

**HEARING TO REVIEW THE DEPARTMENT
OF VETERANS AFFAIRS MEDICAL AND
PROSTHETIC
RESEARCH PROGRAM**

HEARING

BEFORE THE

**COMMITTEE ON
VETERANS' AFFAIRS**

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

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OVERSIGHT HEARING TO REVIEW THE DEPARTMENT
OF VETERANS AFFAIRS MEDICAL AND PROSTHETIC
RESEARCH PROGRAM

Wednesday, June 7, 2006

House of Representatives,
Committee on Veterans' Affairs
Washington, D.C.

The Committee met, pursuant to call, at 12:37 p.m., in Room 334, Cannon House Office Building, Hon. Steve Buyer [Chairman of the Committee] presiding.

Present: Representatives Buyer, Brown of South Carolina, Turner, Michaud, Berkley, Reyes, Brown of Florida, Stearns, Snyder.

THE CHAIRMAN. The full Committee of the House Veterans' Affairs Committee will come to order on June 7th, 2006. Today we are meeting to review the Department of Veterans Affairs medical and prosthetic research programs.

The hearing will focus on: One, the relevance of VA research to the clinical treatment of veterans; two, special research projects identified in the department's fiscal year 2007 budget submission, Operation Iraqi Freedom and Operation Enduring Freedom initiatives, genomic medicine, and the need for upgrading and modernization of VA research facilities.

The VA conducts an extensive array of research and development as a complement to its affiliations with medical schools nationwide. While these programs are specifically targeted to the needs of veterans, they are intentionally recognized and have made important contributions across the spectrum of healthcare.

The department's researchers have played key roles in innovating and improving artificial limbs, lifts, wheelchairs, establishing better treatment for tuberculosis, and developing the cardiac pacemaker, the CAT scanner, the MRI, and others.

The first kidney transplant in the United States was performed at a VA medical center and so was the first multi-organ transplant. VA contributions to medical knowledge have won its scientists many prestigious awards.

The VA's Office of Research and Development oversees a broad research program that focuses on biomedicine, rehabilitation, health services, and clinical trials. Targeted research centers focus on specific conditions or methods of improving quality care throughout the VA.

Four services organized their efforts in the organization of health-care systems around the disease and health conditions that are prevalent among veterans, such as the treatments for mental illness, rehabilitation of those who have suffered loss of limb, spinal cord injury and traumatic brain injury, organ transplants, and kidney dialysis.

The Committee values the research performed by the VA. While veterans are the direct stakeholders in the VA R&D mission, VA research has defined new standards of care that benefit all Americans. In the past year alone, dozens of major research findings have been reported in scientific literature and in the news media.

Good research is expensive. The Administration asked for \$399 million for medical and prosthetic research for 2007, \$13 million below the preceding year. The Administration relied on federal and nonfederal resources such as grants to make up the proposed difference.

On May 19th, the House passed the Military Construction, Military Quality of Life, Veterans' Affairs Appropriation Act appropriating \$412 million for medical and prosthetic research, the same level as last year and a \$13 million increase over the Administration's request.

While that figure is less than this Committee has recommended, time will tell if the awards for the federal and nonfederal sources will pan out as hoped. Now, we want to discuss that with the first panel.

The Administration's fiscal year 2007 budget submission identified two specific research projects: the OIF/OEF initiative and the genomic medicine. This initiative will allow all parts of VA's research office to provide new tools for clinicians to treat the physical and psychological pain of these veterans, determine how to improve access to healthcare and accelerate applications, especially for PTSD diagnosis and treatment, state-of-the-art amputation and prosthetic methods, and polytrauma.

The VA's Genomic Medicine Program, participation in which is strictly voluntary among veterans, will link patients' genetic information with their existing electronic health record. This will help us understand the role of genetics in prevention and cure and potentially even enabling the mass customization of medical treatment.

I am pleased to hear that this program will also address subjects' rights, informed consent, privacy, and ownership of genetic material involved with genetic tissue banking.

The program will be administered and overseen by a Scientific Advisory Committee, an Ethical Oversight Committee, and Veterans'

Advocacy Group. And so we are interested in that, Dr. Watson. That is the purpose of your presence.

Additionally, in March, Secretary Nicholson formed this Advisory Committee of internationally-recognized scientists and veterans' advocates to advise the department on emerging issues in this field of medicine.

We are interested in hearing from the department on how they intend to prioritize these new initiatives against those areas that VA's currently engaged in such as diabetes and cardiovascular disease.

VA research has long benefited from collaboration with teaching schools and other entities, and this Committee has promoted a wider use of innovative collaboration in healthcare delivery generally.

As we enhance how we conduct research and provide care, we must be mindful of the infrastructure we rely on. VA's healthcare and research infrastructure continues to age and will require additional attention.

The Appropriations Committee has recently recommended \$12 million to begin an effort to modernize and upgrade research facilities to ensure the state-of-the-art technology, equipment, and facilities are provided to support state-of-the-art research.

And I will note and I appreciate, Dr. Perlin, my visit to the collaborative research facility in Charleston. The Hollings? It is for cancer, isn't it?

DR. PERLIN. Yes.

THE CHAIRMAN. All right. Thank you.

I look forward to hearing from the witnesses.

At this time, I will yield to Mr. Michaud for any opening statement he may have.

MR. MICHAUD. Thank you very much, Mr. Chairman.

I, too, want to welcome each of the witnesses here today on both panels and want to thank you, Mr. Chairman, for holding this hearing.

The VA has long been at the forefront of needed and innovative research. The work performed by the VA helps perhaps the most deserving population in our society -- veterans and their families.

Breakthroughs have often helped VA and nonveterans alike. VA medical research is an effort that we all support and all wish to enhance as well. Unfortunately, dollars needed to maintain the quality of research are becoming more and more scarce as medical inflation and flat funding erodes budgets.

I look forward to hearing how the VA will prioritize the many research initiatives underway and how VA plans to keep its research facilities on the cutting edge of technology.

VA has a responsibility to focus its research so that it will best assist those that it is supposed to help.

For example, we have, among others, two distinct populations

that need medical research to produce results immediately. Our aging veterans are dealing with end-of-life complications. VA medical research can improve the golden years for these veterans. Operation Enduring Freedom and Operation Iraqi Freedom veterans have significantly different challenges related to the war in which they served. Again, VA research can make breakthroughs and can improve the quality of their lives.

Given the current funding level, I am concerned for the ability of VA to fund research that helps VA's traditional patient base and also returning servicemembers. We need to look at greater collaborations, strengthening of bonds between VA and non-VA public and private entities. We need to encourage researchers to pursue and win grants. But these efforts cannot be a replacement for appropriating additional dollars.

We need to do better than flat funding to ensure that VA continues to attract the best personnel and stays at the forefront of medical research as well. VA research is not an academic endeavor. It is essential for improving the quality of care available to our veterans.

Lastly, on the front page of today's Washington Post, there is an article entitled Data Theft Affects Most In Military. This data breach affected the sensitive personal information of 26.5 million veterans and servicemembers.

In light of this, I would like the VA to address what steps it has taken to safeguard sensitive personal information in its research program and what steps it plans on taking to protect the privacy and security of the genetic information it obtains as part of its Genomic Research Program.

So, Mr. Chairman, again, I would like to welcome each of the panelists. I look forward to their testimony. And I want to thank you for having this very important and meaningful hearing.

THE CHAIRMAN. Thank you, Mr. Michaud.

Mr. Brown, you are recognized for an opening statement.

MR. BROWN OF SOUTH CAROLINA. Thank you, Mr. Chairman.

I also would like to express my thanks to you for holding this very important hearing today and thank you to all of you who have agreed to testify. I look forward to working with you on appropriate prioritization of the research projects and infrastructure needs in the coming years. Again, thank you for being here.

We have a critical oversight role on this Committee as it relates to research. While we tend to focus most squarely on the direct medical care the VA provides to our service men and women, research is a key mission of the VA, and our veterans have come to rely on the many advances that we have developed inside VA's walls and in collaboration with other public and private entities.

I am eager today to accomplish a few things: Number one, first to welcome the new Chief of Research before this Committee, Dr.

Kupersmith; number two, explore the emerging priorities, some of which have been laid out in the Administration's fiscal 2007 budget request, and to better understand the practical clinical application of the proposed initiatives; and, finally, number three, get a better sense of what the research infrastructure requirements will look like in the future.

We are all very aware of the great many successes VA has had in the area of research, but today we are taking a somewhat rare opportunity to showcase it.

As I said at the offset, Mr. Chairman, both of us here on this Committee and the veterans we represent have become increasingly aware of the fruits of VA's research efforts. However, I think that the public in general has had little exposure to just how much the department has contributed to the national research efforts and debate.

Today Dr. Perlin and Kupersmith will have the opportunity to share that in a very public forum.

Again, I welcome everyone here today and thank you, Mr. Chairman, for doing what has been entitled Innovative Week here in the Congress holding a hearing on this very important subject. And I yield back the balance of my time.

THE CHAIRMAN. Thank you, Mr. Brown.

Ms. Berkley, do you have an opening statement?

MS. BERKLEY. If I may, thanks.

THE CHAIRMAN. Yes.

MS. BERKLEY. Thank you. Thank you, Mr. Chairman.

Good afternoon, gentlemen. It is always a pleasure to have you, Dr. Perlin. I am anxious to hear your testimony, so I am not going to talk very long. But I did want to share with you an experience I had and have somebody comment on it.

Since I voted to go into Iraq or give the President authority to go into Iraq, I think it is important to be here when our troops come home. So whenever I have an opportunity -- it is not very often -- I go to Walter Reed and I visit with our troops that have been injured.

There was one in particular the last time I was there a few months back that I visited with. And here is a young man, 24-year-old lieutenant, lost his arm and his leg in an operation in Baghdad and the arm and leg that he has remaining are not working.

And when I went into the hospital room, his young wife was by his bed and his dad, who is a retired school teacher, was at the foot of his bed. And we started talking and, you know, it never fails to amaze me how extraordinary these people are. And rather than talking to me about what happened to him, he shared with me information about the two men that he unfortunately lost in this operation where he lost his arm and his leg.

On top of his bed, there was a chalkboard and there were monthly goals. And it was like March, sit up; April -- and these may not be the

ones, but close enough -- April, stand up; May, fitted for prosthetic devices. And I walked out of the room feeling that, you know, this kid is going places and just a wonderful attitude and a tragedy, however.

Imagine my chagrin when I get the VA budget and the Administration cuts \$13 million out of prosthetic research. Now, I understand that we have moved that up, so now I think we are flat to where we have been in the past. But give me a break.

I mean, we have people coming home that are catastrophically injured. They are missing arms and legs. The least we could do for these people is give them state-of-the-art prosthetic devices and continue this research so that these people can live as normal a life as they possibly can and go on to a great future in this country.

Now, I would like an explanation of why we would possibly be provided with a \$13 million cut in prosthetic devices when we are getting men being blown apart thousands and thousands of miles away from home. And that is one of the many cuts that I found particularly egregious.

So I would appreciate if you would address that concern that I have because I suspect that this war is going to be with us for many years to come and when this war is over, the results of this war are going to be with us many, many, many decades later. And are we providing for that and preparing for that, because this is the cost of war. Prosthetic devices are as much a cost of war as flak jackets as far as I am concerned.

So I would appreciate that and thank you for coming.

THE CHAIRMAN. Thank you very much.

MS. BERKLEY. Thank you, Mr. Chairman.

THE CHAIRMAN. Anyone else have an opening statement?

All right. Dr. Perlin, you are now recognized.

STATEMENT OF JONATHAN B. PERLIN, UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS

DR. PERLIN. Thank you, Mr. Chairman, members of the Committee. Good afternoon. Thank you very much for the opportunity to discuss VA research.

Accompanying me today are to my far left, Dr. Robert Ruff, Acting Director of our Rehabilitation Research and Development Service.

To my immediate left is Dr. Matthew Friedman, Director of VA's National Center for Posttraumatic Stress Disorder.

At the far right is Dr. Michael Watson, member of the Genomic Medicine Program Advisory Committee and Executive Director of the American College of Medical Genetics Foundation.

And I am also very pleased to be able to introduce to the Committee Dr. Joel Kupersmith, VHA's new Chief of Research and Development, Chief Research and Development Officer.

Dr. Kupersmith joined VA last year after a distinguished career as a cardiologist, faculty member, and researcher at the Methodist Real Medical Center or Medical School and the Mount Sinai School of Medicine, University of Louisville, Michigan State University, and serving most recently as the scholar in residence at the Institute of Medicine and the American Association of Medical Colleges.

In fact, he served as well as the Dean of the School of Medicine and Graduate School of Biomedical Sciences at Texas Tech University, and this is Dr. Kupersmith's first opportunity to meet with you officially. In a few moments, he will provide testimony to you on the Office of Research and Development and the activities within VA's Research Program.

VA research is, as was said, not an academic exercise. It is focused around the mission of improving the health and well-being of America's veterans. As also recognized, the benefits created by VA research extend to literally everyone, and I hope we will have the opportunity to discuss some of the circumstances that were created that provide service to all Americans and, in fact, all citizens of the world.

The VA Research Program has been tremendously productive. It has fostered three Nobel laureates and six individual researchers were awarded the Lasker Prize which some consider a sort of pre-Nobel type of recognition.

Before I turn to Dr. Kupersmith, I would like to address an issue of great significance to the future of VA research and healthcare and that is our plans for genomic research. Genomics is not fantasy. Rather genomics supplements what we already know and do today in medicine to focus on and improve care to veterans.

In fact, we already use genomic medicine in patient care in a number of areas. We used genetic testing to identify cancer patients who react better to reduced doses of chemotherapy resulting in lower toxicity.

Patients with the gene for abnormal clotting factor are identified through testing so that we can reduce the chance for stroke or embolism.

Genetic information allows us to lower the number of drug-induced bleeding episodes resulting from warafin, a widely-used drug for thinning blood.

In cancer screening based on molecular, genetic, and proteomic tests identifies the disease earlier in many patients, giving us the opportunity to save many patients who, in fact, once could not be cured.

The first priority of our newly-appointed Genomic Medicine Advisory Committee will be to provide expert counsel on protecting veterans' privacy. They will also establish a strong ethical foundation for VA's use of genetic information.

Our Committee members who are nationally renowned medical ex-

perts in genomic research, bioethics, and disease management will assess the potential impact of genomics on existing VA patient care services, recommend policies and procedures for tissue collection and storage and analysis, and develop a research agenda to optimize knowledge and improve patient care and the health of our veterans.

They will also help us conduct focus group surveys and provide other direct contacts with veterans to learn about and appropriately address issues of importance to them and their families.

Our integrated research program, our benchmark care quality, and our robust Genomic Medicine Program will allow us to maintain our leadership in providing veterans with the state-of-the-art care that they have earned through their service and sacrifice.

We recognize, however, that we must construct a strong and ethical foundation, scientific foundation in partnership with veterans and their families in order to be successful.

At this time, I turn to Dr. Joel Kupersmith to provide his testimony on the current status of VA research. Thank you.

Dr. Kupersmith.

[The statement of Jonathan B. Perlin appears on p. 62]

STATEMENTS OF JOEL KUPERSMITH, CHIEF RESEARCH AND DEVELOPMENT OFFICER, DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY ROBERT L. RUFF, ACTING DIRECTOR, REHABILITATION RESEARCH AND DEVELOPMENT SERVICE, DEPARTMENT OF VETERANS AFFAIRS; MATTHEW J. FRIEDMAN, EXECUTIVE DIRECTOR, NATIONAL CENTER FOR PTSD, DEPARTMENT OF VETERANS AFFAIRS; AND MICHAEL S. WATSON, MEMBER, GENOMIC MEDICINE PROGRAM ADVISORY COMMITTEE, EXECUTIVE DIRECTOR, AMERICAN COLLEGE OF MEDICAL GENETICS

STATEMENT OF JOEL KUPERSMITH

DR. KUPERSMITH. Mr. Chairman and members of the Committee, thank you for the opportunity to discuss specifics about VA research and share some of my thoughts about our future vision.

Although I was aware of the importance of VA research before I took this position, I did not fully appreciate what VA research has contributed to veterans and the nation as a whole.

Veterans who returned from World War II with tuberculosis faced a bleak future until VA research identified and tested new highly-effective treatments.

Veterans wounded in all wars have benefited from VA's work to develop the next generation of Seattle Foot and other prosthetics allow young men and women to become high-performance athletes.

The quality of life for our aging veteran population is enhanced because of CT scanners, MRIs, implantable cardiac pacemakers, a vaccine for shingles, and countless other discoveries by VA clinical researchers.

VA research nested within a healthcare system used by more than five million veterans is a unique national laboratory where research is translated into clinical practice daily and effectively. VA clinicians also initiate and conduct research projects that are directly relevant to the clinical care they provide.

The written statements includes many examples of what I will discuss today, but I would like to highlight one project that shows exactly how VA clinician investigators use VA's unique intramural program.

Clinicians have long noted that individuals with schizophrenia medicate themselves with tobacco to try to clear their brain abnormality. VA research discovered a gene linked to schizophrenia with an additional aspect. It is also linked to the brain center for smoking.

VA research then identified a new drug approved by the FDA for experimental use in humans as a possible treatment. It is now in phase two trials.

VA clinician researchers note something at the bedside, take that observation to the bench, find and test a treatment, move the result back to the bedside in a full circle of translation and a unique system where research is linked to clinical care.

Each year, we are challenged to meet priorities based on the changing needs of the veterans we serve with high-quality science. For the needs of returning Operation Iraqi Freedom and Enduring Freedom veterans, VA has responded with the following:

Neurotrauma research, including work related to traumatic brain injury, which occurs in approximately 30 percent of injured veterans and spinal cord injury; research related to polytrauma and blast injuries; amputation and prosthetic research, including use of futuristic microelectronics, robotics and tissue engineering to create lighter, more functional prostheses; many PTSD and other mental health projects, collaborations with Department of Defense, Walter Reed Army Medical Center, Brook Army Medical Center, and others; research about rehabilitation for the visually impaired, burn treatments, hearing loss, natural neural regeneration to return function to paralyzed veterans and those with brain injuries; and plans to study advanced tissue engineering and the manufacturing of artificial skin to accelerate wound healing.

Regarding our infrastructure, it is crucial that VA investigators have the equipment and facilities necessary to conduct cutting-edge research in the 21st century. To identify where improvements may be needed, the Office of Research and Development has initiated a

comprehensive review of VA's research facilities, including physical and operational infrastructure and major equipment to identify deficiencies and corrective action. The written statement provides details of this project.

In conclusion, the vision for VA research is simple. VA research has made substantial contributions to the health and well-being of veterans and the nation and can do so in the future. We must constantly make certain that our research meets the needs of veterans, is of the highest scientific merit, and adheres to the strictest standards of human subject protection.

The goal is to quickly and efficiently translate research into clinical care and thereby address the pressing needs of our veterans.

Thank you for this opportunity.

THE CHAIRMAN. Thank you very much for all of you being here today.

In my years here in Congress, I have served on three Committees that have had oversight jurisdiction over health research from the Armed Services Committee with the military health delivery system. I serve on the Health Subcommittee of Energy and Commerce and now this Committee.

And Congress has been very careful with all three Committees not to direct. We will send you the funds, but we are not the experts. We have our areas of interest, but we turn it you, the experts, to make competent decisions and come up with a series of prioritizations.

I am going to ask this question though. When I use the term veteran centric research, how would you interpret that? I am going to ask two of you, Dr. Perlin and Dr. Kupersmith. How would you define veteran centric research?

DR. PERLIN. Mr. Chairman, thank you very much for holding this hearing and asking that very central question.

Veteran centric research is research that in my estimation improves the health and well-being of veterans. It allows us to focus specifically on those issues that are unique to the veteran experience which, of course, is predicated on military service and military occupational health exposures. It also is predicated on the issues that are concentrated in the veteran population that we serve.

As you know, our population -- while veterans at large do generally better than the average American, the veterans who come to VA for healthcare happen to be older, sicker, and poorer. In fact, they have three additional physical diagnoses and one additional mental health diagnosis.

And as 49 percent are over age 65, you see very quickly in that demographic that there are certain vulnerabilities conferred upon the population. Chronic illness and age as a mechanism of frailty become two central areas.

So military occupational health exposures, those things unique to

combat service and military service, and those things that are concentrated in the veteran population which we serve are the things that I define as relevant to veterans as veteran centric.

THE CHAIRMAN. Dr. Kupersmith.

DR. KUPERSMITH. Yes. I think it is the spectrum of the issues and conditions that are related to returning veterans of current wars and the issues and conditions related to the aging veteran population as it passes through middle age to older age. And this includes a spectrum of mental health, rehabilitation research, prosthetics, and so forth.

We have an insight, I think, that others may find it more difficult to have because most of our investigators are clinician scientists who are actually taking care of patients and have direct knowledge of what conditions they face. So I think this gives us added insight into dealing with veteran centricity.

THE CHAIRMAN. The reason I ask that question is that we have a VA system today that is much different than it was a decade ago. The reason I make this comment is VA research, I believe, needs to be veteran-centric and it cannot be all things to all people.

In other words, you cannot let the - whatever physical ailments or whatever may depreciate the human body from a nondisabled veteran, a category seven or eight who is very similar to people in the normal population, cannot drive VA research.

That is the reason we here in Congress fund NIH and have doubled NIH funding. And I want to make sure that with our centric meaning we are focusing on every war having different types of injuries and ailments. And so when I use the term veteran centric research, that is what I think of.

Our polytraumas, the blast injuries, the brain trauma, continuing on spinal cord, all these things to me, yes, are combat related, but there are also some workplace injuries that are unique by what we do and the environment in which our servicemembers work. And I want to make sure that in our priorities and how you come to judgment, you keep that in mind.

Mr. Michaud, any questions you may have.

MR. MICHAUD. Thank you very much, Mr. Chairman.

A couple of questions. The National Vietnam Veterans' Longitudinal Study was mandated by statute. The report was supposed to be due to Congress no later than October 1, 2004. It is now approaching two years since that report is due.

In light of the mandate and the law, when will we be able to see results from that report?

DR. PERLIN. Well, thank you, Mr. Michaud, for your focus on this incredibly veteran centric research in the terms that our Chairman just described.

The National Vietnam Veterans Longitudinal Study is the product of a cohort that has been followed over a long period of time. Dr.

Matthew Friedman, who is here with me today, was one of the early founders of the preceding study that gave rise to NVVLS.

As I believe you may know, the Committee may know, the study was stopped by the Office of the Inspector General after significant cost overruns.

I think that within the department, there is an absolute commitment to understanding the needs both in terms of mental health needs and the physical health outcomes of Vietnam era veterans, but there are significant questions about the power of the remaining cohort's data to answer those questions.

There have been briefings to members and staff serving this Committee, and they have discussed a number of alternative approaches both with respect to Vietnam veterans as well as other veterans in terms of looking at health outcomes and PTSD in particular.

One is the use of a Vietnam Era Twin Registry which allows one to compare environmental and genetic exposures and be able to understand both risk and outcomes. Another is something that we have today, but, frankly, we did not have when NVVLS was initiated, and that is the electronic health record.

So rather than being able only to focus on a small group of veterans that sadly diminishes over time, one can actually look at an entire population or sample of that population and look at all health outcomes. And these are proposed mechanisms to get to the intent of that legislation.

Dr. Matthew Friedman has been very closely involved with this study, and I turn to Dr. Friedman to offer any additional comments.

MR. MICHAUD. Are the results forthcoming?

DR. PERLIN. It is in a bit of a holding phase after the Inspector General's investigation of the study. And I would say to you again that there are methodologic issues with the size of the cohort that is left to be able to offer significant insight.

I would think that one could get to those answers as well through use of electronic health records for the Vietnam Era Twin Study, and I would ask Dr. Friedman perhaps to elaborate on that.

DR. FRIEDMAN. Good day.

As Dr. Perlin has indicated, the NVVLS was discontinued based on the background that he has given you. So what I would like to review with you are the goals of the study which were to really understand the longitudinal course of PTSD, the severity of the problem, and one of the unique questions in the NVVLS that was not addressed in the earlier National Vietnam Veterans Readjustment Study, the relationship between PTSD and physical health.

So after the study was discontinued, the Secretary of VA asked Dr. Perlin and his staff to look at alternatives. And the two alternatives that he has mentioned, which I will go into a little more detail about, have been the Vietnam Era Twin Registry and this very exciting OIF

Prospective Pre-deployment, Post-deployment Study.

The Vietnam Era Twin Registry is actually a remarkable database. There are now about 4,000 monozygotic and dizygotic twins. Most importantly, 1,700 of them are discordant for service in Vietnam. What that means is that -- and these are all males, so that is -- one brother was in Vietnam. The other brother was not.

The sample has been surveyed twice, once in 1987 and once in 1997. And two very important findings have been published from this study. One concerns the chronicity of PTSD, and the other concerns brain imaging among Vietnam veterans.

With regard to chronicity, there was a robust dose response curve, showing that the more severe the combat exposure, the greater the likelihood of PTSD. And among the Vietnam veterans with severe exposure, their PTSD remained highly chronic ten years later. So obviously a continued follow-up is important.

Another very important study from this cohort was some of the brain imaging work, looking at hippocampal volume which is one of the structures of the brain that seems to be affected and altered among people with PTSD.

So this is a very valuable research. As you all know, in animal research, one of the things any investigator does is they use inbred genetic strains so that you can control for whatever variability a different genetic endowment might have. We can control for that with the Vietnam Era Twin Registry.

So this is a very extraordinary cohort in which we can follow medical problems, look at risk factors, resilience factors, et cetera. So this is one option that is being looked at very, very carefully right now.

The second option which is, as Dr. Perlin indicated was not on the screen when the NVVLS was first thought about, is a pre-deployment study that is being done mostly at Ft. Lewis and Ft. Hood where at this point in time, over 1,500 men and women have been evaluated with respect to neurocognition, because that was a big concern following the first Gulf War, and given our concerns about traumatic brain injury, it is obviously a very important concern following these current wars. They have also been assessed regarding pre/post-deployment psychological factors including depression, anxiety disorders and PTSD.

So over 1,500 men and women have been assessed prior to deployment. And what is really important, they have been assessed shortly after their return and will be assessed longitudinally into the future. We can really look at the longitudinal course. Also several hundred Guard and Reserve men and women are also in this cohort. So this is a very, very valuable cohort.

So at this point in time, VA sees these two studies as preferable options to the NVVLS.

MR. MICHAUD. Could you provide the Committee, Dr. Perlin, with

the list of research that VA is currently doing, what you would like to do as far as research, and what you are doing collaboratively with other areas as far as research in this area? If you can provide that information to the Committee.

DR. PERLIN. Yes, sir. We would be happy to provide that.

THE CHAIRMAN. Could the gentleman be just a little more specific with regard to which area.

MR. MICHAUD. I am interested in all the research that the department is doing, if they have a list.

DR. PERLIN. We would be happy to provide a summary of all of the research programs. And I believe you were also seeking the collaborative activities specifically about mental health as well, the focus?

MR. MICHAUD. Yes, as well. I am trying to understand better what you are doing and to make sure that the research is prioritized.

My last question, if I might, Mr. Chairman, is, if you look at what is happening, almost 30 percent of the patients admitted to Walter Reed Hospital has a brain injury, and I know it is very difficult to try to diagnose brain injury, if you could very briefly tell me what the VA is doing to improve diagnostic and screening for brain injuries.

DR. KUPERSMITH. Yes. We have an RFA that we have just on that topic. And our projects that we have received span the spectrum from imaging to make a better diagnosis, various kinds of therapy, various other diagnostic techniques, biomarkers, cellular studies to see if we can come up with some basic treatments for it, and a variety of other projects that span from basic science to clinical.

So we are anticipating to fund these about the end of this year, and we will be very heavily into this area.

DR. PERLIN. If I might just elaborate on your question in that you have identified a significant issue which is head trauma and brain injury.

The very significant trauma that someone experiences with other multiple traumas is very obvious. And, of course, one appreciates very quickly that the individual sustained brain injury.

I believe what you may also have been alluding to are the concussive injuries that some may experience that are very subtle in terms of detection. Frankly, VA, DoD, no one at this point has a gold standard for diagnosing very subtle brain injuries, yet it is fairly clear there are some individuals who experience a minor concussion and do have some cognitive disruption. It is unknown what the duration of that is. It is unknown what the best recovery strategies are.

What is clear is that all of us in all segments need to be better at diagnosing it and that specifically is one of the areas of research both of Department of Defense and Walter Reed as well as VA in this request for applications.

THE CHAIRMAN. I thank the gentleman.

Mr. Brown, you are recognized for five minutes.

MR. BROWN OF SOUTH CAROLINA. Thank you, Mr. Chairman.

Dr. Perlin, we have had several veterans come to my office that have ALS and they brought statistics that shows that it is a disproportionate number of pilots that flew over, I guess, Vietnam and the Gulf that have, you know, come down with ALS.

And I was just wondering if you were doing more in your research to try to find a cure for ALS and could you give us an update of where we are on that research.

DR. PERLIN. Well, thank you, Chairman Brown.

This is a tremendously important observation is that the rates of amyotrophic lateral sclerosis or Lou Gehrig's Disease were found initially to be higher in pilots. And then subsequent research actually found that there were higher rates in military at large.

And so this is an area of a very specific enterprise, and I am going to ask Dr. Kupersmith to elaborate on that.

DR. KUPERSMITH. We have a number of projects related to ALS. It is certainly a focus of our interest. And as Dr. Perlin mentioned, there have been reports of increased incidence with various wars and with the military as a whole.

So this is an area of interest. I do not have a list of projects here, but can certainly provide you with such a list.

MR. BROWN OF SOUTH CAROLINA. Well, I guess that kind of leads me to my next question, is how you establish in your funding the priorities, you know, which area has more funding or more attention put than other areas. How do you go about establishing prioritization and where those monies will be addressed or directed?

DR. PERLIN. Let me start that question and then I will ask Dr. Kupersmith to add to that, is that we have a rubric called designated research areas. And these research areas range from those things that are absolutely central to the combat experience, brain injury and multiple trauma and sensory injuries, central nervous system injuries, spinal cord injuries and the accompanying bone loss and degenerative diseases and rehabilitation.

Those are the designated research areas. A lot of these overlap. If you have mental illness, of course, you do not get a bye, you do not get a pass from physical disease. In fact, it may be worse. We have areas that focus on the mental health and well-being in the context of these other areas.

And so we actually have a list of designated research areas and we try to take a look within the dollars that you appropriate to us for VA research to make sure that we are doing as good a job possible as in the words of Chairman Buyer, being better and veteran-centric.

At a time of conflict as we are in now, in fact, the budget increases from 66.8 to \$74.9 million in the 2005 to 2007 period focusing on just these sorts of issues.

We also look at the experience. As Dr. Kupersmith said, the very

clinicians who are taking care of veterans and servicemembers are also the researchers. So one of the most important things about the VA research is that we are not NIH. We are not all things to all people. It is not our aspiration to be that.

And as you may know, I served a brief tenure as the Acting Chief of Research and Development and my litmus test was, “show me that the work is relevant to the care of veterans.” And this is our litmus test.

And the great value of VA in contrast to virtually anywhere else is that the clinicians caring for veterans go back to the laboratory, whether it is basic science or clinical research, armed with the picture of veterans experiencing illness, needing help improving their health and well-being and generate the questions. And they bring forward that knowledge from the bench, from the laboratory, from the research studies to the patient care.

Dr. Kupersmith.

DR. KUPERSMITH. Yes. And I would like to elaborate, give you an example of that. It has been the observation that disabled individuals, paraplegics for example, have obesity as both apparently a metabolic problem and a problem related to their level of activity.

So we have an RFA on that very topic. This is a clinician’s observation, very relevant to the VA, very veteran centric, that we turn around. And then as we have the research projects, we have ways of translating those directly to the patient by several of our research implementation programs.

And I think the VA has really been a pioneer in part because the clinical and the research enterprise are together in how to implement the findings of research to the bedside.

So whatever observations that are made in research in obese, disabled individuals, we can translate directly to the bedside. And this has a tremendous impact. These metabolic conditions have a tremendous impact on their long-time survival. So it is just an example of that.

MR. BROWN OF SOUTH CAROLINA. Mr. Chairman, I know my time is expired, but just one further question to follow-up on that.

I know that in the Medic University and the VA, they have a cooperative research lab there, the Thurman and Nagesi Heart Center.

And I was just wondering with ALS, are we partnering with anybody in the private sector to try to find a cure for this terrible disease?

DR. PERLIN. Let me ask Dr. Ruff. Dr. Ruff actually wears two hats. He is our Chief of Neurology. He is also the Acting Chief of Rehabilitation Research and Development.

Dr. Ruff.

DR. RUFF. Let me address ALS first. ALS is a chronic degenerative condition that comes under the auspices of neurology and also under

the auspices of rehabilitation.

From the clinical side, we are working with to try and enhance the treatment of people with ALS so that people with ALS are able to get treated on spinal injury units when they have advanced to the point of becoming functionally totally dependent for care.

The VA researchers are -- there are several research projects that are jointly funded by the VA and NIH looking at the mechanism of neurodegeneration associated with ALS. And these are projects that are funded through -- most of them are funded through basic science. Some are through rehab.

But one thing I would just like to say without taking too much time is that one of the things that I personally found very exciting and very encouraging about what is going on in the VA is that walls that existed between clinical service, research, and within research are coming down so that we are directing our efforts towards veteran problems rather than being stuck in specific silos.

And I think that Dr. Perlin and Dr. Kupersmith have had a great deal of influence in terms of trying to get a more integrated approach so that there is integration of clinical and research activities and integration within the clinical services.

With respect to the question that was raised about detection of brain injury, this is a very difficult and serious problem. Minimal traumatic brain injury is something that is being recognized as a serious problem for people in the Middle East right now in OIF, OEF.

The PDRECCs, which are the Parkinson's Disease Research and Education Clinical Centers, are working with Department of Defense to explore the utility of a very simple but sophisticated test of all factions as a means of early detection of brain injury and sensitive detection of brain injury.

The nerves that are involved in smell are very fine. They go through a screen-like structure at the base of the skull and they are very easily damaged in head injury. And so it may be possible to use those changes in smell as a way of picking up otherwise very subtle brain injury.

Thank you.

THE CHAIRMAN. Dr. Ruff, I would ask you to be responsive to Chairman Brown's question on whether you have any knowledge whether you are partnering with any outside private entities with regard to ALS.

DR. RUFF. Yes. We are working with Paralyzed Veterans of America which has a strong interest in ALS. There is also the ALS Foundation. We do not have any direct grants with the ALS Foundation, but I met with people from that foundation in order to try and make sure that what we are doing is relevant to their needs and our needs.

THE CHAIRMAN. Mr. Brown.

Ms. Berkley, you are now recognized.

MS. BERKLEY. Thank you, Mr. Chairman. I have three different questions on three different issues, the first directed to Dr. Kuper-Smith.

I listened to your testimony and this 24-year-old lieutenant that I spoke of when I did my opening statement, when I left Walter Reed, I invited him to come to Las Vegas when he was well enough to get out of the hospital. And he is coming.

So the good news is that he is well enough to come to Las Vegas with his wife. And I want to be able to look this kid in the face when I see him.

You mentioned in your testimony about cutting-edge research and I so regard and respect what you are doing, but are you going to be able to do cutting-edge research with a \$13 million cut in prosthetic research?

And perhaps Dr. Perlin would like to -- I do not care who answers, but I want to make sure you get enough resources so you can do your job, so I can do my job with my veterans.

DR. KUPERSMITH. Yes. We are looking at how to essentially make cuts in certain areas and certain programs. For example, we are evaluating our centers to see that they are being productive, that they are leveraging money the way they should, and that they actually are doing what is set out. This is something that all research institutions do. But that is one way that we are looking at trying to conserve some resources for other areas which are important.

Certainly we have an extensive program in prosthetics. I think we have probably led the country in prosthetic research.

MS. BERKLEY. And you can continue this with a \$13 million cut?

DR. KUPERSMITH. Well, we calculated --

MS. BERKLEY. Do you want a \$13 million cut? Do you want the money back?

DR. KUPERSMITH. Well, we have calculated a certain number of projects less based on that, but we will be looking at how to conserve resources in other ways, particularly looking, as I said, at our centers. We are making a review of our cooperative studies program centers and other similar endeavors.

DR. PERLIN. If I might, let me thank all members of this Committee for your support of VA research as demonstrated in the increase of resources for the research program.

Second, let me note that when we provide services to veterans who need a prosthetic device, that does not come out of the research budget. That comes out of the prosthetics budget. And I want to again thank this Committee for your support and leadership in ensuring that we have those resources.

In 2005, we spent \$1.039 billion on prosthetics and assistive devices. That was increased by 188 million for this year's budget of 1.227 billion. And the budget that you have supported adds another 160

million in 2007 to bring that to 1.387. So I can assure every injured servicemember they will have the state-of-the-art device.

As to the research, if I might, this is an area of tremendous focus. Again, the test is veteran centricity, whether it is limb loss prevention, prosthetics engineering, abilities to make the devices more effective, less damaging, the ability to provide rehabilitation, socialization, to advance techniques.

Right now a lot of prosthetics sit on the end of a limb. We have tissue engineering laboratories that will seek to create a different sort of interface, to actually allow people greater function. The list goes on and on. And Dr. Kupersmith makes no exaggeration saying the VA is the leader in the prosthetic device research.

MS. BERKLEY. No doubt. I just want to make sure you have got the resources to do the job that we have tasked you with.

DR. PERLIN. Thank you.

MS. BERKLEY. All right. The second question or second query. As you know, we have been talking for the last couple of years about the Nevada Cancer Institute partnering with the VA in Nevada.

After two years of being at cross purposes and hearing two different stories from the VA and the Nevada Cancer Institute, I took it upon myself to bring both parties into my office this past week when we were home for our Memorial Day break.

And, of course, Ken Clark, the VISN 22 Director, came in, John Bright. Both men I have tremendously high regard for and I have worked very closely with them. We also had Heather Muran and other people from the Nevada Cancer Institute there.

It seems as if we have broken through whatever issues there were, but can I ask you to please keep on this and report back to me so I know that we are on board because I do not want to be talking to you about this two years from now and we have not moved from, you know, the starting line on this issue.

And I agree with you 100 percent that there should be a separate VA healthcare system. I have not been fighting the last several years for a VA hospital clinic and outpatient clinic and long-term care facility for my veterans exclusive of anything else because I do not agree with you.

But on the other hand, when we have an opportunity to partner with a state-of-the-art group like the Nevada Cancer Institute, I would like to do this if it is a benefit to the veterans.

So are you going to keep in touch with me and let me know what is happening?

DR. PERLIN. Absolutely. I appreciate your help in bringing folks together. I have spoken with both Ms. Muran a number of times as well as Mr. Clark. And they understand the ways in which they can partner and they are excited about the potential for collaboration.

MS. BERKLEY. Now, they talked about a number of things in my

conference room. Can you check with Ken Clark and make sure that we are going forward? And, you know, it seems like just a series of miscommunications. Have you already done that?

DR. PERLIN. Yes. In fact, Congresswoman, I am pleased to report that I have spoken to Mr. Clark the issues related to --

MS. BERKLEY. I am pleased to hear it.

DR. PERLIN. -- VA research policies. And I think there is common understanding and enthusiasm.

MS. BERKLEY. Great. The third thing and very quickly, I know in your opening statements, you were talking about the VA's plan for a genetic database with information on potentially millions of VA patients. And obviously we all know that raises several privacy concerns, ethical concerns.

In light of the latest issue with the theft of 26 million veterans' personal information, what are you going to do to keep this information out of the hands of healthcare and insurance companies and what safeguards are you going to implement to ensure that the veterans' genetic health information remains private and a floppy disk does not go home with some idiot employee?

DR. PERLIN. I want to thank you for asking this very important question --

MS. BERKLEY. You are welcome.

DR. PERLIN. -- because it needs addressing. And with the Chairman's permission, if I could have a moment to answer this.

MR. BROWN OF SOUTH CAROLINA. [Presiding] I would just identify that her time has expired, Dr. Perlin, but you certainly may continue if you would.

DR. PERLIN. Well, thank you because I know everyone is curious about this.

First, I want to make very clear the point that the circumstances that occurred are tragic and should never have nor should they ever occur again.

Let me assure as well, the Secretary, Deputy, entire leadership team, every VA employee takes this very, very seriously.

As a third point, I want to also make very clear this did not involve VA's electronic health records, VHA health data, or anything within VHA. These were departmental administrative data resources.

The reason I make this distinction is because in the health setting, all of us have an ethos that really focuses on the privacy of patients, the privacy of health information. This dates back to the Hippocratic oath which actually includes keeping private a patient's health information.

So, in fact, in the health setting, in the health administration, we start with an advantage. We start with an ethos that is directed at security of health information. And that is not sufficient though. We actually have a significant amount of policy within the healthcare

setting as relates to things like HIPPA and privacy laws. And it is not just that policies exist. We are also inspected and there is significant oversight in this area.

That oversight includes in the clinical area the Joint Commission which has an entire chapter devoted on patient privacy and information security. It includes our own internal inspection process, the SOARS process, Systematic Oversight Assessment and Review System, which is like an internal IG. And, of course, the Inspector General also surveys on CAHP reviews our protection of security.

In the area of research, there are handbooks that derive from the departmental policy, significantly amplified by those things unique to healthcare that I have mentioned that require different levels of data security, different data systems, different system of records, different context, different training requirements, and different oversight that are added to again by policy for data protection in the research context.

The Genomic Program is one element that provides the opportunity for research and insight. Another element is simply for treatment. Today there are 14,000 genetic tests that are available. And, in fact, they allow us to choose better medications for mental illness. They allow us to prevent horrible drug toxicities.

For instance, for 299 out of 300 kids with childhood leukemia, 299 will do well. One out of three hundred will die. That outcome is something that is avoidable with genetic information, with one of the tests that is, in fact, available today, and we can know that.

We have a good track record in the health system of keeping private very sensitive information, information about mental illness, information about substance use, information about infectious disease, HIV as an example, sexually transmitted diseases. These are things we keep private.

And it would be on that background that in the clinical context, this privacy would be secured and it would be in the context of the additional oversight provided by institutional review boards and accreditation of VA research programs and the human subjects protections, the Office of Research Oversight, that any data would be generated in the Genomics Program with the additional oversight of the Genomics Advisory Program that Dr. Watson might wish to speak to, and the additional ethical oversight, the veteran input, the service organization input, and what I hope is ever more vigilant management.

MS. BERKLEY. But when you embellish on this answer, I mean, I appreciate that, but with all the track record, the ethos that goes back to the Hippocratic oath, with all the oversight and the regulations and the handbooks, we still ended up with an employee taking these records home.

How do you protect against something like that?

DR. PERLIN. Let me again distinguish. The track record of the

health system --

MR. BROWN OF SOUTH CAROLINA. Dr. Perlin, I hate to interrupt this proceeding, but the five minutes has been ten minutes now and we must have other folks that want to ask questions. And I know this is an important subject.

Maybe Ms. Berkley can have a private meeting with you to discuss these issues.

MS. BERKLEY. You are always welcome in my office.

MR. BROWN OF SOUTH CAROLINA. Sorry to interrupt you, Ms. Berkley, but we must proceed on.

MR. STEARNS.

MR. STEARNS. Thank you, Mr. Chairman. And I appreciate that because like many members, I have another appointment and I did want to come here to talk to you.

And I really had a question like Ms. Berkley mentioned, but I would like to go a little bit more definitive in this.

Is the genetic information encrypted? Just yes or no. Just yes or no.

DR. PERLIN. You are asking a question about clinical information or research information. The answer is --

MR. STEARNS. The research information that you have collected on veterans, is it encrypted?

DR. PERLIN. Well, we have not collected any for this specific program yet.

MR. STEARNS. Okay.

DR. PERLIN. So it is a theoretical question.

MR. STEARNS. So right now you do not have any information on genetic --

DR. PERLIN. We have genetic information.

MR. STEARNS. When a veteran comes in, when a veteran comes in, he signs a form and he or she signs this form and you can do tests and automatically if you have blood samples, you have a lot of information on that veteran including his genetics.

DR. PERLIN. Yes. Health information --

MR. STEARNS. So the question is, is that information that you collect, which can be tied to its genetics, is that encrypted?

DR. PERLIN. No. It exists behind a firewall.

MR. STEARNS. Okay. And what is this firewall?

DR. PERLIN. A firewall is a system to prevent unauthorized use of data, unauthorized use of data.

MR. STEARNS. But let us say someone got access through that firewall, then it is legible? It is not encrypted?

DR. PERLIN. Yes, for a single record.

MR. STEARNS. Okay. Do you have someone identified who is a Chief Security Officer?

DR. PERLIN. Let me answer that in two ways. First, within VA,

VHA, we have individuals at every medical center who deal with patient privacy because it is that significant an issue.

MR. STEARNS. So there is a Chief Security Officer at every medical facility?

DR. PERLIN. There is an Information Privacy Officer. The other is that VA as of about two and a half years ago centralized the information in a cyber security program. And so, in fact, for the architecture of the entire system, there is a central oversight of cyber and information security.

MR. STEARNS. And where is that geographically located?

DR. PERLIN. That is right here in Washington.

MR. STEARNS. Okay. So in Washington, we have all the genetic information collected? Is that true?

DR. PERLIN. No, no, no. I thought you were referring to the cyber security offices here in Washington.

MR. STEARNS. So what is collected here in Washington? All that information?

DR. PERLIN. Well, no. Nothing exists here in Washington. There is clinical information at each medical center.

MR. STEARNS. No. But I am talking about the genetic information is at various hospitals throughout the country; is that correct?

DR. PERLIN. All clinical information --

MR. STEARNS. Yeah, correct.

DR. PERLIN. -- is at hospitals through the country.

MR. STEARNS. And in each one of these hospitals, there is a Chief Security Officer?

DR. PERLIN. There is an information privacy person. There may be one that supervises two consolidated facilities.

MR. STEARNS. Would that same person be the one that was supposed to protect the information that got lost, the 26 million?

DR. PERLIN. No.

MR. STEARNS. It is a different person?

DR. PERLIN. We are talking about health information within the Veterans Health Administration.

MR. STEARNS. So they are not combined?

DR. PERLIN. They are not. The information that was lost was a departmental administrative data set.

MR. STEARNS. Okay. And the information that we are talking about is in a different --

DR. PERLIN. One hundred percent --

MR. STEARNS. -- under a totally different --

DR. PERLIN. -- totally different.

MR. STEARNS. -- security?

DR. PERLIN. Yes.

MR. STEARNS. And with its own Security Chief, Information Privacy Officer?

DR. PERLIN. Again, if I might distinguish, there are Privacy Officers that are germane to health.

MR. STEARNS. Right.

DR. PERLIN. There are Information Security Officers that oversee system intrusion, et cetera. The Privacy Officers would establish and enforce the policy for protection of health information and adjudicate questions about access.

MR. STEARNS. Okay. Is that a policy that you have with this Security Officer? Is that ever audited by you and management or anyone else?

DR. PERLIN. The privacy of patient records is absolutely audited. Every Joint Commission inspection requires an audit of protection of patient privacy. The CAHP reviews --

MR. STEARNS. And is that audit inside or out? Is it people from outside the VA or is that people within the VA who audit it?

DR. PERLIN. Well, the Joint Commission is entirely outside. The Inspector General, of course, reports to the President.

MR. STEARNS. Okay. So in answer to Ms. Berkley's question, you do not think what happened to the administrative information could ever happen to this hospital clinical genetic information, could never occur?

DR. PERLIN. Well, let me answer this way, is that as we go forward in constructing what will be a relational data set, let me assure you that while we believe our systems are very secure, while we believe our ethos is different, there are clearly some lessons, wider lessons.

If a data set exists free-standing, which is not how the electronic health record works, it brings together a bunch of information that is visible for that moment that someone is looking at the screen from different sets, that any data set that exists free-standing is encrypted and secure, that is a lesson.

We believe that our systems are good, but I would be inappropriately assertive if I were to say that we did not learn some lessons that we would apply, and this is a focus area of attention within an entirely different system of records.

MR. STEARNS. Let me just conclude, Mr. Chairman.

What is one of the greatest lessons that you have learned from that information that was lost that applies to your information privacy of this health information? What is one lesson, the greatest lesson that you learned?

DR. PERLIN. Congressman, that is a fantastic question and it comes down to this, which is that however hard the systems are, however strong the policies are, however the great the oversight is, we cannot make up for human error.

That is where the ethos of healthcare helps us focus on the "warm-ware," and we will be coming forward with a number of policies to work on the warm ware, the people, to understand what their respon-

sibilities are and the context of the privilege that they operate in in providing healthcare to veterans.

And with that, whatever the strength of the hardware protections we place, whatever the strength of the oversight, whatever the strength of the polices, all of the forcing functions, human error is still possible.

And we want to create systems that are as resistant as possible, but we also want to work on the way people think about this and make sure that every last person, even in the Veterans Health Administration, which has not experienced this type of data loss, even in that, understands that it's their individual responsibility as part of the privilege of serving veterans.

MR. STEARNS. Thank you, Mr. Chairman.

THE CHAIRMAN. Thank you, Mr. Stearns, for your contribution.

Ms. Brown, you are now recognized for five minutes.

MS. BROWN OF FLORIDA. Thank you, Mr. Chairman.

Dr. Perlin, you and your staff, we are very lucky to have you in the position. The veterans are very lucky to have you with your credentials. And, you know, I am very impressed with your commitment to the veterans and making sure that they get quality care.

In this light, I am concerned as what was raised earlier that the Bush Administration has sent us two budgets in a row that cut appropriation dollars, in 2006 by nine million and 2007 request by \$13 million.

In light of this request, how important is recruitment of physicians and other medical health people, retention as a priority of the VA?

DR. PERLIN. Thank you, Ms. Brown, for just a tremendously important question.

The research dollars allow us not only to perform the research in the interest of improving the health and well-being of veterans, but because the researchers are the very same clinicians and subspecialists who provide the care, it is tremendously important. It is one of the reasons that many people decide to come to VA.

They come for the mission of serving veterans. They come for the model of care that we practice. They come for the ability to really be at the top of the field in terms of advancing the knowledge. And so it is tremendously important in terms of recruiting the best and brightest for the care of veterans.

MS. BROWN OF FLORIDA. Yes. And I know it is not because of the pay that you get, but it is because of the commitment that you have. And I think that is important.

Second question, I was watching the news yesterday where the veterans organization is suing the VA. And I am going to look at filing a friend of the court because I think that there is major problems with - and we have been discussing that - regarding the 26 million veterans and servicemen, the policies and procedures of the Office of Research

and Development. You have explained that.

But what about the other additional procedures and concerns? You talked a little bit about that, but can you assure us today that we will not later learn that some of that information pertaining to VA medical records was lost?

When we heard from the Secretary last week, I was very concerned that it could be others out there that could have taken information and we just happened to find out about this particular data. Go ahead.

DR. PERLIN. I am sorry. Congresswoman, this absolutely positively was not veterans' electronic health records. This was departmental data, administrative data, not veterans' health records.

MS. BROWN OF FLORIDA. So you are assuring me that I will not find out later that any veterans' health records are just floating out there?

THE CHAIRMAN. Will the gentle lady yield for a second?

MS. BROWN OF FLORIDA. Yes, sir.

THE CHAIRMAN. The leadership of the Committee have worked together to lay out a series of hearings in the month of June that is just being announced and one of those -- I know Chairman Reyes just left -- the Subcommittee on Health along with the Ranking Member Michaud will be holding a specific hearing with Dr. Perlin to cover the very same issues that you are covering.

MS. BROWN OF FLORIDA. Okay.

THE CHAIRMAN. And I am sure that you will be able to go into great depth --

MS. BROWN OF FLORIDA. All right.

THE CHAIRMAN. -- at that Subcommittee hearing. I wanted the gentlelady to know.

MS. BROWN OF FLORIDA. Well, thank you.

And so then I will just follow-up that I have a letter for you, Dr. Perlin. I have had a couple of meetings on the issue that we have about the VA clinic in Jacksonville. And we have had two meetings and I am requesting a third that we will have here in Washington.

I know in Washington, a million here and a million there is not any real dollars. But my city, we have spent over \$3 million trying to accommodate the Veterans Administration.

And the people that you have sent down are arrogant. They are basically -- you know, I am trying to be nice, but that is not something that this gentle lady is used to being. I just need a meeting with someone that is not just -- do not care anything about, you know, the veterans. You know, it is just not working in a manner that is acceptable to me, the city, or the veterans who are calling me.

And in Orlando it has been 25 years and we still do not have a hospital. And I am not going to have this happen in Jacksonville.

DR. PERLIN. Well, Congresswoman, I may be the other person in

the room who is equally frustrated at the inability for all of us to get together. It is our desire to serve the veterans that are in Jacksonville.

Let me thank you for your trying to bring together all of the different people and the city and VA to make it work out. I have some information and maybe it would be good for you and I to get together and just compare our notes on what is needed.

I think it will take both of our work to get things together, but our goal is the same, to make sure that we have the clinic sized adequately with adequate parking, able to provide the care to your veterans there in Jacksonville.

MS. BROWN OF FLORIDA. Any time.

DR. PERLIN. Thank you.

MS. BROWN OF FLORIDA. Thank you.

Thank you, Mr. Chairman.

THE CHAIRMAN. Thank you.

Dr. Watson, I have a series of questions for you. What is your role at the American College of Medical Genetics?

DR. WATSON. I am the Executive Director of the American College of Medical Genetics. I am a Board Certified Medical Geneticist by training.

THE CHAIRMAN. And you are a member of the Genomic Committee?

DR. WATSON. Yes, recently appointed. The group has yet to meet, so I cannot express any opinions of theirs yet. However, I can express my own and those of the genetics community.

THE CHAIRMAN. And as you go to this Committee, what are your priorities?

DR. WATSON. Well, certainly to -- well, there are multiple, frankly. I think the opportunity that the VA system offers is tremendous for both the veterans and for genetics.

Genetics is really a translational medicine area of practice now. It is not this research box that sits, that people think of as a basic science entity. It is not necessarily always hardcore, standardized clinical service.

It is using the best systems we have, and certainly the VA has one of the best electronic medical records systems available where we are now able to really validate what we do in genetics and across the spectrum of healthcare. And I think that is the benefit of these systems.

Much of what we practice in medicine today is not well validated and there are many questions as to whether we actually know what we should be doing all the time. And the opportunity to use an electronic medical record to inform us about what is the best of multiple options that might be available to us when we manage a particular condition is significant.

The ability to use the systems to educate physicians who by and

large have not been exposed to much genetics, it has broken lose tremendously over the past decade.

So our ability to bring point of care education through electronic systems is tremendous and to really get at the chronic diseases which I think the veterans allow us to really get at in genetics. And we have done pretty well in rare diseases, you know, the things that have very powerful genetics behind them. But the chronic disease side has been quite difficult to get at.

And I think first starting with a population that has certain environmental or other exposure factors that increase their chances of particular diseases being expressed makes them a very valuable resource for understanding the chronic diseases, and then to really be able to develop how we practice because genetics is going to be an ongoing evolutionary area of practice. We will learn as we go as we have for the past 30, 40 years.

THE CHAIRMAN. Describe what pharmacogenomic profiling is.

DR. WATSON. Pharmacogenomic profiling is really -- it is going to be more than I think what people think it is today. Today when we talk about pharmacogenetics, we do a test to determine whether or not somebody is going to metabolize a particular drug in the way that we would expect them to to get the response that we expect from having been treated.

We know that many people may have an enzyme defect that does not allow them to metabolize that drug appropriately so that we can then determine whether that drug is right for that person. We can also use it to determine whether or not dosing is the issue for that particular person.

I think what -- that is sort of the classic model, I think, of pharmacogenetics today. But I think where it is going is something that Dr. Perlin alluded to which is the Gleevac story in CML where based on the molecular nature of an abnormality that led to a particular condition, we now have molecular treatments that target the very specific molecular abnormality that led to that disease.

And I think that is a very personalized directed kind of pharmacogenetic approach that is not -- there is not a lot of it available right now. Probably three, four drugs that very directly target a molecular structure. That is an acquired abnormality of the genetic material, different than pharmacogenetics now which is an inherited defect in an enzyme that does not allow you to metabolize a particular drug as most people might.

THE CHAIRMAN. All right. Now, let us go to the tough question, and that is how we balance our interests - and we will go to the beginning - how we balance our interests to be veteran centric in our research while being cognizant of something that is on the cutting edge that is so beneficial to our general population. Right? I mean, that is what we have here.

At the same time, because it could leverage into tremendous benefit to us and you have to make a decision here, Dr. Kupersmith, with regard to limited dollars, everybody is in competition for them. Okay? So I am curious here as we do our balancing test. Let me yield to you.

DR. PERLIN. Mr. Chairman, that is a terrific question. First, I would have to say that it is not a question if genetic medicine is coming. It is coming. As Dr. Watson said there is right now the ability to choose medications, and certain patients' pain medicines do not work as well. So in most African-Americans, metabolism of pain-relieving, opiate-type drugs is faster and pain dosing is typically under-dosed.

But to the second part of your question, how is this specifically veteran centric? Well, this is really the window to understand how some people may be differentially susceptible to nerve gas or pyridostigmine bromide or development of PTSD or the treatment.

In fact, I might ask Dr. Friedman to talk about some of the advances in psychopharmacology, treatment for mental health based on genetic differences.

Do you want to elaborate on that as we talked yesterday?

DR. FRIEDMAN. Well, I mean, everyone is different. Everyone is different genetically. That is one of the reasons why the Twin Study is such an important resource. They are different in terms of how exposure to combat trauma might affect them. Are they going to be resilient and be able to do just fine or are they going to be quite vulnerable and develop PTSD or other kinds of problems?

We really feel that the question of resilience is one of the most important questions in the PTSD field. We have studies, collaborative studies at Ft. Bragg right now trying to understand what are the molecular differences as well as the psychobiological difference between people who are resilient and people who are not.

As Dr. Watson said and Dr. Perlin emphasized earlier, these studies also have implications in terms of who is going to be a good candidate for what treatment, whether it is a pharmacological treatment or a psychotherapeutic treatment.

THE CHAIRMAN. I know we have Dr. Snyder here, but let me finish this. I use the word balance, but there are also tradeoffs. So when you propose to us a decrease in funding and then appropriators would come back and we put that back in. Somewhere you are making some judgments and you are making some judgments here to say, okay, we are going to decrease our research on heart disease. Maybe you made that judgment. I can only do supposition to say well, maybe that is where NIH is pushing over there; therefore, we can go here.

I am trying to get into the analysis of your professional judgment. Dr. Kupersmith, what are you doing here? How are you making these judgments to say, okay, Dr. Watson, we like what you are doing, we are going to make some investments here? A decision was made. You

made a priority judgment. You testified on this before, Dr. Perlin. So now Dr. Kupersmith, how are you carrying this out? Let us know where the puts and takes are.

DR. KUPERSMITH. Let me just first say that this is not a choice between doing research in heart disease and doing research in genomics. I am a cardiologist. Genomics is the future treatment of heart disease. The very same pharmacogenomics that Dr. Watson was talking about has already applied in some ways to heart disease in the use of anticoagulants and other drugs.

So this I see as the future of caring for patients with heart disease just as you raised that example. And if we are to look at the future of what is the best way that we can improve the care of veteran patients with heart disease, the judgment here is that this is going to be at the forefront.

So I think that that is part of it. I also think that this is ultimately the most veteran centric kind of research that we can do because it involves the genetic makeup of our veteran populations and how that relates to the diseases we have.

As you know, there has been a tremendous amount of work looking at exposures to various insecticides and other agents. It is not a bad hypothesis that this has a genetic basis, that some people are more susceptible and, therefore, have symptoms from it or diseases from it so that it is another area where we can make advances where there has been really, I think, road blocks to getting ahead in that area of research.

There are many, many - we can go through the entire spectrum of diseases in this way.

THE CHAIRMAN. Dr. Snyder, Dr. Watson has to take off. If you have a question on genetics, genomics, he is our man.

MR. SNYDER. I do not. I do not for Dr. Watson. I do for Dr. Perlin.

THE CHAIRMAN. My last question then on this topic is, as you make these budgetary decisions here, what are you asking for? I mean, what did you ask for, Dr. Kupersmith?

DR. KUPERSMITH. In terms of genomics?

THE CHAIRMAN. Yeah, in terms of genomics.

DR. KUPERSMITH. Yes. Well, this is our --

THE CHAIRMAN. With regard to dollars. How much in dollars are you now putting toward this?

DR. KUPERSMITH. There are a number of items of cost that are related to this. We are embarking on a pilot study over next year to determine how we are going to collect the samples, how we are going to ask for consents. For example, how we ask for consents has a tremendous impact on budget.

So we have not established the final dollar, just to say that this is collection of blood and possibly other tissues which has a limited expense and a number of other aspects to it where the expense may not

be as large as one thinks.

One of the ways we are going to cope with this is to decrease less productive research. And as I said before, looking at our centers is one of the ways of doing this.

But I think that we need to establish the banking of this and many other features of this. We need to work with the Advisory Committee to look at how the consents should be done, what we are going to do to assure special privacy for this.

This is probably not the kind of information that should be available the way the rest of the medical record is. We do this in some ways with psychiatric information. So there are many, many questions about this that we are going to be looking at our Advisory Committee to ask before we can give you the final on that.

THE CHAIRMAN. Dr. Kupersmith and Dr. Watson, as you proceed on this, this is an area of interest also at NIH. And we do that funding. So we are laying appropriate dollars there?

So let me go back to the statement of being all things to all people. When trying to remain centric, taking care of those injuries and diseases specifically related to that military service, at the same time, you have something here that helps the general population of a country and a world really.

What of limited dollars do we begin to take away at the same time we want to press those bounds? We want to be good listeners to you. Okay? And I want you to work with Mr. Michaud and Chairman Brown as we formulate this, as we go into next year's budget.

Dr. Perlin, you may say to us here is our budget, this is our ongoing research, this here, this is so valuable, your Committee may come back and lay down something specific. We do not really do that. We do not really come in here and go, okay, we are going to lay specific dollars on a specific disease. But we want to be open to you.

DR. KUPERSMITH. So much of what we have done in research has benefited everyone, probably most of it. And treatment of tuberculosis, one of the first great veterans' projects, veterans' research projects. This is directed at veterans. This is our purpose. If it helps other people, that is obviously an added advantage and it will help other people.

Our research in prosthetics, our research in traumatic brain injury will help automobile accident victims in this country. So all of our research does that. But I think it is really important to think of this as a -- at least we think of it as a veteran centric intervention. And I think the future will be for veterans to get a tremendous amount of benefit from this.

THE CHAIRMAN. Dr. Snyder.

MR. SNYDER. Thank you, Mr. Chairman. I appreciate you holding this hearing.

I am sorry I was unable to be here for the first part of it. I may ask

you some questions that have already been covered.

To bring this home, this business about research, for me, I was reminded just these last few weeks, Dr. Perlin. My wife and I had a baby 15 days ago, two weeks. He was a big boy, nine pounds, seven ounce boy. And we ended up having to have a C section partly because of his size.

And I called up my 90-year-old aunt and told her about we had a nine and seven ounce baby boy. And she told me when she had her first son like 60 some years ago, she said I did not think anybody could have a bigger baby than Johnny who was nine pounds, five ounces. But she said that the labor was terrible, the delivery was terrible. After he was born, she had to spend 13 days in the hospital. The whole experience was so bad she did not think she would ever want to have another kid again.

Well, so my wife goes in. We try laboring for a while. Doctor said it is not cutting it. We have the C section. We are home in three days. That is not just an accident. You and I know that. And it is because of the great work that has been done by researchers through the years and said here is how we do it and here is how we prevent these terrible problems.

So I think what you all are working on is so important. I have several questions I want to ask.

THE CHAIRMAN. Dr. Watson, you may be excused if you like, if you need to leave. Thank you.

DR. WATSON. Thank you.

THE CHAIRMAN. Dr. Snyder.

MR. SNYDER. Thanks. The issue of when you set the number in the budget, in the President's request, whether it is for this past year or the years to come, this whole issue of the biomedical research inflation rate, it is estimated, I think, at five and a half percent for fiscal year 2005 and a little bit lower than that, a little over four percent for fiscal year 2006, which has reduced in real dollars the VA research budget over those two years by almost \$40 million.

Now, shouldn't we when we are doing this, in fairness to everyone, the veterans, to you, to researchers, to the Congress, shouldn't we start out and say our baseline budget includes an inflationary increase so we will be talking in terms of real dollars from the get-go? Shouldn't that be the way we do this?

DR. PERLIN. Well, first, Dr. Snyder, congratulations on your new baby.

MR. SNYDER. Thank you.

DR. PERLIN. And I am glad the results of research are what they are.

I am, I believe, the first M.D., Ph.D. Under Secretary or Chief Medical Director of the Veterans Health Administration. I am a researcher and I believe passionately in research.

MR. SNYDER. I know you do. I know you do.

DR. PERLIN. The budget was purposefully a lean budget. It was also a budget that looked at the needs of veterans and said, okay, what is veteran centric, where are our priorities. It is a budget that actually raises the amount of focus on those things that are directly veteran centric.

I think one of the things that whatever the budget line is, and let me acknowledge this Committee for your robust support not only of the request but your acknowledgement of the importance of VA research by recommending additional funds, whatever the investment that the American taxpayer on their behalf, you help us make in VA research, it is leveraged substantially.

One of the things that I think is testament to that is that the seed money that is provided actually pays back a 150 percent return on investment. For example, in 2006, this year, \$412 million will actually provide a core of research activity that allows investigators to bring in, if my number is correct, Dr. Kupersmith, \$662 million of additional cost of research.

MR. SNYDER. But that leads to my second question, Dr. Perlin. I will accept what you said. The budget was purposefully lean. The budget was purposefully lean. And I would contend this is the wrong time in our history given both our economic competition and the jobs of the future and the technology of the future but also as a nation at war, that this is the wrong time to be "purposefully lean" in the VA research budget.

My second question, Dr. Perlin, is this. When you talk about leveraging funds, other parts of the budget are held constant also. NIH budget, which you do not have anything to do with, it is held constant in the President's proposal also.

So does it not give kind of a false sense of security to those of us who read these things very quickly when we read, oh, this is going to help us to leverage other funds? Oh, by the way, the funds that we are going to try to leverage, they are being held constant also and sooner or later, somebody has got to take a hit or the purposefully lean idea is not going to be carried out.

DR. PERLIN. Well, let me rephrase. That was a poor choice of words. A better choice is we wanted to be as responsible in assuring that the dollars were maximized for veteran centric research.

And I think the track record is is that investment actually begets a continuing increase in extramural funding and that year over year, 2007 over 2006, 2006 over 2005, there are significantly more external dollars that are brought in to augment the entire VA research portfolio.

MR. SNYDER. By external, you are including dollars from NIH and other federal research?

DR. PERLIN. Yes, I am.

MR. SNYDER. Well, I think I made my point. Those budgets have also been drawn "purposefully lean" and so it is going to be harder for you to leverage that.

My time is up. I had actually several other things.

What is the state of VA research facilities? We have some money that was spent recently. It is for some new square footage in Arkansas, the VA there. It is very nice. But my concern is this. Upgrading facilities takes money. Good research takes good modern facilities.

We have got this lean budget going on. Are we having problems? Are we going to have to take money out of personnel in order to do research facilities or are we going to ignore expansion and modernization of research facilities in order to keep our personnel up? What is the status of research facilities and does the Committee need to do a better job of looking at square footage and kind of the bricks and mortar of research?

DR. KUPERSMITH. Well, I appreciate that question and appreciate the money that I think the Committee has indicated it wishes to spend on that.

First of all, there is clearly an issue throughout the VA system with our research infrastructure. It needs improvement in many areas. I do want to say, though, just briefly that while that is true, the quality of the research is outstanding.

MR. SNYDER. I agree with that. I agree with you.

DR. KUPERSMITH. What we are doing is, first of all, we are gathering together all of the information that has already been provided to us on our research facilities over the past few years. We are organizing that information.

We have sent a questionnaire to research facilities concerning the status of their research. We are going to have a number of site visits before the end of the year. We have a group out of the Gainesville VA that we have detailed to do this, to make a number of site visits to look at the correlation of the information we have with what is happening actually in a number of facilities.

And we intend to survey our 75 major research facilities over the next three years after that. We will have a report in early 2007 on this initial phase that will essentially look at what we are going to have to do.

MR. SNYDER. I hope that the report, and I assume it will be, will be very straightforward with us and will not kind of get lost in the budgetary year stuff of, oh, yeah, we do not really need this.

I mean, the Committee - I am sure I speak for the Chairman -- we just want to know what you need and what you can live with and what has just absolutely got to be improved.

DR. KUPERSMITH. You know, I make site visits as one of my jobs. It is more informal site visits to see a facility and the first thing they show me are research facilities that are dated. So I understand that

we have to really look at this.

And that is why we are doing these site visits ourselves, to really get our own look at this and not just what people's impressions may be. You know, as honest impressions as they are that we want to look at this carefully.

MR. SNYDER. Dr. Perlin, given that anyone out there who follows this business and is paying attention to where your budget number is on research and paying attention to where we are with facilities and so on, you all, you know, are always competing with the private sector for good clinical staff, good research staff, those delightful people that do both research and clinical work.

What kind of a message does it send in terms of your recruitment and trying to recruit somebody to stay with you for ten or fifteen or twenty years when we kind of play -- I do not know, whatever the metaphor is -- Russian roulette or something each year that, well, our budget is going to be lean this year, some people may be cut, some people may not be cut, we are hoping the Congress, nudge, nudge, wink, wink, we are hoping the Congress will add some money so that nobody will actually get cut? Doesn't this have a negative impact on the way you do your recruiting and retention of physicians when those top-rated researchers that you are trying to keep and recruit for your facilities?

DR. PERLIN. In fact, we want to bring forward each year an entire budget that is responsible and meets the needs. We want to make sure that -- and I testified earlier before you arrived that when I was the Acting Chief of Research and Development, my litmus test was that we lived the mission of VA research, improving the health and well-being of veterans.

We have the stewardship responsibility as well which is to make sure that the research that is conducted is valuable. And the Chairman said veteran centric. With all that in mind, we continue to have a growing overall research budget. In fact, within the research budget, we make priorities. In any budget, one makes priorities.

And one of the priority areas has been career development awards to attract today's emerging stars as both the researchers and clinicians for veterans. And this budget, budgets that proceed show an increasing number of career development awards just for that purpose of attracting and recruiting.

We also do want productive researchers, researchers who can compete intramurally and extramurally demonstrating that their research by all merit review is the best research that can possibly be done to answer and address those questions that are relevant to improving veteran health.

MR. SNYDER. I agree with that. The question is, with additional funds, could you do more top-flight research that meets that standard? And I think that you could.

But the last question I want to ask has to do with your discussion and your written statement on neurotrauma. And I was struck by what you say here, that traumatic brain injury accounts for almost 25 percent of combat casualties.

Is that 25 percent of all casualties or those that are hospitalized?

DR. PERLIN. I would have to get you that number.

DR. KUPERSMITH. Yeah. Dr. Ruff may know that offhand.

MR. SNYDER. That seemed a little high to me for 25 percent of all combat casualties. I would have thought there would have been a lot of superficial shrapnel.

DR. PERLIN. Well, maybe the way I can come to that is that -- and we will check on the exact -- but one of the statistics that is absolutely incredible is that if you are injured in combat and you make it to a critical support hospital at the front lines, you stand over 98 percent chance of survival. As you have seen, the injuries are multiple and often include that.

Let me ask Dr. Ruff if --

MR. SNYDER. Well, let me get to my question. The Chairman is being very patient here, if I might.

My question is this. So in your statement, you say 25 percent of combat casualties in both Iraq and Afghanistan are traumatic brain injuries. And I appreciate your accentuating that because that is so important to those veterans and to their families.

And then in your written statement, you say 85 letters of intent to submit a research proposal were received indicating a high level of interest amongst our investigators. Complete proposals will be reviewed in the next several months and we plan to fund as many high-quality projects as the budget will allow, as the budget will allow.

DR. PERLIN. Yes.

MR. SNYDER. And so my question and my comment would be, if you review those 85 and you conclude you can only fund -- or that there is only 30 there that are worth funding, you have plenty of extra money, you are going to fund the 30, that is fine.

My concern is you review those 85 and say, you know, 73 of those are top-flight research, but we only have funding this year for 42. I am just making up numbers. I think that the Committee would be concerned. I think the Veterans' Committee would be concerned. I think those families would be concerned if -- unless you would be very straightforward with this as this process goes along, if you come back to us and said, if we had additional monies, you know. Maybe Mr. Snyder was right. We could have used additional money because we could then fund this additional ten, fifteen, or twenty proposals that would meet our standard for top-flight research because this is so important to the future livelihood and quality of life of these veterans and their families.

And I was really struck. I mean, I appreciate your candor. As the

budget will allow. Well, budgets are set by this Congress and I will want to know if you come back to us and say we could have funded 23 more top-flight research projects with good personnel if you had given us more money because you make the proposal, but eventually we do the appropriations.

And so I hope you will share with us that information so that we can --

THE CHAIRMAN. Will the gentleman yield?

MR. SNYDER. I am finished, Mr. Chairman. I appreciate your indulgence.

THE CHAIRMAN. This is an area where -- I will choose the word collaboration -- this is a great area of collaboration for research between Dr. Perlin and DoD.

DR. PERLIN. Yes.

THE CHAIRMAN. And that is what you need to do is have that kind of conversation because these are active-duty patients. You know, you have them, Dr. Snyder, in your responsibilities on the Personnel Subcommittee. And you make those decisions on medical research in DoD.

I mean, this is an area, when you talk about the funding of combat casualty neurotrauma, this is one that should be a cooperative effort, I would think, between VA and DoD, Dr. Snyder. Would you concur?

MR. SNYDER. Yeah, absolutely. And it is to everyone's interest that it be well funded, I mean, because we want to be able to look back five and ten, fifteen years from now just like I look back on my Aunt Lois and her 60-year-old pregnancy, that we look back and say look at the remarkable things that we did.

But when I see we are only going to do what the budget allows when this Committee, I think -- I think the Congress will be very receptive if you said, you know, we could really do some more top-flight research in traumatic brain injury to help these 25 percent of our injured veterans.

THE CHAIRMAN. Let me bring up the area that I had a conversation with Dr. Perlin about. So I want you to hear this, Dr. Kupersmith. And it deals with the helmet.

DR. KUPERSMITH. Yeah.

THE CHAIRMAN. So Vic Snyder is over there on the Armed Services Committee and we are doing everything we can to give him that body protection. So generally in the past when you have that blast, part of the blast is absorbed by the body.

Now we give them the body armor and they have got on that new kevlar helmet that is strapped onto the head. When the blast comes in, it hits the extremities and part of the force goes up the face. You get maxillofacial injuries. You get blindness, severe traumas to the eyes, takes off part of the nose. And when the force goes up into the

helmet, it cannot escape and we end up with all this traumatic brain injury.

And so, number one, what I am hopeful here is when you look at this combat casualty neurotrauma research that you also do not look and say are we not also contributing to a problem here. We saved the torso and lose the brain. And should this helmet have vents in it or some type of vent system to allow part of that force to go out?

And I am not a doctor. I am not one of these. But I am just saying common sense is saying to me if we can put a man on the moon, we can try to figure out how to provide some relief to a force causing brain trauma.

So I just throw that back to you. And I will work with you, Vic, on something like this.

DR. KUPERSMITH. Let me just first say that our collaboration with DoD in many ways -- I can just speak about the research area -- has increased enormously just since I have been there, but it began to increase well before. And we are collaborating in this, in burns, in prosthetics, in many, many other areas.

And we certainly consider this very high on our agenda, at the top of our agenda to collaborate with the Department of Defense in these. And certainly a collaboration that could evolve in the future is to look at our data on traumatic brain injury in the veterans some years later and what sort of armor, what is one's approach to armor, taking that in light.

So those are a number of research areas that we can get into. I think our funding line is usually about 25 percent. And we will certainly look at these projects and I think --

MR. SNYDER. I am sorry, sir. I did not know, 25 percent -

DR. KUPERSMITH. On a usual RFA, we fund about 25 percent of the research projects that come in.

MR. SNYDER. Oh, okay.

DR. KUPERSMITH. We consider of high enough scientific merit to fund. We do not know how it will come out on this. So when we do know, what we can do in our own sphere is to try to, as I said before, obviously save money in other areas so that we can provide more here.

This is our highest priority. There is no question about that. Perhaps in future budget submissions, some of this will be reflected, but that is essentially how we can work with it at this point.

MR. SNYDER. Well, but I appreciate -

DR. KUPERSMITH. Can I add one more thing to my answer?

MR. SNYDER. It is the written statement here that says as the budget will allow, so that is where my question was coming from.

DR. KUPERSMITH. Okay.

MR. SNYDER. Yeah. You are welcome to augment.

DR. KUPERSMITH. I just want to make the point, and Dr. Ruff made

this point also -- it is very important -- we are looking upon this as taking on a problem and we are going to do this more and more in research, not looking at whether it is health services research or basic or clinical. This is a problem we want to address. We want to address it from the cellular level through to the health system level that we study. And I want to make that point.

MR. SNYDER. Thank you, Mr. Chairman. Thank you for your indulgence.

THE CHAIRMAN. Dr. Perlin, if you could get back to me. I am sort of struggling with really where do I really need to go? Do I need to go over to material command at DoD to say I want you to study the helmet?

If you have an idea here on who I need to touch or how we need to fund or how we want to examine - if you have your studies out there - I know you are going to be looking at other things. But if we have a helmet - if, in fact, there is body armor with this - we are contributing to a problem here, I really do not know who to go to to examine this issue. I really do not.

DR. PERLIN. You raise an important issue that the rate of survival from a forward injury is now greater than ever before. And that is a good thing. But the injuries that are sustained are brutal. The body armor saves lives.

But as you have seen when you visited at Walter Reed, you have learned that the trauma is multiple. It can lead to amputation, spinal cord injury, brain trauma, loss of vision, loss of hearing, all of the mental health issues that are associated with that tragic loss.

And that is the challenge of today's patient and that is where VA is investing its resources, areas like polytrauma. In fact, there are projects that look at mechanisms of traumatic brain injury, the skull interface with the helmet.

In DoD, there is a colonel I know who has been doing some work to try to advance the helmet recognizing that the percussive injury occurs twice, once with the explosion and once with the repercussion with the helmet itself just as you have identified.

THE CHAIRMAN. Dr. Ruff, you passed that note. Do you know the name of the colonel? Will you get it to the Committee? Do you know who is doing this specific type of repercussion research?

DR. RUFF. I do not know the name of the colonel, but I know that there are three projects that we are looking at that look at the skull interface to the source of the pressure, basically what you are talking about in terms of the helmet, how the pressure is delivered and how the pressure is dissipated in terms of what effect that has on the brain.

So that is being looked at in animal models. We are not doing it with people. There are some people I would like to do it with, but that is not ethical.

DR. PERLIN. Mr. Chairman.

THE CHAIRMAN. Yes.

DR. PERLIN. I might suggest, Mr. Chairman, we might want to have a closed joint briefing with the DoD and these folks because some of the stuff we talk about probably ought to be in a closed session in terms of what are the vulnerabilities of our armor.

THE CHAIRMAN. All right. We will do that.

If you will be in touch with the Committee, Dr. Ruff, I would appreciate that.

Thank you very much for your testimony and for the judgments that you are making. This panel is now excused.

All members of the Committee will have five legislative days to enter their statements into the record.

Our second panel, if you could come forward. Our second panel represents the veterans service organizations and groups familiar with medical research.

The first member of the panel is Mr. Carl Blake, Senior Associate Legislative Director for Paralyzed Veterans of America. Mr. Blake is a graduate of the United States Military Academy at West Point.

After graduation, he was commissioned as a Second Lieutenant in the United States Army, assigned to the First Brigade of the 82nd Airborne at Ft. Bragg, North Carolina. He was retired from the military in October of 2000 due to a service-connected disability.

Our second member of the panel is Rick Weidman who is Executive Director of Policy & Government Affairs for Vietnam Veterans of America. Mr. Weidman served as a medic with the Company C 23rd Med, America Division, located with ICOR of Vietnam in 1969.

Mr. Weidman was part of the staff of VVA from 1979 to 1987, serving variously as Membership Service Director, Liaison, and Director of Government Relations. He left VVA to serve in the Administration of Governor Uma as Director of Veterans Employment and Training in the New York State Department of Labor.

Congratulations on your new title.

MR. WEIDMAN. Thank you very much, sir.

THE CHAIRMAN. Our third and final panelist, Dr. Dennis Niewoehner, a Member of the American Thoracic Society and Chief of Pulmonary Section of the VA Medical Center, Minneapolis, Minnesota. He is here testifying on behalf of the Friends of VA Research.

Gentlemen, your written statements, if you have them -- do all three of you have written statements? All but one. Rick Weidman, do you have a written statement?

MR. WEIDMAN. Yes, sir.

THE CHAIRMAN. All three have written statements. If you offer your statements, they will all be submitted for the record, and you each are recognized for five minutes for oral testimony.

Mr. Blake, you are now recognized.

STATEMENTS OF CARL BLAKE, SENIOR ASSOCIATE LEGISLATIVE DIRECTOR, PARALYZED VETERANS OF AMERICA; RICHARD WEIDMAN, EXECUTIVE DIRECTOR, POLICY & GOVERNMENT AFFAIRS, VIETNAM VETERANS OF AMERICA; AND DENNIS E. NIEWOEHNER, MEMBER, AMERICAN THORACIC SOCIETY, TESTIFYING ON BEHALF OF VA RESEARCH, CHIEF, PULMONARY SECTION, VAMC, MINNEAPOLIS, MINNESOTA

STATEMENT OF CARL BLAKE

MR. BLAKE. Thank you, Mr. Chairman. Mr. Chairman, Mr. Michaud, I would like to thank you for the opportunity to testify today on the VA Medical and Prosthetic Research Program.

Before I begin, I would like to introduce someone who is here with me. I would like to introduce Mr. Thomas Stripling. He is PVA's Director for the Research, Education, and Clinical Practice Guidelines Program. He is our subject matter expert on these issues at PVA and he will be available for questions also.

THE CHAIRMAN. Please come up here and have a seat.

Mr. Blake is here testifying. He answers the questions asked. But you know what? I do not have the subject area of that --

MR. BLAKE. I learn quickly, sir.

THE CHAIRMAN. You had a very good answer. Something you learned probably at West Point.

MR. BLAKE. It had to do with the IT section, sir -

THE CHAIRMAN. It was IT.

MR. BLAKE. - and not knowing where it was in the IB.

THE CHAIRMAN. Yes. It was a great question, but this is not a subject area for which I have great expertise, I think. Now you have him to your right.

MR. BLAKE. Yes, sir.

THE CHAIRMAN. We have you covered. You are recognized.

MR. BLAKE. The VA healthcare system is a unique environment combining clinical care, education, and research. VA currently supports approximately 3,800 researchers at 115 VA medical centers.

According to the VA, nearly 83 percent of these VA researchers are practicing physicians. Because of this dual role, VA research often immediately benefits patients.

For example, functional electrical stimulation is a technology using controlled electrical currents to activate paralyzed muscles and is being developed at VA clinical facilities and laboratories throughout the country.

This technology is now being applied to many PVA members receiving healthcare service and rehabilitation therapy at SCI centers. Through this technology, tetraplegic patients have been able to grasp

objects, stand and pivot to assist transfers, and control bladder function. We even anticipate greater capacity for walking short distances.

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 and the MS Centers of Excellence. These centers represent a successful strategy to focus the VHA's system-wide service and research expertise to address two critical care segments of the veteran population.

Since 1997, PVA has worked with VA MS clinicians and administrators as well as with private MS providers and advocates to address the then patchwork service delivery by VHA towards veterans with MS. While we identified the scope and range of these services, it became very apparent that vital elements indeed did exist.

The designation by VA of two MS Centers of Excellence located in Baltimore and Seattle/Portland represents centers without walls engaged in marshaling VA expertise in diagnosis, service delivery, research and education, and making the same available across the country through the hub and spokes' approach.

PVA supports this approach for both Parkinson's disease as well as multiple sclerosis. In fact, there is a similar approach that is used for spinal injury care through the VA.

We would urge the Committee to consider legislation which would permanently authorize these centers because they represent the true value of VHA as a national healthcare system's success story.

PVA recognizes the fact that much like the greater VA infrastructure, research facilities are aging and in need of repair or renovation. For decades, insufficient construction funding has been provided to maintain, upgrade, and replace the VA's aging research facilities. The result is a backlog of research sites that need major and minor construction funding.

Five years ago, the VA received \$25 million specifically for upgrades and enhancements to these facilities. However, no specific funding has been provided since.

We do appreciate that this Committee and the House of Representatives earlier this year earmarked \$12 million for minor construction at VA research facilities. However, we believe a steadier stream of funds must be provided.

We urge Congress to begin investing dedicated funding into the rapidly deteriorating infrastructure in which VA clinicians and researchers conduct their daily activities.

The VA has stated that it will need three years to complete a research facility's assessment before it can invest new money into its

research infrastructure. However, an assessment was just completed in 2003 and we believe that this assessment could be used as the baseline for a faster reevaluation so that much needed upgrades are not held hostage to this process.

In conclusion, Mr. Chairman, our greatest concern with the Medical and Prosthetic Research Program is chronic under-funding. VA research has been grossly under-funded in comparison to the growth rate of other federal research initiatives.

Although the Administration's budget request called for only \$399 million for this account, we appreciate your efforts and the Committee's efforts to provide the additional funding to the program. However, we believe more can be done.

In accordance with the recommendations of the Independent Budget, we believe that the Medical and Prosthetic Research Program requires \$460 million. This would allow the VA to expand the scope of many of its research projects and begin upgrading and expanding its research infrastructure.

Mr. Chairman, I would like to thank you again for the opportunity to testify. And myself and Mr. Stripling will be happy to answer any questions that you might have.

THE CHAIRMAN. Thank you.

Mr. Weidman, you are recognized.

[The statement of Carl Blake appears on p. 84]

STATEMENT OF RICHARD WEIDMAN

MR. WEIDMAN. Thank you, Mr. Chairman. On behalf of Vietnam Veterans of America and our National President, I want to thank you for this opportunity.

We also wish to salute you for your continued emphasis on trying to get VA to focus on the wounds of war and the maladies and wounds of military service per se. It is something that Vietnam Veterans of America since our inception has focused upon and something that seems to be very difficult.

Just one example, even though it has been on the books now for some 24 years, we seem to have difficulty and so does the VA in getting each primary healthcare physician to do something as simple as take a military history on each and every veteran whom they see and relate it back to what maladies should they be testing that individual for, what other conditions, as an example, frostbite if the person served on the ground in Korea.

The VVA strongly supports increased funding for all parts of VA and I think it is indisputable and VVA believe it is indisputable that VA has made many extraordinary contributions to the world of research and medical research today that have spilled over to the rest of medicine and to the rest of the society.

However, we strongly agree and applaud you for saying it has to be veteran specific and veteran centric. It will have applications to other human beings, but it should be focused on what is it as it is going to directly help improve care at VA.

The Genomic Project that they have underway, in fact, may be useful to the entire nation. If so, we should think of it in light of who has the resources. The VA research budget overall is decimal dust, I repeat, sir, decimal dust in comparison to the size of the research budget at the National Institutes of Health. If it is, in fact, in the national interest, and we believe it is, NIH should fund it in whole.

Similarly there are a number of things in our written statement that I would draw your attention to having to do with NIH refusing to pay admin overhead, et cetera, that we would hope that the Commission would address with your counterparts on the appropriate authorizing Committee.

Last, and I want to focus the remaining time here on the National Vietnam Veterans Longitudinal Study, the unfortunate mischaracterization of the GAO report this morning or this afternoon is something that we cannot let rest. GAO does not tell the Executive Branch what to do in any instance. It is, of course, an arm of the Congress.

It was an administrative decision to stop the NVVLS originally taken by the previous Under Secretary who stopped it arguing that \$17 million was too much to spend on this study. This is the same incidentally Under Secretary who was removed for throwing \$374 million down the toilet on hardware and software that did not work at Bay Pines, Florida.

But 17 million was too much money to spend on a longitudinal study. We have difficulty with that, sir. The excuse that is given now for not continuing and completing the replication as required by Public Law 106-4119 of the National Vietnam Veterans Readjustment Study, otherwise known as the National Vietnam Veterans Longitudinal Study, is that they can only find 300 veterans left alive of the 2,500, 2,500 who were sampled.

We would suggest to you, Mr. Chairman, that if only 300 of the original 2,500 are alive, then that would merit a press release and if indeed not a press conference by this Committee to ask what in the world is going on that a statistically valid, random sample of Vietnam veterans, 85 percent of them have died since 1985. There is no reason in our view for any further delay in moving forward on completing the NVVLS.

Two quick comments on a couple of other studies that Dr. Friedman so ably commented on. The Twin Study does not include any African Americans. It does not include any or virtually no Latinos and it includes no women whatsoever, whereas, in fact, the database for the National Vietnam Veterans Longitudinal Study has over-sampled for all three of those groups and would allow us to make

statements about it.

Last but not least on the Twin Study is the Twin Study is really right on the borderline of being too small to allow us to make judgments about the overall veterans' population within the country.

The brain injury work, we certainly applaud and would encourage all of that ancillary research to go on, but that does not substitute for the NVVLS.

Last but by no means least, I would like to just briefly comment that there are a heck of a lot of very curious studies that have been funded instead of the NVVLS over the last three years. Let me just cite three examples that we can supply to the Committee to be part of the record.

First is PTSD plus electroconvulsive shock treatment with them claiming that people were faking symptoms. This came out of the Topeka, Kansas VA Medical Center, but was funded by R&D. The claim there was that because reportedly symptomatology went down after they informed the veteran that we are going to admit him inpatient and for two weeks we are twice a day going to run current through his body and put him into electroconvulsive, electrically induced convulsions, that suddenly his reported symptoms went down.

I would suggest to you, Mr. Chairman, that a veteran with chronic PTSD, acute PTSD, if you and I informed him that twice a day if he reported any more symptoms we were going to take him out in the parking lot and beat the bejeebers out of him, then he would stop reporting symptomatology. I mean, this is not the kind of research, quote, unquote, that we should be reporting.

Additionally, also at that same medical center, there was a study that came to the conclusion that smoking increases your risk of PTSD. This struck us as very odd when, in fact, of course, it is the other way around. There are other factors that cause and increase your risk of getting posttraumatic stress disorder. And smoking is elevated among people who have PTSD, but does not increase the risk, at least from any reasonable point of view that we can see nor have we ever seen any literature whatsoever supporting either of those theses.

Mr. Chairman, we would be glad to answer any questions. We thank you once again for your leadership in pushing to make the few dollars that VA has on for research and development most relevant to America's veterans and to our service men and women who are serving today.

Thank you very much, sir.

THE CHAIRMAN. Thank you very much.

Sir.

[The statement of Richard Weidman appears on p. 95]

STATEMENT OF DENNIS E. NIEWOEHNER

DR. NIEWOEHNER. I am respiratory disease specialist at the Minneapolis VA Medical Center and a Professor of Medicine at the University of Minnesota. While I am a VA employee, I am today testifying as a private citizen on behalf of the Friends of VA Healthcare and Medical Research, better known as FOVA.

FOVA is a coalition of over 80 veterans service voluntary health and medical professional organizations that support funding for veterans' health programs. FOVA is especially committed to ensuring a strong VA Medical and Prosthetic Research Program.

So why support VA Research Program? I will give you three reasons. Good science, good physicians, and good care for veterans.

The VA Research Program produces good science whether it is hepatitis, heart disease, Parkinson's disease, diabetes, or rehabilitation medication. The VA Research Program is producing new approaches and new treatments that are published in the leading medical journals.

VA research is peer reviewed. Like our colleagues at the NIH and other federal funding agencies, all VA research proposals go through a vigorous peer review process to ensure that only the best scientific proposals are funded.

The VA Research Program excels in clinical research. And by clinical research, I mean testing therapies in patients, not in test tubes. Our laboratory colleagues do an excellent job of generating novel ideas from basic research, but somebody has to translate these research ideas into treatments for patients. And the VA Research Program is very good at that task.

Allow me to provide just one example from my own experience. Chronic obstructive pulmonary disease, which is also called COPD or emphysema, is a prevalent disease among our veterans and relevant to the Chairman's previous comments, I think, can be viewed as being veteran centric and is one of the most common reasons for hospital admission. Hospital admissions account for more than one-half of the total medical costs of treating this terrible disease.

In a trial sponsored by the VA Cooperative Studies Program, we demonstrated giving cortisone-like drugs significantly reduced length of hospital stay. So by using this treatment, patients get better sooner and the VA medical system saves money.

These findings were published in the New England Journal of Medicine and these findings have been widely incorporated into clinical practice both within and without the VA medical system.

The VA Research Program helps attract highly-qualified physicians to serve our nation's veterans because it provides a unique opportunity to combine a career in clinical medicine with opportunities to do research.

For me personally, the research program was a major reason that I joined the VA and equally important it is also the reason that I have remained in the VA medical system for nearly 30 years.

Lastly, and I emphasize this point most strongly, the VA Research Program is good for veterans. It focuses resources on diseases of high prevalence among veterans and evaluates new treatments in a highly scientific manner.

The VA Research Program fosters a culture of inquiry where the veterans' care needs drive the research program and in turn findings from the research program drive improvements in veterans' care. In addition, new research findings can be quickly and broadly implemented across the entire VA medical system.

One dark spot on the shining achievements of the VA Research Program is its aging facilities. The subpar research facilities are making it increasingly hard to recruit and retain top-flight physician researchers in the VA medical system.

FOVA greatly appreciates the recent congressional efforts to address this issue in the military quality of life, VA appropriations bills. However, the problem persists. VA has identified a priority of lists of VA labs that are in need of renovation and is committed to executing these renovation projects provided Congress provides the funding.

FOVA strongly recommends that \$45 million be provided to rehabilitate the existing VA data lab space.

Mr. Chairman, I think it is clear that the VA research uses its resources wisely and efficiently to the betterment of veterans' health-care. Thank you for listening to the views and recommendations of FOVA, and I would be happy to answer any questions.

[The statement of Dennis Niewoehner appears on p. 103]

THE CHAIRMAN. Thank you very much to all of you for your testimony.

Mr. Blake, in your testimony, you talked about PVA supporting the building of these Centers of Excellence. So let me go specifically to the one VA currently operates, the Center for Limb Loss and Prosthetic Engineering in Puget Sound, Washington where investigators study amputation prevention, lower limb prosthetic improvement, and patient outcome measurements.

So with that in mind, why should we create a new center which will require additional real dollars instead of just perhaps even beefing up what we presently have?

MR. BLAKE. Well, Mr. Chairman, I think the point that I was trying to make is that one single center across the VA spectrum given what seems to be a fairly significant problem among the newer veterans returning is probably not enough to meet the demand for that growing service within the VA system.

We recognize the importance of that one particular center in pro-

viding service and the research it is conducting. But if you spread that wealth out a little more, instead of having it in one general area, and even though it kind of operates within that hub and spoke approach that I spoke about, you can spread out the different activities that are being done to more than one center so that you meet this growing population of veterans who are dealing with these particular problems.

THE CHAIRMAN. Have you been to this center?

MR. BLAKE. I have not, sir.

THE CHAIRMAN. Have you, Mr. Stripling?

MR. STRIPLING. [Shakes head negatively.]

THE CHAIRMAN. Do not worry. I have not either.

Dr. Ruff, have you been there to this center in Puget Sound?

DR. RUFF. Yes.

THE CHAIRMAN. I know this is a little out of ordinary. Dr. Ruff, can you come forward just a second. Can you tell us about this center in Puget Sound. I mean, if the Senate has a proposal over there and we have limited dollars, should we really be building more centers around the country or beefing up what exists at an existing facility?

DR. RUFF. The Puget Sound center is a center in rehab research. It is one of 15 centers in rehab research. Its mission is shared somewhat by a new center that has been developed in Providence in terms of Providence is looking at ways of enhancing prosthetic design, reducing the deficits that people with amputations have.

The Center in Seattle is focusing a little bit more on prevention of limb loss and they are coordinating their research activities with a podiatry service, clinical podiatry service which leads a program called PACT, which is Prevention of Amputation Care Team, which is a national program within the VA. That focuses on reducing the risk of amputation primarily for older veterans who are at risk due to diabetes and peripheral vascular disease.

The center in Seattle is a research center that coordinates with clinical centers, but I think they are talking about a different type of center. I think that they were talking about a clinical center for prosthetics care maybe to link with the center in Seattle. But I do not want to speak --

THE CHAIRMAN. Well, wait a minute. Let me ask Mr. Blake because I am confused.

What are you asking for, Mr. Blake?

MR. BLAKE. I would say it would be a broad-based center that has both clinical aspects to it as well as research aspects. And we also make recommendations so that these centers put a great deal of emphasis on research in terms of performance standards and improving the equipment that is being placed out there.

Although we recognize that many of the servicemembers who are coming back through places like Walter Reed in particular but

Bethesda or Brooke are receiving high-quality prosthetics, that is being done through a program supported with DoD.

And the VA needs to get in line with that as well, and these centers could kind of align their own prosthetics program with what the DoD is doing in a very small location to ensure that there is continuity of those types of services once those servicemembers are out into the VA and receiving their care there and not directly from DoD.

THE CHAIRMAN. All right. Thank you.

Thank you, Mr. Weidman.

Thank you, Dr. Ruff.

Mr. Michaud, you are recognized.

MR. MICHAUD. Thank you very much, Mr. Chairman.

Mr. Weidman, thank you for your comments about the NVVLS study and the importance of completing the study. I know in the past, you have talked about having a separate line item to complete the study. I believe it was \$25 million to complete the study.

Should that money come out of the \$412 million for research or should that be additional resources to complete the study?

MR. WEIDMAN. First of all, with the indulgence of the Chair, I misspoke earlier. It was not a GAO report. It was an Inspector General's report that was issued September 30th, 2005, but the point still holds. The IG has no line authority to cancel or to start anything.

The 25 million, up to 25 million because, frankly, we do not think it would take 25 million to complete the study. When the study was cancelled in early October of 2003 by Dr. Roswell, they were just on the cusp of delivering their first set of deliverables to the VA. It was mismanagement incidentally. The IG hit the mismanagement of VHA, not Research Triangle Institute.

Were there some people who did not act all that well at RTI? Sure. But that was not the issue. The issue was that VA failed to manage the contract.

When we testified, if you recall, Mr. Michaud, we were asking for a ten percent raise to the R&D budget. That would bring it up to roughly \$443 million and we had intended for it to come out of R&D and not out of patient care dollars.

MR. MICHAUD. Thank you.

Doctor, if we look at the funding for VA research, it is a mix of appropriated dollars plus non-VA dollars.

How should the mix be envisioned for the future? Is there an ideal percentage? Are these dollars fungible or are there ideal uses for the VA dollars that non-VA dollars are not appropriated or vice versa?

DR. NIEWOEHNER. Is this --

MR. MICHAUD. Yes.

DR. NIEWOEHNER. -- directed towards me? I am afraid I did not quite understand the question.

MR. MICHAUD. When you look at VA research, there is a mix of dol-

lars that is appropriated, that Congress appropriates to VA, but also non-VA dollars, such as NIH.

Is there a certain percentage that should be VA specific and, if so, what is that percentage between VA dollars and non-VA dollars?

DR. NIEWOEHNER. Well, the diseases that we are addressing are certainly common. Many of the diseases that we are addressing certainly are common to both VA and non-VA patients. I mentioned COPD as being a veteran centric disease, but there is obviously a huge amount of this disease in the non-VA community as well.

So I think it is very appropriate that the VA devotes additional money towards research into the treatment and prevention of COPD, but recognizing that from a broader societal standpoint that everybody will benefit from this.

And I am not sure that I am prepared to put any specific -- I am not knowledgeable enough to put a specific number on that.

MR. MICHAUD. Thank you.

Mr. Blake, dealing with the spinal cord injury research, your organization is definitely in the forefront in that particular arena.

Do you think the VA is doing enough in this area and, if not, what do you think the VA should be doing?

MR. BLAKE. I think I would like to defer to Mr. Stripling because he is intimately involved with that particular program.

MR. MICHAUD. Thank you.

MR. STRIPLING. Thank you very much for the question, sir. I am not sure we ever get to the point where enough has been done on a lifetime disease or a lifetime disability.

I think the issue becomes one of being able in the VA system to track the kinds of the things that are a repeat problem. So we are never going to cure, if you would, as quickly an injury that happens in a split second.

But when we see urinary infections continuing to be a problem, we see respiratory problems continuing, we see pressure ulcers continuing, we see diabetes continuing, we know we are not doing enough in those areas. We need to isolate them as the VA has in various initiatives whether it is QUERI, whether it is rehab R&D, or whether it is in their Clinical Affairs Division to see whether we can make some progress in those things.

We may not be able to settle the issue of diabetes forever, but we make it a manageable condition. We may not be able to completely take care of emphysema, but we make it a manageable condition.

Bringing more information into the process, we get better clinical outcomes, we get better clinical practice, and we get reduced incidences of those in our area, you know, in our tracking system and we know we are making progress.

So I think that when you have a lifetime condition, there may never be enough that can be ever done because the condition is a lifetime.

But there are management issues that any of us would expect and any of us would accept as ways of living with that condition, that move us from the process of catastrophichness, if you would, to manageability.

And I think those are what we see now in the outcome studies that are being performed across the healthcare system whether in the VA population, in the SCI population, or in the civilian populations.

We have a life expectancy now that we can be proud that we have created. We have gone from a condition that was not manageable to a condition that is survivable to an extent, if you would.

So I think that we continue to monitor ourselves. We continue to see that we get progress in what we are doing. I am not really sure we will ever get to the point where we have done enough.

MR. MICHAUD. Thank you.

And once again, Mr. Chairman, I want to thank you for having this hearing.

And the reason why I asked Dr. Perlin for information on all of what they are doing in research and development, because I think there is an important aspect of what the VA is doing in R&D as well as with DoD, and I was interested in that because I think it is important that they are focused and working together.

But also as equally as important, I know there is a lot of research going out there in the private sector working in different areas. And a good example is the University of Maine, which is doing some research which affects the Navy, the Coast Guard and fishermen on boats and the speed of the boat and the pounding of the boat on the water, as to the impact on the spinal cord.

So there is a lot of research going out there, and I think it is important with the finite amount of R&D dollars that we have as much collaboration not only interagency but also with the private sector to try to get the most bang for the buck.

Thank you. I yield back my time, Mr. Chairman.

THE CHAIRMAN. Thank you very much for the gentleman's contribution.

Mr. Blake, I know that PVA have been very active in your work to establish the two Centers of Excellence for MS, Baltimore and the Seattle/Portland facility. And Mr. Brown and Mr. Michaud are considering making that a permanent authorization.

And I would like to know what do you think that would do? Is that something they should be doing or not?

MR. BLAKE. Absolutely, sir. I think we make that recommendation. We have made it numerous times. I think the reason we make the recommendation is the VA is clearly doing great work there.

And the point is, by permanently authorizing, we ensure that due to some kind of budgetary whim or some other problem that may arise as we talk about here, limitations of dollars, that these centers

do not become victim to cuts that might be necessary just through the fact that there is no money available. And by permanently authorizing them, we can protect them in that manner.

THE CHAIRMAN. To the Friends of the VA, let me thank you for the written testimony. Please express my appreciation to whoever put all this together. If it was you, congratulations. You did good work.

One of our challenges, when you come in with your testimony and say, well, you should upgrade your research by \$45 million, it is not how the budgets get broken out. You know, Dr. Perlin sends over their medical construction and there is not a specific break-out column. We do not get one from you, Doc, that says, okay, this is the medical research construction budget.

I mean, we give dollars to them. Then you have that internal fight with regard to how those dollars are spent. And we have not had a specific break-out with regard to how we do our budgets. I think you know that. So it is hard for us when you go, okay, you tell us there should be a specific \$45 million. It is not all aligned that way. I just want you to know that.

DR. PERLIN. I know.

THE CHAIRMAN. Okay. We do recognize and are cognizant that based off the site visits, he has given his testimony that upgrades need to be made. Dr. Perlin is sitting right next to him. I think given Dr. Perlin, he would have preferred for him to be here himself. But we like Dr. Perlin to bring his team here so he can also hear from his team. And I think it is important as he hears from his team we are also listening to it too.

And so I appreciate the time you put in and please extend that to your team.

Mr. Weidman, thank you.

Mr. Blake, congratulations. You are figuring this place out.

MR. BLAKE. Thank you, sir.

Mr. Chairman, could I made one other point real quick --

THE CHAIRMAN. Sure.

MR. BLAKE. -- just to clarify on the question about the amputation centers? Senator Craig's proposal, I think, just kind of envisioned clinical service centers for veterans who have amputations and their needs for prosthetics.

And in our recommendation both before the Senate and in our statement that we brought here to you today, we take that a step further by introducing the research component into it because we recognize through all the Centers of Excellence and just like through SCI centers the importance of the research aspect and the clinical research that goes on as this care is provided.

THE CHAIRMAN. I have not seen Chairman Craig's legislation. I do not know a lot about it. I have learned more just today. If that is what it is, I am a little more attentive. I do not want to create more

research facilities out there and take away from existing facilities.

Mr. Weidman, you have a closing comment?

MR. WEIDMAN. No. Just a question, Mr. Chairman. If you would entertain at least a link to the Inspector General's report in question. Those reading the record in the future will be confused who is correct about the right reading of the Inspector General's report of September 30th, 2005. If that could be included in the record or at least to link it from the House of Veterans' Affairs web site to the IG's office? I do not know if I am making any sense on that, sir.

THE CHAIRMAN. Try it one more --

MR. WEIDMAN. Okay.

THE CHAIRMAN. Come at it one more time.

MR. WEIDMAN. The Inspector General's report --

THE CHAIRMAN. Yes.

MR. WEIDMAN. -- of September 30th, 2005, in regard to the National Vietnam Veterans Longitudinal Study --

THE CHAIRMAN. Yes.

MR. WEIDMAN. -- there was obviously a difference of opinion as to what that report said.

THE CHAIRMAN. Yes.

MR. WEIDMAN. My question to you, sir, is would you entertain considering having a link from the record of this hearing to that Inspector General's report so that those reading the record, either other members of their staff or the public, in the future have access to it.

THE CHAIRMAN. Yes. I think the fact, Mr. Weidman, that you have now referred to that report, individuals could find it. I prefer not to have that part of our hearing record. But the fact that you have mentioned it, those who may read it now know how to refer to it.

MR. WEIDMAN. Thank you, sir.

THE CHAIRMAN. Okay? Thank you very much.

This hearing is now concluded.

[Whereupon, at 3:06 p.m., the Committee was adjourned.]

APPENDIX

Statement for the Honorable Mr. Brown Full Committee Hearing on Research Committee on Veterans' Affairs June 7, 2006

Good afternoon. Mr. Chairman, I would like to express my thanks to you for holding this very important hearing today. Thank you to all of you that have agreed to testify today and I look forward to working with you on appropriately prioritizing the research projects and infrastructure needs in the coming years. Again, thank you for being here.

We have a critical oversight role on this committee as it relates to research. While we tend to focus most squarely on the direct medical care the VA provides to our servicemen and women, research is a key mission of the VA and our veterans have come to rely on the many advances that were developed inside VA's walls and in collaboration with other public and private entities.

I am eager today to accomplish a few things: (1) welcome a new chief of research before this committee, so Dr. Kupersmith—welcome; (2) explore the emerging priorities, some of which have been laid out in the Administration's FY 2007 budget request and to better understand the practical, clinical applications of the proposed initiatives; and finally, (3) get a better sense of what the research infrastructure requirements will look like into the future.

We are all very aware of the great many successes VA has had in the area of research, but today we are taking the somewhat rare opportunity to showcase it.

As I said at the outset Mr. Chairman, both us here on this committee, and the veterans we represent, have become increasingly aware of the fruits of VA's research effort. However, I think that the public, in general, has had little exposure to just how much the department has contributed to the national research effort and debate. Today, Doctors Perlin and Kupersmith will have the opportunity to share that in a very public forum.

Again, I welcome everyone here today and I thank you Mr. Chairman for-- during what has been titled "Innovation Week" here in the Congress—holding a hearing on this very important subject.

I yield back the balance of my time.

Opening Statement of the Honorable Cliff Stearns**Committee on Veterans Affairs****June 7, 2006**

Full Committee Hearing on the Department of Veterans Affairs (VA) Research

Mr. Chairman, thank you for holding this hearing today on the VA Medical and Prosthetic Research programs.

There are a lot of witnesses here today in which I am interested, and I appreciate your time in coming to testify. Like many of us, I am proud to have a VA Medical Center, the Malcom Randall VA Medical Center, affiliated, and in fact connected via underground tunnel, to an academic medical center, University of Florida Medical School and Shands teaching hospital. They do tremendous research collaborations ranging from psychiatric and PTSD and other mental health disorders research, to diabetes “best practices”. I would say they meet the criteria cited: relevance, quality, and productivity.

I am also interested to hear from Dr. Watson (Executive Director, American College of Medical Genetics). I was proud to be named the first leader of the first Congressional Task Force on Genetics a decade

ago, by then Commerce Committee Chairman Bliley. I held hearings with many witnesses from the genetics community, and I have continued my engagement, offering bills to address genetic nondiscrimination in health insurance protection bills. This interest obviously extends to veterans.

Finally, Dr. Niewoehner, as a pulmonologist, I am pleased to have you here, as well. Two years ago I founded and continue to co-chair, with Rep. John Lewis (D-GA) the Congressional Chronic Obstructive Pulmonary Disease (COPD) Caucus. In 2004, I gave a speech about COPD in the VA. At the time, I remarked that the Veterans Integrated Service Networks treat nearly 600,000 COPD patients annually in all of their treatment milieus, and the system includes 329 pulmonologists and nearly 60 VA-supported COPD researchers. As our nation's largest integrated health care system, it provides the perfect laboratory for research into this disease. I would be interested in an update on the VA's efforts in COPD research and treatment.

Thank you, Mr. Chairman.

Statement of the Honorable Stephanie Herseth
House Committee on Veterans Affairs
Department of Veterans Affairs Medical Research
June 6, 2006

Good afternoon Mr. Chairman and thank you for holding this important hearing.

I want to welcome the witnesses today and look forward to receiving their views and insights on VA medical and prosthetic research.

As the soldiers from the wars in Iraq and Afghanistan return home with wounds suffered in battle, today's hearing is especially appropriate and valuable. The quality of life of these OIF/OEF veterans, along with soldiers from previous wars, is directly impacted by the VA's medical and prosthetic research programs.

Like many of my colleagues, I have had the honor of visiting wounded soldiers at VA medical centers and at the Walter Reed Army Medical Center. These brave soldiers from South Dakota that I visited, like so many wounded OIF/OEF veterans, have been severely wounded and are struggling to overcome their injuries and move forward with their lives.

That is why I was troubled that during a time of war the Administration's budget request for Fiscal Year 2007 proposed to cut funding for VA Medical and Prosthetic Research and called for a reduction in FTEE. While we have worked in the House to restore the VA medical

research funding to last year's funding level, there is much room for improvement. I look forward to working with my colleagues in the future to provide the Medical and Research program with funding that will allow for expanded research initiatives.

The VA has developed unsurpassed clinical, educational, and research programs throughout the country. These programs provide innovative care to patients and develop unique opportunities to VA clinical researchers and doctors. I hope that we will use today's testimony to guide us in making helpful and sensible improvements to the VA medical research that helps expand upon these efforts.

Mr. Chairman, I appreciate the witnesses' views and their efforts to assist us in understanding the VA's research endeavors.

Thank you Mr. Chairman.

Mr. Chairman, I want to welcome each of our witnesses and thank you for holding this hearing.

The VA has long been at the forefront of needed and innovative research.

The work performed by the VA helps perhaps the most deserving population in our society – veterans and their families.

Breakthroughs often help veterans and non-veterans alike.

VA medical research is an effort that we all support and all wish to enhance.

Unfortunately, dollars needed to maintain the quality of research are becoming more and more scarce as medical inflation and flat funding erodes budgets.

I look forward to hearing how VA will prioritize the many research initiatives underway and how VA plans to keep its research facilities on the cutting edge of technology.

VA has a responsibility to focus its research so that it will best assist those it is supposed to help.

For example, we have among others, two distinct populations that need medical research to produce results immediately.

Our aging veterans are dealing with end of life complications. VA medical research can improve the golden years for these veterans.

Our OEF/OIF veterans have significantly different challenges related to the war in which they served. Again, VA research can make breakthroughs that can improve the quality of their lives.

Given the current funding level, I have concerns for the ability of the VA to fund research that helps VA's traditional patient base and also returning servicemembers.

We need to look at greater collaboration, strengthening of bonds between VA and non-VA public and private entities.

We need to encourage researchers to pursue and win grants.

But these efforts cannot be a replacement for appropriated dollars.

We need to do better than flat funding to ensure that VA continues to attract the best personnel and stays at the forefront of medical research.

VA research is not an academic endeavor.

It is essential for improving the quality of care available to our veterans.

Lastly, on the front page of today's Washington Post there is an article entitled "Data Theft Affected Most in Military.

This data breach affected the sensitive personal information of 26.5 million veterans and servicemembers.

In light of this, I would like the VA to address what steps it has taken to safeguard sensitive personal information in its research program, and what steps it plans on taking to protect the privacy and security of the genetic information it obtains as part of its genomic research program.

Mr. Chairman, again I would like to welcome each of our panelists and I look forward to their testimony.

Mr. Chairman, I also again want to thank you for holding this import hearing.

STATEMENT OF
THE HONORABLE JONATHAN B. PERLIN, MD, PhD, MSHA, FACP
UNDER SECRETARY FOR HEALTH
DEPARTMENT OF VETERANS AFFAIRS
ON THE VA MEDICAL AND PROSTHETIC RESEARCH PROGRAM
BEFORE THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS
JUNE 7, 2006

Mr. Chairman and Members of the Committee,

Thank you for the opportunity to appear before you today to discuss the Department of Veterans Affairs (VA) medical and prosthetic research program, including the relevance of VA research to the clinical treatment of veterans; description of priorities for Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF) research; discussion of the Genomic Medicine initiative; and the need to upgrade and modernize VA research facilities. I am pleased to have Dr. Robert Ruff, Acting Director, Rehabilitation Research and Development Service; and Dr. Matthew Friedman, Director, National Center for Post Traumatic Stress Disorder. In addition, I am especially honored to introduce Dr. Joel Kupersmith, Chief Research and Development Officer, to the Committee. We appreciate this invitation to discuss the important work of VA research.

History of VA Research

The original design for the Veterans Health Administration (VHA) Office of Research and Development (ORD) was clear: VA shall carry out a program of medical research to provide health care more effectively and contribute to the Nation's knowledge about disease and disability with emphasis on injuries and illnesses particularly related to service. We hold to that same purpose today.

The history of VA research is full of examples of how VA clinical investigators have improved clinical care.

- VA pioneered the first effective therapies for tuberculosis in the 1940s; veterans returning from the Pacific theater and POW camps in World War II were some of the first to receive these treatments.
- From the 1940's to the present, VA researchers have led the development of better fitting, lighter, more functional artificial limbs. In the late 1970s and early 1980s the Veterans Administration, as it was called then, supported research that led to the Seattle Foot, a prosthetic device for lower limb amputees. This revolutionary device has allowed thousands of amputees from the Vietnam War to return to an active life and participate in activities like basketball, skiing, or running, all of which were impossible with traditional artificial limbs. By 1991, more than 70,000 Seattle feet were in use in the United States. Later, I will describe the exciting work VA research is doing today in the area of robotics and other cutting edge prosthetics.
- In the 1950s and 1960s, the VA cooperative studies program developed the essentials of the multi-site randomized controlled clinical trial that is the standard for testing the safety and efficacy of new treatments today. VA cooperative studies in the 1960's, 70's, and 80's proved the value of such widely used therapies as coronary artery bypass, the use of lithium in bipolar disorders, and

aspirin's ability to ward off heart attacks. More recent VA clinical trials have led to non-surgical treatments for gastro-esophageal reflux disease and prostate enlargement, demonstrated the value of advanced cochlear implants in veterans with profound hearing loss, and established effective treatments for post-traumatic stress disorder (PTSD). Such results have extended life and improved the quality of life for veterans and non-veterans alike.

- In the 1960s, the VA invented the radioimmunoassay, a procedure that is now a mainstay of clinical laboratory testing through the world for detecting biological markers associated with health and disease such as prostate-specific antigen (PSA).
- Also in the 1960s, VA was instrumental in the invention and use of the first implantable cardiac pacemaker. William C. Chardack, chief of surgery at Buffalo's Veterans Administration Hospital, collaborated with Wilson Greatbatch in a partnership to develop the device and surgical techniques that have helped millions of Americans, including our aging veterans.
- VA research contributed significantly to the development of the CT scanner and MRI machine. VA's basic science research in 1960 and 1961 contributed to the development of the computerized axial tomography (CAT scan) in the early 1970s and modern radioimmunoassay diagnostic techniques in the mid-1980s. This illustrates that the progress of discovery is not an overnight task. Sometimes, scientists must work for decades to find solutions to complex problems. Today, veterans and all of us benefit from the basics discovered by VA investigators.
- Smoking and military service have coincided for many years, so VA has a longstanding history of investigating treatments for nicotine dependence. In the early 1980s VA's investigator, Jed Rose at the Durham VA Medical Center (VAMC), worked with others to invent the nicotine patch. Today, VA continues to

support a strong portfolio of research about the effects of nicotine and its relationship with substance abuse, a major concern for many veterans.

- More recently in 2005, the New England Journal of Medicine published the results of a 15 year VA clinical trial that showed an experimental vaccine for shingles cuts its incidence in half and dramatically reduces severity and complications in those that develop the disease. FDA recently approved a license for this vaccine.
- Also, researchers from VHA, Stanford University, and Duke University reported in the October 2005 *New England Journal of Medicine* that the implantable cardioverter defibrillator, although a costly device, is a relatively cost effective way to help prevent sudden cardiac deaths for some high risk patients. This is a good example of collaboration involving our academic partners with funding from another federal agency (the Agency for Healthcare Research and Quality) as well as industry (Blue Cross Blue Shield Technology Evaluation Center).

But, past success is not enough. Research must be future oriented. We must look at how we practice health care today and ask: how can we do better? Our research program builds on its past by identifying and confronting the important questions and challenges of today and then doing the hard work to find solutions for the future.

Genomic Medicine

VA's plans for a Genomic Medicine Program are part of this future. VHA, as a large healthcare system with an integrated research network and an unrivaled electronic medical record system, is distinctively positioned to develop a national Genomic Medicine Program, a program that will be targeted to address veteran-specific concerns.

Value of Genomic Medicine. While it is crucial that VA research address the issues of today and this current conflict, it is equally important that we invest in the achievable possibilities of genetic medicine to understand the role of genetics in the prevention and cause of disease; to improve how clinicians prescribe medications; to prevent adverse drug reactions; and to learn how to use genetic information effectively in everyday practice. I want to emphasize the importance of this especially with the treatment of chronic disease which is a major part of VA's clinical care. In fact, we already have evidence of the value of genomic medicine.

- Prevent adverse drug reactions. When persons who have certain cancers and low levels of a specific enzyme (thiopurine S-methyltransferase) receive standard doses of specific immunosuppressants (mercaptopurine and azathioprine), they risk life-threatening, drug-induced suppression of blood cell production. Genetic testing can identify these people, and then physicians can treat them with greatly reduced doses that are much less toxic than the standard dose.
- Personalize clinical care. Patients with two copies of the gene for an abnormal clotting factor face a risk of developing blood clots in the leg that is 50-100 times greater than that of the general population. We can use this information today to improve the quality of care for patients who may be immobilized for a substantial period, such as following major orthopedic surgery.
- Customize drug treatments. Individuals with mutant allelic variants of the cytochrome P450 (CYP) 2C9 genotype slowly metabolize warfarin, a drug used to thin blood. The slow metabolism of warfarin may increase the risk of hemorrhage when warfarin is first used. A small pilot study conducted at the Marshfield clinic suggests that by obtaining the genotype prior to initiation of therapy, clinicians can reduce the dose of warfarin given the patients most at risk, and that this intervention may result in fewer drug-induced bleeding episodes.
- Improve care. Genetic analysis is becoming part of standard care for treatment of many cancers, including most leukemias and lymphomas, brain tumors, colon cancer and breast cancer. These analyses are used both to diagnose the disease and to determine responsiveness to both chemotherapy and radiation.

Cancer screening based on molecular genetic and proteomic tests will help to catch disease earlier, enabling cures for patients who now go on to develop metastases and die.

These examples show that the move to genomic medicine has begun and that the potential exists for major advances in customizing care to the needs of each individual veteran. Just as VA has pioneered the advantages of the electronic health record, we can do the same in genomics.

Privacy and Ethical Foundations. I want to assure the Committee that VA will maintain the integrity of the privacy of veterans' records. We have built-in safeguards today within the electronic health record to assure privacy, and we will build the necessary protections into our genomics program. As a first step, VA has appointed a Genomic Medicine Program Advisory Board composed of nationally renowned medical experts in genomic research, bioethics, and disease management. While the Committee will assess the potential impact of a VA genomic medicine program on existing VA patient care services; recommend policies and procedures for tissue collection, storage and analysis; and develop a research agenda and approaches to incorporate research results into routine medical care, its first priority will be to provide expert counsel about protecting veterans' privacy and establishing a strong ethical foundation for VA's use of genetic information. Questions about consent, identification of samples, and disclosure of information are a few of those that the group will address. And, we will be sure to consult with veterans about their concerns by using focus groups and other contacts to learn about and then appropriately address issues expressed by veterans themselves. Genomics medicine is the next step into the future to improve and customize health care. We want to take the time necessary to construct a strong ethical and scientific foundation in partnership with the veteran community.

VA Research as a Unique Laboratory

A special advantage of the VA research program is that it is nested within a health care system that serves more than 5 million veterans. This creates a unique national laboratory for the discovery and application of new medical knowledge. Translating research into clinical practice is talked about throughout the medical community, but VA is one place where we apply research every day. VA research has made direct contributions to current clinical practices for hypertension, PTSD, diabetes, and other chronic diseases. VA clinicians who have responsibility for providing care for patients and for training future health care providers are the same scientists who initiate our research projects; nurture the proposal through VA's rigorous scientific merit review; identify and secure additional funding from other Federal agencies, non-Federal sources, and industry; conduct the research; publish the results in prestigious medical journals; and then complete the circle back to the bedside. VA research truly brings scientific discovery from bedside to bench and then back to the bedside.

In fact, the chance to conduct research has been a strong tool for VA to recruit and retain high quality physicians and other clinicians. This directly and continually leads to enhanced quality of care for veterans. Other health care systems rarely provide physicians and other clinicians with the opportunity to research questions that are most relevant to patient care. VA's healthcare system allows that we promote the idea of research within our unique research setting with tools such as the computerized patient record system and protected time for research.

Studies by the Institute of Medicine, RAND, and others have highlighted the delays that occur from the time of scientific discovery to the time an evidence-based practice becomes routine – in US healthcare, on average, the likelihood of receiving a treatment based on credible scientific evidence is only about 50 percent. VA far exceeds that level of performance on virtually every evidence-based indicator. Furthermore, VA has established a unique program, the Quality Enhancement Research Initiative (QUERI), whose mission is to bring researchers into partnership with health system leaders and

managers in order to ensure the care we provide to veterans is based on the most current scientific evidence.

The record of translation is clear. For example

- VA clinicians have long noted that veterans with schizophrenia often have extremely high rates of tobacco usage, and found that nicotine receptors have a critical role in processing sensory input in such patients – in essence, such veterans were medicating themselves with tobacco to correct their brain abnormality. A team from the Denver VA Schizophrenia Research Center discovered that a gene coding for part of the brain's nicotine receptor is responsible for the inheritance of risk for schizophrenia. Subsequent work by VA researchers has successfully translated these insights to develop potential new clinical treatments for schizophrenia, including a compound derived from sea worms that works like nicotine but does not have its adverse health effects. VA studies of this compound in an animal model of schizophrenia have enabled the Food and Drug Administration (FDA) to approve the first experimental use in humans, and the drug holds the promise of recovery for many persons with schizophrenia that fail to respond to existing therapies.
- VA investigators have demonstrated that intravenous infusion of adult-derived, bone marrow stem cells can protect against brain damage in a rat model of cerebral ischemia. The ability to reverse brain damage has important implications for such disabling conditions as stroke, brain trauma, and spinal cord injury.
- Translation of findings occurs outside of basic science as well. VA investigators at Hines, Illinois and Cleveland, Ohio are developing and testing electronic microstimulators which may have important implications for the quality of life of individuals with spinal cord injury (SCI). Such stimulators, when implanted into leg muscles, may recreate the ability to walk and maneuver in their local environment. When implanted into breathing muscles, they may recreate breath and cough patterns that will avoid respiratory complications that are currently the leading cause of death in SCI patients.

These specific examples illustrate how VA take issues of concerns to veterans and improves care directly through research by VA clinical investigators.

Emerging Priorities of VA Research

Although in any given year the bulk of VA's research budget is committed to on-going investigation, each year we re-evaluate our priorities based on the changing needs of the veterans we serve, and attempt to fund high quality science that meets those priorities. I would like to highlight our current areas of focus for VA research.

Operation Iraqi Freedom and Enduring Freedom (OIF/OEF). In order to better serve military personnel injured during OIF/OEF, VA has implemented a new research agenda which brings all parts of ORD together to develop new treatments and tools for clinicians to use to ease the physical and psychological pain of the men and women returning from conflicts, to improve access to VHA services, and to accelerate discoveries and applications, especially for PTSD diagnosis and treatment, state-of-the-art amputation and prosthetics methods, and polytrauma.

Neurotrauma (including traumatic brain injury and spinal cord injury). Traumatic Brain Injury (TBI) accounts for almost 25 percent of combat casualties suffered in OIF/OEF by US Forces. SCI is also a possible consequence of these combat casualties. In November 2005, VA issued a program announcement to stimulate research in the area of combat casualty neurotrauma. This research initiative seeks to advance treatment and rehabilitation for veterans who suffer multiple traumas from improvised explosive devices and other blasts. Eighty-five letters of intent to submit a research proposal were received, indicating a high level of interest among our investigators. Complete proposals will be reviewed in the next several months, and we plan to fund as many high quality projects from this initiative as the budget will allow.

Polytrauma and Blast-Related Injuries. Improvements in body armor and battlefield medicine have resulted in higher survival among wounded soldiers but also new combinations of critical injuries, including head injuries, vision and hearing loss, nerve damage, infections, emotional problems, and in some cases amputation or severed spinal cords. This is a new challenge for VA, and we need to develop the knowledge base to manage these conditions over the remaining lifetime of the veteran. VA has devoted its newest QUERI center to polytrauma and blast-related injuries with a focus on using the results of research to promote the successful rehabilitation, psychological adjustment, and community reintegration of these veterans. Other VA scientific studies are currently underway to characterize these injuries and determine their outcomes and costs, and to identify geographic areas where the need for rehabilitation is greatest. Such information is critically important in helping VA redesign its care delivery system to meet the needs of these veterans.

Amputation and Prosthetic Research. VHA ORD currently supports a broad research portfolio pertaining to amputation and prosthetics, and more research in this area is planned. Areas of interest include:

- Nanofabrication, microelectronics and robotics to create lighter, more functional prostheses. ORD is funding two new Prosthetics Rehabilitation Engineering and Platform Technology Centers that are national resources to develop computerized state-of-the art prosthetic limbs with the goal of using the latest advances in orthopedic surgery, tissue engineering, nanotechnology, and microelectronics to create prosthetics that look, feel, and act more like one's own limb.
 - The Providence VA Medical Center, in collaboration with Brown University and the Massachusetts Institute of Technology, is working to develop a "biohybrid" limb that will use regenerated tissue, lengthened bone, internal and external implants and sensors to allow amputees to use brain signals and residual limb musculature to have better control of their limbs and reduce the discomfort and

secondary complications associated with current prostheses. These researchers are already publishing and presenting about their work.

- The Advanced Platform Technology (APT) Center at the Cleveland VA Medical Center focuses on sensory and implanted control of prosthetic limbs, accelerated wound healing, and biological sensors for the detection of health and function to accelerate the use of new materials and innovative micro-mechanical or nanotechnologies to provide more independence to veterans with disabilities.
- ORD is partnering with the Department of Defense (DoD), Walter Reed Army Medical Center, the Defense Advanced Research Projects Agency and Brooks Army Medical Center to compare prosthetic designs; define standards of function; evaluate psychological issues faced by returning service personnel; determine psychosocial issues that challenge successful reintegration; and initiate longitudinal studies to study veterans care over time.
- VA investigators are examining rehabilitation for the visually impaired; new treatments for burn victims; restoration of hearing and maximizing function for those with hearing loss, especially for polytrauma victims; and natural mechanisms of neural regeneration to return function to paralyzed veterans and those with brain injuries. VA investigators also plan to study advanced tissue engineering and the manufacturing of artificial skin to accelerate wound healing.

Mental Health and PTSD Research. Special attention is being paid to the circumstances of the returning OIF/OEF veteran related to mental health and Post Traumatic Stress Disorder (PTSD) research. Examples include:

- *Long-Term Studies.* Baseline data has been collected on military personnel prior to their deployment to Iraq. These soldiers will be reassessed upon their return and several times after that to identify possible changes that occurred in emotion or thinking as a result of their combat exposure. In another program, a VA

scientist is collecting information prior to deployment, however in this study, from Army Reserve personnel. This is important because Reserve personnel have not been as well studied as active military and may have different readjustment issues. They will be reassessed twice afterwards to determine whether they have increased symptoms, distress, or increased utilization of healthcare services. Information from these types of programs will help identify factors that change as a result of military service and those which may be important in healthy readjustment. Support of these types of prospective, longitudinal studies is important and should be able to provide insight about the effect of combat exposure and the ability of soldiers to return to high levels of functionality afterwards.

- *Interagency Collaboration regarding OIF/OEF Mental Health.* VA, the National Institutes of Health (NIH) and DoD jointly issued a Request for Applications (RFA) in FY 2006 to address questions of risk evaluation, risk reduction, psychotherapies, internet treatments, etc. involving active-duty or recently separated National Guard and Reserve troops from OIF/OEF. This RFA specifically encouraged participation of clinicians and researchers who screen, assess or provide direct care to at-risk, combat exposed troops, and emphasized interventions focusing on building resilience for veterans suffering from mental health problems, including PTSD, and developing new modes of treatment that can be sustained in community-based settings. Among the approaches being considered are novel pharmacological, psychosocial and combination treatments as well as the use of new technologies (e.g., World Wide Web, DVD, Virtual Reality, Tele-health) to extend the reach of VA's health care delivery system. Fifty-five proposals were received earlier this year in response to this RFA, and those proposals deemed to have scientific merit and relevance to veterans will start October 1, 2006.
- *Women and PTSD.* An estimated 8 - 10% of active duty and veteran women currently have PTSD resulting from having experienced some form of trauma. A

large multi-site cooperative study is targeted to determine the best treatment for women veterans by providing either prolonged exposure therapy (PE) or a comparison therapy focused on current problems (PCT). The initial results from this study show that women with PTSD who were treated through PE therapy had more improvement in their PTSD symptoms and functioning than the women receiving PCT. This study is important because it is dedicated to treating female veterans who may experience PTSD differently than male veterans, and also because it identifies the more effective psychotherapeutic strategy, which essentially allows the patient to reorganize and eventually control some aspects of their disruptive memories and symptoms.

Projects in Planning. ORD is currently considering solicitations for studies involving the long-term care needs of veterans with TBI; an assessment, in collaboration with DoD, of the long-term changes in health status resulting from combat deployment; and burn treatment and recovery.

General Mental Health. Mental health research is spread throughout many parts of the ORD research portfolio including aging, health systems, special populations, military occupations and environmental exposures, substance abuse, and other chronic disease. In FY 2005 the total mental health research portfolio totaled \$67,323,105 in active mental health research projects to understand the underlying causes and to effectively diagnose and treat mental disorders. This is nearly 17 percent of the FY 2005 Medical and Prosthetic Research appropriation of \$402,348,000. This total does not include support from non-VA research sponsors or support from other VA resources such as the Quality Enhancement Research Initiative (QUERI), Mental Illness Research, Education, and Clinical Centers (MIRECCs), and medical care support for clinicians engaging in research. The scope of mental health research includes studies about substance abuse, cognitive and behavioral issues, PTSD, stress, TBI, as well as brain diseases and mechanisms.

Depression. Implementation of an evidence-based collaborative care model for depression called "TIDES" (or Translating Initiatives in Depression into Effective Solutions) has demonstrated significant improvements in depression symptomatology among patients referred by their primary care providers. This study plus two companion evaluations of the processes, outcomes, and costs of implementation (called WAVES or Well-Being among Veterans Enhancement Study and COVES or Cost and Value of Evidence-based Solutions for Depression) are part of national VA strategic planning and rollout for improving the quality of depression care.

Other projects. One study involves research about the role of smoking and nicotine dependence among veterans with PTSD. This fall, ORD will begin a multi-site clinical trial to study the effects of risperidone on PTSD. ORD will continue to support other studies that test the effectiveness of virtual reality therapy and other new treatments for PTSD. It is important to note that this research will also have direct applications for all veterans and not simply those involved in OIF/OEF.

Gulf War Veterans' Illnesses. VA research places a high priority on scientific research aimed at improving the quality of life for veterans of the 1990-1991 Gulf War affected by chronic multisymptom illnesses commonly referred to as Gulf War Veterans' Illnesses (GWVI). Some veterans who participated in Operations Desert Shield and Desert Storm have reported conditions and chronic symptoms such as fatigue, weakness, gastrointestinal difficulties, cognitive dysfunction, sleep disturbances, persistent headaches, skin rashes, respiratory problems, and mood changes at rates that significantly exceed those reported by comparison groups. VA research continues to expand its efforts to understand and treat GWVI. The core objective is to improve the health of ill Gulf War veterans. It is important to note that Gulf War veterans with chronic unexplained symptoms are eligible for disability benefits even when the cause of their illness cannot be determined.

VA has committed \$15 Million in FY 2006 for a collaboration with the University of Texas – Southwestern Medical Center and has also funded VHA ORD investigators for

on-going projects. These ongoing studies address areas of interest that include: chronic multisymptom illnesses (CMI) affecting GW veterans; conditions and/or symptoms frequently reported by GW veterans; long-term health effects of potentially hazardous substances, alone and in combination, to which GW veterans may have been exposed during deployment; and any of the 21 Research Topics forming the framework for the Annual Report to Congress of Federally Sponsored Research on GWVI.

Women's Health. According to information from the VA's Center for Women Veterans, in 1973, women in the active duty military accounted for 2.5 percent of the armed forces. By fiscal year 2001, however, the number of women significantly increased making up 15 percent of the armed forces and those numbers are expected to increase. To respond to this demographic change and develop a more comprehensive VA women's health research agenda, a VA Women's Health Research Planning Group recently identified the needs of women veterans and a corresponding research agenda. VA researchers currently are investigating optimal strategies for conducting preventive health and disease screening activities among women veterans (e.g., cervical cancer screening) and developing and evaluating computerized, interactive educational programs to enhance VA staff awareness of women veterans and their health-care needs.

Chronic Disease

VA researchers conduct extensive research to discover how to prevent and treat chronic disease.

Diabetes. According to the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health, 20.8 million people—7 percent of the population—have diabetes. An estimated 4.6 million people are diagnosed and 6.2 million people are undiagnosed. In 2005, 1.5 million new cases of diabetes were

diagnosed in people aged 20 years or older. Diabetes affects nearly 20% of veterans receiving health care from VA: 1 million veteran users. An estimated 2 million veterans without diabetes have metabolic syndrome, which places them at high risk for diabetes. The cost is tremendous: 30% of VA health care costs (in- and out-patient and pharmacy) are attributable to patients with diabetes. This includes 1.7 million days of hospital care. VA investigators have completed the first study to compare the quality of diabetes care among patients in VA and commercial managed care organizations. Quality of care measures were compared for seven diabetes processes of care, three diabetes intermediate outcomes, and four dimensions of satisfaction. Results from this study showed that VA patients had better scores than commercially managed care patients on all assessed quality of care measures. VA patients also had better low-density lipoprotein control and were slightly more satisfied with the overall quality of diabetes care at VA.

Identifying the most effective treatment methods is crucial to reducing the incidence of diabetes among veterans. Although more patients are accessing medical information on the Internet, few studies have examined the effects of web-based interventions that incorporate an interactive component requiring feedback from patients. A VA study tested diabetes care management using a web-based system for veterans with poorly controlled diabetes. Results showed that web-based care management improves poorly controlled diabetes in veterans. Veterans participating in the web-based management program had significant improvements in HbA1c over one year compared to usual care, and persistent website users had even greater improvements compared to intermittent users.

ORD has also initiated the VA Diabetes Trial to determine whether intensive control of blood sugar, compared to standard methods, can reduce macrovascular blood vessel damage and other complications. Smaller trials to determine the value of the interventions will come first, with more research to follow.

Obesity. Results from the 2003-2004 National Health and Nutrition Examination Survey (NHANES) indicate that an estimated 66 percent of U.S. adults are either overweight or obese. The problem is similar or worse among VA's patient population, with 73% of veteran patients overweight or obese. Obesity contributes to increased heart disease, diabetes, and sleep apnea, and an estimated 300,000 Americans die annually from illnesses related to overweight and obesity.

Findings from VA studies to assess the efficacy and safety of weight loss medications, as well as the effectiveness and adverse events associated with the surgical treatment of obesity, demonstrated that surgical treatment is more effective than non-surgical treatment for weight loss in severely obese patients; weight loss was maintained for up to 10 years and longer and was accompanied by significant improvements in several comorbid conditions.

Other examples of VA research include studies on traditional and new approaches to prevent and treat obesity, such as a comparison of lower extremity functional electrical stimulation on obesity and associated co-morbidities in comparison to upper extremity aerobic exercise for persons with paraplegia; an assessment of the impact of walking aides on quality of life and physical activity in overweight and obese veterans with osteoarthritis; and explorations of drug therapies.

Alzheimer's Disease. Alzheimer's Disease (AD) and related dementias affect 7.3% of veterans over age 65. VA research is helping to discover new facts about AD and other diseases and conditions that affect older veterans. For instance, researchers at the Bronx VA medical center have reported that diet-induced insulin resistance, a cause of type II diabetes, promoted beta-amyloid production concurrent with decreased insulin-degrading enzyme (IDE) activity in an animal model of AD. Beta-amyloid is the major component of amyloid plaques, the hallmark of AD pathology. IDE has been proposed to be responsible for the degradation and clearance of beta-amyloid in the brain. Such research is needed to form the basis of future interventions to prevent or reverse this devastating condition.

Influenza. VA health services researchers have been instrumental in improving vaccination rates for veterans with chronic diseases that place them at high risk for complications from influenza, as well as enhancing vaccination among health care workers and veteran groups that historically have had low vaccination rates, such as minorities, smokers, and those with spinal cord injuries and disorders.

Pandemic influenza infection has the potential for causing significant morbidity and mortality in the United States and elsewhere. ORD is responding, along with other federal agencies, to this unprecedented public health threat by initiating studies that examine optimal dosing strategies for the antiviral agent oseltamivir (Tamiflu®) in the event of an emerging pandemic of human infection with an avian or other influenza strain for which an effective vaccine is lacking.

HIV/AIDS. AIDS (acquired immunodeficiency syndrome) is caused by HIV (human immunodeficiency virus). The virus kills or damages the body's immune system, which lowers the body's ability to fight infections and certain cancers. According to the Centers for Disease Control, at the end of 2003, an estimated one million persons in the United States were living with HIV/AIDS, with 24-27% undiagnosed and unaware of their HIV infection. VHA is the largest single provider of HIV care in the US, with nearly 20,000 patients seen annually with the disorder. Accordingly, ORD funds a full range of studies from bench research aimed at elucidating the underlying mechanisms of HIV to implementation projects that improve VHA's effectiveness in caring for this population. Researchers at the VA South Texas Health Care System and the University of Texas Health Science Center recently showed that people who have 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. These findings, cited as one of the top articles published in the eminent journal *Science*, have important implications for the treatment and prevention strategies for HIV/AIDS and possibly other infectious diseases as well.

Infrastructure

It is crucial that VA investigators have the equipment and facilities necessary to conduct cutting-edge research in the twenty-first century. To identify where improvements may be needed, ORD has initiated a comprehensive review of VA's research facilities to identify deficiencies and corrective actions. The objectives of the Research Infrastructure Evaluation and Improvement Project are to review the overall adequacy and utilization of research space and infrastructure (including animal research facilities); to develop a plan to update and maintain facilities; to ensure compliance with biosafety and research laboratory security requirements; to enhance collaborations between the local VA Medical Center and its academic affiliate; and to ensure that the needs for highly specialized research programs (e.g., Rehabilitation Research and Development (RR&D) and Health Services R&D (HSR&D) Centers of Excellence) are met.

Survey teams including VA research administrators and scientists, as well as other VA employees and engineering contractors, will review documentation and visit facilities to evaluate the physical infrastructure (including the animal facility, research laboratories and common equipment rooms); operational infrastructure (capability to conduct research while meeting requirements for compliance with safety, animal welfare, and human subjects protection regulations); and equipment (major items of equipment used for the conduct of research) of VA facilities with active research programs. The data collected from the surveys will be used to develop financial needs and an asset management plan. We expect to have a report to Congress early in 2007.

In addition, ORD recently funded proposals as part of the Shared Equipment Evaluation Program that is managed by the Biomedical Laboratory and Clinical Science Research and Development Services. The purpose of this program is to fund new or replacement research and animal facility equipment. The program requires that facilities identify dollar-for-dollar matches in order to leverage the VA contributions. As a result of a December 2005 request for applications, a total of \$2,086,173 for facility projects and research equipment has been funded for the following sites: Decatur, GA; Chicago, IL; Cleveland, OH; Miami, FL; Loma Linda, CA; Memphis, TN; Nashville, TN; New Orleans,

LA; Omaha, NE; Palo Alto, CA; Philadelphia, PA; Portland, OR; Richmond, VA; San Francisco, CA; Seattle, WA; San Diego, CA; San Antonio, TX; and Los Angeles, CA.

Other proposals for research equipment are pending funding with decisions expected later this fiscal year. This program was suspended for a number of years, but plans are to begin funding proposals on an annual basis after a review to determine merit and priorities.

VA Research Past, Present, and Future

Past. The achievement record for VA research is impressive. VA physicians and scientists developed practices that have revolutionized medicine. They pioneered tuberculosis treatment, developed the cardiac pacemaker, the nicotine patch, and contributed to development of the high-tech diagnostic procedures of magnetic resonance imaging (MRI). The first successful drug treatments for high blood pressure and schizophrenia were pioneered by VA researchers, as were kidney and home dialysis techniques. The Seattle Foot, created by VA, allows amputees to walk, run and jump.

In 1977, the Nobel Prize for Medicine went to two VA physicians -- Dr. Rosalyn S. Yalow of the Bronx VA Medical Center, who was recognized for her landmark work in the development of the radioimmunoassay; and Dr. Andrew V. Schally of the New Orleans VA Medical Center, for his research on brain hormones.

In 1998, Ferid Murad, M.D., Ph.D., shared the Nobel Prize in Medicine in part for research he conducted while at the Palo Alto VA Medical Center. Studies by Dr. Murad have been instrumental in illuminating the role of nitric oxide in body functions, including the relaxation of blood vessels and regulation of blood pressure.

And, a most recent accomplishment is the FDA licensure of a vaccine to prevent shingles. VA researchers conducted the clinical trials that tested the efficacy and safety

of this new vaccine that will help millions of veterans and the nation as a whole.

Present. Today, we are briefly discussing what VA researchers are presently doing. For example, in rehabilitation research, we have described how VA researchers are developing and testing cutting edge artificial limbs. Also, VA's Center of Excellence on Innovative Visual Rehabilitation in Boston is developing a microelectronic retinal implant to restore vision to patients with age-related retinal degenerative disorders, including macular degeneration (the leading cause of legal blindness in the VA healthcare system) and retinitis pigmentosa. The implant is beginning to be tested in patients. Stimulation is applied to the retina where damaged cells had been which makes it easier for the nervous system to interpret or make sense of the images.

In biomedical and clinical research, we are searching for more effective treatment for cancer and other problems. For example, one of the most common treatments for cancer is chemotherapy or drugs that kill cancer cells. The problem is that these drugs also harm healthy cells, so VA researchers are studying targeted chemotherapy drugs to disrupt the ability of cancer cells to divide and multiply, but generally not affect healthy cells. Some of these drugs are already in clinical use. One well-known example is Gleevec, approved to treat a rare type of gastrointestinal cancer and some leukemias. This drug, developed and tested with the help of VA researcher Dr. Michael Heinrich in Portland, "turns off" an enzyme that enables cancer growth.

Another example comes from the lab of VA scientist Dr. Andrew Schally, a Nobel Prize winner. Schally, formerly in New Orleans and now in Miami, is testing compounds that stop tumors by blocking a hormone that fuels their growth. He is also developing another form of smart chemotherapy: His group identifies tumors with an affinity for certain hormones, and then packages manmade versions of those hormones with tumor-suppressing drugs. In animal and cell-culture studies, the resulting compounds appear to zap cancer cells without harming healthy cells.

Future. But, past success and present efforts are not enough. Research must be future oriented. We must look at how we practice health care today and ask: how can we do better? Our research program builds on its past by identifying and confronting the important questions and challenges of today and then doing the hard work to find solutions

As an academically trained researcher, I understand the complexities of the research process, and I am fascinated by the results. I fully support this program and advocate to you that its value, both to veterans as well as the nation, far exceeds the costs. The history of VA research is impressive, and the future promises even more important advances. Can we apply genomics to improve the quality of care for veterans? Can we prevent infections that hamper the use of biohybrid limbs? Can we develop artificial retinas so that wounded OIF/OEF soldiers and our aging veterans can regain their sight? Can we use our computerized medical record system and genetic samples to individualize drug and clinical treatments, or identify those veterans who may have a predisposition for a particular disease and prevent the onset of, rather than treat, the symptoms? Can we continue to examine ourselves to find out how to deliver patient care more effectively? The answers to these questions must be "yes", as no other health system is better positioned than VHA to make these discoveries, and no other group of patients is as deserving as America's veterans to receive the benefit of such innovation.



**STATEMENT OF
CARL BLAKE
SENIOR ASSOCIATE LEGISLATIVE DIRECTOR
PARALYZED VETERANS OF AMERICA
BEFORE THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS
CONCERNING
THE DEPARTMENT OF VETERANS AFFAIRS
MEDICAL AND PROSTHETIC RESEARCH PROGRAM**

JUNE 7, 2006

Mr. Chairman and members of the Committee, Paralyzed Veterans of America (PVA) would like to thank you for the opportunity to testify today on the Department of Veterans Affairs (VA) Medical and Prosthetic Research program. 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.

Chartered by the Congress of the United States

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We understand that this hearing will address three focus points: (1) the relevance of VA research to the clinical treatment of veterans; (2) two special research projects—the OIF/OEF initiative and genomic medicine—identified in the FY 2007 budget submission; and (3) the need for upgrades and modernization of VA research facilities. We will address each of these points individually.

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.

Within the VA's Office of Research and Development are two services that directly support the importance of VA research to clinical treatment of veterans. The Health Services Research and Development Service (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. Ultimately, the underlying objective of health services research in VA is to understand and improve clinical decision-making and care.

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.

Since 1997, PVA has worked with VA MS clinicians and administrators, as well as with private MS providers and advocates to address the then 'patchwork' service delivery by VHA towards veterans with MS. While we identified the scope and range of VA's patchwork of MS services, it became very apparent that vital elements indeed existed; if only they might be brought together in mutual support of VA's mission to serve MS veterans.

The designation by VA of two MS Centers of Excellence located in Baltimore and Seattle/Portland represents “centers without walls” engaged in marshaling VA expertise in diagnosis, service delivery, research and education and making the same available across the country through a ‘hub and spokes’ approach. The mid-term evaluation of these two centers very positively acknowledges the success of VA’s strategy.

Regarding the PADRECC’s, PVA recognizes again that these centers are a specific approach to give VA a focus for health care service and research. The treatment breakthroughs, including very delicate surgical procedures, of recent years must be localized so that they might best be assimilated into VA-wide practice. PVA supports this approach for both Parkinson’s disease as well as Multiple Sclerosis. We would urge the Committee to consider legislation which would permanently authorize these centers because they represent the true value of VHA as a national health care system success story.

Likewise, since 1976, VA has built a system of Geriatric Research, Education, and Clinical Centers (GRECCs) in anticipation of the impact of the aging of World War II and Korean War veterans on health care needs and delivery. The system has grown to 21 centers in 19 of the VA’s 21 Veterans Integrated Service Networks (VISNs). In 2005, the GRECCs accounted for nearly 10% of the VA’s total research activity, expending over \$100 million investigating the diseases, disabilities and rehabilitation needs of elderly veterans and developing and testing innovative approaches to care for them. Almost \$80 million of that came from outside the VA. GRECCs provide advanced clinical expertise for caring for some of our most medically complex and frail veterans. They have developed, tested, and disseminated numerous clinical

innovations. They are responsible for training almost 2/3 of the doctors specializing in geriatric care in the United States. Perhaps most importantly, because of the GRECCs research productivity, they actually return to their host VISNs across the entire VA more capital than they cost the system.

Noteworthy recent accomplishments of these cost-effective geriatric centers of excellence are too numerous to list in full, but a few examples are offered to provide an indication of the scope and range of GRECC contributions. GRECC researchers at the Puget Sound, Minneapolis, New England, Ann Arbor, and Madison GRECCs have dramatically advanced the understanding of Alzheimer's disease, the molecular mechanisms of brain destruction, who is at risk for it, how to identify those at risk, how that risk may be modified, and models of care in the home and in institutions for those who are affected. GRECC clinician-scientists at Baltimore, Cleveland, Miami, Pittsburgh and Palo Alto have explored new approaches to rehabilitation strategies for those afflicted by stroke, trauma, and neurological diseases like Parkinson's Disease, multiple sclerosis and myasthenia gravis—employing a wide range of strategies including regeneration of nerve and muscle tissue, electrical stimulation and computer-assisted limb prostheses, innovative exercise regimens, and lifestyle and environmental modifications. Other sites have made similar dramatic strides in addressing spinal cord injury care, end of life care, cancer regimens, the aging immune system (including the recent introduction of an effective vaccine against shingles), medication use, mobility, urinary dysfunction, swallowing disorders, hearing and speech disorders, arthritis, osteoporosis, and thyroid disease.

The budget submission includes plans for two special research projects to begin in 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 envisions a wide ranging number of research efforts, including targets in post-traumatic stress disorder and other mental health issues; amputation and prosthetics research; and returning personnel reentry and reintegration. 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. This data will help focus the project on additional areas that need to be studied.

This project would directly support the important role that research plays in the clinical setting. Through this project clinicians would 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 will 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.

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.

PVA believes that this project could be paired with Amputation and Prosthetic Centers of Excellence as introduced in legislation in the Senate (S. 2736). 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. Through research and clinical trials, it can then transfer learned approaches for specific care to the broader VA health care system, and ultimately, throughout the entire medical world. The Senate 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. PVA believes that these centers could be the spearhead for research and development of evidence-based performance test standards for amputee and prosthetic devices.

The second special research project would focus on genomic medicine. The thrust of this project is to link veterans' genetic information with the VA electronic health record. The budget submission states that "the goal is to develop genetic assessments that will potentially enable 'mass customization' of medical treatment." 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.

PVA recognizes the fact that, much like the greater VA infrastructure, research facilities are aging and in need of repair or renovation. For decades, insufficient construction funding has

been provided to maintain, upgrade, and replace VA's aging research facilities. The result is a backlog of research sites that need major and minor construction funding. Moreover, researchers are often limited by the lack of state-of-the-art facilities. And yet, VA clinicians and researchers still need laboratory space, clinical settings, and record keeping. These three elements need to be as current as possible.

Five years ago, the VA received \$25 million specifically for upgrades and enhancements to research facilities. However, no specific funding has been provided since. We appreciate this Committee and the House of Representatives earmarking \$12 million for minor construction for VA research facilities this year. However, a steadier stream of funds must be provided. Sporadic funding does not enable the agency to plan appropriately for either on-going research or new initiatives. We urge Congress to begin investing dedicated funding into the rapidly deteriorating infrastructure in which VA clinicians and researchers conduct their activities.

The VA has informed FOVA that it would need three years to complete a research facilities assessment before it could invest new money into its research infrastructure. However, an assessment was just completed in 2003. That assessment could be used as the baseline for a faster reevaluation so that much-needed upgrades are not held hostage to this process.

PVA believes that one particular change could 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 additional funding to support indirect costs of their projects. Indirect costs include infrastructure

that the VA researchers use to conduct their work. This seems to be inherently unfair and needs to be changed.

In conclusion, our greatest concern with the Medical and Prosthetic Research program is chronic under funding. VA research has been grossly under funded in comparison to the growth rate of other federal research initiatives. Although the Administration's Budget Request called for only \$399 million for this account, we appreciate the efforts of the Committee to provide additional funding to the program. However, we believe more can be done. In accordance with the recommendations of *The Independent Budget*, we believe that the Medical and Prosthetic Research program requires \$460 million. This would allow the VA to expand the scope of many of its research projects and begin upgrading and expanding its research infrastructure.

Mr. Chairman, PVA appreciates your continued interest in maintaining a viable research program. We look forward to working with the Committee 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.

Information Required by Rule XI 2(g)(4) of the House of Representatives

Pursuant to Rule XI 2(g)(4) of the House of Representatives, the following information is provided regarding federal grants and contracts.

Fiscal Year 2006

Court of Appeals for Veterans Claims, administered by the Legal Services Corporation — National Veterans Legal Services Program— \$252,000 (estimated).

Fiscal Year 2005

Court of Appeals for Veterans Claims, administered by the Legal Services Corporation — National Veterans Legal Services Program— \$245,350.

Paralyzed Veterans of America Outdoor Recreation Heritage Fund – Department of Defense – \$1,000,000.

Fiscal Year 2004

Court of Appeals for Veterans Claims, administered by the Legal Services Corporation — National Veterans Legal Services Program— \$228,000.

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Carl Blake is the Senior Associate Legislative Director with Paralyzed Veterans of America (PVA) at PVA's National Office in Washington, D.C. He is responsible for federal legislation and government relations, as well as budget analysis and appropriations. He represents PVA to federal agencies including the Department of Defense, Department of Labor, Small Business Administration, and the Office of Personnel Management. In addition, he represents PVA on issues such as homeless veterans and disabled veterans' employment as well as coordinates issues with other Veterans Service Organizations.

Carl was raised in Woodford, Virginia. He attended the United States Military Academy at West Point, New York. He received a Bachelor of Science Degree from the Military Academy in May 1998. He received the National Organization of the Ladies Auxiliary to the Veterans of Foreign Wars of the United States Award for Excellence in the Environmental Engineering Sequence.

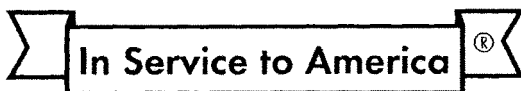
Upon graduation from the Military Academy, he was commissioned as a Second Lieutenant in the United States Army. He was assigned to the 1st Brigade of the 82nd Airborne Division at Fort Bragg, North Carolina. Carl was retired from the military in October 2000 due to a service-connected disability.

Carl is a member of the Virginia-Mid-Atlantic chapter of the Paralyzed Veterans of America.

Carl lives in Fredericksburg, Virginia with his wife Venus, son Jonathan and daughter Brooke.

Statement of

VIETNAM VETERANS OF AMERICA



SUBMITTED BY

Richard F. Weidman
Executive Director
for Policy and Government Affairs

BEFORE THE

HOUSE VETERANS AFFAIRS COMMITTEE

REGARDING

**THE DEPARTMENT OF VETERANS AFFAIRS MEDICAL AND
PROSTHETIC RESEARCH PROGRAMS**

JUNE 7, 2006

Chairman Buyer and distinguished members of the House Veterans Affairs Committee, on behalf of Vietnam Veterans of America (VVA) and our National President John P. Rowan, I thank you and your distinguished colleagues for the opportunity to testify before you today regarding our views on VA research programs.

VVA has been concerned about the use of VA Medical & Prosthetic Research & Development (R&D) funds for many years. As you know, VVA strongly believes that the VA health care system must move toward becoming a true veterans' health care system and not just a general health care system that happens to be for veterans. Similarly, the R&D funds that VA receives should be spent, in the main, on research that will directly impact the quality of care of veterans, and particularly will help VA practitioners better care for those wounds and maladies that are a result of the veterans' military service.

VVA has testified to this effect countless times over the years before this Committee. We have made our case to a succession of Secretaries and other officials at the VA, including a succession of Directors of Research & Development. In 2002 we thought that finally we had a director of that activity that would be responsive to this most central need of the VA health care system. However, that R&D Director left the VA, and the Deputy Director that also agreed with that key central priority was also forced out.

Dr. Kupersmith has now been the head of Research & Development for more than a year now, and has yet to even meet with the veterans service organizations to ask any of us what we think the priorities should be in this area. Despite the lack of reaching out on his part, many of us have repeatedly made clear two things to the Congress, to the Undersecretary, and to others: one, our commitment to having adequate research funds at the VA in order to attract and retain the best physicians is of high priority; and, two, research at VA should be related to the wounds, injuries, and maladies that are or may have been caused by virtue of military service.

The National Institutes for Health (NIH) has a budget that is so much larger than the VA research budget that it is no exaggeration to say the VA program is "decimal dust" in comparison to the funding accorded to NIH. The VA is doing an increasingly good job of seeking out cooperative research arrangements, and in many cases outside research funding for specific projects. However, there just is not enough in the way of resources to try and "be all things to all people" in the research undertaken at VA and the affiliated schools that use the VA facilities.

I believe that we are all very much aware of how much has been done with comparatively little at the VA, from the revolutionary "C" leg that has made such a dramatic positive difference in the lives of high bi-lateral amputees, to the recent advances in research regarding Parkinson's disease, to the identification of the Hepatitis C, to the work that led to the first successful liver transplants ever, all of which were done at VA facilities or affiliated institutions. There is also much work that has contributed to the understanding of the deep brain functions, and much extraordinary and extremely valuable work that has been done on schizophrenia. As the onset of this terrible disease typically happens in the

late teens or early twenties, when many young Americans are serving in the military, there is the opportunity to study this disease with an abundance of subjects. While much of this work has been done through the Mental Illness Research & Educational Centers (MIRECC), much has been done through the, a great deal has also been done via funding from the Research office as well.

VVA has consistently strongly advocated before this committee and the Appropriations committees for more funding for research at the VA, at the same time as we have pressed for more focus on the needs of veterans.

National Institutes of Health (NIH)

VVA also wishes to bring to the attention of this committee the fact that as VA becomes more adroit in securing grants from NIH entities to do vitally needed research at VA or VA affiliated facilities, the NIH continues to refuse to pay for administrative overhead at the normal rate they would reimburse any other grant recipient at any other grantee's institution. This is nothing short of outrageous on the part of NIH.

The above noted difficulty with securing administrative overhead cost reimbursement is, we believe, just one more instance of NIH not being sensitive to the needs of our nation's veterans, even as we are in a time of war.

Another such instance is the fact that we know of no "veteran specific" grant from any of the National Institutes. The NIH has subgroup specific grants for seemingly every other discrete group of Americans, but not for veterans. Even the grants awarded to the VA are not really veteran specific, but rather "general" research grants. The problem with the way in which most of these projects are carried out, however, is that unless veteran status (and thus hazardous exposures) that veterans have is taken into account and tested against the "null hypothesis" then it is not only not going to be of maximum use to treating veterans at the VA and elsewhere, but it is just bad science.

VVA urges you to reach out to your colleagues in the committee of jurisdiction in the House to address both of these issues outlined above before the end of the 109th Congress, to set the stage for definitive and effective corrective action next year.

Genome Mapping

The Secretary of Veterans Affairs has announced that the VA is launching a major and very expensive multi-year effort to map the genes of every living American veteran, or at least those who utilize the VA and who are in the military today, who will soon become veterans.

VVA believes that this is an interesting idea, but one that is fraught with problems and difficulties. First, VVA opposes this expenditure of funds from the VA's relatively meager resources. There are many research projects that can be done that will result in

better and more effective treatment for veterans within just a few short years, whereas it is a long shot as to whether this project will ever be useful to VA physicians in the direct care of the specialized wounds and maladies that veterans suffer by virtue of military service to country.

It is said that this effort will benefit all Americans. If so, let the NIH do it and/or pay the total and complete cost of it.

Second, until the complete privacy of any additional personal information held by VA can be certified, VVA opposes the gathering of any additional data. The policies and Information Technology (IT) systems that VA has now are not nearly stringent enough for the data they already have, as witness the mess that has come to light in the past month.

Third, VVA questions the fact that there are funds to mount this very expensive effort, which may or may not be of some use to veterans at least indirectly at some time in the distant future, but there is no money to meet the requirements of Public Law 106-419 and complete the National Vietnam Veterans Longitudinal (Lifetime) Study? This is just preposterous and a matter of legitimate outrage to VVA, as it should be to all of the distinguished Members of this Committee.

National Vietnam Veterans Longitudinal Study

In 1984 the Congress directed VA to initiate a large-scale survey of the psychiatric and socio-medical components of Post Traumatic Stress Disorder (PTSD) in Vietnam and Vietnam-era veterans. VA contracted with the Gallup organization to produce the statistically valid sample populations, and with Research Triangle Institute (RTI) to actually conduct the study, which included face-to-face interviews. This study, commonly referred to as the National Vietnam Veterans Readjustment Study (NVVRS), is the largest nationwide psychiatric study ever done to date.

Results of the NVVRS demonstrated that some 15.2 percent of all male and 8.5 percent of all female Vietnam theater veterans were current PTSD cases (i.e., at some time during six months prior to interview). Rates for those exposed to high levels of war zone stress were dramatically higher (i.e., a four-fold difference for men and seven-fold difference for women) than rates for those with low-moderate stress exposure. Rates of lifetime prevalence of PTSD (i.e., at any time in the past, including the previous six months) were 30.9 percent among male and 26.9 among female Vietnam theater veterans. Comparisons of current and lifetime prevalence rates indicate that 49.2 percent of male and 31.6 percent of female theater veterans, who ever had PTSD, still had it at the time of their interview.

The NVVRS also found that while African American veterans and Latino veterans had a higher rate of PTSD, they were much less likely to seek assistance. This and other

findings made it possible for VA to better shape policies and service delivery mechanisms to deliver more effective services to veterans, especially combat veterans.

The NVVRS was a landmark investigation in which a national random sample of all Vietnam Theater and Vietnam era (those who served at the time, but not in Southeast Asia) veterans, who served between August 1964 and May 1975, provided definitive information about the prevalence and etiology of PTSD and other mental health readjustment problems. The study over-sampled African-Americans and Latinos, as well as women, enabling conclusions to be drawn about each subset of the veterans' population. A small follow up study was done shortly thereafter that produced similar results regarding Native Americans.

Initially it was only through the NVVRS that the American public and medical community becomes aware of the high rates of current and lifetime PTSD, and of the long-term consequences of high stress war zone combat exposure. Because of its unique scope, the NVVRS has had a large effect on VA policies, health care delivery and service planning. In addition, because the study clearly demonstrated high rates of PTSD and strong evidence for the persistence of this disease, it became a seminal work in the field that has made possible such effective efforts as administering to those who suffered PTSD as a result of being involved directly in the attacks on 9/11.

In 2000 Congress, by means of Public Law 106-419, mandated the VA contract for a subsequent report, using the exact same participants, to assess their psychosocial, psychiatric, physical, and general well being of these individuals. It would enable it to become a longitudinal study of the mortality and morbidity of the participants, and draw conclusions as to the long-term effects of service in the military period, as well as about service in the Vietnam combat zone in particular. The law requires that VA use the previous report as the basis for a longitudinal study. In 2000 the VA solicited proposals for non-VA research institutions to conduct a longitudinal study of the physical and mental health status of a population of Vietnam era veterans originally assessed in the NVVRS. Research Triangle Institute (RTI) was awarded the contract.

It is apparent that a longitudinal follow-up to the NVVRS is necessary in order to meet the requirements of the law, and to do just what makes sense in both policy and scientific terms. Not only has the VA failed to meet the letter of the law, there has been no effort to build upon the resources accumulated from this unique and comprehensive study of Vietnam veterans in a highly cost-efficient and scientifically compelling manner. More important, however, is that such a longitudinal study could provide clues about which VA health care services are effective and about ways to reach the veterans who receive inadequate services or do not seek them at all. And this has important consequences for America's current and future veterans.

VA Acting in a Contemptuous Manner

It is now clear that the VA is being contemptuous of the law and the Congress, and plain refusing to do the study. They are trying to justify this by means of specious pseudo-scientific reasons, and use the failed "Twins" study data base at the Centers for Disease Control (CDC) because they do not want a longitudinal study nor do they want to have validated the results of what the NVVLS may demonstrate in regard to very high mortality and morbidity of Vietnam veterans, especially those most exposed to combat. While VVA has written to the Secretary regarding this matter, we have never received a substantive reply that makes any sense.

Frankly, VVA would take them to Federal court after exhausting administrative remedy which we have done), but the case law demonstrates that the judiciary in the last twenty years believes that it is up to the Congress to enforce such mandates on the Executive branch to perform such studies. The only way for the Congress to force VA to comply with the law is by means of the appropriations process and/or by means of this Committee publicly and vocally refusing to absorb this blatant disrespect for the clear need, the law, and for this Committee.

Mr. Chairman, there is much that is excellent and deserving of great respect in the Research program, and in the qualities of the individuals who are the top leaders of the Veterans Health Administration (VHA) and of VA in general. However, their behavior in regard to this study can only be regarded as inimical to their own principles. The reasons for not proceeding with the NVVLS, at a cost of about \$17 million, are seemingly that they do not want the results or the information that they think might be contained in the results of the longitudinal study. This is not a medical or a scientific decision, as that would involve the search for truth wherever it led. Sadly, one can only draw the conclusion that this is a political decision.

Hopefully, with your bold leadership and help in this matter Mr. Chairman, this study can be completed within the next tow to two and one half years, so that we will be better prepared to meet the needs of our veterans returning from OIF/OEF, as well as better meeting the needs of Vietnam veterans.

Mr. Chairman, again all of us at VVA thank you for this opportunity to present our testimony before you today. I will be pleased and honored to answer any questions that you or your distinguished colleagues may have.

Vietnam Veterans of America**House Veterans Affairs Committee
June 7, 2006****VIETNAM VETERANS OF AMERICA
Funding Statement
June 7, 2006**

The national organization Vietnam Veterans of America (VVA) is a non-profit veterans membership organization registered as a 501(c)(19) with the Internal Revenue Service. VVA is also appropriately registered with the Secretary of the Senate and the Clerk of the House of Representatives in compliance with the Lobbying Disclosure Act of 1995.

VVA is not currently in receipt of any federal grant or contract, other than the routine allocation of office space and associated resources in VA Regional Offices for outreach and direct services through its Veterans Benefits Program (Service Representatives). This is also true of the previous two fiscal years.

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RICHARD WEIDMAN

Richard F. "Rick" Weidman serves as Executive Director for Policy & Government Affairs of Vietnam Veterans of America (VVA). As such, he is the primary spokesperson for VVA in Washington. He served as a 1-A-O Army Medical Corpsman during the Vietnam War, including service with Company C, 23rd Med, AMERICAL Division, located in I Corps of Vietnam in 1969.

Mr. Weidman was part of the staff of VVA from 1979 to 1987, and from 1998 to the present, serving variously as Membership Service Director, Agency Liaison, and Director of Government Relations. He left VVA to serve in the Administration of Governor Mario M. Cuomo (NY) as statewide director of veterans' employment & training (State Veterans Programs Administrator) for the New York State Department of Labor from 1987 to 1995.

He has served as Consultant on Legislative Affairs to the National Coalition for Homeless Veterans (NCHV), Senior Advisor to the Chairman of the Veterans Affairs Committee of the New York State Assembly, and served at various times on the VA Readjustment Advisory Committee, the Secretary of Labor's Advisory Committee on Veterans Employment & Training, the President's Committee on Employment of Persons with Disabilities - Subcommittee on Disabled Veterans, Advisory Committee on veterans' entrepreneurship at the Small Business Administration, and numerous other advocacy posts in veteran affairs. He has testified many times before the Congress, the Institute of Medicine, and other forums, regarding the health care, rehabilitation, and multiple other needs of veterans, particularly disabled veterans.

Mr. Weidman was an instructor and administrator at Johnson State College (Vermont) in the 1970s, where he was also active in community and veterans affairs. He attended Colgate University (B.A., (1967), and did graduate study at the University of Vermont.

He is married and has four children.

FOVA

Friends of VA Medical Care and Health Research

A coalition of national
organizations committed to quality
care for America's veterans

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STATEMENT OF
**THE FRIENDS OF VA MEDICAL CARE AND
HEALTH RESEARCH (FOVA)**

ON

**FUNDING FOR THE
VA MEDICAL AND PROSTHETIC
RESEARCH PROGRAM**

BEFORE

THE HOUSE COMMITTEE ON VETERANS' AFFAIRS

June 7, 2006

The Friends of VA Medical Care and Health Research (FOVA) is a diverse coalition of 86 national academic, medical, and scientific societies; voluntary health and patient advocacy groups; and veterans service organizations, all committed to high quality health care for veterans. The coalition appreciates the opportunity to testify today regarding the successes of the VA Medical Research and Prosthetics Research, the program's role in attracting and retaining physicians who care for veterans, and the funding hurdles standing in the way of even greater success. FOVA urges your support for a fiscal year (FY) 2007 appropriation of \$460 million for the research program as well as \$45 million for research facilities so this important program can continue to build on its history of solid successes.

VA MEDICAL AND PROSTHETIC RESEARCH PROGRAM

The VA Medical and Prosthetic Research program is one of the nation's premier research endeavors. The program has a strong history of success as illustrated by the following examples of VA accomplishments:

- Developed effective therapies for tuberculosis following World War II.
- Invented the implantable cardiac pacemaker, helping many patients prevent potentially life-threatening complications from irregular heartbeats.
- Performed the first successful liver transplants.
- Developed the nicotine patch.
- Developed Functional Electrical Stimulation (FES) systems that allow patients to move paralyzed limbs.
- Found that an implantable insulin pump offers better blood sugar control, weight control and quality of life for adult-onset diabetes than multiple daily injections.
- Identified a gene associated with a major risk for schizophrenia.
- Launched the first treatment trials for Gulf War Veterans' Illnesses, focusing on antibiotics and exercise.
- Began the first clinical trial under the Tri-National Research Initiative to determine the optimal antiretroviral therapy for HIV.
- Launched the largest-ever clinical trial of psychotherapy to treat posttraumatic stress disorder.

Results of the program have continued to come in within the last few months. Of note, VA researchers studied and demonstrated the effectiveness of a new vaccine for shingles, a painful skin and nerve infection that affects older adults. Investigators also reported that a 15-year study of 5,000 individuals yielded conclusive results that secondhand smoke exposure increases the risk of developing glucose intolerance, the precursor to diabetes.

The VA research program is exclusively intramural; that is, only VA employees holding at least a five-eighths salaried appointment are eligible to receive VA awards. Unlike other federal research agencies, VA does not make grants to colleges and universities, or to any other non-VA entity. As such, the program offers a dedicated funding source to attract and retain high-quality physicians and clinical investigators to the VA health care system. This in turn ensures that our nation's veterans receive state-of-the-art health care.

Why is the research program so successful?

1. The program's focus on the needs of veterans.
2. Congressional and administration understanding of the importance of research to recruitment and retention of physicians and advancing health care.
3. Dedication of VA researchers.
4. Affiliations between VA and medical schools.
5. Strong peer review.
6. The VA health system's connectedness, whether evidenced by electronic medical records or research collaborations among separate VA medical centers.

ROLE OF VA RESEARCH IN THE RECRUITMENT AND RETENTION OF PHYSICIANS

The mission of the Veterans health care system is "to serve the needs of America's veterans by providing primary care, specialized care, and related medical and social support services." The Veterans Health Administration (VHA) operates one of the largest comprehensive, integrated health care delivery systems in the United States. Organized around 21 Veterans Integrated Service Networks, VA's health care system includes 154 medical centers and operates more than 1,300 sites of care, including 875 ambulatory care and community-based outpatient clinics, 136 nursing homes, 43 residential rehabilitation treatment programs, 206 Veterans Centers, and 88 comprehensive home-care programs.

More than 5.3 million unique patients received care in VA health care facilities in 2005. That same year, VA inpatient facilities treated 587,000 patients and VA's outpatient clinics registered nearly 57.5 million visits. VHA has experienced unprecedented growth in the medical system workload over the past few years. The number of patients treated increased by 29 percent from 4.1 million in 2001. In FY 2007, VHA estimates it will care for almost 5.5 million veterans.

Despite limiting access of enrolled veterans, a significant backlog of delayed appointments has resulted from an inadequate supply of clinical physicians. While the VHA has made commendable improvements in quality and efficiency, the *Independent Budget* veterans service organizations cite excessive waiting times and delays as the primary problem in veterans' health care. Without increases in clinical staff, veterans' demand for health care will continue to outpace the VHA's ability to supply timely health-care services and will erode the world-renowned quality of VA medical care.

To accomplish its medical care mission, VHA acknowledges that it needs to provide "excellence in research," and must be an organization characterized as an "employer of choice." VA currently supports 5,143 researchers, of which nearly 83 percent are practicing physicians who provide direct patient care to veteran patients. As a result, the VHA has a unique ability to translate progress in medical science directly to improvements in clinical care.

The affiliations between VA medical centers and the nation's medical schools have provided a critical link that brings expert clinicians and researchers to the VA health system. As stated in seminal VA Policy Memorandum No. 2 published in 1946, the affiliations allow VA to provide veterans "a much higher standard of medical care than could be given [them] with a wholly full-time medical service." At present, 130 VA medical centers have such agreements with 107 of the

126 allopathic medical schools. This represents 84 percent of the 154 VA medical centers. These long standing affiliations with the academic health care community are a major factor in ensuring quality care for U.S. veterans and represent a model partnership between the federal government and non federal institutions.

Over six decades, these affiliations have proven to be mutually beneficial by affording each party access to resources that would otherwise be unavailable. It would be difficult for VA to deliver its high quality patient care without the physician faculty and residents that are available through these affiliations. In return, the medical schools gain access to invaluable undergraduate and graduate medical education opportunities through medical student rotations and residency positions at the VA hospitals. Faculty with joint VA appointments are afforded opportunities for research funding that are restricted to individuals designated as VA employees.

These faculty physicians represent the full spectrum of generalists and specialists required to provide high quality medical care to veterans, and, importantly, they include accomplished subspecialists who would be very difficult and expensive, if not impossible, for the VA to obtain regularly and dependably in the absence of the affiliations. According to a 1996 VA OIG report, about 70 percent of VA physicians hold joint medical school faculty positions. These jointly appointed clinician-investigators are typically attracted to the affiliated VA Medical Center both by the challenges of providing care to the veteran population and by the opportunity to conduct disease-related research under VA auspices.

FISCAL YEAR 2007 APPROPRIATIONS FOR THE VA MEDICAL AND PROSTHETIC RESEARCH

FOVA recommends an FY 2007 direct research appropriation of \$460 million for VA medical and prosthetic research and development. Investments in investigator-initiated research projects at VA have led to an explosion of knowledge that is advancing the understanding of disease and unlocking strategies for prevention, treatment, and cures. The complexity of research, combined with biomedical research inflation, has increased the cost of research. Biomedical research inflation alone, estimated at 5.5 percent for FY 2005 and projected at 4.1 percent for FY 2006, has reduced the purchasing power of the VA Research appropriation by \$22.7 million and \$16.5 million respectively for a total impact of \$39.2 million over just two years. In the absence of commensurate increases, VA is unable to sustain important research on diabetes, hepatitis C, heart diseases, stroke and substance abuse while also addressing emerging needs for more research on post traumatic stress disorder and long-term treatment and rehabilitation of veterans with polytraumatic blast injuries. Additional funding is needed to take advantage of burgeoning research opportunities within the VA to improve quality of life for our veterans and the nation as a whole.

FOVA thanks the House Committee on Veterans' Affairs for its views and estimates with regard to FY 2007 funding for the VA Medical and Prosthetic Research program. House and Senate recommended increases, ranging from \$28 million up to \$51.5 million over the Administration's budget request for the VA research program, affirm their ongoing support for our nation's veterans.

Administration's Budget Recommendation

The Administration's FY 2007 budget request includes \$399 million for the VA Medical and Prosthetic Research program, a \$13 million (3.2 percent) reduction from the final FY 2006 appropriation of \$412 million. These VA research funds provide direct support for research projects as well as the salaries of non-clinician investigators.

FOVA members are deeply disappointed with the Administration's budget request and note that if enacted, it will have significant adverse consequences for the VA research program. In its budget summary, the VA anticipates that this \$13 million reduction will result in the elimination of 82 investigator-initiated programs, 15 special research initiatives, and 7 multi-site research projects. Furthermore, the department would reduce the number of VA's direct research employees by 286.

In FY 2007, VA expects to increase funding for studies of acute and traumatic injury as well as central nervous system injury and related disorders. However, to fund these new studies with a shrinking budget, VA projects cuts to research in aging, cancer, infectious diseases, kidney diseases, diabetes, lung disorders, and heart diseases, among others. In other words, VA is proposing to rob Peter to pay Paul.

As in prior years, the Administration's FY 2007 budget includes projections for VA research spending from the VA medical services appropriation. This "medical care support" is slated for a \$13 million increase, from \$353 million in FY 2006 to \$366 million in FY 2007. While this increase might seem to offset the proposed cut to direct research funding, the medical care support allocation does not directly support research projects. As the budget submission indicates, this allocation funds "facility costs of heat, light, telephone, and other utilities associated with laboratory space; the administrative cost of human resource support, fiscal service, and supply service attributable to research; research's portion of a medical center's hazardous waste disposal and nuclear medicine licenses; and, most importantly, the time clinicians devote to their research activities."

The VA budget also includes non-VA funding sources among the lines of support for VA research. The budget optimistically projects a \$13.24 million increase (from \$662 million in FY 2006 to \$675 million in FY 2007) in other federally funded research conducted at VA, funds that have primarily come from the National Institutes of Health (NIH). However, the Administration's FY 2007 budget for the NIH is flat, making it highly unlikely that VA will enjoy significant growth in NIH-funded research grants.

Though the administration's projected private contributions for VA research have been inflated in previous years, the VA budget anticipates a reasonable \$4 million increase for FY 2007 (from \$204 million in FY 2006 to \$208 million in FY 2007). This funding comes from industry for support clinical trials as well as foundations and other non-profit entities to support a variety of research projects.

Programmatically, the VA research budget includes plans for two special research projects to begin in FY 2007. The first project focuses on the special needs of service personnel returning from Operation Iraqi Freedom and Operation Enduring Freedom. The project envisions wide ranging research efforts, including post-traumatic stress disorder and other mental health issues; amputation and prosthetics research; and returning personnel reentry and reintegration. A

second special project would focus on genomic medicine. The thrust of this project is to link veterans' genetic information with the VA electronic health record. According to the budget submission, "The goal is to develop genetic assessments that will potentially enable 'mass customization' of medical treatment." These new projects necessitate additional funding over FY 2006 levels plus an accommodation for biomedical research inflation if VA is to continue pre-existing endeavors as well implementing these new initiatives.

The coalition wholeheartedly supports 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 conditions. Such expansion of the program requires new resources so VA's other research areas, which are equally important to the care of large numbers of veterans, do not languish in the meantime.

VA Research Infrastructure

State-of-the-art research requires state-of-the-art technology, equipment, and facilities. Such an environment promotes excellence in teaching and patient care as well as research. It also helps VA recruit and retain the best and brightest clinician scientists. In recent years, funding for the VA medical and prosthetics research program has failed to provide the resources needed to maintain, upgrade, and replace aging research facilities. Many VA facilities have run out of adequate research space, and ventilation, electrical supply, and plumbing appear frequently on lists of needed upgrades along with space reconfiguration. Under the current system, research must compete with other facility needs for basic infrastructure and physical plant improvements which are funded through the minor construction appropriation.

FOVA appreciates the efforts of the House Committee on Appropriations to secure \$10 million for research facility upgrades in FY 2007. The committee also gave attention to this problem in the House Report accompanying the FY 2006 appropriations bill (P.L. 109-114), which expresses concern that equipment and facilities to support the research program may be lacking and that some mechanism is necessary to ensure the Department's research facilities remain competitive. It noted that more resources may be required to ensure that research facilities are properly maintained to support the Department's research mission.

To ensure that funding is adequate to meet both immediate and long term needs, FOVA recommends an annual appropriation of \$45 million in the minor construction budget dedicated to renovating existing research facilities and additional major construction funding sufficient to replace at least one outdated facility per year until the backlog is addressed.

Earmarks and Designation of VA Research Funds

The members of FOVA oppose earmarking the VA research appropriation because these earmarks jeopardize the strengths of the VA Research program. VA has well-established and highly refined policies and procedures for peer review and national management of the entire VA research portfolio. 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.

VA research encompasses a wide range of types of research. Designated amounts for specific areas of research compromise VA's ability to fund ongoing programs in other areas and force VA to delay or even cancel plans for new initiatives. While Congress certainly should provide direction to assist VA in setting its research priorities, earmarked funding exacerbates resource allocation problems. FOVA urges Congress to preserve the integrity of the VA research program as an intramural program firmly grounded in scientific peer review. These are principles under which it has functioned so successfully and with such positive benefits to veterans and the nation since its inception.

Again, FOVA appreciates the opportunity to present our views to the Committee. While research challenges facing our nation's veterans are significant, if given the resources, we are confident the expertise and commitment of the physician-scientists working in the VA system will meet the challenge.

Administrators of Internal Medicine
 Alliance for Academic Internal Medicine
 Alliance for Aging Research
 American Academy of Child and Adolescent
 Psychiatry
 American Academy of Neurology
 American Academy of Orthopaedic Surgeons
 American Association for the Study of Liver
 Diseases
 American Association of Anatomists
 American Association of Colleges of Nursing
 American Association of Colleges of Osteopathic
 Medicine
 American Association of Colleges of Pharmacy
 American Association of Spinal Cord Injury Nurses
 American Association of Spinal Cord Injury
 Psychologists and Social Workers
 American College of Chest Physicians
 American College of Clinical Pharmacology
 American College of Physicians
 American College of Rheumatology
 American Dental Education Association
 American Federation for Medical Research
 American Gastroenterological Association
 American Geriatrics Society
 American Heart Association
 American Hospital Association
 American Lung Association
 American Military Retirees Association
 American Occupational Therapy Association
 American Optometric Association
 American Osteopathic Association
 American Paraplegia Society
 American Physiological Society
 American Podiatric Medical Association
 American Psychiatric Association
 American Psychological Association
 American Society for Bone and Mineral Research
 American Society for Pharmacology and
 Experimental Therapeutics
 American Society of Hematology
 American Society of Nephrology
 American Thoracic Society
 Association for Assessment and Accreditation of
 Laboratory Animal Care International
 Association for Research in Vision and
 Ophthalmology
 Association of Academic Health Centers
 Association of American Medical Colleges
 Association of Professors of Medicine
 Association of Program Directors in Internal
 Medicine
 Association of Schools and Colleges of Optometry
 Association of Specialty Professors
 Association of VA Chiefs of Medicine
 Association of VA Nurse Anesthetists
 Blinded Veterans Association
 Blue Star Mothers of America
 Clerkship Directors in Internal Medicine
 Coalition for Health Services Research
 Digestive Disease National Coalition
 Federation of American Societies for Experimental
 Biology
 Gerontological Society of America
 Gold Star Wives
 Hepatitis Foundation International
 International Foundation for Functional
 Gastroenterological Disorders
 Juvenile Diabetes Research Foundation
 International
 Legion of Valor of the USA, Inc.
 Medical Device Manufacturers Association
 Medicine-Pediatrics Program Directors Association
 Military Officers Association of America
 National Alliance on Mental Illness
 National Association for the Advancement of
 Orthotics and Prosthetics
 National Association for Uniformed Services
 National Association of VA Dermatologists
 National Association of VA Physicians and Dentists
 National Association of Veterans' Research and
 Education Foundations
 National Mental Health Association
 Nurses Organization of Veterans Affairs
 Osteogenesis Imperfecta Foundation
 Paralyzed Veterans of America
 Paralyzed Veterans of America Spinal Cord
 Research Foundation
 Partnership Foundation for Optometric Education
 Society for Investigative Dermatology
 Society for Neuroscience
 Society for Women's Health Research
 Society of General Internal Medicine
 Spinal Cord Research Foundation
 The Endocrine Society
 United Spinal Association
 Veterans Affairs Physician Assistant Association
 Veterans of the Vietnam War and the Veterans
 Coalition
 Vietnam Veterans of America