The economic and social impacts of this is just tremendous, $68 billion annually. One figure I read was there are currently over 400,000 older Americans who are in nursing homes strictly because of blindness, which is costing Medicare $11 billion a year for those individuals to be in nursing homes. And a lot of those could function independently if they were able to have rehabilitation.

One of the most common causes of individuals being admitted to nursing homes is actually falls.

The other thing is that as of September 25th, 2007, this number constantly changes, there have been 27,767 servicemembers wounded in Iraq and Afghanistan. The number of men and women requiring air and medical evacuation from Iraq between March 19th, 2003, and September 17th, 2007, was 8,298 of which 1,162 or 13 percent had sustained combat eye trauma. Thirteen percent of all those wounded evacuated from OIF and OEF have sustained serious combat eye wounds.

This is the highest percentage of eye wounded evacuated in any war in 100 years. This is a staggering number and, in fact, the previous witness who testified about pain being the silent aspect of the injuries, Bob Woodruff from *ABC News* who attended our convention said that eye injuries apparently is the silent epidemic of war casualties in the sense that these numbers, you never hear about them.

And I am alarmed. And even in our previous testimonies, we found, you know, difficulty in getting any accurate numbers.

The other aspect of this is the traumatic brain injuries which are associated with a large percentage of vision-related complications. Of the 3,900 TBI patients, it is estimated that 80 percent of those complain of visual-related symptoms. And at the polytrauma centers, 62 percent of the patients are diagnosed as having a TBI-related diagnosis with dysfunction of diplopia, convergence disorders, photophobia, ocular motor dysfunction, inability to read.

We are proud of the fact that the VA has devoted a lot of new resources into expansion of low vision outpatient services and the support that this Committee has given that effort. We are also pleased that one of their research projects is on retinal research up in Boston on development of an artificial retinal implant.

But what concerns us is that the amount of funding that is dedicated toward both DoD and VA vision research, we feel, is far too low.

I would be happy to answer questions about all that. We appreciate the ability to present our testimony today.

The one thing that would help us tremendously, we feel, is passage of H.R. 3558 which was introduced by a couple Members of this Committee. The "Military Eye Trauma Treatment Act of 2007" would create a Military Eye Trauma Center of Excellence and eye trauma registry.

And this is vital, we feel, because until there is an accurate accounting of these eye casualties and this information is shared with the VA, then what we hope will come out of this is new best practices like they are doing with prosthetics and new research geared toward the experiences that the DoD ophthalmologists and the VA ophthalmologists are now having to cope with.

And so, again, I appreciate this opportunity to present our testimony and look forward to your questions.

[The prepared statement of Dr. Zampieri appears on p. 38.]

Mr. MICHAUD. Mr. Blake.

STATEMENT OF CARL BLAKE

Mr. BLAKE. Mr. Chairman, Mr. Miller, and Mr. Brown, on behalf of PVA, I would like to thank you for the opportunity to testify today on the research programs administered by the VA.

As you know, research is a vital part of veterans' healthcare and an essential mission for our National healthcare system.

In testimony during the 109th Congress, PVA supported legislation that would create Amputation and Prosthetic Rehabilitation Centers of Excellence similar to those that are done for Multiple Sclerosis and for Parkinson's Disease. The need for these centers is amplified by the number of veterans of OIF and OEF who have amputations.

We believe these centers could partner with the new Military Advanced Training Center that was just spoken about in some detail that recently opened at Walter Reed. This partnership could enhance the long-term provision of these services to veterans as it would allow the VA to remain on the cutting edge of amputation and prosthetic research in conjunction with DoD.

This is particularly important as the VA will likely be responsible for caring for these men and women throughout the course of their lives.

Additionally, VHA should be required to partner with manufacturers, dealers, payers, and advocates to develop performance test standards for amputee and prosthetic devices.

An example of these types of test standards is the American National Standards Institute, ANSI, and Rehabilitation Engineering and Assistive Technology Society of North America, RESNA, wheelchair performance standards. These standards are a collaborative effort with specific impacts on wheelchair research and development, consumer disclosure, and payer decisions.

PVA believes that these centers could be the spearhead for development of evidence-based performance test standards for amputee and prosthetic devices within the VA.

PVA also has a particular interest in research projects that the VA administers as it continues to address neurotrauma and sensory loss primarily as a result of spinal cord injury or disease or traumatic brain injury.

As you are well aware, TBI is recognized as the signature injury of combat in Iraq and Afghanistan. According to the VA's estimates, TBI and various degrees of spinal cord injury account for nearly 25 percent of the combat casualties sustained by servicemembers in OIF and OEF.

Despite the positive gains by advancements in body armor, the head as well as the cervical spine are exposed to significantly more trauma. This has not only led to specific injuries related to TBI and paralysis, but also vision loss, psychological problems, and the larger polytrauma aspect. As such, it is absolutely essential that continued research in the areas of TBI and SCI continue to advance.

Likewise, PVA believes more research must be conducted to evaluate symptoms and treatment methods of veterans who have experienced TBI. This is essential to allow VA to deal with both the medical and mental health aspects of TBI including research into the long-term consequences of mild TBI in OEF/OIF veterans.

Furthermore, TBI symptoms and treatments can be better assessed for previous generations of veterans who have experienced similar injuries.

PVA is particularly interested in the VA's special research project that focuses on genomic medicine. The thrust of this project

is to link veterans' genetic information with the VA electronic health record. The program will ultimately allow clinicians to make better decisions for veterans based on their genetic information.

Furthermore, it will address patients' rights, informed consent, privacy, and ownership of genetic material involved with genetic tissue banking.

However, despite the expectations of this exciting field, we must reiterate that additional new funding will be necessary. Genomic medicine cannot be advanced by simply reshuffling funding priorities within existing VHA research and development funding. If it is placed into a stream where it will compete with current VA projects, the sheer scope and cost of genomic medicine alone will overrun all other ongoing projects.

Finally I must emphasize our concern about funding for the overall Medical and Prosthetic Research Program. We certainly appreciate the fact that the appropriations bills passed by the House and Senate meet or exceed the $480 million recommended by the Independent Budget for fiscal year 2008 and we appreciate this Committee's support for those measures.

However, with the outcome of the appropriations still hanging in limbo and the fact that no appropriation has been provided even as the start of the new fiscal year has already passed, we remain concerned about the ongoing viability of the VA Research Program.

Mr. Chairman and Members of the Subcommittee, again I would like to thank you for the opportunity to testify and I would be happy to answer any questions that you might have.

[The prepared statement of Mr. Blake appears on p. 46.]

Mr. MICHAUD. Thank you very much, Mr. Blake.

Ms. Ilem.

STATEMENT OF JOY J. ILEM

Ms. ILEM. Thank you, Mr. Chairman and Members of the Subcommittee, for inviting the Disabled American Veterans to provide testimony on VA research programs.

There are a number of research areas we believe warrant special attention including prosthetics, traumatic brain injury, mental health, women veterans, the aging veteran population, Gulf War, and minority veterans.

A significant number of young servicemembers are returning from Iraq and Afghanistan with complex polytraumatic injuries. VA will be responsible for the health maintenance of this population for decades. Therefore, it is essential that VA remains the leader in advancing new technologies in prosthetic and orthotic items while refining rehabilitation models and promoting good health outcomes for veterans with amputations and other trauma.

Traumatic brain injury or TBI is another area of particular concern for DAV. While severe brain injuries are more easily recognized, some servicemembers exposed to explosive blasts have no obvious or visible injury. It is believed that many OEF/OIF veterans have suffered mild brain injuries or concussions that have gone undetected.

Emerging literature strongly suggests that even mild TBI injuries may have long-term mental health consequences. With the influx of servicemembers returning with mild or moderate TBI, re-

search should be expanded on the evaluation and treatment of this injury in new veterans. However, studies undertaken by VA should also include older veterans of past military conflicts who have suffered similar injuries that were undetected, undiagnosed, or misdiagnosed and untreated.

Combat-related mental health readjustment issues should also be a critical research priority for VA. Veterans of these current wars have a wide range of possible mental health conditions such as readjustment disorder, anxiety, depression, PTSD, and substance abuse.

Early studies suggest that substance abuse is a growing problem in a large number of returning war veterans. Therefore, we urge VA to continue research into this critical area as well and to identify the best treatment strategies to address substance abuse and associated mental health and readjustment issues while continuing to address the needs of older veterans with these problems.

We urge Congress to remain vigilant to ensure that mental health research and appropriate treatment programs are authorized and sufficiently funded.

With increasing numbers of women serving in the military today and with more women veterans seeking VA healthcare following military service, VA must be prepared to meet their unique physical and mental health needs. Women's health research is essential to fully understand the healthcare needs of this population and to develop high-quality services and treatments.

While many of the health problems of male and female veterans returning from combat operations will be similar, VA must address the health issues that pose special challenges for women.

DAV has recommended that VA focus its women health research on finding the healthcare delivery model that demonstrates the best clinical outcomes for women veterans, assesses the barriers that women perceive or have experienced in seeking VA healthcare services, conduct a long-term health study of women who served in combat theaters, and conduct research to fully understand the dual burden of military sexual trauma and combat-related PTSD.

While additional research and resources must be provided to better treat our newest generation of combat veterans, VA still has a large number of aging veterans. In that respect, research focused on diabetes, hypertension, heart disease, dementia, and other chronic illnesses affecting older populations must continue.

Likewise, additional research is needed to explore and develop systematic methods for efficacious treatments for Gulf War veterans with unexplained medical symptoms and illnesses so that a collection of best practices becomes available to all VA clinicians in the field.

A June 2007 VA study found that racial and ethnic disparities appear to exist in all clinical areas. Researchers noted that this finding was especially troubling since it may indicate that disparities in healthcare delivery contribute to disparities in health outcomes. It is clear from this study that VA needs to continue this important research and find solutions to this problem.

From its earliest days, biomedical rehabilitation and health services research has been an integral part of VA's overall mission. Today the VA system offers veterans the best care anywhere as

confirmed by numerous health industry experts. But millions of sick and disabled veterans depend on the VA healthcare system to help them overcome severely disabling injuries.

We urge VA to press forward and to remain on the cutting edge of healthcare through its esteemed research program and we encourage this Subcommittee to maintain necessary oversight of VA research programs and to provide sufficient funding to help VA improve service and health outcomes for disabled veterans.

Mr. Chairman, that concludes my testimony and I will be happy to answer any questions you may have. Thank you.

[The prepared statement of Ms. Ilem appears on p. 48.]

Mr. MICHAUD. Thank you very much. And I thank the other two panelists as well.

Everyone on this panel agrees that VA should continue to put money and resources into research and development, although money is limited, so we have to sometimes make priorities.

I would like to ask all three of you what should the VA's top three priorities be as they relate to research and development? We will start with Dr. Zampieri.

Mr. ZAMPIERI. I think that from our perspective, you know, one of the unique aspects of the war and the injured coming back is that when you look at all the different types of research, you are not going to find in the private sector a thousand severe, you know, eye trauma cases.

I mean, you talk to private university ophthalmologists who do emergency room work and you look at national eye registry data, you know, like three percent of all Americans who go in the emergency rooms suffer from a severe type of industrial eye injury.

And, you know, we feel that there are certain types of military injuries that should be a priority as far as whether it is amputation, prosthetics research, vision research, spinal cord injury (SCI), you know, speaking for my friends here, because you cannot just go out in the private sector and find those dollars.

I mean, you know, these are unprecedented. One of our attachments shows you pictures of what we are talking about. And, you know, I was upset that in the Congressionally directed DoD research, there is $4.9 million for eye research. And I am saying to myself, you know, is something wrong with this picture in regards to—you know, there are certain things that we have a responsibility for and I just think that anything related to combat trauma, the Blinded Veterans Association thinks should be a priority.

The other aspect of this is one of the difficulties is technology. Everybody is overwhelmed. The good news is there are lots of new adaptive technology equipment that is out there and sorting through those and testing those and finding out which ones really work the best is actually overwhelming for some of the staff that I talk to.

So it is a good news, bad news story. You have so much emphasis nowadays on technology research, but, you know, how do you sort that out within the VA and Department of Defense as to which really work well? And if you are going to invest money into those, is your return going to be, you know, valuable?

Anyway, thank you.

Mr. BLAKE. Well, Mr. Chairman, I would say first that I do not think that is a fair question because the scope of research programs conducted by the VA is so broad that I do not know that we could pinpoint certain ones.

As an advocate for Paralyzed Veterans of America, I do not think I would be doing my job if I did not say that we believe neurosensory loss and trauma associated with spinal cord injuries should be at the top of the list, but I think that falls into a broader category in some fashion.

Like Tom mentioned about combat-related traumas and injury, I do not think that you can tailor research to that because there are so many avenues under that whether it be TBI, psychological disorders and research associated with that, those sorts of things. But I think there is probably a broader field associated with it.

I believe that the genomic medicine research is going to be a growing field. It is a massive scope in that program, but I think a lot of focus is going to be placed there because of the potential for it. But outside of that, I do not know that I could give you one, two, or three items that would be the way to go.

Ms. ILEM. I think I would have to concur with my colleagues that it is a difficult question to try to pinpoint if you had to pick the top three. And I think probably VA is grappling with that as well. They have, you know, a limited amount of funding and they have to choose the areas that they feel are the most critical. And I would assume they are looking at issues that they think they are going to have the largest problem in those populations.

And obviously they want to, I am sure, remain on the cutting edge with prosthetic technology that is coming out and make sure that this small group, relatively small group maintains, you know, to continue to have these really incredible prosthetic items available to them throughout their lifetime.

And the traumatic brain injury, obviously everyone is very concerned about it in the mild and moderate category, not just the most severe, and what are the long-term consequences for that population.

And I think mental health too. Everybody is very concerned about that because of the long-term chronic consequences that can lead to a lot of other issues.

So it is a difficult question, but I think that we all agree that anything related to military service, VA should have the funding available to do the research necessary to make sure that the appropriate programs and services are available and the best treatments in the world for these veterans.

Mr. MICHAUD. Well, you all did a very good job answering the question and part of it, I expected your answer to be what it was. So I appreciate it.

I will give you an easy one to answer. What ideas do you have on how VA and DoD and other government agencies can improve on how to conduct research in a collaborative manner? What works best?

Mr. BLAKE. What works best?

Mr. MICHAUD. Yes. I mean, can VA and DoD and other agencies do a better job on collaborative research and development?

Mr. BLAKE. Well, I would say the key is to ensure that as we move forward, at least particularly with the newest generation of veterans, that DoD and the VA do not operate their own programs within a vacuum. That is not saying that they do. The VA does an outstanding job of working with academic affiliates, the private sector, and within the VA. The DoD has done some degree of research, particularly with the newest related casualties from Iraq and Afghanistan and it is important to ensure that some kind of link is established in all of these areas.

I think the prosthetics issue is going to be a big issue because a lot of the men and women out at Walter Reed, Bethesda, and certain other locations are getting the most advanced prosthetics and it is important to ensure that the VA is tied in to what is going on there so that they understand this ever-evolving technology because they will be the ones in the long term responsible for meeting the needs of these men and women.

Ms. ILEM. Yeah. I would agree with that. And I think that VA and DoD, you know, we hear about some of these collaborative projects and things that they are working on. And it is great to hear that VA is being allowed to, you know, bring their prosthetists and other folks out there, you know.

But I think we would like to see more of that right from the get-go in terms of, you know, they are both interested in what is happening with this population and it crosses over. And, you know, however they can work together to make sure that all of these treatments and best practices are both developed in both, you know, agencies as a collaborative effort, I think, is in the best interest of our veterans.

Mr. MICHAUD. Great. Thank you.

Mr. Miller.

Mr. MILLER. Thank you, Mr. Chairman.

Let the record reflect I will not ask the panel a difficult question that they cannot answer. It is very unfair of you to do that.

One question because our time is running short, I know we have a vote coming up shortly. One thing that we find in the Federal bureaucracy is that there are many agencies doing duplicative work, research. There is such a competition for research dollars.

Do you feel, and this could go to any or all of you, and TBI a perfect example, that there should be a single Federal clearinghouse agency for medical research? Would that aid in what we are trying to accomplish, providing the best care to those who need it?

Mr. BLAKE. Well, that is not an easy one either.

Ms. ILEM. I know. That is not easy either.

Mr. MILLER. I did not say it was easy.

Mr. ZAMPIERI. That is sort of like, you know, can we reform the Tax Code.

Mr. MILLER. Yes, we can.

Mr. ZAMPIERI. You know, I guess you could, but it is not going to be easy. Speaking as a person who is a clinical provider as a physician assistant for 25 years, you know, the universe of Federal research and university research and private foundations is complex.

And I guess, you know, my way of approaching this is that, again, that, you know, I think that DoD and VA should look at a

way to partner even more on the specific research again with these different types of injuries and stuff from the war.

And, you know, like I mentioned, one of the things that we would like to see is whether it is associated with this Eye Center of Excellence, but a joint technology sort of research center, you know, where they work together on all this, you know, advanced technology development, similar to what they are doing now in regards to amputee prosthetics, you know, and just build on that.

I think the problem once you get off into the world of the National Institutes of Health (NIH) and all that is the complexities of the competitive research that goes on outside. I do not think one "Federal research czar" could handle this.

Mr. BLAKE. I think it is certainly an idea worth consideration. I think the problem that you run into is although the vast majority of research programs benefit a broad cross-section of the general population maybe in different ways, one type of research does not necessarily benefit the other type of group.

And we would certainly hate to see any kind of a national management of research where a program is managed that does not benefit veterans in some fashion. That is not to say that even research conducted with the VA benefits all of a society, but we believe it does. But we need to ensure that the VA has that directed expertise as it relates to the issues surrounding veterans and their own experiences.

So I am not sure that a single agency could manage research in that fashion and ensure that it is universally applicable and would benefit everyone.

I would say that NIH maybe on some level does a little bit of that now because a lot of research in some fashion passes through the doors of NIH before it comes back out to wherever it goes. Even the VA has its own partnerships in most cases with research through NIH.

Ms. ILEM. I mean, I would not have much more to add than I think what both my colleagues have said other than, you know, I think it is an idea worth exploring or looking at. However, I think I would need more time to really think about that and the implications.

And the thing that first came to mind was thinking about, you know, making sure not just about the duplication but make sure there is not stunting of creativity and thoughts and ideas and different avenues of approaching things.

But certainly it is something that we could, you know, further explore and get back to you or your staff with.

Mr. MILLER. That is it.

Mr. MICHAUD. Mr. Brown.

Mr. BROWN OF SOUTH CAROLINA. Mr. Chairman, I am going to be pretty easy on the panel. I have a yes or no answer.

I know down in Charleston, I think we mentioned with the other panel that we do have, you know, combined with heart, with the Strom Thurmond Gazes Research, you know, Clinic.

And so I would ask the question if you do not think in order to be able to utilize the best taxpayers' dollars is to combine some kind of oversight to all of these agencies and also include in the

private sector because I think there is a lot of duplication of effort out there and I know competition is always good for the funds.

But would you agree that by including the private sector that that gives us another dimension of intellectual capital that we probably would not have just within our own bounds?

Mr. ZAMPIERI. I would agree that, you know, that there is obviously, so I do not get misquoted, I think that there should be effective coordinated private-sector research, you know, from the VA perspective.

You know, a lot of the physicians that I worked with, for example, in Houston, Texas, at the VA Medical Center, we did a lot of prostate cancer research in association with Baylor University. And, in fact, most of the VA urologists would have said that we would not have been able to do some of that research without the support of the, you know, outside universities.

And so, you know, my background gives me that, you know, that this is very important. I guess, you know, my concern, though, is that there is again sometimes specific military and VA types of research that it would be difficult to find that type of private university research going on.

While I do know that there is a lot of retinal research going on in private university driven programs and retinal implants and optic nerve and things like that, so there is a relationship there that they could draw upon.

Mr. BROWN OF SOUTH CAROLINA. I was just hoping that you would just say yes and we would not have to reinvent the wheel. And I know a lot of times, there is a lot of research being focused on, you know, the same issue in many different areas. And if they could combine those resources, it seems like it would be better utilization of our taxpayers' dollars.

And I know that buzzer just went off and that means that we are going to have to go vote pretty shortly, so I will just leave the other two panelists an option to say yes or no.

Mr. BLAKE. How about maybe?

Ms. ILEM. Same.

Mr. BROWN OF SOUTH CAROLINA. Thank you very much.

Thank you, Mr. Chairman.

Mr. MICHAUD. Thank you.

And, Dr. Snyder.

Mr. SNYDER. Thank you, Mr. Chairman. I will not ask any questions because we have votes going on.

But I appreciate your all's advocacy on funding for medical research and proper funding and the detail in your written statements that you go on about what that means for the folks that are members of your organizations. I think your advocacy is absolutely vital and I appreciate your doing it year after year. Thank you.

Thank you, Mr. Chairman.

Mr. MICHAUD. I would like to thank this panel.

And I do not know if we can fit the third panel in within the next 5 minutes. The third panel is Dr. Joel Kupersmith, who is an M.D. He is the Chief Research and Development Officer from the VHA. He is accompanied by Dr. Tim O'Leary and Dr. Michael Selzer.

I would like to thank you very much, Dr. Kupersmith, and look forward to hearing your testimony.

STATEMENT OF JOEL KUPERSMITH, M.D., CHIEF RESEARCH AND DEVELOPMENT OFFICER, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY TIMOTHY O'LEARY, M.D., PH.D., DIRECTOR, BIOMEDICAL LABORATORY AND CLINICAL SCIENCE RESEARCH AND DEVELOPMENT, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; AND MICHAEL E. SELZER, M.D., PH.D., DIRECTOR, REHABILITATION RESEARCH AND DEVELOPMENT, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS

Dr. KUPERSMITH. Thank you very much, Mr. Chairman.

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to discuss the Department of Veterans Affairs Medical and Prosthetic Research Program.

With me are Dr. Timothy O'Leary, Director of Biomedical Laboratory and Clinical Science Research, and Dr. Michael Selzer, Director of Rehabilitation Research and Development.

For more than 80 years, VA research has been a valuable investment with remarkable and lasting returns. The history of VA research is filled with examples of how it has improved care including developing numerous advances in prosthetics, developing a system that allows tetraplegics' brain waves to turn on lights and open e-mails, pioneering, understanding, and treatment of post traumatic stress disorder or PTSD, identifying genes associated with Alzheimer's disease, premature aging, schizophrenia, and diabetes.

In recognition of their innovative work, VA researchers have received three Nobel Prizes and six Lasker Awards.

VA research is an intramural program where clinical care and research occur under one roof. This unique advantage allows VA investigators to bring scientific discovery from the laboratory bench to the patient's bedside making this program a most effective tool to improve veterans' care.

All our veterans from those who served in World War II to those returning from current conflicts in Iraq and Afghanistan deserve the very best care possible. Therefore, VA has a comprehensive research agenda using all the tools of modern science to develop new treatments for physical injuries, illnesses, and mental health disorders, to improve access to healthcare, and to address long-term needs.

A priority area for VA research is health issues of veterans of Operation Iraq and Enduring Freedom or OIF/OEF such as prosthetics healthcare, pain, traumatic brain injury, spinal cord injury, sensory loss, mental health, and polytrauma.

Let me provide a few examples of exciting research in these areas. VA researchers are developing improved materials and designs for prostheses. One project under way involves building a new flexible prosthetic wrist to allow upper arm amputees to interact with objects in a more life-like fashion and with fewer mechanical failures.

In addition, VA recently unveiled a computer-driven ankle foot prostheses that helps restore amputees' ability to walk normally. In a preliminary study of the prototype, patients used less energy dur-

ing walking, had fewer balance problems, and walked 15 percent faster.

To learn more about combat-related mental health, VA researchers are collaborating with DoD to collect risk factors and health information from military personnel prior to the deployments to Iraq. These soldiers will be reassessed upon their return and several times afterward to identify changes that occurred following combat duty and to identify risk factors for PTSD and other health conditions.

An additional goal is to examine whether and how PTSD and traumatic brain injury are related.

Excruciating pain is experienced by more than 50 percent of patients after spinal cord injury. VA investigators have identified a particular mechanism responsible for conveying pain signals to the brain and are now using that discovery to develop a new pain treatment. This research has the potential to benefit the general public as well as veterans.

Other priority research areas include treating and preventing chronic diseases such as diabetes, obesity, HIV/AIDS, and heart disease, understanding healthcare needs and service utilization of women veterans, treating conditions including substance abuse, adjustment and anxiety disorders, psychotic disorders, dementia and memory disorders, and related brain damage and providing personalized medicine.

VA is at the forefront of developing treatment that is tailored specifically to an individual based on genetic medicine also known as personalized medicine. It will increase the effectiveness and safety of healthcare, drug treatments, and disease prevention efforts. Personalized medicine is considered the direction for healthcare in the 21st century.

VA research supports a broad initiative examining access to healthcare aimed at identifying system-wide gaps in care, assessing specific access issues and barriers for special populations, assessing the impact of new programs, practice structures, and organizations, and developing and evaluating quality improvement efforts, organizational and management interventions, implementation initiatives, and new technologies.

Further, meeting the long-term care needs of the aging veteran population continues to be a high priority for VA research. A major focus is on research that will enhance care coordination to improve quality of life for long-term care patients.

Other projects include those aimed at caregivers and a new initiative focused on developing approaches to community-based long-term care.

In conclusion, VA research with its distinguished history of discovery and innovation today remains an essential part of VA's efforts to ensure the health and well-being of our Nation's veterans. VA takes great pride in research that keeps it at the forefront of modern medicine and healthcare and expects to see further remarkable discoveries in the future.

Mr. Chairman, that concludes my statement and I will be pleased to respond to any questions you or the Subcommittee Members may have. Thank you.

[The prepared statement of Dr. Kupersmith appears on p. 55.]

Mr. MICHAUD. Thank you very much, Dr. Kupersmith. You are actually saved by the bell. So I will be submitting my questions for the record as will Ranking Member Miller as well.

Dr. Snyder.

Mr. SNYDER. I am sure other Members may have questions for the record also.

Dr. Kupersmith, the issue of the funding has been kind of a nod at some of us over the last several years because I thought the President's budgets have always been grossly inadequate. They do not keep up with the medical inflation rate or whatever that term is, the research inflation rate. They include funding that, you know, they just anticipate that there is going to be robust funding from NIH and other agencies or private funding. Those budgets were inadequate also.

So we have a catch-up phenomenon going on. But I mean, do we not still have some more work to do in terms of overall funding and what could be done given all the things that you just outlined, the challenges that our veterans and our new generation of veterans are facing? Would you all not benefit from additional funding?

Dr. KUPERSMITH. Well, as you know, I support the President's budget. I can certainly tell you——

Mr. SNYDER. My question was, will you not benefit from additional funding?

Dr. KUPERSMITH. I am sorry?

Mr. SNYDER. My question, though, was, I understand you are supporting the budget, but my question was, would you all not be able to do additional good things if you had additional funding?

Dr. KUPERSMITH. Yes. Yes. The answer is yes. Certainly I think our portfolio is moving certain directions which I think will be very beneficial to veterans and others in the future. We are obviously moving more toward conditions related to OIF/OEF and research on that level.

We always balance our portfolio between the newer veterans coming back or we have in the past few years and the chronic diseases that veterans have. And genomic medicine actually bridges both of those. Some of our first projects in genomics will be on PTSD and TBI.

And so some of the things that were mentioned today, pain, for example, we have been increasing our portfolio on that and we are very interested in that. We even have it as part of our Research Career Development Award Program.

So the answer is, yes, we do have a number of things that we would do.

Mr. SNYDER. Is it not a question not just of projects? I mean, I assume that you have a good system for sorting through, okay, we have this many research projects from around the country that we could fund. We think we are going to come up with our list of ones that we think are good. We have adequate funding for this many. There are still some we would like to fund. I mean, that is part of it.

But is not another part of it, unless we have robust funding, researchers are going to find other places to go to and other countries to go to and private sector places to go to? Is that not an issue, too,

that we need to have robust, reliable funding so that to keep the kind of personnel that you want at the VA?

Dr. KUPERSMITH. Surely it is. And I think that, you know, it is both. And I will answer that if we had more money, we would—you know, the retention of physicians is a very important part or research is a very important part of retention of physicians in the VA and our research program in general. Obviously researchers go where there is funding. And, you know, again, we support the President's budget. If we had more funding, those are some of the things that we would think about certainly.

Mr. SNYDER. Thank you, Mr. Chairman.

Mr. MICHAUD. I would like to thank this panel as well and the two previous panels for your testimony today. And we will submit additional questions for the record.

Dr. KUPERSMITH. Can I just ask one? May we respond to some of the questions that were asked to the other panelists? We would appreciate that opportunity also.

Mr. MICHAUD. In writing, yes.

Dr. KUPERSMITH. Yes.

Mr. MICHAUD. Yes, absolutely.

Dr. KUPERSMITH. Thank you very much. I appreciate that.

Mr. MICHAUD. This hearing is adjourned. Thank you.

[Whereupon at 11:27 a.m., the Subcommittee was adjourned.]

A P P E N D I X

Prepared Statement of Hon. Michael H. Michaud, Chairman, Subcommittee on Health

At this hearing, we will examine the Department of Veterans Affairs Research Programs.

Research is one of the core missions of the Veterans Health Administration (VHA). The VA is unique, in that it has the capability to provide clinical services and conduct research within the same organization. As a result, the VA has done ground-breaking research on topics ranging from post-traumatic stress disorder, prosthetics, smoking cessation and treatment of heart disease.

The purpose of this hearing is to examine VA research programs, particularly in light of the current conflict. As we all know, Operations Enduring and Iraqi Freedom have presented us with some new challenges in caring for and treating injured soldiers. In recent years, we have seen a dramatic increase in the number of returning veterans with conditions such as PTSD, TBI, and traumatic amputations.

These conflicts have produced nearly 28,000 severely injured veterans, over 700 of which have had traumatic amputations. It is vital that the VA continue to push the edge of research in order to provide these brave men and women with the most up-to-date care available—whether they need prosthetics, pain-management, eye-care, or any number of other services.

It is also important that the VA work in collaboration with the Department of Defense, academic partners and other public and private entities to leverage their resources and knowledge—and to produce the best research possible.

I would like to send a special welcome to one of our witnesses today.

On the 21st of June, 2003, Major David Rozelle was leading a convoy west of Baghdad when his vehicle struck a landmine, which resulted in the loss of his right foot. After spending 8 months recovering at Fort Carson, Colorado, Major Rozelle returned to Iraq as a Troop Commander conducting operations in Baghdad and Tal Afar—he was the first troop commander to redeploy to the same battlefield as an amputee in recent military history.

Major Rozelle is currently serving as an Administrative Officer at the Military Advanced Training Center at Walter Reed Army Medical Center. Drawing on his personal and professional experience, Major Rozelle helped plan and design this brand new facility—using the most state-of-the-art research available.

Welcome, Major Rozelle.

Continued research is vital to improving healthcare, saving lives and improving the quality of life for our sick and injured. I look forward to hearing from our witnesses about what the VA is doing—and what the VA should be doing—to advance their core mission of research.

Prepared Statement of Hon. Jeff Miller, Ranking Republican Member, Subcommittee on Health

Research is necessary to generate new knowledge and achieve scientific and clinical excellence.

The Department of Veterans Affairs (VA) is world renowned for its medical research, and VA's research program has a strong history of success and is credited with pioneering life saving therapies and treatments that have improved health care not only for veterans but for patients as a whole. This year, for example, the first vaccine for shingles was approved as a result of VA research.

Modern molecular medicine and rapidly advancing medical technology make a strong research enterprise more important to veterans than ever.

As we map the future of VA research, we must work to ensure that VA's research goals align with the special health care needs of both our new generation of veterans from the Global War on Terror and our older veterans of previous wars.

Recognizing the value of VA research, we must also be aware that nothing is more important than translating research from the "bench" to the "bedside".

I am pleased to see that we will hear from the Administrative Officer from the Military Advanced Training Center and have the opportunity to discuss collaborative efforts on federal research for the benefit of our military and veterans.

Thank you, Mr. Chairman, and I yield back the balance of my time.

Prepared Statement of John R. Feussner, M.D., MPH
Professor and Chairman, Department of Medicine
Medical University of South Carolina, Charleston, SC
and Volunteer Staff Physician, Ralph H. Johnson Veterans Affairs Medical Center on behalf of Friends of VA Medical Care and Health Research

Good morning Mr. Chairman and members of the committee. My name is John Feussner, and I am Professor and Chairman of the Department of Medicine at the Medical University of South Carolina in Charleston. I am also a volunteer staff physician at the Ralph H. Johnson VA Medical Center and was the Department of Veterans Affairs Chief Research and Development Officer from 1996 until 2002. I am testifying on behalf of the Friends of VA Medical Care and Health Research (FOVA), a coalition of over 80 organizations dedicated to ensuring that America's veterans receive the highest quality health care by promoting the long-term sustainability of the VA Medical and Prosthetics Research Program.

On behalf of FOVA, I want to thank the members of the committee for the opportunity to present the coalition's views on the importance of the VA research program and the challenges the program faces in the upcoming years. In addition, I wish to thank the Committee for its support of the VA Medical and Prosthetics Research program, as evidenced by your recommendation of a $480 million appropriation for VA research for fiscal year (FY) 2008. The support for this program across party lines is indicative of its success and the common understanding of the importance of the program for America's veterans. FOVA encourages Congress to deliver the appropriations bill funding the VA medical care and research programs to President Bush quickly so veterans and researchers will not have to wait for access to appropriate resources.

The VA Medical and Prosthetics Research Program is one of the nation's premier research endeavors, attracting high-caliber clinicians to deliver care and conduct research in VA health care facilities. The success of the VA program—which can be seen in the array of achievements attributed to VA researchers, such as the invention of the implantable cardiac pacemaker, the creation of a new vaccine for shingles, and the development of state-of-the-art prosthetics, including a new bionic ankle—is a function of its structure, leadership, and the secured availability of resources.

The VA research program is an intramural program; grantees must be VA employees with at least a five-eighths appointment to the VA. The program, therefore, offers a dedicated funding source to attract and retain high-quality physicians and clinical investigators to the VA health care system, who in turn provide first-class health care to our Nation's veterans. With this effective mechanism for attracting top researchers, VA has been able to make significant advances in areas of research that benefit the veteran population. VA investigators have been at the forefront of research that impacts newly returning veterans from Operation Iraqi Freedom and Operation Enduring Freedom, including research on post-traumatic stress disorder, polytraumatic blast injuries, and massive burns. In addition, VA has taken the lead on issues affecting the aging population of veterans who continue to constitute the largest portion of veterans seeking treatment in the VA system. Investigators in the VA research program have contributed to significant advances in pain management, substance abuse treatment, mental health disorders, respiratory medicine, diabetes, and Alzheimer's disease.

FOVA would like to stress the importance and value of the VA program's peer review system in articulating the agency's research portfolio. Congress may encourage VA to consider new research areas; however, it is vital to the integrity of the program that scientific merit remains the predominant criteria for funding. Peer review of proposals ensures that VA's limited resources support the most meritorious research. Additionally, centralized VA administration provides coordination of VA's national research priorities, aids in moving new discoveries into clinical practice,

and instills confidence in overall oversight of VA research, including human subject protections, while preventing costly duplication of effort and infrastructure.

While VA has been effective in its mission to provide the best possible care to the nation's veterans, veterans from the current wars in Iraq and Afghanistan are returning with injuries and conditions that will require treatment over many years. Additionally, veterans are returning with injuries never before experienced in such severity, which require additional research, and in turn, additional resources. FOVA greatly appreciates this Committee's support for the program in FY 2008; however, the $480 million appropriation only provides a starting point when consideration is given to long-term inflationary pressures.

To fund new research while still supporting traditional research areas that benefit the majority of veteran patients, FOVA encourages Congress to support significant increases to the program over the next three years. Additional funding can support research into such issues as traumatic brain injury (TBI), mental health treatment of veterans, and the effects of limb loss on other co-morbid conditions. Research is needed to understand the physical and psychological effects of TBI injuries and long-term funding is required to conduct post-deployment surveillance for TBI. Research into the potential long-term effects of exposures and risk factors among veterans of hazardous deployments can offer potential treatments for returning veterans while leading to the development of preventative medicine for future deployments. Advances in VA's rehabilitative research portfolio can improve treatment for paralysis and lead to greater limb function in injured veterans.

Additional funds could also restore previous funding levels for scientific awards. Due to previous years of inadequate funding, VA capped scientific awards at $125,000 annually. This level of grant support—which is barely enough to hire one laboratory technician and purchase necessary supplies—is significantly lower than the average grant awarded by other federal granting agencies. The amount diminishes productivity, slows the translation of research from the bench to the bedside, and hinders recruitment to the VA program.

Moreover, while the promise of medical research lies in the potential to create new treatments and cures for diseases and injuries, these efforts are not achieved by one grant or project. Research is a long-term ambition that cannot be fully successful in one funding cycle but must be sustained if treatments are to be discovered. FOVA encourages the Committee to consider the long-term needs of VA investigators when promoting future funding allocations for the program. As most VA research awards are three years in duration, the coalition encourages Congress to consider a planned growth for the VA research budget over the course of the next three years to continue the upward trajectory of the program in an orderly fashion.

However, even with sustained growth, VA will be ineffectual in advancing new treatments if it does not have the appropriate infrastructure in place. For years, VA has been aware of the inadequacies of its research infrastructure. An internal review of the infrastructure of VA laboratories was implemented in 2001 when I was at Central Office. The Research Evaluation Project assessed the state of the research infrastructure by surveying sites on the quality of the physical infrastructure, the organization structure in place to support research, and the availability of biomedical equipment. Based on that evaluation and the list of necessary improvements subsequently compiled, your predecessors and I reached an understanding that a dedicated funding allocation of $40 million a year was required to maintain VA research facilities. In May 2004, then Secretary of Veterans Affairs Anthony J. Principi approved the Capital Asset Realignment for Enhanced Services (CARES) Commission report that called for enhancement of VA research space, and this Committee and appropriators have called on VA to update these studies.

Under the current system for funding infrastructure improvements, research must compete in the minor construction budget with other facility needs. This system has led to an even greater accumulation of necessary research facility upgrades including improved ventilation, electrical supply, plumbing, and space configuration. FOVA applauds the Committee for recommending a $15 million minor construction funding stream for research facilities in its views and estimates for the FY 2008 budget. This step certainly brings needed attention to this matter. FOVA recommends at least a $45 million allocation for research facilities improvements under the minor construction account. Considering the significant needs recognized in 2001, this level of funding would just begin to address the agency's infrastructure problems.

While VA can take advantage of its relationships with affiliated medical schools and non-profit foundations to garner additional funding for infrastructure improvements, these funds are limited and VA must assume responsibility for the cost of its own research facilities. Based on preliminary accounts of yet another survey assessing VA research facilities, FOVA is under the impression that at least half of

the facilities received failing grades, which signifies that dedicated minor construction funding is vital to sustainability of the program.

There are a number of examples of the poor state of research laboratories in the VA system. When an animal facility is too small, investigators bring the animals into their regular laboratories, exposing themselves and staff to occupational illnesses. Occupational Safety and Health Administration (OSHA) inspectors have expressed concerns about VA research facilities and, in one case, said that if it was up to OSHA, the building would be shut down. Meanwhile, a researcher in Seattle, Washington, received a grant that required storing tissue samples in sub-zero freezers. Space was allocated, but the facility was unable to provide $30,000 to upgrade the electrical system to support the freezers. VA researchers in Gainesville were unable to conduct certain types of research because their "wet lab" countertops are made of particleboard and Formica, rather than the standard stone, and are easily burned and stained from exposure to heat and chemicals.

Substandard facilities make VA a less attractive partner in research collaborations with affiliated universities, reduce VA's ability to leverage the research and development appropriation with other federal and private sector funding, and make it difficult to attract cutting edge researchers to pursue careers in VA. Facility R&D Committees regularly disapprove projects for funding consideration because the facility does not have the necessary infrastructure and has little prospect of acquiring it. Upgrading facilities should proceed hand-in-hand with increasing funding for the VA research program to yield successful outcomes important to veterans and all patients.

Again, thank you for the opportunity to present FOVA's views on the VA research program. I look forward to your questions.

Prepared Statement of Major David Rozelle,
Administrative Officer, Military Advanced Training Center,
Walter Reed Army Medical Center
Department of the Army, U.S. Department of Defense

Chairman Michaud, Congressman Miller, and distinguished Members of the subcommittee, thank you for inviting me to participate in this hearing alongside my colleagues from the Department of Veterans Affairs (VA). I am Major David Rozelle, an Armor Officer and Administrative Officer of the Military Advanced Training Center at Walter Reed Army Medical Center. I am excited to talk with you today about the use of advanced technology at the MATC and at the Center For the Intrepid (CFI) at Brooke Army Medical Center in San Antonio, Texas. The openings of the CFI on the 29th of January 2007 and the MATC on September 13, 2007, were noteworthy events that demonstrated the tremendous support of the American people for our wounded warriors. These facilities are also representative of the significant advances that are being made in the care provided to our courageous servicemembers. Although the two centers mirror each other in capabilities, the CFI is monumental in appearance while the MATC is strictly utilitarian. The MATC, however, will eventually move its capabilities to a more permanent home once Walter Reed closes.

One patient recently described the interior of the MATC as "where the magic happens." It is a mix of technology and philosophy that allows our warriors to return to a lifetime of the highest physical, psychological and emotional function. Each servicemember is treated as a "tactical athlete"—the MATC brings the latest advances in sports medicine to bear on their treatment. Within the walls of the MATC there is a multidisciplinary health professional team that works together to seamlessly bring the patient from recently wounded status to a return to warrior status. This team includes representatives from the Veterans Benefits Administration, VA Social Workers, and VA Vocation Education and Rehabilitation counselors. While the team includes those thought to be part of the traditional rehabilitation team—the physical therapists, occupational therapists, physiatrists, and nurse case managers—it also includes psychological liaison providers, biomechanists, the patients, the patients' family members, and others.

The facilities boast many "state-of-the-world" or "state-of-the-art" capabilities:

- The *fire arms training simulation room* utilizes Blue Tooth technology to replicate the weight, feel and response of actual weapons, the M16 and M14 rifles and the 9mm pistol. This allows the servicemember to regain confidence in their ability to carry out the roles of a combat Soldier. It is also utilized to clear individuals prior to their participation in some of the outdoor recreational activities like skeet shooting and hunting.

- The *gait labs* are among the largest and most sophisticated in the world. With a 23 camera capture system, a dual force plate treadmill, and force plates of different sizes arranged in an array in the floor, the gait lab is able to analyze the gait patterns of our clients while they utilize a variety of prosthetic components and apply the results to both prosthetic adjustments and to physical therapy and occupational therapy treatment plans.
- The *Computer Assisted Rehabilitation Environment or CAREN System* is another "state-of-the-art" technology that provides tremendous potential for our clients. Imagine a helicopter simulator and replace the helicopter with a platform and an imbedded treadmill with dual force plates under the treadmill. Now link this through a computer system to a screen that projects an image which is linked to your actions as you move on the platform. We can have you walking up and down a hilly trail with the platform shifting to mirror the changes on the screen, if you speed up the system detects it and speeds up both the projection and the treadmill, if you slow down the system responds accordingly. It can generate a city street scenario, beginning with walking down a quiet street, then adding in stressors, additional people, cars backfiring, trash on the side of the road, pedestrian tunnels, and allow our psych staff to work with you as you approach these stressors. This is a new and exciting technology that is applicable not only to our patients with limb loss, but also those with traumatic brain injury or combat stress.
- The facility offers a variety of opportunities to work on advanced skills that are applicable to both leisure activity and military skills. This includes both a *climbing wall* and a *treadwall*—the climbing wall adds the challenge of functioning at height while the treadwall challenges the patient cardiovascularly.
- The *SoloStep* is an overhead support system that permits the patients to be supported as they progress from walking to running. The MATC offers the only Solostep system in the world that goes in a continual loop. Rather than a 20 foot straight run where the patient has to continually stop and turn around, ours goes around the entire length of our track. This support system frees the therapist from having to hold the patient as they ambulate and allows the therapist to watch the patient and make immediate corrections to their gait.
- *Elevating parallel bars* were developed specifically for the military amputee patient population. The Army Medical Department has the only three sets in the world. This allows the patients to train for community obstacles which they will frequently encounter such as sloping streets, sidewalks, or ramps. These also will play a significant role in research efforts to provide our warriors with more functional prosthetic devices.
- A *vehicle simulator* is available to provide the initial training with hand controls. We collaborate with the VA, who will provide the follow on training out on the street in actual vehicles. One of our staff members, a VA employee, has developed software programs for the simulator to specifically address driving issues related to deployment. Known as combat driving, it includes such practices as rolling stops and wide lane changes to avoid obstacles in the road. While these are potentially life saving measures in theater, they may be extremely dangerous if practiced stateside. By working on modifying these behaviors on the simulator we are able to better prepare our patients for a return to driving.

A very active community reintegration program has been developed which includes a variety of activities from field trips to a museum or a mall or a wide range of sports activities to include skiing, kayaking, scuba, cycling, mountain climbing, and surfing. This was a lesson learned during the Viet Nam war as the military worked to help patients return to the civilian community. The success of that program has kept it an integral part of the military amputee rehabilitation process. Another program that has been very successful is our running program, training our clients for a range of distance races, biathlons, and triathlons.

As mentioned earlier, much of our success is due not to the technology advances, but to the philosophy and approach to patient care. Again, during the Viet Nam war it was identified that having the patients work in larger cohort groups appeared to have greater benefit than working independently, close to home. Many veterans with limb loss from previous wars have volunteered to be peer visitors for our patients. This ability to see the future, whether it is seeing a recently injured warrior who is one or two months ahead of you, or seeing the more distant future provided by the peer visitors, provides a sense of purpose and focus for our patients to strive toward.

Technology has played a significant role in prosthetic restoration. New methods of measurement have resulted in more efficient methods of measuring the service-

member's amputated limb with better precision, efficiency, and quality. These methods include Computer Aided Design Computer Aided Manufacturing (CADCAM), optical digitizing and stereo lithography where CT Scans are digitized and used to print an accurate 3 dimensional model of the residual limb including any existing heterotopic ossification. Additionally, the treatment for servicemembers in the Global War on Terror has resulted in current technology being utilized in new ways. The U.S. Armed Forces Amputee Patient Care Program at WRAMC was the first in the world to utilize the micro-processor prosthetic knee as an early rehabilitation knee unit, providing newly injured servicemembers increased stability, safety and confidence in the use of a prosthetic limb.

The Program pioneered and implemented the use of the Military Ambulatory Diagnostic Prosthesis philosophy for the lower limb amputee. Under this philosophy, the prosthetic sockets are rapidly produced with extremely durable temporary materials and coupled with the most technologically advanced components. The patients receive multiple and frequent sockets to accommodate the volume and shape changes common during the early post-operative phases.

Similarly, with upper extremity limb loss, the concept of Early Post-Operative Prosthesis was resurrected and coupled for the first time with a policy of utilizing external powered prosthetic components. The use of myo-electric prosthetic components instead of body powered components places much less stress on the residual limb and permits the patient to begin to train much earlier in the rehabilitation process. The ability to rapidly manufacture and change sockets to accommodate upper extremity residual limb changes has permitted our patients to continue to use a prosthesis throughout the early stages of rehabilitation and makes them much less likely than their civilian counterparts to reject prosthetic use.

The innovative use of current state of the art technology has attracted many manufacturers to the program. These manufacturers are seeking to provide new technology to the program prior to release to the general population. The early release of this technology allows the military prosthetists to obtain critical knowledge of the technology and provide expert feedback to the manufacturer.

The current emphasis on care of the military amputee patient has stimulated the application of a wide range of advanced technologies into the development of enhanced prostheses, which can much more closely simulate the human body.

Collaboration between the DoD and the VA is ongoing and has already led to several significant successful projects. Among these is the development of the VA/DoD Clinical Practice Guidelines (CPG) for Care of the Amputee. This CPG sets in place the clinical pathway for both pre and post amputation patient care. Additionally, the establishment of a VA/DoD Clinical Rotations Program allows for rehabilitation practitioners (physical therapist, occupational therapist and prosthetist) all from the same Veteran Integrated Service Network (VISN) to train as a team simultaneously with counterparts at MATC and the CFI. This unique program bridges the span between the VA and DoD practitioners and provides an understanding of operations at the varying installations which ultimately leads to better care of the injured servicemember.

With the financial support of Congress, we have been able to develop a research program that has already provided some exciting developments and, with the advanced care centers, promises to significantly change how we provide warrior care in the future.

Over 82% of amputations in the U.S. occur as the result from complications of diabetes and dysvacular disease, with a greater prevalence rate of individuals over the age of 65. Data obtained from OEF and OIF reveal a much different patient population. As of September 2007, there have been over 700 servicemembers, who have sustained a major limb amputation in support of GWOT. Twenty-three percent (23%) of these individuals have lost an upper limb and over 20% have lost more than one limb. Nearly 90% of these servicemembers have been under the age of 35 and as a result have unique psychosocial needs and generally seek to return to a more active lifestyle than older individuals. Additionally the majority of combat related amputations do not occur in isolation. Over 50% have had a documented traumatic brain injury (TBI), some with vision and/or hearing loss, many have significant remote fractures and significant soft tissue wounds, others with co-morbid paralysis from peripheral nerve injury or central cord injury and nearly all with contaminated wounds requiring frequent surgical washouts and extensive antibiotic use. These complex medical, surgical and rehabilitation challenges require a unique approach to treatment and warrant dedicated research programs to optimize care.

The advanced training centers have proven to be an ideal setting for training in advanced techniques related to amputee care and prosthetics. In addition to the VA/DoD Clinical Rotation Program, we have held a number of courses attended by mili-

tary therapists and Veterans Affairs therapists and prosthetists from around the country.

The combination of advanced technologies, innovative clinical practices, caring providers and an amazing group of warriors in transition with the strength and courage to seek the high ground and continually move forward has led to revolutionary changes in our understanding of the capabilities of individuals with limb loss.

I thank you for inviting me to talk with you today about the capabilities and the magic of the Military Advanced Training Center at Walter Reed and the Center for the Intrepid in San Antonio. Your continued support for our wounded, ill, and injured is very much appreciated by the Soldiers and staff at Walter Reed and throughout the Army.

Prepared Statement of Mark J. Lema, M.D., Ph.D.
Chair, Department of Anesthesiology, Critical Care and Pain Medicine
Roswell Park Cancer Institute, Buffalo, NY, Professor and Chair,
Department of Anesthesiology, University of Buffalo, State University of New York, School of Medicine and Biomedical Sciences, and
President, American Society of Anesthesiologists,
on behalf of Pain Care Coalition

Mr. Chairman and members of the Subcommittee, my name is Mark J. Lema, M.D., Ph.D. I am Chair of the Department of Anesthesiology, Critical Care and Pain Medicine at the Roswell Park Cancer Institute in Buffalo, New York, and Professor and Chair of the Department of Anesthesiology at the University of Buffalo, State University of New York, School of Medicine and Biomedical Sciences. I also serve as the current President of the American Society of Anesthesiologists.

I am pleased to testify today on behalf of the Pain Care Coalition, a national advocacy effort of the American Academy of Pain Medicine, American Pain Society, American Headache Society and American Society of Anesthesiologists. Collectively, these organizations represent more than 50,000 physicians and other clinicians, researchers, and educators who provide clinical leadership in the increasingly specialized field of pain management. Some of these individuals work either full or part time in the VA health system, and many others are involved in collaborative relationships with research and clinical care programs throughout the VA system.

We appreciate the opportunity to appear today and present our views on the state of pain research at the VA. As professionals in the pain care field, nothing we do is more important than assuring that those who serve our country in times of war get the very best pain care possible during all stages of their service, and in all settings of the military and veteran health and medical systems. These settings range from the battlefield to the clinics, hospitals, rehabilitation centers and long term care facilities of the VA. As a complement to these clinical care responsibilities, those of us in pain medicine have a continuing interest and responsibility in pain care research within the VA's Medical and Prosthetic Research Program, as well as other public and private research efforts with which the VA collaborates.

THE SCOPE OF THE PAIN PROBLEM

Pain is a very large public health problem in this country. It is the most common reason people access the medical care system, a major cause of lost productivity in the workplace, and a substantial contributor to short and long term disability. It affects Americans at all stages of life and in all walks of life. For example, 26 million Americans of working age have frequent back pain, and chronic back pain is the leading cause of disability for those under 45 years of age. Twenty-five million suffer from migraine headaches. Four million, mostly women, suffer from a complex pain syndrome known as fibromyalgia. Forty million have arthritis pain.

Pain imposes a terrible burden on those who suffer and on their families, and it imposes large costs on the health care and disability income systems. Medical costs and lost productivity alone are estimated to top $100 billion annually. Pain is often poorly understood by those who suffer and by those around them. It is often undiagnosed or misdiagnosed, and under-treated or mistreated. Sometimes pain is the symptom of other diseases as in the case of cancer, arthritis, heart disease, and diabetes. Other times, pain is the disease itself as with migraine, chronic back pain and various diseases associated with damage to the nervous system, such as postherpetic neuralgia, diabetic neuropathy, or injuries to the nervous system such as commonly occur in combat, including phantom limb pain, post-injury or post-surgery neuralgias, and traumatic brain injury.

The most recent complete study of soldiers enrolled in VA Polytrauma Centers show that more than 90% have chronic pain, that most have pain from more than one part of the body, and that pain is the most common symptom in returning soldiers. Advances in neuroscience, such as neuroimaging, now demonstrate that unrelieved pain, regardless of its initial cause, can be an aggressive disease that damages the nervous system, causing permanent pathological changes in sensory neurons and in the tissues of the spinal cord and brain.

Pain can be acute and effectively treated by short term interventions, or it can be chronic, often without effective "cures" and sometimes without consistent and effective means of alleviation. Those who suffer severe chronic pain see their daily lives disrupted—sometimes forever. Their pain and their constant search for relief affects their function, their relationships with those they love, their ability to do their work effectively, and often their self esteem. Chronic pain is often accompanied by or leads to sleep disorders, emotional distress, anxiety, depression, and even suicide.

If these facts are true in the general population, which we know them to be, then they are doubly true in the military and veteran populations. The physical and emotional stresses of military service make inevitable the disproportionate incidence of both acute and chronic pain among active duty personnel. If miners, movers and construction workers suffer low back pain from heavy lifting, imagine the toll on the spine of those in active duty combat situations. If truckers develop back pain from long hauls, imagine the toll of armored vehicles going long distances on poor or nonexistent roads. If the stresses of daily civilian life serve as triggers for those suffering severe migraine, imagine the impact of battlefield conditions.

The incidence of acute pain among those injured in current conflicts will be virtually 100%, and for far too many, the original short term trauma will be followed by chronic pain of significant dimension and duration. For example, virtually all of those suffering the loss of one or more limbs in combat will suffer from phantom limb pain. While this can be managed with varying degrees of effectiveness, there is no known "cure." Virtually all veterans fitted with prostheses will suffer some degree of pain at the device/body "interface." Again, this can be managed to some degree, but it is rarely eliminated.

Far less visible, but even more prevalent, is the extensive damage to the central and peripheral nervous systems resulting from the horrific explosive devices deployed in the current conflicts. Unlike broken bones, flesh wounds and burns, many of which will eventually heal after aggressive treatment, extensive nerve damage may only be manageable, not curable, given the current state of science and clinical practice. Most returning veterans with extensive nerve damage will be chronic pain sufferers and will require long term pain management, with varying prognoses for success. Ironically, the proportion of these chronic pain sufferers among returning wounded servicemen and women will be far greater in the current conflicts than in previous wars because of the remarkable successes of military medicine which now keep so many of the very severely injured alive.

PCC'S INVOLVEMENT IN PAIN MANAGEMENT FOR VETERANS

On the battlefield and upon returning home from service, critically wounded men and women must receive the best, most advanced pain management interventions available. Members of the Pain Care Coalition have made significant contributions toward efforts to alleviate the suffering of our brave soldiers.

For example, Lt. Col. Chester "Trip" Buckenmaier III, an Army anesthesiologist and member of the American Society of Anesthesiologists, has been at the forefront of providing revolutionary pain care to wounded veterans. During a deployment to Iraq several years ago, Dr. Buckenmaier used portable infusion pumps to alleviate the pain of soldiers with grave injuries to their arms and legs. In a recent Wall Street Journal article, Dr. Buckenmaier described a situation in which a soldier changed his evaluation of his pain from 10 on a 10 point scale—"the worst pain imaginable"—to zero, after being treated with a portable infusion pump.

This example underscores the life-saving, life-changing pain management techniques increasingly used in military medicine. In fact, during an October 2005 hearing of the House Committee on Armed Services, Deputy Surgeon General Joseph G. Webb, Jr., highlighted the advances of pain medicine benefiting our soldiers. He said, "Wounded soldiers in Iraq and Afghanistan benefit from receiving some of the most advanced technologies and techniques in medicine today . . . The benefits of advanced pain management, during and after surgery, are improved postoperative outcomes and the potential to eliminate chronic pain, particularly in amputees."

Dr. Buckenmaier's story and Major General Webb's testimony illustrate the potential and the challenge of deploying innovative and advanced pain management techniques to treat our veterans.

THE VA'S CURRENT PAIN RESEARCH EFFORT

Perhaps more than any other federal agency, the VA has been a leader in focusing institutional resources on the assessment and treatment of pain. Under a "National Pain Management Strategy" initiated in November 1998 ("Strategy"), and pursuant to VHA Directive 2003–021, the Veterans Health Administration has made pain management a national priority. Among the specific objectives of the Strategy are:

- providing a system-wide standard of care to reduce suffering from "preventable" pain;
- ensuring consistency in the assessment of pain;
- ensuring prompt and appropriate treatment for pain;
- promoting an inter-disciplinary approach to pain management; and
- providing adequate training to and resources for clinicians in VA healthcare to achieve these objectives.

The Pain Care Coalition applauds the Strategy and generally supports its specific goals and objectives. At the same time, the Coalition has significant concerns with the current VA effort:

- Directive 2003–021 is only a five-year plan. It is scheduled to expire in May of 2008;
- there has been, to the Coalition's knowledge, no comprehensive assessment of the Strategy's strengths, weaknesses and accomplishments; and
- reports from the field suggest that implementation has been far from consistent. Some VA facilities have made great strides in improving pain care, while for others it is more an aspirational goal than an operating reality. As a result, veterans get widely different treatment for pain depending on the expertise and resources of the particular VA facility at which they receive their care.

Significantly, and directly germane to the Subcommittee's current inquiry, **the Pain Care Coalition believes that, in order to ensure effectiveness, the VA's pain management Strategy must be accompanied by and integrated with a significant research commitment to advancing the science of pain care, and to translating developments in the science to improved clinical care throughout the system.**

The VA has had a long and continuing research interest in the phenomenon of phantom limb pain, with current work focused at the molecular level. It also has current research efforts in neural repair, which might someday lead to improvements in therapy for those veterans currently returning with significant damage to the nervous system. And it recently completed a successful study of the effectiveness of a shingles vaccine in older veterans which validated research findings elsewhere, and will improve care in the general population. Other important pain research initiatives are scattered amongst NIH research institutes.

In 2006, through an initial grant funded privately, the VA brought together research investigators with interests in pain as part of a VA sponsored conference on pain and palliative care. That meeting identified several research interest groups including post-deployment pain, primary care pain programs, and opioid analgesics. These groups generated a number of new research projects, several of which have earned Merit Award funding through the peer-review process of the VA's Office of Research Development ("ORD"). Work from these groups also spawned important articles in major journals and a special issue of the Journal of Rehabilitation Research and Development devoted to pain research. Based on this success, the VA's ORD funded a second meeting of pain researchers just held in September of 2007. At this meeting, researchers identified other important projects which demonstrated the breadth and depth of research that is possible if a focused effort is made to organize and promote a VA research agenda dedicated to the basic and clinical sciences of pain medicine. I look forward to making the results of this most recent meeting available to the Subcommittee in the near future.

It is imperative that pain research be placed high on the list of current VA research priorities. Alarmingly, the VA's justification accompanying the Administration's proposed FY 2008 budget for the Medical and Prosthetic Research Program barely mentions pain. The Coalition is aware of no VA data to show what proportion of the research budget is devoted to pain, but we suspect it is a very small percentage.

The VA has identified four research priorities related to the current conflicts:

- polytrauma;
- neurotrauma;
- burns; and
- chronic illness generally.

Three others are considered continuing priorities relevant to these and all preceding conflicts:

- prosthetics;
- PTSD; and
- vocational rehabilitation.

Pain is central to each of these seven priorities, and effective pain management is crucial to the restoration of a reasonable quality of life for all of these conditions, but there is little indication that pain research has been integrated with other research efforts in these seven areas, or coordinated across these and other research programs.

Unfortunately, pain is not an area where the VA's leveraged research approach can rely on leadership from research partners at the NIH or in private industry. For example, despite the documentation that chronic pain is one of the most costly of all health problems to the U.S. economy, a recently conducted review of the NIH pain research portfolio showed that only 1% of NIH's annual research funding is devoted to projects with a primary focus on pain. If projects where pain is a secondary concern are added, it only rises to 2%. There is no Institute or Center at NIH to provide a central home for pain research, and efforts to coordinate pain research across the various institutes and centers are in the very early stages of development.

While private industry has significantly advanced drug and device therapies for particular types of pain or classes of pain patients, industry alone can not be expected to carry the load of long term basic science research needed to better understand the mechanisms of pain, and in particular how chronic pain syndromes develop despite successful treatment of the original trauma.

RECOMMENDATIONS OF THE PAIN CARE COALITION

The Pain Care Coalition believes the VA's pain research effort can and must be significantly enhanced. We urge the Subcommittee to develop targeted legislation with several basic components.

First, the Congress should require the VA to establish within the Medical and Prosthetic Research program at VA headquarters a focused program of research and training directed at acute and chronic pain. That program should identify research priorities in pain most relevant to veterans returning from the current conflicts, and should promote and coordinate basic and applied research on these priorities both within the VA, and with its research partners. The same centralized pain research program should boost education and training of VA personnel to ensure that research advances are rapidly disseminated throughout the VA care system.

Second, Congress should authorize and the VA should designate an appropriate number of cooperative centers throughout the country for research and education on pain. Each such center should take the lead on a priority area of basic science research on pain, or an aspect of acute or chronic pain most relevant to veterans returning from the current conflicts. At least one of the centers should be designated as the lead center for research on pain attributable to central and peripheral nervous system damage, and one such center shall be designated as the lead center to coordinate the work of all the centers.

Third, Congress should authorize these newly created pain research centers to compete on an equal basis with other priority research areas (TBI, PTSD, polytrauma, prosthetics and others) for funds appropriated each year to the Department's overall medical and prosthetic research budget.

CONCLUSION

Mr. Chairman and members of the Subcommittee, pain is often characterized as an invisible disease—we can not see it, and unlike such diseases as cancer, diabetes, and heart disease, there are no affordable and widely available lab or imaging tests to confirm its presence and quantify its severity. But that's no excuse for letting research efforts lag behind those of other priorities. The Pain Care Coalition is committed to advancing the practice of pain management. We strongly support new and increased efforts within the VA's research, education and clinical care programs to ensure that our brave men and women returning from combat receive the best pain care possible. The Coalition, along with each of the organization's it represents, stands ready to work with the Subcommittee and the VA toward that end.

Prepared Statement of Thomas Zampieri, Ph.D.,
Director of Government Relations, Blinded Veterans Association

INTRODUCTION

Chairman Michaud, Ranking Member Miller, and Members of the House Veterans Affairs Subcommittee on Health, on behalf of the Blinded Veterans Association (BVA), thank you for this opportunity to submit our testimony on VA Research Programs. BVA is the only congressionally chartered Veterans Service Organization exclusively dedicated to serving the needs of our Nation's blinded veterans and their families. BVA has now worked for more than 62 years with VA Blind Rehabilitation Service in order to improve VA's ability to provide high quality outpatient and inpatient rehabilitation training for blinded veterans.

BVA appreciated the approval granted earlier this year by former Secretary Nicholson and Under Secretary of Health Dr. Kussman for a three-year, $40 million expansion of the full continuum of blind and low vision outpatient rehabilitation services. With the now growing numbers of wounded entering the VA health care and benefits system from both Operation Iraq Freedom (OIF) and Operation Enduring Freedom (OEF), along with the large numbers of aging veterans with degenerative eye diseases, this expansion of clinical services is vital.

As of September 25, 2007, a total of 27,767 servicemen and women had been wounded in Iraq. The number of men and women requiring air medical evacuation from Iraq between March 19, 2003 and September 17, 2007 was 8,298, of which 1,162, or 13 percent, had sustained combat eye trauma. The 13 percent figure represents the highest percentage of eye wounded for any of the American wars of the past 100 years.

The staggering nature of these numbers reflects the probability that young veterans will, in the very near future, depend on VA blind and low-vision services in order to live independently in their own homes and, hopefully, enter the workforce once they have fully recovered from their injuries. According to the Defense Veterans Brain Injury Center (DVBIC), some 3,900 of the Traumatic Brain Injured personnel have sustained injuries sufficiently severe that they are experiencing neurosensory complications. Epidemiological Traumatic Brain Injury (TBI) studies have found that 80 percent of the these 3,900 complain of visual symptoms related to their TBI while 62 percent have associated neurological visual disorders of diplopia, convergence disorder, photophobia, ocular-motor dysfunction, and an inability to interpret print. Some TBIs result in visual field loss with enough loss to meet the standard for legal blindness. Like other generations of disabled veterans who have desired to live independently, the current generation of OIF and OEF veterans deserves the same opportunity.

PREVALENCE AND INCIDENCE OF BLINDNESS

Low vision or blindness affects one in 28 Americans over the age of 40, which amounts to approximately 3.3 million Americans. This 2004 figure, when broken down, consists of 2.3 million Americans with low vision and about one million being legally blind. Every year, 200,000 Americans develop age-related macular degeneration, which is the most common cause of blindness in people over age 65. Diabetic retinopathy is the most frequent cause of new blindness in individuals between 40 and 65. People who move from visual impairment to blindness have a 50 percent greater chance of becoming injured or depressed and a 2.5 to 3 times greater chance of needing skilled nursing or a long-term care facility.

Approximately 648,000 Americans age 80 and older are blind. While only 4.3 percent of the 65 and older population live in nursing homes, 16 percent of those who are visually impaired and 40 percent of those who are legally blind reside in nursing homes with an estimated cost of close to $11 billion in direct nonmedical costs for seniors with visual disorders. By 2020, the number of Americans age 40 and over with low vision or blindness is projected to reach 10.5 million, almost three times what it was in 2004.

VA estimates that there are currently 169,000 legally blinded veterans throughout the country, of which 47,450 are enrolled in Veterans Health Administration (VHA) services. The number is projected to reach 55,000 within 10 years. In addition, blindness within the total veteran population of 24 million is expected to increase over the next two decades, just as it is increasing within the general American population from glaucoma, macular degeneration, diabetic retinopathy, and cataracts.

It should be clear to Members of this Committee that a new generation of OIF and OEF blinded and impaired low vision veterans will require specialized research programs to meet their needs. The older veterans who are now beginning to lose their sight have equally important needs. Rehabilitation research programs for both groups and their families must be individualized.

ECONOMIC AND SOCIAL IMPACT

- Of the $68 billion annual cost of vision impairment and eye disease as estimated by the National Eye Institute, the annual financial burden to the American economy of blindness and low vision in adults age 40 and over—driven in large part to advanced macular degeneration, cataracts, diabetic retinopathy, and glaucoma—is estimated at $51.4 billion. This includes $16.2 billion in direct medical costs, $11.2 billion to other direct costs, and $8 billion in lost wages and productivity, as well as $16 billion in excess monetary impact due to vision loss. The following points illustrate the potential importance of vision rehabilitation research in reversing the negative consequences of loss of sight in our veteran population. It is seven times more expensive to provide nursing home care for a blind individual than for one that is trained and able to function independently at home. Falls associated with vision loss is the sixth leading cause of nursing home admissions.
- "The Employment Experience of Persons with Limitations in Physical Functioning," a University of California study published in 1999, found that even after adjusting for age and gender differences, persons reporting functional limitations are less than half as likely to be in the labor force as those with no functional limitations. Part-time employment and job loss are also more common among persons with functional limitations. Three quarters of those experiencing a job loss reported that the loss created a major problem in their lives. Only half of those with no limitations reported that the problem created by the loss was a major one.
- Literature reviews on employment among persons with disabilities indicate that such persons experience lower labor force participation rates, higher unemployment rates, and higher rates of part-time employment than persons without disabilities (Yelin, 1997; Bennefield & McNeil, 1989). These findings are consistent across numerous national surveys, including the Current Population Survey (CPS), Survey of Income and Program Participation (SIPP), the National Health Interview Survey (NHIS), a survey of Trupin and Armstrong in 1998, and a survey of Trupin, Sebesta, Yelin, and LaPlante in 1997. Disabilities in these studies are defined as factors that limit work capacity and functional activity (McNeil, 1993).
- The National Health Interview Survey (NHIS), conducted by the National Center for Health Statistics (NCHS) and reported in a March 2003 article, revealed that working age individuals with visual impairments had lower employment rates and lower mean household incomes than those without visual impairments. The employment rate was 54 percent for the severely visually impaired age 18–54 in statistics compiled in 1994–95.
- The National Organization on Disability Research found that, despite improvements in transportation during the past decade, inadequate or inaccessible transportation was reported by 30 percent of the disabled. The lack of transportation made employment, social participation, and commercial activities less likely, causing increased depression and medical costs.
- In the aforementioned study, lower mean household incomes and lower employment rates were found among those with disabilities related to mobility (43.3-percent rate of employment), agility (46.0-percent rate of employment), speaking (41.7 percent employment), mental function or ability to learn (47.5 percent employment), hearing loss disability (62.7 percent employment).
- A study by Hendricks, Schiro-Geist, and Broadbent (1997) at the University of Illinois showed a link between disability and employment outcomes for those who had, from 1948 to 1993, completed both a university education and rehabilitation services. Using a regression analysis for those disabled with a degree, the study revealed a salary gap of 8.3 percent between disabled and nondisabled workers. While this and similar other studies have found that the disabled with higher education and rehabilitation earn more than the disabled without this level of education and training, the income levels and earning capacity are still lower in all comparisons with working age non-disabled individuals.
- National Council on Disability (NCD) today October 1, 2007, on the first day of National Disability Employment Awareness month, released a report that presents the best practices in the public and private sectors and the promising public policies and initiatives that increase employment opportunities for people with disabilities. However, the employment rate of working age people with disabilities remains still only half that of people without disabilities (38 percent compared with 78 percent in 2005).

NEUROLOGICAL IMPACT OF TBI DYSFUNCTION

Perception plays a significant role in our ability to live life. It aids in providing information about the properties in our environment and allows us to act in relation to those properties. In other words, our perceptions provide us with the means to experience our environment and live within it. We perceive what is in our environment by a filtered process that occurs through our complex neurological visual system. Although all senses play a significant role, the visual system is one of the most important, providing more than 70 percent of our sensory awareness. With various degrees of visual loss, we are no longer able to clearly adjust and see our environment, resulting in increased risk of injuries, loss of functional ability, and unemployment. Impairments range from an inability to successfully navigate one's visual field to loss of visual acuity, loss of color vision, photophobia, and difficulty in recognizing faces.

Among the numerous ways one can acquire visual deficits, and a leading one at that, is injury to the brain. Damaging various parts of the brain can lead to specific visual deficits. Although some cases have reported spontaneous recovery, complete recovery is unlikely and early intervention is critical. Currently complex TBI-visual research is being examined in an attempt to improve the likelihood of recovery. The training of certain areas of the brain has been found to improve vision deficits in some disorders. Nevertheless, researchers have stressed that the extent of recovery can be limited and will usually require long term follow-up often with specialized adaptive devices and prescriptive equipment.

The brain is the most intricate organ in the human body. Visual pathways within this vital organ are also very complex. Due to the interconnections between the brain and visual system, damage to the brain can bring about various cerebral visual disorders. The visual cortex has its own specialized organization, causing the likelihood of specific visual disorders if damaged. The occipitotemporal area is connected with the "what" pathway. Thus, injury to this ventral pathway leading to the temporal area of the brain is expected to affect the processing of shape and color. This can make perceiving and identifying objects difficult. The occipitoparietal area (posterior portion of head), on the other hand, relates to the "where," or "action" pathway. Injury to this dorsal pathway leading to the parietal lobe will increase the likelihood of difficulties in position (depth perception) and/or spatial relationships. In cases of injury, one will find it hard to determine an object's location and may also discover impaired visual navigation. It is also highly unlikely that a person with TBI will have only one visual deficit. He/she will usually experience a combination of deficits due to the complexity of the organization between the visual pathway and the brain. The most common cerebral visual disorder after brain injury involves visual field loss. The loss of peripheral vision can be mild to severe enough to result in legal blindness. It requires specific visual field testing to be correctly diagnosed and different prescribed devices to adapt to this loss. While the DVBIC reports about 10% as severe open head injuries, most TBI cases are closed head injuries that can result in a variety of visual deficits from overt to subtle.

In addition to considering these complex neurological effects on the patient, BVA would ask Members of this Subcommittee to consider the huge emotional effects of TBI on the servicemember or veteran when deciding what level of support should be given to research in this area. These emotional effects may be equaled or even surpassed by those inflicted on the patient's family. Brain injuries are known for causing extreme distress on family members who must take on the role of caregiver in addition to facing the many other challenges associated with this type of injury to a son, daughter, father, mother, brother, sister, or even an extended family member.

VA MEDICAL AND PROSTHETICS RESEARCH

BVA has supported investments in veteran-centered research projects within VHA. Such projects in the past have led to an explosion of knowledge that has advanced the understanding of many different diseases and unlocked strategies for prevention, treatment, and cures. Additional funding is needed to take advantage of the burgeoning opportunities to improve the quality of life for our blinded and low vision veterans and for the Nation as a whole. VA must concurrently address the needs of its longstanding patient base as well as the evolving challenges being presented by our newest war-wounded veterans. With increased directed vision research funds, it is expected that VA will begin pursuing the following in Fiscal Year 2008: new adaptive prosthetics, aging vision diseases, and specialized vision research. This funding increase should also allow for an increase in funding for Rehabilitation Research & Development (RR&D), now so desperately needed with the ever-increasing numbers of combat eye injuries. BVA points to the success of new retinal research of great importance, the continuation of RR&D initiatives in Bos-

ton, where investigators are working on the development of artificial retinal implants for those with vision loss due to retinal trauma.

RECOMMENDATIONS

Examples of four separate categories identified by the National Alliance for Eye and Vision Research (NAEVR) as vital vision research are listed below. NAEVR believes that such research is sufficiently significant that it be supported by Members of Congress and utilized by both DoD and VHA.

Eye Trauma, Healing, Infection/Inflammation Control, and Rehabilitation

This research relates to acute and chronic implications of corneal and retinal eye trauma, healing, infection/inflammation control, and associated vision rehabilitation.

- Treatment of eye trauma caused by a physical, chemical, or biological agent insult; associated healing; and infection/inflammation control (including infections associated with skin around the eye, the corneal surface, or within the ocular globe, and the impact of environmental conditions that promote infection).
- Ocular surface reconstruction and treatment of corneal damage by corneal transplantation or through corneal stem cell transplantation.
- Retinal and optic nerve regeneration (through identification of the genes involved and associated gene therapy, or through other biomedical processes).

Visual Function/Visual Acuity

This research relates to the metabolic and physiological processes that relate to visual clarity, contrast sensitivity, and spatial orientation.

- Impact of metabolic modulation or stress on visual acuity and contrast sensitivity (i.e. effect of lowered blood glucose levels on central vision).
- Visual image processing (better understanding of the biological/electrochemical interface in the vision process to improve acuity and advance "artificial vision" and other assistive technology).
- Sensory dysfunction associated with TBI, such as extreme light sensitivity (photophobia).
- Spatial orientation processing (relation of motor control and perception, especially relating to depth perception of objects in a visual field) to enhance peripheral vision.
- Next-generation refractive error correction and vision augmentation research (i.e. LASIK, visual implants/prostheses, and associated corneal healing issues).

Vision Health Disparities

This research relates to characterization of visual disparities based upon gender, race, or age, and determination of the underlying physiological basis to develop treatments and therapies.

- Epidemiological studies of military populations to determine extent/physiological basis of vision health disparities (i.e. greater incidence of glaucoma, cataracts, and diabetic retinopathy in the African American/Native American/Hispanic populations).
- Research into low vision caused by traumatic eye injury or chronic eye diseases such as age-related macular degeneration or glaucoma.
- Age-related macular degeneration research (leading cause of blindness in the United States and the leading cause of blindness in Americans age 60 and over).

Emerging Adaptive Technology Research

- Optimal vision rehabilitation management after acute injury, facilitating the advancement of evidence-based best practices for blind and low vision rehabilitation. This could become possible by the joint funding of RR&D and HSR&D projects that target the development of rigorous, solid best practices guidelines with a strong emphasis on vision loss resulting from neuro-trauma. It would also address visual impairment concerns of minority veterans, rural veterans, and other key target groups.
- Establishment of a Blind Rehabilitation Service-focused technology evaluation and assessment center in conjunction with experienced blind agencies charged with identifying the highest quality of vision rehabilitation through independent, scientific testing on both devices and training. Emphasis would be on quick, timely turn around of results so veterans can access these newly proven adaptive technologies.

CONCLUSIONS

Serious combat eye trauma occurring in Operation Iraq Freedom and Operation Enduring Freedom has become the third most common injury in both of these conflicts. Only PTSD and TBI are now more common. We urge all members of this Subcommittee to support H.R. 3558, the Military Eye Trauma Treatment Act of 2007. The Act creates a Center of Excellence and Eye Trauma Registry. Already having included the provisions for the establishment of PTSD and TBI Centers of Excellence in the Wounded Warrior Act, Congress could now, with this critical legislation, substantially improve the multidisciplinary coordination, treatment, rehabilitation, and research of eye trauma as it relates to TBI. Visually impaired servicemembers and veterans within both the DoD and VA systems are depending on passage of this bill. We respectfully request that it be passed soon.

BVA supports specialized, directed research programs in the area of vision that will benefit the aging population of blinded and visually impaired veterans. The Association also strongly supports language in the House Armed Services appropriations that includes recommendations for more research for traumatic vision injuries. Together with NAEVR's advocacy, BVA strongly requests that "Eye and Vision Research" maintain its eligibility for funding within the Congressionally Directed Medical Research Program (CDMRP) in FY 2008 Department of Defense (DoD) appropriations. BVA also believes that such funding must be significantly increased from the limited $4.8 million appropriated in FY 2007.

Chairman Michaud and Ranking Member Miller, BVA expresses thanks to both of you again for this opportunity to present our testimony. The current need to increase VA research is tremendous when considering the overwhelming numbers of veterans suffering from traumatic visual injuries, traumatic brain injury dysfunction, and age-related causes of blindness. The future strength of our Nation depends on the willingness of young men and women to serve in our military. This willingness depends, in turn and at least in part, on the willingness of our government to meet its full obligation to them as veterans.

Attachments
Clinical Update: Cataract
Wounds of War: Part One: Eye Surgeons in Iraq and Afghanistan

By Denny Smith, Senior Editor*
Eyenet Magazine
May 2006 Edition

American Academy of Ophthalmology Web Site: www.aao.org
Original URL: http://www.aao.org/aao/publications/eyenet/200605/comprehensive.cfm

The cost of war is often counted in fallen soldiers. But war's survivors, both soldier and civilian, may also pay a tremendous price, by enduring traumatic, disfiguring and life-altering injuries. Ophthalmologists, like many other physicians and medical workers, have been tending the wounded in Afghanistan and Iraq for over three years now. More than 17,000 American servicemen and women have been wounded since the U.S.-led invasions began.[1]

"The survivors often have very bad injuries, and there's no way to completely repair many of them," said Thomas H. Mader, MD, a retired U.S. Army colonel who served in Iraq in 2004 and who is the primary author of a recent report in *Ophthalmology* describing ocular and adnexal injuries treated by U.S. Army ophthalmologists.[2] "Occasionally you treat a patient with a relatively minor injury, which can be repaired in 10 minutes and the prognosis is excellent. But then there are explosive globe injuries, and other terribly mutilating trauma, where there is absolutely no chance at all of salvaging the eye." Dr. Mader is now practicing ophthalmology at the Alaska Native Medical Center in Anchorage.

Eye and brain injuries appear to be more frequent in Afghanistan and Iraq compared with previous U.S. conflicts, even though the number of deaths per injured troops has decreased. This apparent spike in head injuries is partly a statistical illusion: The body armor of troops in Iraq and Afghanistan, much improved over what soldiers had in World War II, Korea and Vietnam, protects internal organs but not

*__EDITOR'S NOTE:__ *As the conflict in Iraq enters its fourth year, Army ophthalmologists continue treating wounded troops there and in Afghanistan.* EyeNet *presents the first of two reports on the experiences of Eye M.D.s confronting combat-related ocular injuries. NEXT MONTH: Soldiers Journey Home for Recovery.*

[1] www.dior.whs.mil/mmid/casualty/castop.htm.

[2] Mader, T. H. et al. *Ophthalmology* 2006; 113(1):97–104.

faces and limbs. So, ironically, doctors now confront profoundly injured troops who once would have died of massive thoracic or abdominal wounds before nonfatal injuries to eyes and extremities got medical attention.

For Every War, a Dread Weapon

Many of the injuries logged in Iraq result from disastrously effective improvised explosive devices (IEDs). These are simple, homemade bombs, such as artillery shells filled with glass or rocks, that are detonated remotely as troop convoys pass by. The sheer concussive force of IEDs is dangerous in itself, but most injuries are related to debris propelled by the blast. "These fragments can range in size from a grain of sand to something the size of your fist," said Dr. Mader.

Sean M. Blaydon, MD, is a former lieutenant colonel who commanded the Army's first eye surgical team to be deployed in the Iraq conflict, in 2003 and 2004. "Roadside bombs became more common as the conflict dragged on," said Dr. Blaydon. "Many of the injuries were devastating, including large areas of the face or both eyes. It's very troubling to see young kids with both eyes missing. I don't know anybody who didn't get personally affected by it." Prior to his service in Iraq, Dr. Blaydon was director of ophthalmic plastic, orbital and reconstructive surgery and the ocular trauma service at Brooke Army Medical Center in San Antonio. He is now a clinical assistant professor at the University of Texas, San Antonio, and in private practice in Austin.

A different, but just as troubling, injury profile was described by Lt. Col. Mark F. Torres, MD, who served in Afghanistan in 2003 at Bagram Air Base, north of Kabul. "In Afghanistan there are fewer IED-related injuries and more wounds related to land mines. This is a country with 20 years of recent war, and so there are many, many land mines planted throughout the country. Now, thanks to better armor, they cause fewer injuries to the thorax or abdomen. But that doesn't save the extremities, head and neck. And the majority of victims are children, who often approach the mines out of curiosity, like they would a toy. These typically cause a lot of damage to the face and limbs." Dr. Torres is now assistant chief of ophthalmology at Madigan Army Medical Center in Tacoma.

Care for the Globe

Physicians witnessing modern warfare are standing at a frontier of visually appalling and medically daunting trauma. But the goal for treating a battle-related ocular wound is the same as it would be for any big-city ER trauma: Save the globe and preserve vision.

"We always erred on the side of attempting to preserve badly damaged globes," said Dr. Mader. "Even when it looked like an injury was so severe that the chance of the eye's survival was minimal, we always brought them into the OR and tried to do the best repair possible. There are times when an injury is so drastic that you just cannot anatomically put the eye back together. When that happens you have to know when to call it quits. But we always tried to salvage the eye even if the prognosis for useful vision seemed poor."

Dr. Blaydon concurred. "The philosophy of my team was to do as much as we could to salvage the globe. No matter how severe the injury, if we could put the globe together somehow, we did. We knew that in a good 50 percent of severely injured eyes there was little chance that vision was going to be saved, and very likely the eyes would eventually be enucleated. But these soldiers were badly injured, and sedated, and not able to give consent. If they were enucleated right then, they might later second-guess what was done. They may wonder, 'I came in with 10 other guys and maybe they just didn't have time to save my eye.' We wanted them to be able, later on, to understand how serious the injury was and how every effort was made to save the eye. After that, psychologically, they do better if they have an enucleation."

Working shoulder to shoulder. The care given in the first minutes and hours after an injury must be intensely organized even in the middle of chaos. Dr. Mader described a typical scene. "Our team worked in Baghdad in the heavily fortified Green Zone. We had a general ophthalmologist, an oculoplastics specialist, neurosurgeons and maxillofacial surgeons. We all worked together, often on the same patients, because so many troops with eye injuries had other wounds of the face and brain."

Dr. Blaydon shared a similar picture. "These soldiers often had multiple injuries. On top of a wounded eye, a guy could have had traumatic amputation below the knee on one side, lost a foot on the other, and they're still trying to save one arm. Many times we had to delay our surgery because the orthopedic surgeons were trying to save arms and legs."

When assessing a newly injured soldier, Dr. Mader hoped to be able to communicate with him or her. "Some were unconscious, suffering from horrible head wounds. For others, it was helpful if they were still conscious, because you could question them, assess their visual loss, ask if they could see light or moving fingers." Sometimes, grimly, the prognosis was obvious, even to the patient. "One young fellow who had lost both eyes in a blast came in fully conscious and was talking clearly to me. He knew what had happened to him."

Dr. Blaydon described wounds that seemed almost impossible to approach. "You may see ruptured globes in civilian practice, but in combat trauma it could be hard even to distinguish pieces of sclera. In everyday urban trauma, a bad rupture is usually stellate, with sharp edges, and it's straightforward to repair. In combat-related, high-velocity injuries, not only do you have complex cornea and sclera lacerations and intraocular contents coming out, but the edges are so necrotic it's hard to even sew them back together."

Neither bombs nor balm discriminated. Army ophthalmologists have been treating soldiers and civilians in almost equal numbers. "We treated both American and allied troops, as well as Afghan military and enemy combatants. The majority of casualties we saw were actually Afghan civilians," said Dr. Torres.

The same was true for Dr. Mader. "An injured person could randomly be an American or an Iraqi, soldier or civilian. When someone was brought into the hospital, we treated everybody the same, whether a civilian, a child or enemy combatant."

Clinical Update: The Wounds of War: Part Two
Soldiers Journey Home for Recovery

By Denny Smith, Senior Editor*
Eyenet Magazine
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Even as the conflicts in Afghanistan and Iraq roll on, wounded servicemen and women are returning home with injuries that may require years of medical and psychological rehabilitation. Last month EyeNet featured the experiences of Thomas H. Mader, MD, Sean M. Blaydon, MD, and Mark F. Torres, MD, each of whom served on Army surgical teams close to combat zones. The soldiers they treated are now filling polytrauma facilities in the United States.

Whisked Away From War

Troops wounded in Iraq or Afghanistan undergo emergent primary repairs to life- and sight-threatening injuries often within minutes of sustaining the injury. When stable enough, they are transported several times to various levels of care.

The first stop is Landstuhl Army Medical Center in Germany, then on to Walter Reed Army Medical Center in Washington, D.C., or Brooke Army Medical Center in San Antonio, and finally on to tertiary-care hospitals around the country.

These later stages of care can be the hardest part for both doctors and patients. "It's one thing to sew somebody up as best we could do, and it's another thing to provide the follow-up care," said Dr. Mader. "That is a very, very difficult job, both professionally and emotionally. As you can imagine, the psychological impact of a young man losing one or both eyes has to be dealt with by both patient and physician."

Physicians and families take a long view. The community ophthalmologist may be seeing more such veterans, and they will need multiple levels of care for many years, according to Glenn C. Cockerham, MD, chief of ophthalmology at the VA Palo Alto Health Care System and clinical associate professor of ophthalmology at Stanford University.

"When they come to us they are entering a period in which late complications, including retinal detachments, corneal decompensation, traumatic cataracts or posterior capsular opacifications, may present," said Dr. Cockerham. "If one eye, usually on the side of the blast, is severely damaged, it is extremely important to take special care of their better-seeing eye. But many of them have head injuries and

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*__At the Joint Meeting in November,__ Herbert P. Fechter, MD, will moderate a panel of military ophthalmologists who will share their experiences in Afghanistan and Iraq. Photos and videos will demonstrate the special considerations of ophthalmic war surgery and will address a variety of combat-related injuries (Instruction Course #590).

resulting memory problems, so we include families in the rehabilitation process to watch over their loved one and make sure they get to appointments. Their families are usually very supportive, having been there for them throughout."

Collaborative care is key. Dr. Torres explained how the community ophthalmologist can offer veterans care. "There are a lot of joint arrangements between military hospitals and the VA, and between the VA and civilian academic medical centers. The average comprehensive ophthalmologist offering long-term management of a combat-related trauma should, pretty easily, be able to consult with combat-experienced ophthalmologists."

Dr. Blaydon agreed. "The general ophthalmologists can manage these returning vets, but they might be seeing a different trauma than they would in an emergency room. Much of it is explosive, high-velocity, blunt trauma to the face, which means there's a lot of soft-tissue damage and underlying skeletal damage. Many had globe ruptures that were severe and complex, and there are often fine, foreign bodies embedded in the cornea. Even if the rupture is repaired perfectly, the patient remains corneally blind. Many of these will go on to corneal transplant. Some of them have bad retinal injuries from just blunt trauma."

Courage and Candor Beyond the War

Most returning veterans are very young, between their late teens and early twenties. Dr. Blaydon maintains a deep regard for their emotional well-being. "I am in awe of the attitude and the motivation of these young guys. Before you address their specific injury, it's important to consider the psychology of the veteran. They went over there to serve their country and to serve alongside their comrades, and they want us to respect the fact that they were doing their job when they got their injury. These patients need a lot of physical and emotional therapy to get back into society."

Americans are deeply divided over the Iraq conflict. And yet, Dr. Blaydon has observed that the soldiers are coming home to a country that cares for them. "This war is as divisive as any we've had in the past. The difference now is that returning vets are receiving support from both sides of the fence. That's an important part of welcoming these soldiers home."

Hope for vision preempted. Conceivably, some of these soldiers could benefit from research into artificial retinas, research that has received significant funding from the Department of Energy. But Dr. Blaydon said the devastating nature of many injuries means that few of these veterans would be good artificial retina candidates. "The anterior visual camera, the optic nerve and visual pathway must all be intact for an artificial retina to be considered." These crucial structures are obliterated in many vets.

Precautions slow to appear. One of the questions now haunting the military is whether U.S. troops were provided adequate protection for battle. Since the Afghanistan and Iraq conflicts began, Army ophthalmologists have repeatedly asked for troops to be given better eyewear. While no form of protection can eliminate all injuries, many could have been prevented or lessened in severity. In fact, Dr. Mader writes in *Ophthalmology,* "Polycarbonate ballistic eyewear could have prevented many, but not all of the ocular injuries we report."[1]

Dr. Blaydon noted that ophthalmologists had long lobbied the Army for the type of ballistic eyewear that protects against low-velocity projectiles. The Army had developed eye armor known as Ballistic/Laser Protective Spectacles, but almost none of the soldiers had them. "The Army, as far as we could tell, did not issue them. Eye armor just was not part of the issue," Dr. Blaydon said.

The Army did issue Sun, Wind and Dust Goggles, which can protect the eye against some minor injuries. But they are cumbersome, and can often impair clear, full peripheral vision. "Soldiers just do not like to wear them. What they do like to wear are Wiley X ballistic goggles that fit closely to the face. But the soldiers had to purchase these on their own. The Army soon realized how severe and frequent the eye injuries were and began purchasing these goggles and mandating that they be worn," Dr. Blaydon said. Even these goggles cannot protect against the most potent improvised explosive devices, but, he noted, "The incidence of injuries has since gone down, depending on the tempo of operations."[2]

From a distance. These physicians tend to deflect credit for their own heroic service into recognition of others still working in the combat zones. "Many soldiers would have died had it not been for the premier care they got in Baghdad. The surgeons there are the top-of-the-line and that care is as good as you're going to get in a critical care hospital," said Dr. Blaydon.

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[1] Mader, T. H. et al. *Ophthalmology* 2006;113(1):97–104.
[2] Gawande, A. *N Engl J Med* 2004;351(24):2471–2475.

Dr. Mader regards his experience with equanimity. "If there was any positive thing about being there, I would say I worked with some of the finest young people I've ever met in my life. Had I been wounded and brought to that 31st Combat Support Hospital, I would have had complete faith in the medical personnel working there."

Dr. Torres shared a similar sentiment. "It's a rewarding experience in unfortunate circumstances. You feel like you're doing something positive, even if the world around you is not."

Prepared Statement of Carl Blake
National Legislative Director, Paralyzed Veterans of America

Mr. Chairman and members of the Subcommittee, Paralyzed Veterans of America (PVA) would like to thank you for the opportunity to testify today on the research programs conducted by the Department of Veterans Affairs (VA). Research is a vital part of veterans' health care, and an essential mission for our National health care system. PVA is very involved in many aspects of medical and prosthetic research because of the long-term impact that these initiatives can have on our members.

The VA health care system is a unique environment combining clinical care, education, and research. VA currently supports approximately 3,800 researchers at 115 VA medical centers. The research program serves as an excellent recruitment tool for young doctors as well as scientists because it gives them an opportunity to develop skills as clinical researchers. According to the VA, nearly 83 percent of VA researchers are practicing physicians. Because of this dual role, VA research often immediately benefits patients. For example, functional electrical stimulation, a technology using controlled electrical currents to activate paralyzed muscles, is being developed at VA clinical facilities and laboratories throughout the country. This technology is now being applied to many PVA members receiving health care service and rehabilitation therapy at spinal cord injury centers. Through this technology, tetraplegic patients have been able to grasp objects, stand and pivot to assist transfers, and control bladder function. We anticipate greater capacity for even walking short distances.

PVA interacts a great deal with the VA's Office of Research and Development. Most of our attention is focused on the Rehabilitation Research and Development (RR&D) and Health Services Research and Development Service (HSR&D). RR&D projects involve technologies such as wheelchair development and testing, seating systems, functional electrical stimulation (FES), audiology, prosthetics and orthotics, and other components. HSR&D projects are multidisciplinary activities that involve expertise in a combination of clinical fields—physicians, nurses, therapists—as well as social sciences—psychology, sociology. It involves delivery system research and application. This particularly involves the Quality Enhance Research Initiative (QUERI), which includes spinal cord injury (SCI). PVA's Research Department has been a direct participant in the QUERI executive group as well as the SCI QUERI since their inception.

Meanwhile, the Clinical Sciences Research and Development Service (CSR&D) conducts clinical trials and epidemiological research on key diseases that impact veterans. CSR&D research project accomplishments include key research findings across a range of diseases and definitive evidence for clinical practice.

Through the system's scope of primary, secondary, and tertiary care, as well as long-term care, with multi-disciplinary academic affiliations, the VA brings validation and innovation to the delivery of the best care for today's veterans. Perfect examples of this idea are the Parkinson's Disease Research Education and Clinical Centers (PADRECC) and Multiple Sclerosis (MS) Centers of Excellence. These centers represent a successful strategy to focus the Veterans Health Administration's (VHA) system-wide service and research expertise to address two critical care segments of the veteran population. They integrate direct health care services, education, and research to the benefit of veterans in the system.

In testimony during the 109th Congress, PVA supported legislation that would create Amputation and Prosthetic Rehabilitation Centers of Excellence (similar to those for MS and Parkison's disease). The need for these centers is amplified by the number of veterans of Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) who have amputations. As we stated with regards to the Parkinson's disease and MS Centers of Excellence, the VA has the essential expertise to focus dedicated services on a wide range of medical conditions. It then transfers learned approaches for specific care to the broader VA health care system. However, the Veterans Health Administration (VHA) often times lacks the financial wherewithal to

create a needed focal point or center. This legislation calls for the creation of these focal points and the need for resources to actuate that goal. We must emphasize, however, that additional real dollars will likely be needed to establish these centers.

Furthermore, these centers could partner with the new Amputation and Prosthetic clinic recently opened at Walter Reed Army Medical Center. This partnership could enhance the long-term provision of these services to veterans as it would allow the VA to remain on the cutting edge of amputation and prosthetic research in conjunction with DoD. This is particularly important as the VA will likely be responsible for caring for the men and women with prosthetic needs over the course of their lives.

Additionally, VHA should be required to partner with manufacturers, dealers, payers, and advocates to develop performance test standards for amputee and prosthetic devices. An example of these types of test standards is the American National Standards Institute (ANSI) and Rehabilitation Engineering and Assistive Technology Society of North American (RESNA) Wheelchair Performance Standards. These standards are a collaborative effort with specific impacts on wheelchair research and development, consumer disclosure, and payer decisions. PVA believes that these centers could be the spearhead for development of evidence-based performance test standards for amputee and prosthetic devices. Furthermore, expertise on these matters could be drawn from such projects as the VA's Human Engineering Research Laboratories (HERL), a project being conducted in collaboration with the University of Pittsburg and supported by PVA's Research Foundation, and focused on mobility technologies.

PVA has a particular interest in research projects that the VA administers as it continues to address neurotrauma and sensory loss, primarily as a result of spinal cord injury or disease (SCI/D) or traumatic brain injury (TBI). As you are well aware, traumatic brain injury is recognized as the signature injury of combat in Iraq and Afghanistan. According to the VA's estimates, TBI and various degrees of SCI account for nearly 25 percent of the combat casualties sustained by servicemembers in OIF/OEF. Despite the positive gains by advancements in body armor, the head (and by extension the brain), as well as the cervical spine, are exposed to significantly more trauma. This has not only lead to specific injuries related to TBI and paralysis, but also vision loss, psychological problems, and the larger polytrauma aspect.

As such, it is absolutely essential that continued research in the areas of TBI and SCI continue to advance. PVA has long been a leader in the field of spinal cord research. Through the PVA Research Foundation, we continue to work to find a cure for SCI/D and alleviate the effects of similar conditions. Through the PVA Education Foundation, we develop tools to share the broad-based knowledge for SCI/D care with all types of health care professionals. Finally, PVA, as a partner in the Consortium for Spinal Cord Medicine, promotes the use of evidence-based clinical practice guidelines and consumer guides. PVA also supports numerous efforts in the field. For example, at the Center for Neuroscience and Regeneration Research at Yale University, scientists study nerve regeneration that may ultimately lead to better treatments for SCI or possibly even a cure. This work is conducted in conjunction with the VA.

Likewise, PVA believes more research must be conducted to evaluate the symptoms and treatment methods of veterans who have experienced TBI. This is essential to allow VA to deal with both the medical and mental health aspects of TBI, including research into the long term consequences of mild TBI in OEF/OIF veterans. Furthermore, TBI symptoms and treatments can be better assessed for previous generations of veterans who have experienced similar injuries.

PVA also supports a couple of specific research projects that the VA instituted during FY 2007. The first project focuses on the special needs of service personnel returning from Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF). The project will develop new treatments and tools for clinicians to ease the physical and psychological pain of men and women returning from the combat theaters, improve access to VA healthcare services, and accelerate discoveries and applications, especially for neurotrauma, sensory loss, amputation, polytrauma, and related prosthetic needs. We appreciate that even as the VA begins to move forward with this project, it is already collecting data to determine if the health care needs of amputees and severely injured veterans from OIF and OEF are being met and to identify areas where improvement is needed. These data will help focus the project on additional areas that need to be studied.

This project directly supports the important role that research plays in the clinical setting. Through this project clinicians can learn and apply new tools to the treatment of physical and psychological conditions experienced by the men and women returning from the Global War on Terror. Furthermore, findings from this research

project can be shared with Department of Defense (DoD) treatment facilities, particularly Walter Reed Army Medical Center and Brook Army Medical Center, as well as the Defense Advanced Research Projects Agency. This collaboration will be absolutely essential as it will provide for new screening tools, clinical applications, and long-term follow-up.

As a member of the Friends of VA Research (FOVA) coalition, we wholeheartedly support the vision to expand the VA research program to encompass the needs of service personnel returning from current conflicts, whether they include polytrauma, massive burn injury, or mental health conditions. Such expansion of the program requires new resources so that VA's other research areas, which are equally important to the long-term care of veterans, do not suffer.

The second special research project focuses on genomic medicine. The thrust of this project is to link veterans' genetic information with the VA electronic health record. The program will ultimately allow clinicians to make better decisions for veterans based on their genetic information. Furthermore, it will address patients' rights, informed consent, privacy, and ownership of genetic material involved with genetic tissue banking. We believe that the human genome reports of recent years have provided a strategy to integrate clinical symptomology with genetic testing to create a predictive model that could extend health care delivery to a truly preventive service.

However, despite the expectations of this exciting field, we must reiterate that additional new funding will be necessary. Genomic medicine cannot be advanced by simply reshuffling funding priorities within existing VHA R&D funding. If it is placed into a stream where it will compete with current VA projects, the sheer scope and cost of genomic medicine will overrun all other ongoing projects. This will simply not be a cheap field to study, so the burden should be shared by the Veterans Health Administration (VHA) and DoD. Moreover, the genomic priorities of NIH should be marshaled with VHA.

PVA also believes that one particular change should be made that would allow the VA to invest additional resources into its infrastructure. Currently, many VA researchers are primary grantees from the National Institutes of Health (NIH). However, these researchers do not receive any funding to support management and physical plant costs of their projects. Their physical infrastructure and administrative costs (also called indirect costs), which are vital to the support of the research enterprise, are not funded by NIH to VA researchers. However, if that same VA researcher carries that same grant through an academic affiliate, then NIH would provide full indirect support. If the VA is going to attract clinician researchers, they must provide the best environment; otherwise, they are placed at a significant competitive disadvantage. Simply put, Congress must provide funding for capital improvement and support the VA research enterprise or NIH should be required to pay fair indirect costs to the VA.

Finally, I must emphasize our concern about funding for the overall Medical and Prosthetic Research program. We certainly appreciate the fact that the appropriations bills passed by the House and Senate meet or exceed the $480 million that *The Independent Budget* calls for in FY 2008. However, with the outcome of the appropriations still hanging in limbo, and the fact that no appropriation has been provided even as the start of the new fiscal year has passed, we remain concerned about the ongoing viability of the VA research program. It is time to put the games aside and complete the appropriations work that these programs so vitally rely upon.

Mr. Chairman, PVA appreciates your continued interest in maintaining a viable research program. We look forward to working with the Subcommittee to ensure that adequate resources are provided for Medical and Prosthetic Research. Quality research outcomes can only lead to better patient care for veterans.

Thank you again. I would be happy to answer any questions that you might have.

Prepared Statement of Joy J. Ilem
Assistant National Legislative Director, Disabled American Veterans

Mr. Chairman and Members of the Subcommittee:

Thank you for inviting the Disabled American Veterans (DAV) to provide testimony on Department of Veterans Affairs (VA) research programs. As an organization of more than one million service-disabled veterans, DAV has a genuine concern about the health and well-being of the men and women who are serving today or who have served our country and suffered physical and mental disabilities as a result of military service.

VA's research program, developed following World War II, has a rich and robust history with a clear mission, "To discover knowledge and create innovations that advance the health and care of veterans and the nation." The program is distinguished by three Nobel Laureates, six Lasker Prize winners, and a number of important discoveries and inventions. Today, VA's offices of Health Services Research and Development and Rehabilitation Research and Development are focusing on a number of important areas including: posttraumatic stress disorder (PTSD); mental health and substance abuse; spinal cord injury; genomic medicine; and women's health. The complex and unique injuries sustained by troops serving in Iraq and Afghanistan have created the need for new research and treatment strategies focused on addressing the unique needs of the newest generation of combat disabled veterans who have traumatic brain injury (TBI); polytrauma; spinal cord injury; burns; amputations; and hearing and vision loss. Although VA has been the leader in conducting research on many war-related injuries in the past, it is critically important that proper funding be made available for VA to expeditiously conduct research and effectively implement related advances in treatment for all of these devastating injuries. My testimony will focus on several of these areas in more detail.

Prosthetics

Many veterans who served in Operations Enduring and Iraqi Freedom (OEF/OIF) have sustained catastrophic or polytraumatic injuries during their military service to include severe brain injury, spinal cord injury and traumatic amputation. Most servicemembers begin the recovery and rehabilitation process at Walter Reed Army Medical Center (WRAMC) or other specialty military treatment facilities. "Warrior Rehab" as it is known is an extraordinary example of the incredible journey many severely injured veterans travel as they are rehabilitated, fitted and trained to use state-of-the-art prosthetics. The new rehabilitation center at WRAMC and the extraordinary Center for the Intrepid (which was sponsored by DAV and our contributors), are two of the world's most technologically advanced rehabilitation centers for amputees. As servicemembers transition to veteran status and into VA care, we encourage VA to significantly increase research on amputation, prosthetics, and orthotics to help improve health outcomes and make available the newest technologies for this unique patient population. A significant number of servicemembers and veterans returning from OEF/OIF today are young—and aggressive rehabilitation programs are helping them return to very active lifestyles. VA will be responsible for the long-term health maintenance of this population for decades; therefore, it is appropriate that VA develop research initiatives that ensure VA is the leader in advancing new technologies and prosthetic and orthotic items, and rehabilitation models that promote good health outcomes for veterans with amputations. Any research should also include older veterans from previous generations who could benefit from these studies.

Traumatic Brain Injury

Mr. Chairman, Traumatic Brain Injury (TBI) and spinal cord injury account for almost 25% of the combat casualties sustained by our soldiers in OEF/OIF. Blast injuries that violently shake or compress the brain within the closed skull cause devastating and often permanent damage to the brain—and veterans with severe TBI will likely need a lifetime of care for their injuries.

Military service personnel who sustain catastrophic physical injuries, and suffer severe TBI, are easily recognized and the treatment regimen is well-established. However, VA experts note that TBI can also be caused without any apparent physical injuries when a veteran is in the near vicinity of improvised explosive device (IED) detonation. Veterans suffering a milder form of TBI may not be detected so readily, but symptoms can include chronic headaches; irritability; disinhibition sleep disorders; confusion; memory problems; and depression. With nearly 15,000 IEDs now reported in Iraq alone, it is believed that many OEF/OIF servicemembers have suffered mild brain injuries or concussions that have gone undiagnosed, and that symptoms may only be detected later, when these veterans return home.

We are concerned about emerging literature that strongly suggests that even "mild" TBI patients may have long-term mental health and other health consequences. According to VA's mental health experts, mild TBI can produce behavioral manifestations that mimic PTSD or other symptoms. TBI and PTSD can also be co-existing conditions. Much is still unknown about the long-term impact of these injuries and the best treatment for mild/moderate TBI. The influx of OEF/OIF servicemembers returning with brain injury and trauma has increased opportunities for research into the evaluation and treatment of such injuries in newer veterans; however, we suggest that any studies undertaken by VA include older veterans of past military conflicts who may have suffered similar injuries that thus far have gone

undetected, undiagnosed, and untreated. Their experiences could be of enormous value to researchers interested in the progression of these injuries on a long-term basis. Likewise, such knowledge of historic experience could help both Department of Defense (DoD) and VA better understand the procedures and policies needed to improve screening, diagnosis and treatment of mild TBI in the newest generation of combat veterans.

We are pleased that VA has designated TBI as one of its special emphasis programs, and is committed to working with DoD to provide comprehensive acute and long-term rehabilitative care for veterans with brain injuries. We urge Congress to remain vigilant to ensure that VA research programs are sufficiently funded and are *adapted* to meet the unique needs of the newest generation of combat service personnel and veterans with TBI, while they continue to address the needs of older veterans with severe physical disabilities, as well as posttraumatic stress disorder (PTSD) and other combat-related mental health challenges.

Mental Health

Current research findings indicate that OEF/OIF combat veterans are at higher risk for PTSD and other mental health problems caused by their experiences and exposure in these wars.

VA reports that veterans of these current wars have sought care for a wide range of possible medical and psychological conditions, including mental health conditions, such as adjustment disorder, anxiety, depression, PTSD, and the effects of substance abuse. Through July 2007, VA reported that of the 252,095 separated OEF/OIF veterans who have sought VA health care since fiscal year 2002, a total of 94,921 unique patients had received a diagnosis of a possible mental health disorder. Over 45,000 of the enrolled OEF/OIF veterans had a probable diagnosis of PTSD, and almost 38,000 reported nondependent abuse of drugs. Also, critically, 31,000 OEF/OIF veterans have been diagnosed with depression.

In a recent study, VA New Jersey-based researchers examined substance abuse and mental health problems in returning veterans of the war in Iraq. Researchers noted that although increasing attention is being paid to combat stress disorders in veterans of the Iraq and Afghanistan conflicts, there has been little systemic focus on substance abuse problems in this cohort. In the group studied (292 New Jersey National Guard members who had returned from Iraq within the past 12 months) there was a 39.4 percent prevalence of a substance abuse problem; 37.1 percent reported problem drinking; and a 21.2 percent prevalence of alcohol abuse or dependence. Highlights of the study included the following findings: nearly 47 percent of veterans studied had reported a mental health and/or substance abuse problem. Substance use problems were found to be higher among veterans with mental health problems; access to treatment both during and after deployment was especially low for those needing substance abuse treatment (among veterans with dual disorders—41 percent received mental health treatment but only 9 percent received treatment for substance abuse). We urge VA to continue research into this critical area and to identify the best treatment strategies to address substance abuse and other mental health and readjustment issues collectively.

We urge VA to continue research that is veteran-centered and specifically focused on rehabilitation of veterans with physical and cognitive impairments related to military service and studies to identify and promote effective and efficient strategies to improve the delivery of healthcare to veterans. We believe VA's research priorities should include:

- A study to objectively and systematically measure the expectations of OEF/OIF veterans to help VA better serve this population. These veterans are younger, have family and community support systems in place, and are frequently dealing with complicated post-service readjustment, employment, education and other issues. VA should conduct health services and other research to identify services to meet their mental health needs.
- Studies to address access issues for this new population including tracking of OEF/OIF veterans to learn what services they utilize. VA should also examine barriers to care, especially those that relate to attitudes of veterans and their families toward being treated in the VA, and any breakdown in access this may cause.

The DoD and VA share a unique obligation to meet the health care—including mental health care—and rehabilitation needs of veterans who are suffering from readjustment difficulties and various injuries as a result of combat service. Both agencies need to ensure that appropriate research is conducted and that federal mental health programs are *adapted* to meet the unique needs of the newest generation of combat service personnel and veterans, while continuing to address the needs of

older veterans with substance abuse problems, PTSD and other combat-related readjustment issues and other mental health challenges. Congress must remain vigilant to ensure that research and treatment programs are authorized and sufficiently funded.

Women Veterans

With increasing numbers of women serving in the military, and with more women veterans seeking VA health care following military service, it is essential that the VA be responsive to the unique demographics of this veteran population cohort. In addition, VA must ensure that its special rehabilitation programs are tailored to meet the unique health concerns of women who have served in combat theaters and those who have suffered catastrophic disabilities as a result of military service. Women's health research is essential to achieving these objectives—specifically to fully understand the healthcare needs of this population and to develop high quality services and treatments.

In 2004, VHA's Office of Research and Development held a groundbreaking conference, "Toward a VA Women's Health Research Agenda: Setting Evidence-Based Research Priorities for Improving the Health and Care of Women Veterans." The participants of the conference were tasked with identifying gaps in understanding women veterans' health and health care, and with identifying the research priorities and infrastructure required to fill these gaps. In April 2005, a special solicitation was issued for intramural VA research proposals to assess health care needs of women veterans and demands on the VA health care system in targeted areas, such as mental health and combat stress, military sexual trauma (MST), PTSD, homeless women veterans, and differences in era of service (e.g., Iraq vs. Gulf War service periods). An entire issue of the *Journal of General Internal Medicine* was dedicated to VA research and women's health in March 2006. Published findings included articles on why women veterans choose VA health care; barriers to VA health care for women veterans; the health status of women veterans; PTSD and increased use in certain VA medical care services; and MST.

We have strongly encouraged VA, as it takes steps to advance this agenda, to focus on research and programs that enhance VA's understanding of women veterans' health issues and discover new ways to optimize health care delivery and improve health outcomes for this special VA patient population.

Mr. Chairman, one area of particular interest to DAV is the incidental impact of VA's primary care model on women's health. There has been a trend in the Veterans Health Administration (VHA) to move away from dedicated women's health clinics, to general primary care, for the purpose of providing both primary and gender-specific health care to women veterans within unified clinics. According to VA, less than half of its facilities surveyed provide care to women through mixed gender primary care teams, referring women to specialized women's health clinics for gender-specific care. In the mid-1990s, VA reorganized from a predominantly hospital-based delivery care model, to an outpatient health care delivery model, focused on preventative and health maintenance care. While we believe that shift was appropriate, we are concerned about the incidental impact of the primary care model on the quality of health care delivered to women. VA's 2000 conference report, "The Health Status of Women Veterans Using Department of Veterans Affairs' Ambulatory Care Services," noted that with the advent of primary care in VA, many women's clinics were being dismantled and that women veterans were assigned to primary care teams on a rotating basis, without regard to gender. Findings from that report indicated that this practice further reduced the ratio of women to men in any one practitioner's caseload, making it increasingly unlikely that an individual clinician would gain the clinical exposure necessary to develop and maintain expertise in women veterans' health. We understand that a follow-up study is currently being conducted and that VA researchers will study the impact of the practice structure on the quality of care for women veterans, and the fragmentation of care including unmet health care needs of those with chronic physical and mental health conditions.

VA acknowledges that full-service women's primary care clinics that provide comprehensive care, including gender-specific care, are the optimal milieu for providing care to women veterans. Or, in cases where there are relatively low numbers of women being treated at a given facility, it is preferable to assign all women to one primary care team, or provider, in order to facilitate the development and maintenance of provider clinical skills in women's health. VA also notes that the health care environment directly affects the quality of care provided to women veterans and has a significant impact on a patient's comfort, privacy, feeling of safety, and sense of welcome.

According to VA researchers, although women veterans surveyed reported that they prefer receiving primary and gender-specific health care from the same pro-

vider or clinic, in actuality, their care is often fragmented, with different components of care being provided by different clinicians with variable degrees of coordination and expertise in caring for women. Additionally, researchers have found a number of barriers to delivering high quality health care to women veterans. Specifically, insufficient funding for women's health programs; competing local or network priorities; limited resources for outreach; inability to recruit specialists; lower numbers of women veterans' caseloads; limited availability of after-hours emergency health services; and an insufficient number of clinicians skilled in women's health, have been identified as current barriers to care for women veterans.

VA Researchers made several recommendations to address these barriers, including concentrating women's primary care delivery to designated providers with women's health expertise within primary care or women's health clinics; enhancing provider skills in women's health; providing telemedicine-based access to experts to aid in emergency health care decisionmaking; and increasing communication and coordination of care for women veterans using fee-basis or contract care services. We urge this Subcommittee to provide oversight and to monitor VA's progress in this area. We also encourage VA to continue to make women's health a research priority and to develop new knowledge about how to best provide for the health and care of women veterans.

Addressing the Needs of Women Veterans Who Served in OEF/OIF

The challenge of addressing the health care needs of the growing number of women veterans exposed to combat with and without obvious injury is daunting. In the future, the needs will likely be significantly greater with more women seeking access to care, increased health care utilization, and a more diverse range of medical conditions. It is unlikely the past experience of women veterans in the VA will serve as an accurate guide because of the unique experiences and exposures of women veterans who served in OEF/OIF.

Given the increasing role of women in combat deployments, and with more than 70,000 women now having served in the OEF/OIF combat theaters, we are pleased that the Women's Health Science Division of VA's National Center for PTSD (hereinafter Center) is evaluating the health impact of combat service on women veterans, including the dual burden of exposure to traumatic events in the combat theater and the potential of MST. According to the Center, although there is no current empirical data to verify MST is occurring in Iraq at a higher rate than expected, there have been numerous reports in the popular press citing cases of sexual misconduct in theater. In the Center's Women's Stress Disorder Treatment Team, of 49 returning female veterans, 20 (41 percent) reported MST. This is very disturbing to DAV and we believe it warrants greater attention by VA in its research portfolio.

Additionally, the Center notes that anecdotal reports from OEF/OIF veterans suggest a number of unique concerns that have a more direct impact on women than on their male counterparts returning from combat theaters, including lack of privacy in living conditions; sleeping and showering areas; limited gynecological healthcare in theater; healthcare impact of women choosing to stop their menstrual cycle; and health consequences of dehydration and chronic urinary tract infection. Findings also suggest distinct differences occur in homecoming, including that women may be less likely to have their military service recognized or appreciated by their communities; possible differential access to VA treatment services; and increased parenting and financial stress that they must endure.

DAV is pleased that the Center is examining gender differences in mental health; MST in the combat theater; gender differences and other stressors associated with OEF/OIF service and homecoming, including treatment of PTSD in women; enhancing sensitivity toward, and knowledge of, women veterans and their healthcare needs among VA staff; and MST among reserve components of the armed services.

We also understand a number of VA research projects are focused on evaluation of the VA's MST screening and treatment programs including identifying the prevalence of MST and the associated mental and physical health conditions (especially among all VA users and OEF/OIF veterans), establishing the association between MST screening and later use of MST-related treatments, and identifying key characteristics of VA facilities that influence successful implementation of MST screening and treatment practices.

Some women suffer from severe PTSD and will require intensive evidence-based treatment. VA has conducted ground-breaking research on evidence-based treatment for PTSD, including a recent study that established its efficacy for women. While these developments are an important first step, they will only have an impact on the thousands of women veterans affected when these techniques are fully deployed throughout the VA system and easily accessible to providers and patients. This is not currently the case, as acknowledged by the National Center representative in

recent testimony before the President's Commission on Care for America's Returning Wounded Warriors.

We acknowledge that VA is attempting to address the needs of women veterans returning from combat theaters in a variety of ways, and has provided guidance for medical facilities to evaluate the adequacy of programs and services for returning OEF/OIF women veterans in anticipation of gender-specific health issues. However, additional research including improvement in sharing data and health information between DoD and VA is essential to understanding and best addressing the health concerns of women veterans. At this time we do not fully understand the barriers that may prevent OEF/OIF women from accessing VA care. We do know from recent studies of OEF/OIF active duty and reserve component personnel that stigma is a major barrier in accessing mental health services; with over 40% reporting that stigma would impact their decision to seek care. We believe further research is necessary that looks at the barriers that women veterans perceive or have experienced in seeking VA health care.

VA needs to ensure priority is given to women veterans' programs so quality health care and specialized services are made available equally for women and men. VA must continue to work to provide an appropriate clinical environment for treatment, even where there is a disparity. Given the changing roles of women in the military, VA must also be prepared to anticipate the specialized needs of women veterans who were sexually assaulted in military service and/or catastrophically wounded in combat theaters. Although it is anticipated that many of the health problems of male and female veterans returning from combat operations will be similar, VA facilities must address the health issues that pose special challenges for women. DAV has recommended that VA focus its women's health research on finding the health care delivery model that demonstrates the best clinical outcomes for women veterans. Likewise, VA should develop a strategic plan, in conjunction with DoD, to collect critical information about the health status and continuing care needs of women veterans with a focus on evidence-based practices to identify other strategic priorities for a woman's health research agenda.

DAV makes the following research recommendations to better serve women veterans returning from combat theaters.

- VA should conduct research involving recently discharged active duty women and recently demobilized female Reserve component members to assess the barriers that they perceive, or have experienced, to seeking health care through VA. Research should include assessments of the effect of stigma, driving distance to the nearest source of care, lack of child care, understanding of VA eligibility and services, user friendliness of VA services for those who have attempted to access care, cultural sensitivities that differentially affect women, and other key potential barriers.
- VA should quickly disseminate and deploy resources to make evidence-based PTSD treatment easily accessible for women veterans across the country, and explore options for providing child care for those needing it to enable them to achieve access to treatment.
- DoD should fund a prospective, population-based health study of women who served in OEF/OIF. An epidemiologic study with at least a 10-year follow-up period is needed. This study should be carried out by DoD, VA, and University researchers collaboratively.
- VA should conduct a comprehensive assessment of its Women Veterans' Health Programs, including specialized programs for women who are homeless or have substance-use and/or mental health challenges, and develop an action plan to improve services for this population and projected future needs of OEF/OIF women veterans.
- VA should conduct research to fully understand the dual burden of military sexual trauma and combat-related PTSD, and develop the best treatment practices and programs for this population.

Other areas relevant to MST that could benefit from additional research resources:

- Expand evidence-based treatment for mental health conditions associated with MST, beyond PTSD (e.g., depression, substance abuse, eating disorders, and difficulties with sexual functioning).
- Increase research into the physical health co-morbidities associated with MST and how to more effectively work with MST and veterans in the primary care setting.
- Focus on ways in which existing MST treatments can be adapted to for men (In general, men are an understudied population when it comes to MST.)

- More research into barriers both male and female veterans face when trying to access MST-related treatment services.
- Research into the prevalence and consequences of MST during OEF/OIF combat deployments.
- Greater understanding of the phenomenology and dimensions of MST within VA (e.g., what specific harassment and assault experiences are captured by the existing MST screening mechanism.)
- Program evaluation research focused on demonstrating the effectiveness of innovative treatment programs prior to exporting the programs to additional facilities and programs.

Aging Veteran Population

While additional research and resources must be provided to better treat our newest generation of combat veterans, VA stills has a large cohort of aging veterans who served in earlier periods. In that respect, research focused on diabetes, hypertension, heart disease and other chronic illnesses affecting older populations must continue. Also, we are concerned that VA research address the needs of elderly veterans with co-morbid mental health and substance-use disorder problems.

DAV recommends that VA consider research for this population that:

- Addresses the health care needs of aging veterans with traumatic injuries (spinal cord injury, amputations, sensory loss), who now also must cope with the diseases of old age (such as heart disease, diabetes, chronic obstructive pulmonary disease, hypertension, etc.). Clinicians report they are seeing Vietnam veteran population cohorts who are already beginning to experience these problems;
- Develops innovative interventions to aid family caregivers who are providing home-based care for service-injured veterans. This caregiver burden needs to be evaluated to look at ways that the VA can best support them—from the perspective of caregivers who are elderly themselves to our newest generation of family caregivers of severely injured OEF/OIF veterans (e.g., parents, siblings, grandparents and spouses); and
- Supports genomic medicine—additional resources should be provided for VA to expand its new Genomic Medicine Program. VA's electronic medical record system allows VA to longitudinally follow its patient population and is uniquely positioned to develop this new science. Genomics offers the possibility of new, highly targeted patient treatments in the areas of mental health and chronic disease that minimize the effect of adverse reactions to clinical interventions.

Gulf War Veterans

Studies indicate about 30 percent of veterans who served in the Gulf War suffer from unexplained medical symptoms and illnesses termed Gulf War Illnesses. In 2004, then VA Secretary Principi committed up to $15 million per year for 5 years for Gulf War Illnesses research. The following year VA Secretary Nicholson announced a funding increase and establishment of a research treatment center and a pilot program to further study and treat veterans suffering with Gulf War Illnesses. Additionally, the Fiscal Year 2006 Defense Appropriations Act provided $5 million to DoD's Gulf War Veterans' Illnesses Research Program administered through the Office of Congressionally Directed Medical Research Program. The seed money for this program attracted a remarkable number of proposals (80) indicating significant interest to find effective and immediate treatment for Gulf War illnesses; however, DoD has excluded additional funding for the program from its proposed 2008 budget.

VA's own Research Advisory Committee for Gulf War Veterans Illnesses notes little effort has been made to utilize VA's heralded group of research clinicians currently treating Gulf War veterans. No mechanism is currently in place for compiling data on treatments and outcomes documented in the medical records of ill veterans seen by these VA clinicians. Additional research is needed to explore and compile good health outcomes related to efficacious treatments that are used in treating ill Gulf War veterans and to share best practices with other VA facilities.

We believe that while research into causative factors should continue, efforts should be made toward more research into treatments and interventions that take into account all effective treatments being used by VA clinicians for this population, since roughly 200,000 veterans have been suffering from Gulf War illnesses for over 16 years.

Minority Veterans

For many years, the VA has expressed its commitment to eliminating ethnic and racial disparities in health care to ensure equal access and quality health care for

all veterans using VA services. In June 2007 the VA Health Services Research and Development Service (HSR&D) released a new report, *Racial and Ethnic Disparities in the VA Healthcare System: A Systematic Review.* This research examined a number of clinical interests including: arthritis and pain management; cancer; cardiovascular diseases; diabetes; HIV and Hepatitis C; mental health and substance abuse; preventative and ambulatory care; and rehabilitative and palliative care. The study concluded that disparities appear to exist in all clinical arenas, and a number of hypotheses were suggested to explain why disparities exist. More notably, researchers commented in nearly each case that the underlying causes of disparities in care and outcomes were not fully explored or remained unclear. One key finding was that in studies examining quality indicators representing immediate health outcomes—such as control of blood sugar, blood pressure, or cholesterol—minority veterans generally fared worse than Caucasians. The researchers noted that this finding was especially troubling since it may indicate that disparities in health care delivery contribute to disparities in health outcomes. It was also noted that fewer studies examined Hispanics, American Indians, and Asians and that in general, disparities in the VA appear to impact African American and Hispanic veterans most significantly.

The study relates specific sources of disparities and offers a number of future research recommendations to further elucidate and reduce or eliminate racial disparities in VA health care. It is clear from this study that much more needs to done in this area; therefore, we encourage VA to continue this important research.

Conclusion

In closing, the Veterans Health Administration is a unique health care system with much to offer its large and diverse patient population. And from its earliest days, research has been an integral part of VA's overall mission, while maintaining a veteran-centric focus. Today, the VA system offers veterans the "best care anywhere" as reported by independent researchers, the Institute of Medicine, health industry experts and numerous media outlets. Millions of the nation's sick and disabled veterans need and depend on the VA health care system to help them overcome severely disabling injuries suffered during their military service. We urge VA to press forward and to remain on the cutting edge of health care through its esteemed research program, and we encourage this Subcommittee to maintain necessary oversight of VA's research and to provide sufficient funding so that VA can improve services and health outcomes for sick and disabled veterans as it continues its quest for excellence.

Mr. Chairman, this concludes my testimony and I will be happy to address questions from you or other Members of the Subcommittee.

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Mr. Chairman and members of the Subcommittee, thank you for the invitation to appear before you today to discuss the Department of Veterans Affairs (VA) medical and prosthetic research program. I appreciate this opportunity to discuss the vital role VA research and development has in ensuring the health and well-being of our Nation's veterans. With me are Dr. Timothy O'Leary, Director of Biomedical Laboratory and Clinical Science Research and Development, and Dr. Michael Selzer, Director of Rehabilitation Research and Development.

Introduction

Let me first say that the future of medicine is determined by research. Just as the advances in medicine that save and improve lives today would not have occurred without yesterday's research, the advances in medicine that we have all grown to expect will not occur without today's and tomorrow's research.

Dating back more than 80 years, VA research has been a valuable investment with remarkable and lasting returns for veterans and the Nation as a whole. I am sure that you are familiar with the many awards won by VA investigators—3 Nobel prizes, 6 Lasker awards, and many others. But what is more important is the large number of treatments and procedures that have been developed and effectively proven by VA investigators. VA research has taken special advantage of its connection to clinical care and is replete with examples of how it has improved care, including:

- Developing numerous advances in prosthetics, including better-fitting and lighter artificial limbs, prosthetics that can sense, artificial hands that are capable

of very fine motion, a biomechanical foot, and the Seattle foot—a great early example of these advances;
- Pioneering understanding of and treatment for post-traumatic stress disorder (PTSD), including exciting new treatment advances proving the effectiveness of prolonged exposure therapy and a drug to significantly reduce trauma nightmares and other sleep disturbances in PTSD;
- Identifying genes associated with Alzheimer's disease and premature aging;
- Laying the groundwork for the development of the computerized axial tomography (CAT) scan;
- Pioneering research efforts leading to new home dialysis techniques;
- Developing the nicotine patch and other therapies to help smokers quit;
- Developing the cardiac pacemaker and many other advances for abnormalities of heart rhythm, high blood pressure, and coronary artery disease; and
- Developing a system that decodes brain waves and translates them into computer commands that allow tetraplegics to perform simple tasks like turning on lights and opening e-mails by using only their minds.

VA's Cooperative Studies Program deserves special mention. It has received national media attention for its groundbreaking work improving treatment for a host of critical medical conditions, including:

- A series of studies that established the cornerstone for treatment of hypertension;
- One of the first studies to ascertain the long-term effects of coronary artery bypass surgery;
- An investigative study on the use of cortisone to treat patients with septic shock;
- A landmark study that showed aspirin reduces deaths and heart attacks in patient with unstable chest pain;
- A vaccine for shingles;
- New innovative drugs and therapies to treat PTSD; and
- A study that showed balloon angioplasty plus stenting did little to improve outcomes for patients with stable coronary artery disease who also received optimal drug therapy and underwent lifestyle changes.

But past success is never enough. Research must be future-oriented. VA's research program builds on its past by identifying and confronting the important questions and challenges of today and conducting the hard work to find solutions for the future.

VA Research as a Unique Laboratory

A particular advantage of VA research is that it is an intramural program where clinical care and research occur together under one roof. For this reason, VA has the capacity to bring scientific discovery from the patient's bedside to the laboratory bench and then back to the care of patients, making this program one of VA's most effective tools to improve the care of veterans. Embedding research within an integrated health care system with a state-of-the-art electronic health record creates a national laboratory for the discovery of new medical knowledge and the translation of that knowledge into improved health. Furthermore, the opportunity to conduct research assists VA in recruiting outstanding clinicians and creates a culture of continuous learning and innovation ensuring VA's continued leadership in health care.

Additionally, VA research has a unique program, the Quality Enhancement Research Initiative (QUERI), which creates durable partnerships between VA researchers, clinicians, and policy-makers to accelerate the implementation of research evidence into routine practice. Allow me to give you one example of this innovative program—administration of influenza and pneumococcal vaccine to individuals with spinal cord injury. People with spinal cord injury are at higher risk for influenza and pneumonia. To increase these patients' rates of vaccination, VA QUERI investigators partnered with VA clinical leaders in spinal cord injury. Working together, they increased the rate of influenza vaccination from 28 to 61 percent, and the rate of pneumonia vaccination from 40 to 79 percent. These improvements continued even after the initiative ended, with the vaccination rates reaching 72 and 86 percent, respectively, when last measured.

This advance for veterans with spinal cord injury can be attributed to researchers working within VA's health delivery system to improve the process of care. I think this exemplifies the value of having research and clinical care "under one roof", working together to improve the delivery of care.

Priorities of VA Research

Each year we re-evaluate our priorities based on the changing needs of the veterans we serve, and strive to fund the highest quality science that meets those priorities. The following are some of the current priority areas for VA research:

- Research related to Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) veterans and deployment health;
- Mental health;
- Personalized medicine;
- Chronic diseases;
- Access to care;
- Long-term care; and
- Women's health.

Details about these priority areas are given below.

Research Related to Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) Veterans and Deployment Health

VA has implemented a comprehensive research agenda to develop new treatments and tools for clinicians to ease physical and psychological pain, improve access to VA health care services, and address the full range of health issues of OEF/OIF veterans. This research also has direct relevance for veterans of other conflicts, as well as for civilians suffering from disability due to injury or disease.

Specific areas of focus in OEF/OIF and deployment health related research include:

- *Traumatic Brain Injury (TBI) and Other Neurotrauma*

Although Kevlar helmets and improved body armor save lives, they do not protect against blasts and impacts to the head, face, and cervical region of the spinal cord. Those that survive blast force and impacts may suffer injuries to internal organs, limb loss, sensory loss, paralysis, cognitive loss, chronic pain, and psychological disorders.

To advance the treatment and rehabilitation of soldiers returning with these types of injuries, VA issued a request for research proposals that focus on TBI; cervical spinal cord injury (SCI); co-morbid conditions such as PTSD and trauma to extremities; screening and diagnostic tools related to mild TBI, especially field-based; and continuity of care between the Department of Defense (DoD) and VA. Applicants were asked to pay special attention to cooperative projects with DoD.

Many exciting projects have emerged from this solicitation and other funding mechanisms to help veterans suffering from TBI, including: (1) studying neural repair after brain injury to build a better understanding of cognitive rehabilitation, as well as find potential targets for practical treatments that enhance quality of life; (2) developing a project exploring community re-integration for servicemembers with TBI (to promote seamless transition between servicemembers currently being treated, or who will one day be treated, in both DoD and VA medical facilities); and (3) several studies assessing the relationship between TBI and PTSD and their impact on health outcomes.

In addition, several VA scientists with expertise in neuroimaging and neuropsychology are turning their efforts to further understanding the brain changes that occur in TBI. This is important because following TBI there may be subtle or distinct brain damage that results in memory, attention, thinking, and personality changes that are difficult to diagnose and treat with current knowledge. A new study will start this year combining state-of-the-art imaging techniques (e.g., three-dimensional brain imaging and diffuser tensor imaging to examine white matter changes) with comprehensive neuropsychological assessments to fully characterize patients with TBI compared to other types of brain damage such as stroke. Knowledge from this study will help inform rehabilitation and diagnostic strategies.

VA researchers are also studying many ways to help veterans with SCI. Investigators are developing practical functional electrical stimulation systems that may allow individuals with incomplete SCI to walk. VA researchers are also preparing to conduct clinical studies of a neuroprosthetic system for restoration of hand–arm function in veterans with a cervical level SCI. It is hypothesized that users will demonstrate significant improvements in their pinch strength, range of motion, and their ability to perform grasp-release tasks with their hands and also show better control of their forearms and elbows. VA investigators are also testing microstimulators to recreate breathing and coughing patterns that will avoid respiratory complications which are currently the leading cause of death in SCI patients. Further, VA researchers are continuing to improve the mobility and function of veterans with

SCI and other disabilities through innovative engineering for wheelchairs and other assistive technologies.

In one exciting study, VA researchers and others recently demonstrated that a neuromotor prosthesis (NMP) could enable a tetraplegic to operate an artificial hand, robotic arm, computer, or television by using only his thoughts (*Nature*. 2006; 442(7099):164–171). A NMP is a brain-computer interface that helps replace or restore lost movement in paralyzed patients. This technology uses an electrode that picks up brain signals and sends them to a computer for decoding. The brain signals are translated into commands to power electronic or robotic devices, including prosthetics.

One of the most common conditions in returning OEF/OIF veterans due to blast exposure is tinnitus (ringing noise in the ear). VA researchers are developing a diagnostic test to identify this condition, which is currently done by self-report. In collaboration with DoD, VA investigators are planning a study to determine which auditory processing disorders are more often associated with exposure to high-explosive blasts, whether there is spontaneous recovery of auditory function after blast exposure, how much recovery may be expected, and how rapidly it occurs.

In addition, VA investigators are developing behavioral strategies to cope with conditions of low vision and blindness. VA researchers also continue to make progress on the development of an artificial retina for those who have lost vision due to retinal damage. As reported in one recent publication, the threshold electrical current needed to stimulate the retina of a rabbit in which the device was implanted was very low (*Journal of Neural Engineering*. 2005; 2(1):S48–S56). This was encouraging because using lower currents would reduce the chance of damage to surrounding eye tissue. Analogous approaches may prove useful in combat-related vision loss.

- *Combat-related Mental Health*

Among active duty Army and Marine Corps personnel who participated in combat during OEF/OIF, 11.2—17 percent reportedly met screening criteria for major depression, generalized anxiety disorder, or PTSD. These areas of readjustment mental health disorders are actively being pursued in ongoing VA research.

In a landmark ongoing study, VA researchers, collaborating with DoD, are collecting risk factor and health information from military personnel prior to their deployments to Iraq. These soldiers will be reassessed upon their return, and several times afterward, to identify possible changes that occurred in emotions or thinking following their combat duty in Iraq and to identify predisposing factors to PTSD as well as other health conditions. To date, researchers have already reported that troops who had served in Iraq showed mild deficits in some tasks of learning, memory, and attention, but scored better on a test of reaction time, compared with non-deployed troops. The researchers have proposed longitudinal follow-up studies to determine if these neuropsychological effects might fade over time, or be a precursor to PTSD (*Journal of the American Medical Association*. 2006; 296(5):519–529). An additional goal for this research is to examine the neuropsychological associations of TBI with the development of PTSD at long-term follow-up.

Veterans with PTSD commonly experience nightmares and sleep disturbances, which can seriously impair their mood, daytime functioning, relationships, and overall quality of life. In an exciting new treatment development, VA investigators have found that prazosin, an inexpensive generic drug already used by millions of Americans for high blood pressure and prostate problems, improved sleep and reduced trauma nightmares in a small number of veterans with PTSD (*Biological Psychiatry*. 2007; 61(8):928–934). Plans are under way for a large, multi-site trial to confirm the drug's effectiveness.

One of the more interesting recent findings in PTSD research being pursued in the field now is the idea that traumatic memories may be "extinguished" or weakened with a medication administered as the memory is "replayed" or reactivated under controlled circumstances. A small clinical trial is being conducted to determine whether the drug, propranolol, is more effective than a placebo in reducing PTSD symptoms such as hyper-arousal, re-experiencing, or avoidance when a distressing memory is reactivated. Research participants will be veterans of the Iraq or Afghanistan conflicts.

In addition, VA investigators are currently conducting the first ever clinical trial of a medication to treat military service-related chronic PTSD. It will also be the largest placebo controlled, double-blind study of its kind ever conducted, meaning that it is the most rigorous type of clinical trial. It will involve 400 veterans diagnosed with military-related chronic PTSD from 20 VA medical centers (VAMCs) nationwide. The main objective of the study is to determine if risperidone is effective

in veterans with chronic PTSD who continue to have symptoms despite receiving standard medications used for this disorder.

Risperidone is being studied since it has been shown to be safe and has received the most study in the treatment of PTSD patients.

• *Pain*

Veterans from all eras may experience chronic pain related to traumatic injuries. Accordingly, VA has issued a solicitation for research proposals that seek to develop novel approaches for the treatment and management of chronic pain associated with TBI, SCI, amputation, and burn injury that may result from OEF/OIF deployment as well as multiple sclerosis and other disorders.

Excruciating pain is experienced by more than 50 percent of patients after SCI. VA investigators have identified a particular form of sodium channel (of which there are more than 10) responsible for conveying pain signals to the brain (*Nature.* 2006; 444(7121):831–832). VA researchers are now exploiting this finding to develop a new pain treatment.

In addition, VA and DoD are jointly funding a study to examine the short- and long-term benefits of implementing early advanced regional anesthesia techniques for pain control following major traumatic injuries to extremities encountered during OEF/OIF combat. It is hoped that these techniques will result in a significant reduction in pain disability as well as in the incidence and severity of mental health disorders due to early pain intervention on the battlefield.

It is well-known that limb trauma causing fractures and/or nerve injuries can lead to the development of a disorder called complex regional pain syndrome (CRPS). To address this issue, VA researchers have developed a rat fracture model resembling CRPS. Using molecular approaches, the investigators will attempt to characterize chronic changes in key mediators such as cytokine signaling after limb trauma, which will demonstrate the feasibility of promising new treatments for post-traumatic pain and inflammation. This work could potentially be an important step toward the ultimate goal of improving clinical efficacy and safety in the pharmacologic management of CRPS.

• *Prosthetics and Amputation Health Care*

While nearly two-thirds of adult amputations may arise due to peripheral vascular disease of the lower extremity, they are complemented by those necessitated by trauma, in the present case, the trauma related to high explosive blasts or through other combat scenarios. High-impact explosive trauma from improvised explosive devices has become the signature injury of the OEF/OIF theaters.

Tendon losses are common in military trauma and in degenerative diseases such as rheumatoid arthritis and osteoarthritis. In mutilating injuries, a tendon grafted from another part of the individual's body may improve function; however, only a limited supply of these tendon grafts exists. VA investigators are working to create biocompatible tissue-engineered tendon grafts, which will have wide applicability in improved reconstruction of extremities for veterans.

In addition, joint cartilage may be lost or degenerated as a result of trauma, disease, or aging, which leads to reduction in mobility and quality of life. VA investigators are using tissue engineering methods to develop an implant that can help regenerate cartilage.

The care of the wounds following amputations has been the subject of extensive research. This type of wound care is particularly challenging, owing more to the conditions surrounding the original injury than those of the surgery. VA researchers are investigating three management strategies in current standard of care for residual limbs after surgery: (1) soft dressings, (2) rigid plaster dressing, and (3) commercial prefabricated rigid prostheses. Studies of this nature are critical to a better understanding of wound care in a variety of settings extending from the "dirty" wound characteristic of a roadside bombing all the way to the healing capacities in an elderly diabetic veteran. These kinds of studies can potentially improve outcomes of amputations and burns. Most critically, improved wound healing methodologies actually have the potential to minimize the need for amputation itself.

VA researchers are also developing improved materials and designs of prostheses. In addition, VA investigators are gathering information about how prosthetic devices are used, amputee satisfaction, comparisons of selected prosthetic devices, associated costs, and various prosthetic procurement alternatives, so VA can better match technology to an individual veteran's needs.

Another project that is under way involves building a new flexible externally powered two-degree-of-freedom prosthetic wrist for use in upper-extremity prostheses. This will provide prosthetic users with electric-powered prosthetic components that

interact with objects in a more lifelike fashion and devices that will be more robust and less prone to mechanical failure.

Currently available prostheses for trans-tibial (below the knee) amputees do not help promote normal walking; in fact, their "passive" design can result in balance difficulties and slow walking speed. VA has funded research that addresses this problem by developing a powered ankle–foot prosthesis that promises to help restore amputees' ability to walk normally. A preliminary study involving three trans-tibial amputees confirmed the benefits of the new prototype: the patients expended less energy during walking, had fewer balance problems, and walked 15 percent faster. This device has recently received significant media attention.

• *Polytrauma*

As a result of new modes of injury (improvised explosive devices), improved body armor, and surgical stabilization at the frontline of combat, more soldiers are returning with complex, multiple injuries ("polytrauma"), including amputations, brain and spinal cord injuries, eye injuries, musculoskeletal injuries, vision and hearing loss, burns, nerve damage, infections, and emotional adjustment problems.

In response, VA has established a Polytrauma and Blast-Related Injury (PT/BRI) QUERI coordinating center to promote the successful rehabilitation, psychological adjustment, and community reintegration of these veterans. Two priorities have been identified: (1) TBI with polytrauma, and (2) traumatic amputation with polytrauma. The primary target is OEF/OIF VA patients, many of whom remain on active duty during their initial course of treatment in VA. However, the center's activities will benefit all VA patients with complex injuries, regardless of service era and mechanism of injury.

The PT/BRI QUERI is working closely with VA Polytrauma Rehabilitation Centers (PRCs) to identify needs and gaps in care, as well as best practices. For example, one needs assessment study found that PRC patients are demographically and clinically different from inpatient rehabilitation patients treated before OEF/OIF. The systems of care, facilities, and individual health care teams are rapidly changing to meet the needs of these unique patients.

VA also recently issued a special solicitation for research projects on the long-term care and management, including family and community reintegration, of veterans with polytrauma, blast-related injuries, or TBI.

• *Gulf War Veterans' Illnesses*

While there were few visible casualties associated with the 1990–1991 Gulf War, many individuals returned from this conflict with unexplained medical symptoms and illnesses. Nonspecific symptoms such as fatigue, weakness, gastrointestinal difficulties, cognitive dysfunction, sleep disturbances, headaches, skin rashes, respiratory problems, and mood changes that often occur together in a constellation have been termed Gulf War veterans' illnesses (GWVI). Despite a large number of studies and considerable funding over the past decade, the causes and successful treatment of GWVI remain illusive. VA continues to expand its efforts to understand and treat GWVI.

There is also persistent concern that Gulf War veterans may be at increased risk for amyotrophic lateral sclerosis (ALS, also known as Lou Gehrig's disease), multiple sclerosis (MS), and brain cancer, as a result of their service. In addition to the studies that examine the causes and treatment of these diseases in the general veteran population, VA is funding studies to examine them specifically in Gulf War veterans. Accordingly, VA is supporting a broad research portfolio composed of studies dedicated to understanding chronic multi-symptom illnesses, long-term health effects of potentially hazardous substances to which Gulf War veterans may have been exposed to during deployment, and conditions or symptoms that may be occurring with higher prevalence in Gulf War veterans.

Beyond OEF/OIF and deployment health related research, VA's research priorities include several areas affecting the larger veteran population, including:

Mental Health Research

In addition to combat-related mental health, VA continues to support a strong behavioral and psychiatric disorders research portfolio focused on further understanding and treating mental health problems in veterans. Investigations are directed toward substance abuse, PTSD, adjustment and anxiety disorders, psychotic disorders, dementia and memory disorders, and related brain damage. Many laboratory studies are being conducted to better understand the changes that take place when someone is suffering from adjustment problems or mental illness. Clinical trials are under way to test novel drug and therapy treatments specifically targeted to help veterans. Additionally, VA has a strong program for developing and implementing better mental health care, including enhancing collaborative care models,

improving access to mental health care through innovations such as telemedicine and the Internet, and reducing barriers to veterans seeking mental health care. Several ongoing projects are investigating how veterans with mental illness might benefit from rehabilitation approaches, including vocational rehabilitation, skills training, and cognitive therapy to improve everyday functioning and work performance. Future research will enable VA to determine how to care for veterans with mental illness so that they can return to their highest level of functioning.

Personalized Medicine

Personalized medicine means tailoring care to the individual, in this case the veteran. In 2006, VA launched the Genomic Medicine Program as part of its Personalized Medicine Initiative. Genomic medicine is **the** direction for health care in the twenty-first century. It could allow VA to provide care that is tailored specifically to the genetic makeup of individual veterans, increasing the effectiveness and safety of health care and disease prevention efforts. Currently, VA is funding over 140 research projects related to genomics. These include studying the complete set of DNA of many people to determine what genetic changes are associated with a certain disease (genome-wide scans), the role of specific genes, and genetic determinants of variable responses to drugs (pharmacogenomics). These studies are investigating the role of genetics in many diseases of importance to veterans—including psychiatric disorders (e.g., schizophrenia, depression, PTSD, and anxiety); cancers of the prostate, breast, colon, lung, and bladder; heart disease; diabetes; Alzheimer's disease; stroke; Parkinson's disease; autoimmune disorders, including rheumatoid arthritis and lupus; GWVI; and chronic viral infections such as HIV.

VA investigators recently conducted a genome-wide search for schizophrenia susceptibility genes. The study included 166 families with more than two affected individuals, from seven VAMCs. There are 216 affected sibling pairs in these families, comprising the largest North American sample of schizophrenic sibling pairs to date. Preliminary data from the researchers' genome scan suggest the involvement of a small region on chromosome 18. The team will continue to narrow the search by fine-mapping this region and seeking specific genes.

VA has established a Genomic Medicine Program Advisory Committee (GMPAC) comprised of the nation's leading clinicians, scientists, administrators, as well as veteran representatives. The Committee has recommended the establishment of several working groups. It has also discussed issues such as who should have access to data generated by this program, assessment of veterans' attitudes toward genomic medicine, and establishing veterans' trust.

An Ethics Advisory Working Group, which will report through the GMPAC, has also been established. Members of this working group include bioethicists, a member of the clergy, and veterans. The first meeting of this group was in May 2007. Topics of discussion included the ethics of the informed consent document, special populations (e.g., those with mental illness), and the role of group vs. one-on-one discussions for educating veterans about the program.

In addition, last week VA held the first meeting of its PTSD Genetics Working Group to explore and define a research program to identify the genes that are important in how an individual responds to the experience of deployment, especially their response following combat exposure. By carefully characterizing those affected by combat-related PTSD and conducting genetic analyses, VA will be in a position to identify genetic variants that contribute to PTSD and other post-deployment adjustment disorders such as major depression. Once this program is established, this resource will be available for continued research including studying the genetic relationship to treatment response.

Chronic Diseases

Promoting good health and managing chronic conditions remain high priorities for VA health care and VA research, especially in the aging veteran population. The following are examples of efforts by VA investigators to discover how to prevent and treat chronic diseases.

- *Diabetes*

Nearly a quarter of the veterans receiving care from VA have diabetes, and a far greater number (73 percent) are at risk due to overweight or obesity. VA researchers are studying innovative strategies and technologies—including group visits, telemedicine, peer counseling, and Internet-based education and case management—to improve access to effective diabetes care and outcomes. In addition, VA investigators have initiated studies to identify and define the impact of traditional rehabilitation treatment for veterans who have diabetes, and to develop innovative treatments to prevent and improve diabetes outcomes in special populations such as the elderly, amputees, minorities, and spinal cord injured veterans. VA is also supporting major

clinical trials on treating kidney disease and coronary artery disease in diabetic patients.

It has been long known that type 2 diabetes runs in families and that certain populations are at a higher risk than others (e.g., Hispanic veterans and American Indian veterans). However, it was not until the recent advances in genetic technologies that researchers began to investigate associations between specific genes and diabetes.

VA investigators have been honing in on genes that boost the risk for type 2 diabetes and obesity. Working with Mexican-American families enrolled in the Veterans Administration Genetic Epidemiology Study, VA investigators have compared small differences in the DNA of people with and without the disease. Earlier work by members of the group had suggested that a specific region of chromosome 6 was involved. This region contained several hundred genes, and initially it was not clear which gene played a role in causing disease. But using recent advances in genome-sequencing, the researchers have combed through the region and narrowed their search to seven genes. The precise functions of these genes are still unknown. Two are involved in metabolic pathways not previously connected with diabetes or obesity. The remaining five appear to be "master regulators" that can alter the expression of hundreds of other genes. Ongoing research is aimed at determining how these genes raise the risk of diabetes and obesity.

- *Obesity*

The VA patient population, like that of the U.S. in general, is experiencing an epidemic of overweight and obesity. In terms of treatment options, recent findings from VA investigators indicate that surgical treatment is more effective than diet and medications for weight loss in severely obese patients. Weight loss was maintained for up to 10 years or longer, and it was accompanied by significant improvements in diabetes, hypertension, and high cholesterol (*Annals of Internal Medicine.* 2005; 142(7):547–559; *Annals of Internal Medicine.* 2005; 142(7):532–546).

Ongoing VA studies are seeking to identify and define the impact of traditional rehabilitation treatment for overweight and obese veterans, and also to develop unique treatment measures to prevent and improve obesity outcomes. In addition, VA researchers are investigating the influence of obesity on the quality of care that veteran patients receive. VA investigators are also focusing on unique populations at risk for obesity, such as patients with spinal cord injury.

- *Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS)*

VA is the largest single provider of HIV care in the U.S., with nearly 20,000 patients with the disorder treated annually. Accordingly, VA funds a full range of studies from bench research aimed at elucidating the underlying mechanisms of HIV to implementation projects that improve VA's effectiveness in caring for this population.

VA investigators recently showed that people with a below-average number of copies of a particular immune-response gene have a greater likelihood of acquiring HIV and, once infected, of progressing to full-blown AIDS. Researchers examined blood samples from 4,308 HIV-positive and HIV-negative volunteers of various geographical ancestries. Depending on the study sub-population, each copy of the gene CCL3L1 decreased the risk of HIV infection by 4.5 to 10.5 percent. These findings, cited as one of the top articles published in the eminent journal *Science* in 2005, have important implications for the treatment and prevention of HIV infection and AIDS, and possibly other infectious diseases as well (*Science.* 2005; 307:1434–1440).

The same group has gone on to show that a person's genetic makeup—in this case, the genes CCL3L1 and CCR5—could be a more accurate predictor of disease progression than currently used laboratory markers, such as CD4+ T cell counts and viral loads. The researchers also demonstrated that the combination of laboratory and genetic markers captures a broader spectrum of AIDS risk than either set of markers alone (*Journal of Immunology.* 2007; 178:5668–5681).

- *Heart Disease*

Heart failure is the most common diagnosis causing hospitalization of veterans, with resulting high costs and resource utilization over time. VA researchers recently found that the use of an implanted defibrillator reduced the risk of dying and improved quality of life for veterans with heart failure (*Journal of the American College of Cardiology.* 2005; 45(9):1474–1481). VA researchers are also studying non-invasive care for heart failure. In addition, nurse researchers are preparing to link biochemical markers of heart failure with patterns of depression to aid in earlier screening and treatment for depression in patients with heart failure. Nurse re-

searchers are also exploring the role patients can play in their own heart failure care.

Coronary artery disease, a narrowing of the arteries that supply blood to the heart muscle, is the leading cause of death in both men and women. More than half a million Americans die each year from coronary artery disease.

A U.S.-Canadian trial sponsored in part by VA's Cooperative Studies Program found that balloon angioplasty plus stenting did little to improve outcomes for patients with stable coronary artery disease who also received optimal drug therapy and underwent lifestyle changes. The researchers concluded that if a patient with heart disease is doing well on medical therapy alone, there is no added preventive benefit to angioplasty and stenting (*New England Journal of Medicine.* 2007; 356:1503–1516).

Access to Care

VA has a prominent and unique role in meeting the health care needs of veterans and ensuring equitable access to quality care for the most recent veterans, veterans from previous service eras, vulnerable populations who rely on VA for health care, and future veterans. The VA health care system continues to strengthen efforts to improve health care to veterans by identifying barriers to care and assessing and implementing system improvements to improve access to quality care. VA research supports and guides these system improvements through a diverse range of studies that analyze factors and interventions impacting access to the VA health care system. VA research identifies system-wide gaps in care to veterans; assesses specific access issues and barriers to care for special populations; assesses the impact of new programs, practice structures, and organizations of care on access and quality of care; and develops and evaluates the impact of quality improvement efforts, organizational and management interventions, implementation initiatives, and new technologies on improved access and health care to veterans.

Over the past decade, VA has added to the number of Community-Based Outpatient Clinics (CBOCs) to increase access to primary care for veterans. CBOCs have been an integral part of VA's transition from an inpatient-oriented system to an outpatient-oriented system. A VA study compared inpatient and outpatient utilization and expenditures of veterans seeking primary care in 108 CBOCs and 72 affiliated VAMCs in fiscal years 2000 and 2001. Findings show that CBOCs provided veterans with improved access to primary care and other services, but costs were contained because they had fewer health care visits and hospital stays than veterans receiving care at VAMCs. These results held even after adjusting for demographics, patient risk, and distance from care. CBOC patients had significantly lower odds of having specialty, mental health, or ancillary (e.g., radiology, laboratory, other outpatient) visits than VAMC patients. CBOC patients also were less likely to be hospitalized *(BioMed Central Health Services Research;* 7(1):56).

Evidence-based practices designed for large urban clinics are not necessarily transportable into small rural practices. Implementing collaborative care for depression in small rural primary care clinics presents unique challenges because often on-site mental health specialists cannot be hired. The Telemedicine-Enhanced Antidepressant Management (TEAM) study evaluated a collaborative care model adapted for small rural VA CBOCs using telemedicine technologies (interactive video equipment for mental health and no on-site psychiatrists/psychologists). Participants in the intervention had better medication adherence, were more likely to respond to treatment, and were more likely to experience a remission than those with usual care. Patients also had better quality of life and higher satisfaction. These findings suggest that collaborative care models can be successfully adapted using telemedicine to address rural disparities (*General Hospital Psychiatry.* 2006; 28(1):18–26; *Psychiatric Services.* 2006; 57(12):1731–7).

In addition, VA is beginning a new access to care research initiative for OEF/OIF veterans that will build on the body of VA research examining access to care issues and innovations. This research is expected to enhance OEF/OIF veterans' access to practices that improve well-being and function after physical injury sustained in war, that mitigate suffering due to chronic medical conditions, and that are effective for the treatment needed by veterans returning from the wars in Iraq and Afghanistan. It is hoped that VA's OEF/OIF access research initiative will help facilitate improved access to care for eligible veterans and more efficient and effective systems of care that meet the health care needs of the OEF/OIF veteran population.

Long-term Care

Meeting the long-term care needs of veterans is growing in importance as the number of veterans most in need of these services—those 85 years old and older—is expected to reach 1.3 million by 2012. In addition, a younger population of vet-

erans with different long-term and care coordination needs is emerging as a result of the OEF/OIF conflicts.

Many veterans prefer to receive long-term care in non-institutional settings, so they can stay connected with their community and loved ones. However, the success of such long-term care is critically dependent on the ability of veterans' family and friends to assist in their care. Caregiver burden is common and frequently limits the ability of family and friends to provide assistance. Caregiving can also have significant negative consequences on the health and well-being of caregivers, yet little is known about how to ameliorate the impact of the burden of care. VA has initiated several efforts to understand and support the needs of caregivers. These include special efforts to survey the needs of caregivers of blast injury and TBI patients, as well as a research initiative focused on developing new approaches to community-based long-term care.

In addition, VA is funding several projects to assess the effectiveness of telemedicine technologies for rehabilitation of veterans who are older, disabled, and/or in difficult to reach, rural areas as compared to home visits by health care personnel and usual care. Tele-rehabilitation may be particularly useful for older and disabled veterans with long-term care needs because it empowers them to take responsibility for their own health by providing ongoing communication with the VA health care system and may allow them to remain independent in their homes as long as possible.

Women's Health

In response to the increasing number of women veterans, documented expansion of the number of women in the military, and special health care needs of female veterans, VA has focused additional attention on women's health research. VA research efforts are aimed at better understanding the general health care needs and service utilization of women veterans; examining the unique experiences of women veterans regarding risks, treatment, and health care outcomes related to military traumas; and assessing VA's organization of care for women veterans and the implications for improved quality of care.

Examples of VA research studies relevant to women veterans' health include further understanding the cellular mechanisms underlying breast and cervical cancers, the role of hormones in stroke and aging, further characterizing basic neurobiological changes in women who have undergone severe trauma, and specific prosthetic designs for women.

In the largest randomized clinical trial to date involving women veterans with PTSD, VA investigators and colleagues found that prolonged-exposure therapy—a type of cognitive behavioral therapy—was effective in reducing PTSD symptoms and that such reductions remained stable over time. Women who received prolonged-exposure therapy—in which therapists helped them recall their trauma memories under safe, controlled conditions—had greater reductions of PTSD symptoms than women who received only emotional support and counseling focused on current problems (*Journal of the American Medical Association.* 2007; 297(8):820–830). Together with a strong mental health research program, VA research is well positioned to continue to enhance health care for women veterans.

Conclusion

Because more than 70 percent of VA researchers are also clinicians caring for veterans, VA is uniquely positioned to move scientific discoveries from investigators' laboratories into patient care. In turn, VA clinician investigators can identify new research questions for the laboratory at the patient's bedside, making research one of VA's most effective tools to continue improving the care of veterans. The fundamental goal is to address the concerns of the entire veteran population from the youngest soldier who returns with injuries from recent conflicts to the aging veteran, and to use research findings proactively to benefit the future veteran. VA takes great pride in the research that keeps it at the forefront of modern medicine and health care and expects to see further remarkable discoveries in the coming decades.

Mr. Chairman, that concludes my statement. I am pleased to respond to any questions you or the Subcommittee members may have.

Thank you.

Statement of National Association of Veterans' Research and Education

The National Association of Veterans' Research and Education Foundations (NAVREF) appreciates the opportunity to submit a statement for the record of the hearing being conducted on October 4, 2007, by the Health Subcommittee of the House Committee on Veterans Affairs regarding the Department of Veterans Affairs (VA) Medical and Prosthetic Research program.

NAVREF is the voluntary membership association of the VA-affiliated nonprofit research and education corporations (NPCs) established and operated in accordance with 38 U.S.C. §§73617368. NAVREF's mission is to promote high quality management and communication among the NPCs, and to pursue issues at the government level that are of interest to its members. NAVREF accomplishes this mission through education, interactions with agency and congressional officials, and advocacy. Additional information about NAVREF is available on its Web site at www.navref.org.

Background About the NPCs

In 1988, Congress allowed the secretary of the Department of Veterans Affairs to authorize "the establishment at any Department medical center of a nonprofit corporation to provide a flexible funding mechanism for the conduct of approved research and education at the medical center." [38 U.S.C. §7361(a)] At this time, 85 facilities are taking advantage of this authority, providing each VAMC with a highly valued means for administering non-VA federal and private sector funds in support of VA research and education.

We encourage the Subcommittee to review the VA's most recent report on the NPCs which VA submitted to Congress in accordance with requirements stated at 38 U.S.C. §7366(b) through (d). This compilation of information provided by NPCs presents a comprehensive overview of NPC revenues and expenditures, the activities they support and the oversight provided by VA through the VA NPC Program Office and the VA NPC Oversight Board as well as annual audits by independent auditors. This report demonstrates that NPCs have become an integral component of VA facility research programs, administering $227 in non-VA federal and private sector revenues and approximately 5000 projects at any one time during the last year.

NPCs are fully dedicated to serving the needs of VA research and VA investigators. In the course of administering research, they support a variety of project-related costs such as salaries for research personnel, supplies, equipment and travel for scientific conferences and training. Additionally, they support a number of activities that foster a vibrant research environment at VA medical centers across the nation. Such activities include supporting institutional review boards (IRB) and other compliance measures, core research equipment and services, seed and bridge funding and VA staff recruitment. NPCs also donate to VA the services of approximately 2500 NPC research employees who work under VA without compensation (WOC) appointments with the background, security and training requirements such appointments entail—side-by-side with VA-salaried employees.

Current Reviews of NPCs and Oversight

Internal control failures experienced by three NPCs in 2006 prompted the VHA Office of Finance and the Office of the Inspector General (IG) to undertake separate reviews of the NPCs that were performed during 2007. Although we believe that NPC boards and employees are for the most part conscientious stewards of NPC funds, NAVREF applauds VA for acting forthrightly to confront NPC management deficiencies that do come to light, and we consider the results of these reviews to be learning opportunities for NPCs. We have invited both the VHA and IG auditors to present their objectives, methodologies, findings and recommendations during the NAVREF 2007 Annual Conference in November so that all of the NPCs may learn from VA's substantial investment in conducting the reviews. The IG report, which originally was scheduled for completion in August, is not yet complete, but we remain hopeful that it will be published in time for discussion during the conference. Additionally, eight hours of the NAVREF conference program will be devoted to internal controls training for both large and small organizations, and VA is planning separate training specifically for members of NPC boards. NAVREF anticipates using the IG's recommendations to focus its own future educational programs on areas identified to be in need of improvement.

To improve VA oversight of NPCs, we encourage the Subcommittee to support the Office of Research and Development's plan to recruit as director of the VA Nonprofit Program Office a fully dedicated GS–15 with expertise in nonprofit management, accounting and governance. This office is tasked with providing NPC oversight and when staffed with the appropriate level of expertise will be a welcome partner in ensuring high standards of NPC management.

Proposal to Update and Clarify the NPC Authorizing Statute

Nearly two decades after enactment of Public Law 100–322, the success of the NPCs in supporting VA research and education demonstrates that the NPC authorizing statute has been effective in accomplishing Congress's purpose of providing VA with flexible funding mechanisms for the conduct of VA-approved research and education. Its authors successfully crafted a unique private-public partnership that has served VA facility research programs and investigators well. However, during the intervening years, VA health care delivery systems, the VA research program and the NPCs have evolved. Prompted in part by the upcoming twentieth anniversary of the authority to establish NPCs, during the last twelve months the NAVREF board conducted a comprehensive review of the NPC authorizing statute in light of accumulated years of experience working within its terms.

After much deliberation, and discussions with the Office of Research and Development and the VA Office of General Counsel as well as Paralyzed Veterans of America and staff of the House and Senate Committees on Veterans Affairs, NAVREF concluded that it would be of benefit to VA and the NPCs to update and clarify the NPC authorizing statute. This will also benefit veterans by helping NPCs meet their full potential in supporting VA research and education that ultimately results in improved treatments and high quality care for veterans. Guided by these discussions, early this year NAVREF began developing a statutory proposal that is nearing completion and that we expect to submit to Congress in December for consideration and enactment during the second session of the 110th Congress.

NAVREF's primary objective in proposing statutory revisions is to allow "multi-site" NPCs. That is, voluntary sharing of one NPC among two or more VAMCs while still preserving their fundamental nature as medical facility-based organizations. We have two purposes for seeing this objective. First, it would allow VAMCs with small research programs to join with larger ones or for several small programs to join together to pool their resources for purposes of efficiency and ensuring sound management. Second, it would allow reasonable, but not overly burdensome, board composition by requiring the medical center director of each facility to serve on the board to ensure local accountability. Otherwise the board of a multi-site NPC would be required to have as VA members just one Chief of Staff, Associate Chief of Staff for Research and Associate Chief of Staff for Education. Beyond this proposed statutory minimum, our proposal would leave it up to each multi-site NPC board to determine the combination of VA and non-VA members best suited to its own needs. In our view, requiring all of these personnel from each facility to serve on the board is not a good use of their valuable time and results in an unnecessarily large and logistically cumbersome board.

This change in the NPC statute would benefit VA by reducing the number of NPCs that VA is required to oversee and would eliminate the need for duplicative local effort at the same time as it would increase the resources each NPC would have available for management. NAVREF anticipates that as many as twenty low-revenue VA research programs may welcome the opportunity to partner with other nearby facilities to share NPCs.

NAVREF's other proposed revisions in the NPC authorizing statute are designed to clarify—**not change**—the legal status of the NPCs as independent organizations, exempt from taxation under Section 501(c)(3) of the Internal Revenue Service (IRS) code and subject to VA oversight and regulation. Additionally, proposed revisions clarify the NPCs' purposes as well as their funds acceptance and expenditure authorities. Our objective in making these changes is to resolve longstanding uncertainty and sometimes outright confusion and disagreement among VA officials, internal VA and external overseers, funding organizations and NPC personnel. NAVREF is also suggesting a general re-organization of the statute to pull together in separate sections the various provisions addressing status, purposes and powers.

As NAVREF considered statutory revisions, it also identified a number of issues that while not requiring legislation, could benefit from discussion in congressional report language or inclusion in an updated version of VHA Handbook 1200.17 which contains VA's interpretation of the NPC statute and VA policy pertaining to NPCs. For example, NAVREF has included a recommendation for requiring VA to approve the establishment of a new NPC on the basis of an assessment of the ability of the

facility's research or education program to generate a revenue stream sufficient to support the NPC infrastructure, and assurance that qualified staff will be available to manage the NPC. The NPC statute already states, "The Secretary may authorize the establishment at any Department medical center of a nonprofit corporation . . ." Therefore, no explicit statutory language is needed to give VA the ability to determine which facilities may establish new NPCs. However, it may be useful to include in report language a sense that there should be some minimum expectations of research programs contemplating establishing an NPC and then more specific policy guidance regarding the process of applying for VA approval could be provided in the handbook. This and a number of other recommendations will be provided to Congress as an addendum to NAVREF's statutory proposal. We would be pleased to work with the Subcommittee to determine which the Subcommittee may wish to address in report language.

Conclusion

The NPCs represent a unique means for VA to maximize the benefits of externally funded research conducted in VA facilities. The NPCs are performing as Congress intended, serving as flexible funding mechanisms for the conduct of VA-approved research and education. NPCs facilitate research that benefits veterans, and they foster vibrant research environments at VA medical centers, enhancing VA's ability to recruit and retain clinician-investigators and other staff who in turn apply their knowledge to state-of-the-art care for veterans. Some even contend that their NPCs and the contributions of services, personnel and equipment they provide in support of VA research have become an essential component of successful research programs.

However, NAVREF recommends that in 2008, 20 years after the VA–NPC public-private partnership was first authorized, and co-incident with expiration of authority to establish new NPCs, it is time to update and clarify the NPCs' enabling legislation. Experience working within the statute has brought to light its many strengths, but also areas that could benefit from updating and clarification, particularly in light of continuing evolution of VA health care and the increasing complexity of both research and nonprofit compliance. NAVREF would be pleased to work with the Subcommittee toward revisions in the statute that will allow NPCs to meet their full potential in supporting VA research and education while ensuring VA and congressional confidence in their management.

Thank you for the opportunity to submit a statement for the record. If you have questions, please do not hesitate to contact NAVREF Executive Director Barbara West.

Statement of Orthotic and Prosthetic Alliance

Mr. Chairman, thank you for the opportunity to submit this testimony on behalf of the Orthotic and Prosthetic Alliance ("O&P Alliance"). The O&P Alliance is a coalition of four of the primary organizations representing the field of orthotics (orthopedic braces) and prosthetics (artificial limbs). The four organizations include the American Academy of Orthotists and Prosthetists ("AAOP"), the National Association for the Advancement of Orthotics and Prosthetics ("NAAOP"), the American Orthotic & Prosthetic Association ("AOPA"), and the American Board for Certification in Orthotics, Prosthetics, and Pedorthics ("ABC"). The O&P Alliance represents the professional, scientific, research, business, and quality improvement aspects within the fields of orthotics and prosthetics.

Professional orthotic and prosthetic care combined with appropriate medical, surgical, and rehabilitative management provides the Veteran with limb loss and/or limb dysfunction the opportunity to live a highly functional life. The O&P Alliance would like to stress the importance of funding prosthetic and orthotic research and development. The past 30 years has seen great clinical and technological advancements in the orthotic and prosthetic fields. We have amputees and others with limb impairments to achieve unprecedented levels of function with the assistance of artificial limbs and orthopedic braces. The orthotic and prosthetic field must continue to advance in several areas to more accurately replicate human function and develop better measurement tools to assess quality and compare the relative effectiveness of orthotic and prosthetic interventions.

Historically, the Department of Veterans Affairs ("VA") has realized considerable success in conducting orthotic and prosthetic research. For example, the VA developed a method of fabricating a transparent plastic to assess the quality of prosthetic

socket fit in lower-limb amputees; the VA was among the first to design an energy-storing and releasing prosthetic foot that spawned a new generation of far more responsive prosthetic feet for application to lower limb amputees with extensive mobility needs. The functional benefit of prosthetic feet of this design has been shown to reduce the walking fatigue and create a more fluid gait. The VA has also supported the adaptation of Computer Aided Design/Computer Aided Manufacture (CAD–CAM) to the field of prosthetics and orthotics, yielding significant new advancements and efficiencies in measurement, fitting, and fabrication of orthotics and prosthetics.

Within the private sector of the organized field of orthotics and prosthetics we have seen many technological advancements that have become the standard of care for amputees and those with orthopedic impairments. The 1980's and 1990's were a time of significant industry investment in orthotic and prosthetic development that yielded many new advances achieving greater comfort, lighter weight, improved durability, and especially, increased function. It should be noted that the VA Prosthetic and Sensory Aids Service has adopted many of these advancements in O&P technology and routinely cover these technologies for veterans with orthotic and prosthetic needs.

While technology has come a long way since the days of wooden legs and heavy metal braces, much remains to be done. To help plot a research agenda, the American Academy of Orthotists and Prosthetists has recently conducted a series of consensus conferences designed to prioritize such research. In addition, significant efforts have been undertaken in this area by the National Center for Medical Rehabilitation Research at the NIH. O&P technology research has also been supported by at least three other federal agencies, including the National Institute on Disability and Rehabilitation Research within the Department of Education, the National Science Foundation, and the Department of Defense.

The pace of technological research and development has not been matched by the pace of outcomes research in the O&P field. The VA amputee population alone is widely disparate. It includes both aging and geriatric veterans who have become accustomed to more traditional technology, and newer, younger amputees returning from conflict abroad whose expectations for prosthetic rehabilitation are extremely high. In order to build on the successes the VA and the O&P field has had to date, it is necessary that the VA take into consideration that the patient population they serve is both growing and changing. We believe that these factors will make it vital for the VA to work more closely with the private sector to help lead the way for all users of orthotics and prosthetics, veterans and non-veterans, to benefit from continued research and quality care in this field.

The demand for orthotic and prosthetic services continues to increase, not only from the influx of amputees and those with musculoskeletal injuries returning from combat abroad, but also from chronic disease at home. There are nearly 200,000 members of the armed forces now in war zones who will be eligible for VA services as they leave the military. Young men and women returning from Iraq and Afghanistan may need VA services for the rest of their life. Diabetes, and the precursor to this chronic illness, obesity, are on the rise and are major contributors to amputation rates and other orthopedic conditions in this country. As the "baby boom" generation continues to age, the incidence and prevalence rates of orthopedic conditions will continue to increase significantly.

For these reasons, there is a national need to improve the evidence base of prosthetic and orthotic care. Research is needed to develop better measurement instruments that will assist an orthotist or prosthetist with clinical decisionmaking and verify whether an orthotic or prosthetic intervention achieves a particular clinical goal. The ability to quantify functional outcomes will result in more accurate and clinically relevant cost-benefit analyses. These analyses, in turn, will enable more reliable quality of life studies as related to the application of new technologies currently being marketed directly to the public.

Furthermore, research is needed to provide measurement tools for the practitioner to be able to assess performance of the orthosis and/or prosthesis and measure outcomes in environments outside the traditional clinic setting. It is difficult to utilize multi-center studies for orthotics and prosthetics due to the problems inherent in the inter-laboratory reliability of measurements involving gait laboratories. Research is needed to improve multi-center measurement reliability. In order to be statistically significant, this research should involve studies of sufficient size.

The practice of orthotics and prosthetics is a very personal relationship between the patient and the practitioner. It is highly clinical and technical, and is for the remainder of the person's life. The process of creating a complex treatment plan, coordinating treatment with the various medical and ancillary disciplines necessary for successful outcome is necessarily protracted. There are many steps in the process

requiring many appointments to achieve comfort, stability, and function. The end result is a melding of human flesh and man-made/designed hardware that is uniquely fit to meet the medical and functional needs of the patient, affording the Veteran the maximum degree of independence. The entire process is purely customized to the particular individual. As such, the practice of quality orthotics and prosthetics demands practitioner expertise and skilled technique which can vary considerably from practitioner to practitioner. There is a need for systems which can capture scientifically the subjective decisionmaking skills of practitioners recognized for their high level of expertise so that these skills can be shared more widely. When fully realized, the development of these tools and measurements will improve patient care across a broad spectrum of the public at a lower cost.

To conduct effective evidence-based research, we believe it is imperative that there be a strong partnering between the VA and private sector O&P professionals who have potentially more current experience with such patients. Currently, many of the O&P services provided by the VA are performed under contract though private O&P practitioners. By teaming with the private sector on a comprehensive research agenda, the VA will be able to conduct more reliable research and serve all orthotic and prosthetic patients more effectively in the future. Considering the interests of the Department of Defense in providing quality orthotic and prosthetic care to wounded service men and woman, it stands to reason that DoD would also be a logical partner in this joint enterprise.

We therefore propose that the VA and DoD fund a joint initiative with active involvement from the private sector to create a Prosthetic and Orthotic Outcomes Research and Treatment Center. Such a center would enable the military and VA health care systems to work with and alongside the civilian O&P profession to further develop the evidence base in the field. Such a center or network of centers could work cooperatively to further define common terms, refine functional measurement tools, conduct comparative studies of various technologies, and measure outcomes of prosthetic and orthotic interventions to clearly identify which treatment protocols are most effective.

In this manner, patients would benefit from improved, evidence-based approaches to maximize their functional capacity. Health care payers (both military and civilian) would have additional data in which to base their coverage decisions and maximize their investment in prosthetic and orthotic services and the prosthetic and orthotic research community would be spurred into developments that are still on the horizon and improve education and training or O&P clinicians.

Conclusion:

The O&P Alliance appreciates the opportunity to testify on this very important issue. We urge the members of the Committee to continue to fund and conduct research in the areas of orthotics and prosthetics, and to work with the private sector to ensure that this research investment is optimized. We stand ready to work with this Committee to address these critical issues. Thank you for your consideration of our views. If you wish to discuss these issues further, please contact Peter W. Thomas, counsel to the O&P Alliance, at 202–466–6550.

Statement of Alvin C. Pike, CP, Lead Prosthetist
Minneapolis, MN, Veterans Affairs Medical Center
Veterans Health Administration, U.S. Department of Veterans Affairs

Congressman Michaud and members of the Subcommittee on Health, thank you for this opportunity to allow my statement to be a part of your proceedings.

The views and opinions expressed are my own, and do not necessarily represent those of my current employer, the Department of Veterans Affairs, or those of the VA research community. They do however represent my 43 years as a prosthetist with a portion of that time in upper management with the world's largest manufacturer of components for artificial limbs, and leadership offices within the prosthetics and orthotics profession.

Today we see in the news media—brought about by the coverage given to amputees from Operation Enduring Freedom/Operation Iraqi Freedom—new high tech components for prostheses. An essential component to the success of this new technology is the man/machine interface that is called the socket. Although there have been numerous variations on socket design over the intervening half century, there have been no significant biomechanical studies of this integral portion of the prosthesis since research done at University of California Los Angeles in the fifties. Any

variations on basic designs have primarily come from the work of independent clinical prosthetists in private practices.

In addition to socket design, I believe more research is needed on how the alignment of the components effect function, on socket suspension methods, and on the development of evidence based practice.

In 2006, Northwestern University Rehabilitation Engineering Research Center in Orthotics and Prosthetics conducted an online forum followed by a meeting of prosthetists, orthotists, research engineers, and users of artificial limbs and braces. The report generated by this forum/meeting (attached) corroborates the pressing need for the type of research I have listed above. In fact, though virtually all participants agreed on the importance of research, most believed the current quantity of research to be insufficient. I believe this must be rectified to appropriately serve our veterans.

The following is taken from: *Prosthetics/Orthotics Research for the Twenty-first Century: Summary 1992 Conference Proceedings*—John W. Michael, MEd, CPO, John H. Bowker, MD.

> *"The period from 1945–1965 is now viewed as a time of unparalleled scientific and technical advances in O&P. Key findings from this era still provide the conceptual basis for virtually all contemporary techniques. Although many factors have contributed to the long-term successes of this era, two key aspects were the coordination of research and evaluation efforts and the long-term commitment of significant governmental funding."*
>
> *"Although the field is currently in a relatively high state of clinical development, most advances in recent decades have been technical. Little or no advances in fundamental principles have occurred since the termination of significant governmental funding for O&P research and development in the sixties."*

In closing I would like to quote the Hon. Anthony J. Principi from a speech given on November 17, 2003, in Arlington, Virginia.

> *"Good afternoon, and thank you for inviting me to help launch a new beginning for both VA's orthopedic and prosthetics research and development, and for a brighter future for America's disabled servicemembers and veterans,* ***men and women who now bear the burdens of mid-20th century technology even as they live surrounded by the envelope pushing technologies of the 21st century."***

Respectively submitted,

Alvin C. Pike, CP
(Board Certified Prosthetist)
Past President—American Academy of Orthotists and Prosthetists

Attachments: NU State of the Science Report [The attachment is being retained in the Committee files.]

Statement of Hon. John T. Salazar
a Representative in Congress from the State of Colorado

Thank you Mr. Chairman for an opportunity to discuss the important issues of VA Research programs.

I would like to especially thank our witnesses this morning for their commitment to our troops.

We have made such advancements in the field of medicine that the likelihood of dying on the battlefields today is less than in previous wars.

This is the reality. However we'll never be able to turn those advancements into real life benefits for our men and women in uniform without the proper funding.

Earlier this year during the budget process, the Administration requested $411 million for FY 2008, a decrease of $2.7 million below FY 2007 levels.

This Committee recommended $452 million, a $38.3 million increase above FY 2007 levels, and $41 million above the VA's request.

Research is one of the core missions of the Veterans Health Administration, and we're committed to providing the resources necessary to accomplish that mission.

This Committee, and this Congress, have made a promise to care for our veterans, and fighting for proper funding is part of that promise.

POST HEARING QUESTIONS AND RESPONSES FOR THE RECORD:

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 11, 2007

Joel Kupersmith, M.D.
Chief Research and Development Officer
Veterans Health Administration
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Dr. Kupersmith:

Thank you for testifying before the U.S. House of Representatives Committee on Veterans Affairs Subcommittee on Health at the hearing on "VA Research Programs" held on October 4, 2007.

Please provide answers to the following questions by November 26, 2007.

1. Infrastructure

- As the VA moves forward with construction of new hospitals, what types of infrastructure should be incorporated into these facilities in order to support research activities?
- How specifically does aging infrastructure impact the VA's ability to conduct research?

2. Collaboration With Other Departments

- How does the VA partner with other agencies (DoD, HHS) in research?
- What can the VA do to work more effectively with other agencies to do research and to share resources and information—to ultimately benefit veterans?

3. Phantom Limb and Stump Pain

- What specific research projects does the VA have to address the issue of phantom limb and stump pain? What future plans does the VA have to conduct research on this issue?

4. Eye Trauma

- How many OEF/OIF veterans are returning with eye problems?
- What is the VA currently doing in terms of eye research? What types of research is planned for the future to help these veterans?

5. Research Priorities

- What should be the VA's top 3 research priorities?
- Do you see these priorities changing over the next 10 years? 20 years? If so, how?

6. Barriers to Collaboration

We have heard from several sources that there are barriers to the VA getting research money agencies such as NIH and NIMH.

- Can you please comment on this issue? What is the nature of these barriers?
- What can the VA do to make it easier for it to get research money from these agencies?

7. Intellectual Property

There has been some discussion recently about VA research and intellectual property—who owns the research.

- Can you please comment on this issue?
- How does the intellectual property issue affect the availability of the most current medical treatment to veterans?

Again, thank you for your testimony. The Subcommittee looks forward to receiving your responses by November 26, 2007.

Sincerely,

MICHAEL H. MICHAUD
Chairman

Questions for the Record
Hon. Michael Michaud, Chairman
Subcommittee on Health House Veterans' Affairs Committee
October 4, 2007

VA Research Programs Hearing

Infrastructure

Question 1: As the VA moves forward with construction of new hospitals, what types of infrastructure should be incorporated into these facilities in order to support research activities?

Response: Most research within the Department of Veterans Affairs (VA) is carried out by researchers who are affiliated with medical schools or other institutions of higher learning. In general, a decision to include research space within a new VA facility depends upon the strength of the current VA and academic affiliate research efforts (in the case of replacement facilities), or on the research potential of the academic affiliate (in the case of new facilities). In general, it is not a prudent use of resources to build research infrastructure at a VA hospital in the absence of a strong academic affiliate or nearby Federal laboratory.

In those facilities where establishment of a research program is appropriate, such as those affiliated with top medical schools, it is critical that it be built for flexible long-term use. Current laboratory research requires laboratories which are readily reconfigured to meet new research demands. This generally requires more electrical power, better ventilation and more plumbing than are found in older laboratories or in less expensive "fixed" laboratory designs. Such laboratories are likely to be appropriate for state-of-the-art genomic and physiologic research. Facilities may need specially configured rooms for modern human and animal imaging equipment, including magnetic resonance imaging systems and microscopes, computed tomographic scanners and the like. Similarly, construction of flexible animal facilities that are capable of providing humane care for a variety of species ranging from rodents to primates is advisable. Engineering laboratories that are capable of fabricating prosthetic devices as well as microelectromechanical systems facilitate research efforts to restore function to veterans suffering traumatic injuries in war. State-of-the-art clinical research units facilitate the translation of basic research findings into life-saving and life-enhancing medical treatments. All require information technology support which is both state-of-the-art and specific to the research undertaken in an individual facility.

Question 2: How specifically does aging infrastructure impact the VA's ability to conduct research?

Response: Aging infrastructure at some VA facilities negatively impacts VA's ability to conduct research by impeding the recruitment of new investigators, who are often put-off by aging facilities. Inadequate electrical supplies and ventilation makes it difficult to support state-of-the-art research equipment, making it both more difficult for investigators to compete for scarce VA and National Institutes of Health (NIH) research funding, and more difficult to carry out uniquely VA research aimed at improving the physical and mental health of those suffering injury during military service. In spite of these limitations, however, VA researchers continue to carry out world-class laboratory and clinical research which is published in top journals such as *Science, Nature* and *The New England Journal of Medicine*. This research improves the health of veterans and often that of the general public and is America's most cost-effective medical research investment.

Collaborations With Other Departments

Question 3: How does the VA partner with other agencies (DoD, HHS) in research?

Response: Through VA's academic affiliations and collaborations with other entities, VA research is fully integrated with the larger biomedical research community. VA scientists partner with colleagues from other Federal agencies [e.g., the Department of Defense (DoD) and the National Institutes of Health (NIH)], academic medical centers, non-profit organizations and commercial entities nationwide to further expand the reach and scope of VA research. Partnering and coordinating is accomplished at both the national and local levels. At the national level, VA scientific program managers work closely with their colleagues in other agencies to develop joint solicitations, identify partnering opportunities, review programs to eliminate redundancy and establish mechanisms such as joint scientific conferences to keep our research at the cutting edge. Additionally, national program staff enlist scientists from

DoD, NIH, other Federal agencies and academia to participate on peer review panels of VA research, and assist in finding VA scientists to serve on the peer review panels of other agencies. On the local level, VA scientists collaborate extensively with other agencies through collaborative research projects, intergovernmental personnel agreements, memoranda of understanding, interagency workgroups and other mechanisms.

Question 4: What can the VA do to work more effectively with other agencies to do research and to share resources and information—to ultimately benefit veterans?

Response: VA is currently implementing NIH's electronic research administration (eRA) system for the submission, review and tracking of research proposals submitted by VA investigators. By sharing a common platform and database for research, scientific program managers in VA and other agencies can better coordinate scientific efforts. Additionally, VA's Office of Research and Development (ORD) is working with VA's Office of Information and Technology and other Federal agencies to develop secure systems for data sharing and exchange.

Phantom Pain and Stump Pain

Question 5: What specific research projects does the VA have to address the issue of phantom limb and stump pain? What future plans does the VA have to conduct research on this issue?

Response: VA's ORD supports a growing portfolio in pain-related research. VA investigators are examining the complexities of pain and how best to ameliorate its disabling effects among veterans, including those with phantom limb pain, as well as pain related to the residual limb, spinal cord injury, multiple sclerosis, osteoarthritis, back disorders and other conditions.

Basic research is aimed at understanding the underlying molecular basis for pain, while applied work is examining traditional pharmacologic means and interventions such as cognitive behavioral therapy. It is anticipated that discoveries from these projects will provide information in pain management and underlying sources of pain.

In one exciting recent study, VA investigators identified specific channels responsible for conveying pain signals to the brain (*Nature.* 2006; 444(7121):831–832). VA researchers are exploiting this finding to develop new pain treatments.

In other ongoing projects, VA researchers are conducting imaging studies to identify and examine sources of pain; investigating enhancements to pain control from conservative therapy, including oral and topical analgesics, to corticosteroid injections, electrical stimulation and socket reshaping; and examining the effectiveness of exercise (e.g., strengthening, flexibility-enhancing and cardiovascular enhancements) to ameliorate pain.

VA's research program plans to expand on its current pain research initiatives to develop novel therapies to address pain, develop new ways to improve coping strategies and rehabilitative outcomes and test new paradigms of pain assessment, management and treatment.

Eye Trauma

Question 6: How many Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans are returning with eye problems?

Response: Since the majority of the eye injuries requiring eye surgery are cared for by military (DoD) ophthalmologists prior to release from active duty, DoD would be the appropriate source for comprehensive data related to eye injuries or traumatic brain injury (TBI) suffered in OEF/OIF combat and any vision loss resulting from those injuries. VA Eye Care Services is collaborating with DoD to develop a database related to eye injuries and TBI related vision loss.

VA does have data on OEF/OIF patients who have received rehabilitation services in the VA blind rehabilitation centers. In July 2007, data from President's Commission on Care for America's Returning Wounded Warriors indicated that 48 OEF/OIF veterans had been treated by VA blind rehabilitation centers; as of October 2007, 53 OEF/OIF veterans were admitted for treatment.

Question 7: What is the VA currently doing in terms of eye research? What types of research are planned for the future to help these veterans?

Response: VA's ORD supports a broad portfolio of vision-related research seeking to improve everyday function and quality of life among veterans suffering from vision loss, whether from acute trauma or due to age-related changes. Research extends from practical aspects of way-finding (i.e., maneuvering in the environment)

to the development of advanced intraocular transplants. Several individual research projects and two centers of excellence (Aging Veterans with Vision Loss; Innovative Visual Rehabilitation) focus on the rehabilitation of low-vision and blind veterans.

VA supported research has led to measurement tools such as the VA Low Vision Visual Functioning Questionnaire (long and short form) that is used in clinical practice to measure functional ability of low vision patients and to measure patient-centered outcomes of low vision rehabilitation. This questionnaire is used in both VA and non-VA clinics.

Current work involves advanced orientation and way-finding technologies for low vision and blind veterans to allow them to navigate independently in various environments. This includes the use of talking Braille signs, global positioning systems and virtual reality training systems to use in rehabilitation activities. Work is also under way to develop a retinal implant (type of neuroprosthesis) to restore vision to the blind.

Future planned research includes visual robots for orientation and way-finding of low vision and blind veterans; further development of retinal implant technology; and rehabilitation strategies for veterans with dual sensory impairment (vision and hearing), which is occurring due to trauma, as well as age-related phenomena.

Research Priorities

Question 8: What should be the VA's top 3 research priorities?

Response: It is crucial that VA's research programs remain focused on veterans' high priority healthcare needs. The quality of the research and relevance to the veteran population remain the determining factors in deciding what studies to fund.

The top three priority areas for VA research include:

- The needs of returning OEF/OIF veterans, including TBI and other neurotrauma, such as sensory loss and spinal cord injury; post-deployment mental health, including post-traumatic stress disorder and depression; prosthetics and amputation healthcare; pain; polytrauma (i.e., complex, multiple traumas); and access to care for OEF/OIF veterans;
- The needs of the aging veteran population, particularly treatments for chronic diseases; and
- Personalized medicine, meaning increasing our understanding of the role of genetics and other individual issues in diagnosis and treatment of illnesses to allow VA to provide care that is tailored specifically to the makeup of individual veterans. VA is uniquely positioned to lead in this area because of its large patient population that is stable, diverse and treated in a variety of settings, care system with outstanding investigators and an integrated research network and unrivaled electronic health record.

Question 9: Do you see these priorities changing over the next 10 years? 20 years? If so, how?

Response: Because the mission of VA research is to improve veterans' lives, our priorities will adapt as the needs of veterans change. Although we cannot predict all those needs for the future, we do rely on projections in the veteran population as well as trends in medical research and medical care. It is certain that VA research will need to increasingly address the needs of OEF/OIF veterans, including the long-term outcomes of post-traumatic stress disorder (PTSD), TBI and other blast injuries, which are creating the types of complex co-occurring illnesses previously limited to elderly. OEF/OIF TBI veterans may have a life expectancy of 50 years or more, so their health and care-giving needs are considerable. Additionally, as the demographics of the military change (e.g., increased women veterans and minority veterans) our research will adapt to address their unique issues.

We also anticipate by changing the expectation of veterans and their caregivers, VA research will be prompted to create innovations that promote more personalized, community-based options for care. Rapid learning and needs assessment using improved tools for "data mining" the personalized health record is a critical strategy for the next 10 years and beyond.

Finally, based on recent and projected advances in our understanding of biological systems underlying illness, we anticipate that genomics and related research will play an increasingly larger role in VA's research portfolio. Genomic medicine has the potential to significantly improve the quality of care for veterans, especially in the treatment of chronic diseases. Recent research findings have shown that genomic medicine shows great promise to prevent adverse drug reactions, personalize clinical care, customize drug treatments and improve outcomes.

Barriers to Collaboration

We have heard from several sources that there are barriers to the VA getting research money from agencies such as NIH and NIMH.

Question 10: Can you please comment on this issue? What is the nature of these barriers?

Response: VA investigators have, in fact, been successful in competing for and receiving increased funding from the NIH and other Federal research sponsors over the past several years. Much of this funding is administered by academic affiliates or by VA-affiliated nonprofit research and education corporations (NPC) which provide a flexible funding mechanism for the administration of non-VA funds.

While there are no statutory or regulatory barriers to VA obtaining research funds from NIH and other Federal agencies and administering them through academic affiliates or NPCs, there are some administrative barriers. Currently, a limited number of NPCs administer Federal funds, and many lack the resources and expertise needed to do so. Dual-appointment researchers (i.e., VA and academic affiliate) generally have its Federal funds administered through the university, but the few VA researchers without university appointments do not have this option.

Question 11: What can the VA do to make it easier for it to get research money from these agencies?

Response: VA is currently working on solutions regarding the administration of federal funds by NPCs, including consolidation and training.

Intellectual Property

There has been some discussion recently about VA research and intellectual property—who owns the research.

Question 12: Can you please comment on this issue?

Response: If intellectual property (IP) is created in the course of VA research, VA may assert ownership of the IP and file patent applications, as appropriate, or pursue other means of protecting and encouraging the development of the research discovery. The decision to assert ownership depends on the presence and degree of VA contribution, including facilities, funds, information, equipment, materials and employee time.

Because most VA investigators have dual appointments with an academic affiliate, one or more university partners may also assert ownership to VA intellectual property. To address this unique relationship and to facilitate cooperation between the VA and academic affiliates, VA developed a Cooperative Technology Administration Agreement (CTAA). This legal agreement outlines relevant definitions, terms and conditions for managing the intellectual property, and allows the joint owners to work as one decisionmaking body in the best interest of technology transfer and development. The CTAA preserves VA ownership, while granting the university the necessary authority to protect and market the IP.

If IP is created in the course of privately sponsored VA research, VA maintains ownership of all data and IP emerging from these agreements. The sponsor often is granted an up front, non-exclusive license to IP resulting from the study.

Question 13: How does the intellectual property issue affect the availability of the most current medical treatment to veterans?

Response: It generally has no effect because discoveries that emerge from VA research are typically in an early stage of development, requiring further reduction to practice, validation and scale-up before they can provide any benefit to veterans. This development work is generally beyond the scope and mission of VA, so a commercial partner who is willing to commit considerable resources and assume significant risk is needed. Patents allow the commercial partner to take the development risk with some promise of financial return.

The VA currently is reviewing several allegations of patent infringement in which the patent owners allege that their inventions are used or manufactured by or for VA without license of the owner thereof. The technologies range from cardiovascular stents to hearing aids. If the allegations are proven, the ultimate costs of providing such devices to veterans may increase. However, a perfected government use license acquired in consideration of VA contributions may be offered as a defense.

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 5, 2007

Honorable Gordon Mansfield
Acting Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary Mansfield:

On Thursday, October 4, 2007, Dr. Joel Kupersmith, MD, Chief Research and Development Officer, Veterans Health Administration, testified before the Subcommittee on Health on the U.S. Department of Veterans Affairs Research Programs. As a follow-up to the hearing, I request that Dr. Kupersmith respond to the following questions in written form for the record:

1. Please list the number of invention patents VA has processed, retained ownership rights, and retained sole ownership rights since VA's Technology Transfer Program was established in 2000. Additionally, provide an estimate of the number of "lost opportunities" and the reason the Department did not pursue these opportunities.
2. Please explain the mechanisms of joint patents filed by VA with its academic partners. Specifically, how are respective "contributing shares" determined? Assuming the subsequent licensing of those patents, how are royalty distributions between partners determined? Are royalty distributions received by the VA under those circumstances, in force over the life of the patent, or are VA's royalties received in one lump sum?
3. What are some challenges VA faces in deploying the latest state-of-the art prosthetics research into prosthetic care for veterans?
4. What collaborative activities are VA and the U.S. Department of Defense (DoD) currently conducting? Is there a Memorandum of Agreement or Memorandum of Understanding between VA and DoD for collaborative research? What about for other federal departments?
5. How do VERA funds support VA research? Are such funds actually received by the medical center, and in the research laboratory? How does VA know this to be the case? What monitors does VA use to ensure these funds are allocated to research?
6. Has VA completed its study to identify deficiencies in VA's research infrastructure? Has VA developed a prioritized plan to renovate and modernize VA research infrastructure? If so, please provide a list of the prioritized research facility projects and include the cost of the project and implementation timeline.
7. What training does VA provide researchers on VA Data Security and Privacy policies? How is this training verified and tracked? How many VA researchers have not received the training? Does VA require encryption for all researchers accessing VA data?
8. The Office of Inspector General has released a number of reports recently on problems with researchers operating outside the scope of practice. What steps is VA taking to ensure that researchers are acting within their scope of practice? Does VA believe that a researcher operating outside their scope of practice constitutes a violation of human subjects protections? How are researchers trained on human subjects protections? Is this training documented? How often is this training provided?

The attention to these questions by the witnesses is much appreciated, and I request that they be returned to the Subcommittee on Health no later than close of business, 5:00 p.m., Friday, November 2, 2007. If you or your staff have any questions, please call Dolores Dunn, Republican Staff Director for the Subcommittee on Health, at 202–225–3527.

Sincerely,

Jeff Miller
Ranking Member

Questions for the Record
The Honorable Jeff Miller, Ranking Republican Member
Subcommittee on Health
House Committee on Veterans' Affairs
October 4, 2007

VA Research Programs

Question 1: Please list the number of invention patents VA has processed, retained ownership rights, and retained sole ownership rights since VA's Technology Transfer Program was established in 2000. Additionally, provide an estimate of the number of "lost opportunities" and the reason the Department did not pursue these opportunities.

Response: Since 2000, the Department of Veterans Affairs' (VA) Technology Transfer Program (TTP) has received 1,226 invention disclosures. VA retained rights to 744 of these inventions. Of those inventions, 69 are solely owned by VA.

Each of VA's inventions has undergone a commercial and patentability assessment by either VA or the academic affiliate. As such, VA's TTP has taken advantage of all opportunities on those inventions disclosed since the program was established in 2000. The commercial and patentability assessment can include discussions with the VA inventor, patentability opinions from VA contract patent attorneys and technology assessments from marketing contractors. VA has marketed all its inventions in hopes of finding a licensee or a cooperative research and development partner to advance the technology and bring it to market.

Question 2: Please explain the mechanism of joint patents filed by VA with its academic partners. Specifically, how are respective "contributing shares" determined? Assuming the subsequent licensing of those patents, how are royalty distributions between partners determined? Are royalty distributions received by the VA under those circumstances, in force over the life of the patent, or are VA's royalties received in one lump sum?

Response: Most VA investigators have dual appointments with an academic affiliate. This often results in co-ownership of an invention between VA and the academic affiliate. To address this unique relationship and facilitate and enhance the cooperation between VA and academic affiliates, VA developed a cooperative technology administration agreement (CTAA). This agreement outlines relevant definitions, terms and conditions for handling co-owned intellectual property (IP). Using the CTAA preserves VA ownership while providing the university the needed authority to effectively patent and market the IP. The ClM also has a provision that if the university chooses not to patent or market an invention VA has the right to do so. Currently, VA has executed 76 ClMs with some of the leading research institutions in the country, including Harvard, Yale, Stanford and the entire University of California system.

VA's "contributing shares" are calculated in terms of the number of VA inventors as a proportion of the total number of inventors. For example, if an invention has two inventors, one full-time VA staff and one non-VA university staff, the "net revenue" split would be 50 percent to VA and 50 percent to the university.

"Net revenue" is defined as total revenue, minus royalties paid to the inventors, expenses (e.g., patent filing costs) and a 15 percent administrative fee. All net revenues are to be paid annually over the life of the patent or for the term specified in the license.

Question 3: What are some challenges VA faces in deploying the latest state-of-the-art prosthetics research into prosthetic care for veterans?

Response: New and emerging technology (e.g., bionics, microprocessors and electric and myoelectric components) is becoming commercially available at a very quick pace. In addition, manufacturers make claims and develop criteria about new products for which there is very little scientific or clinical evidence. We have in the past worked with researchers and developers on new and emerging technologies in clinical settings, where we have fit a variety of new devices over the years. Some examples include: Advanced Body Powered Arm; Synergetic Prehensor; Modular Electronic Locking/Unlocking Actuator (for elbow); and the Hypobaric Lower Limb Suspension Systems. It is critical that VA continue to evaluate these new products in the process, and develop criteria by consulting with clinicians and researchers specializing in new and emerging technology.

Question 4: What collaborative activities are VA and the U.S. Department of Defense (DoD) currently conducting? Is there a Memorandum of Agreement or Memo-

randum of Understanding between VA and DoD for collaborative research? What about for other federal departments?

Response: In the context of research, VA's Office of Research and Development (ORD) has a long history of collaboration with DoD and collaboration has substantially increased over the last 2 years. Individual research projects currently under way are examining a wide range of topics, including traumatic brain injury (TBI), polytrauma, prosthetics and amputation healthcare, post-traumatic stress disorder (PTSD) and other post-deployment mental health, burns and pain.

High-level planning and coordination of research efforts in response to the needs of Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans began in May 2006, with an interagency workgroup planning conference that mapped the landscape of post-deployment mental health issues. The conference report is available at: www.research.va.gov/news/announcements/deployment-meeting.cfm. This planning conference led to an inter-agency solicitation for research proposals.

A subsequent senior leadership meeting held at Fort Detrick, MD, on November 13, 2006, articulated further principles for collaboration and identified TBI and PTSD as key topics for coordinated effort.

ORD scientific leadership participated June 11–13, 2007, in a DoD-sponsored PTSD/TBI vision setting meeting, in which plans were articulated for the use of the $300 million supplemental appropriation received by Defense Health Programs for PTSD and TBI research. Senior ORD scientific staff continues to work closely with the DoD's Congressionally mandated medical research programs to implement the $300 million supplemental appropriation in support of PTSD and TBI research. It is anticipated that VA researchers will submit proposals and collaborate extensively with their DoD counterparts in this Congressionally directed initiative.

In addition, ORD is currently planning, in collaboration with DoD investigators, a state-of-the-art conference on OEF/OIF-relevant research, which will be presented to a joint VA/DoD audience in the spring of 2008.

Furthermore, VA and DoD regularly involve each other in the evaluation of research proposals and funding selections.

Memoranda of Understanding exist between VA and DoD, as well as other Federal departments, for specific research projects.

Question 5: How do VERA funds support VA research? Are such funds actually received by the medical center, and in the research laboratory? How does VA know this to be the case? What monitors does VA use to ensure these funds are allocated to research?

Response: The Veterans Equitable Resource Allocation (VERA) allocates research support funds based on the total expenditures of funded research at each medical center. These expenditures are weighted based on whether the research is administered by VA or is peer reviewed. The total amount allocated in VERA is based on the estimates for medical care support to research as submitted in the President's medical programs budget request.

Networks distribute to medical centers research support funds as they are computed for each medical center, care line or product line. Each medical center, care line or product line explicitly accounts for, and obligates, research support funds to support the salaries of clinician-researchers, and research facilities and administrative costs. Research support expenditures are monitored on the local level by administrative officers for research, working in partnership with facility fiscal staff.

Question 6: Has VA completed its study to identify deficiencies in VA's research infrastructure? Has VA developed a prioritized plan to renovate and modernize VA research infrastructure? If so, please provide a list of the prioritized research facility projects and include the cost of the project and implementation timeline.

Response: VA's Office of Research and Development has established a research infrastructure evaluation and improvement project to review VA's research facilities and identify deficiencies.

A detailed questionnaire regarding current research space allocation and condition was disseminated to all field sites to gather preliminary information. Preliminary results showed a need for research infrastructure corrections across the system. To better document and prioritize issues identified in the preliminary assessment, a comprehensive evaluation instrument designed to ensure a thorough and consistent system-wide review of research space was developed and tested at three pilot sites. A summary of the three pilot surveys completed will be provided in a report to Congress in the near future.

In addition, VA recently selected a contractor to complete the research facility site visits. Three site visits were conducted in September 2007. Over the next 3 years,

approximately 70 more site visits will be conducted. VA plans to issue reports to Congress periodically, as appropriate, describing the efforts undertaken.

Because the research infrastructure evaluation and improvement project is still under way, a prioritized list of research facility projects is not available.

Question 7: What training does VA provide researchers on VA Data Security and Privacy policies? How is this training verified and tracked? How many VA researchers have not received the training? Does VA require encryption for all researchers accessing VA data?

Response: All staff involved in VA research, not just researchers, are required to take the course *VA Research Data Security and Privacy.* This includes all VA research office personnel, researchers, study coordinators, research assistants, trainees such as house officers and students, administrative support staff (including secretaries and clerks) and members of the Institutional Review Board (IRB) and Research and Development Committee. Personnel includes compensated and without compensation employees and those on Intergovernmental personnel agreements (IPAs). Local VA facilities must maintain documentation that training requirements have been met.

As of October 12, 2007, 20,929 people have taken the course since VA began offering it in February 2007. Data does not exist on how many researchers have not taken the course.

In addition, all Veterans Health Administration (VHA) staff are required to take the *VA Cyber Security Awareness Training Course* and the *VHA Privacy Policy Training Course.*

VA Handbook 6500 requires that VA sensitive information, including sensitive research data, must be in a VA protected environment at all times or it must be encrypted. All portable media (e.g., laptops, portable drives, thumb drives, compact discs) that contain VA sensitive information must be encrypted.

Question 8: The Office of the Inspector General has released a number of reports recently on problems with researchers operating outside the scope of practice. What steps is VA taking to ensure that researchers are acting within their scope of practice? Does VA believe that a researcher operating outside their scope practice constitutes a violation of human subjects protections? How are researchers trained on human subjects protections? Is this training documented? How often is this training provided?

Response: VA's Office of Research and Development (ORD) requires a scope of practice for researchers and staff working on human subjects research protocols. The scope of practice is based on the occupational category under which the person is hired and the person's qualifications, including licensure and training. In addition, the scope of practice is agreed upon by the person's immediate supervisor and the associate chief of staff for research and development.

Each VA facility is responsible for the credentialing of all research employees and the local research office ensures that this is done and that a scope of practice has been developed. The principal investigator for each protocol is responsible for all aspects of that research and, as such, ensures that the research staff is qualified to perform their duties and that the duties are consistent with the scope of practice.

Working outside of a scope of practice may or may not represent harm to subjects. It depends on the specific task or procedure that was conducted and the specific research protocol. Working outside the scope of practice may also violate other Federal and State laws such as practicing medicine without a license.

All staff involved in VA human research (except secretarial support staff) is required to have annual training in good clinical practices and the ethical principles of human research protection. Most individuals meet this requirement by taking the same online *Collaborative Institutional Review Board Training Initiatives* (CITI) course used by many academic institutions. If VA facilities obtain permission from ORD, they may substitute other comparable training (e.g., in person courses that cover the material). CITI keeps electronic records of everyone who completes the course. This is an annual training requirement.