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MEDICAL AND PROSTHETIC RESEARCH IN THE DEPARTMENT OF VETERANS AFFAIRS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

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MEDICAL AND PROSTHETIC RESEARCH IN THE DEPARTMENT OF VETERANS AFFAIRS

THURSDAY, APRIL 10, 2003

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

The subcommittee met, pursuant to notice, at 1 p.m., in room 334, Cannon House Office Building, Hon. Rob Simmons (chairman of the subcommittee) presiding.

Present: Representatives Simmons, Bradley, Renzi, Rodriguez, Snyder, Strickland, and Ryan.

Ex-officio present: Representative Evans.

OPENING STATEMENT OF CHAIRMAN SIMMONS

Mr. SIMMONS. The subcommittee will come to order. We welcome our distinguished guests, and I know we will have more, and thank him for his attendance. I understand he has a 1:30, so we will move quickly.

Today, we will be highlighting the accomplishments of the medical and prosthetic research programs of the Department of Veterans Affairs and also reviewing some of the challenges that the VA has in this field. They carry out an extensive array of research and development as a complement to its affiliations with medical and health professional schools and colleges nationwide. While they target their activities on the needs of veterans, it should also be understood that the work has defined new standards of care that benefit all Americans.

Among the major emphases of VA research are aging, chronic disease, mental illness, substance abuse disorders, sensory loss, and trauma-related illnesses. Their research programs are internationally recognized and have made important contributions to virtually every area of health and health care. I should note that their work with paralyzed veterans has also set the standard for health care in America.

Just last week, we learned that research at the Minneapolis VA discovered that influenza shots may shield the elderly against future cardiac-related diseases. And so this is another example of how the VA research into medical health care is so important. Earlier this year, VA researchers in Portland found that a certain combination of drugs can reduce the suffering and length of hospital stays for schizophrenia patients.

In assessing these developments, the subcommittee wants to help build a foundation to improve the funding of VA's research pro-

grams. The President proposed an increase of only 2 percent in 2004. This committee, under the able leadership of our chairman and ranking member, recommended an additional $52 million to be added to the 2004 budget in order for VA research to keep pace with funding developments in the federal biomedical research community. I am pleased to lead the charge for VA research. At this point I will ask if my friend from Texas, Mr. Rodriguez, has a statement he would like to make.

[The prepared statement of Chairman Simmons appears on p. 39.]

OPENING STATEMENT OF HON. CIRO D. RODRIGUEZ

Mr. RODRIGUEZ. Thank you very much, Mr. Chairman. And let me first of all also thank my fellow colleague who will be testifying before us. I look forward to hearing your testimony. Let me just also indicate that research is a vital mission within the VA and serves veterans as well as other Americans. Research is an important both recruitment and retention tool for health care providers in a highly competitive workforce market.

I want to welcome Dr. Wray and I hear that you are a good Texan and, most important, San Antonio-bred, okay? So welcome to Washington. Dr. Wray I know will be telling us about the important accomplishments of the VA medical as well as prosthetics research programs over the years. And I have special interest in the population that are traditionally under-served by our nation's health care system. So I am grateful and gratified that you have provided us, Dr. Wray, and you identified the rule on ethnic disparities in health care as a priority for VA research. I want to personally thank you for that.

Among its accomplishments also, San Antonio VA Medical Center operates a Mexican-American Medical Treatment Effectiveness Research Center in San Antonio. And the medical center there is also currently involved in more than 500 research projects. It has made significant strides in areas, including both aging, renal diseases, diabetes, cancer, as well as HIV and AIDS. The Biomedical Research Foundation of South Texas has also been operating for many decades and research has benefitted greatly from it. And so I know we have Dr. Lennon, and I will be looking forward to her statements to find out what more we can do to enhance the relationship between the VA and the non-profit research corporations and affiliates.

I am concerned also that change in the budget allocations for medical support funding announcements in the 2004 budget has the potential of short-changing not only San Antonio but the VA as a whole and other research-intense facilities, particularly they are involved in a lot of research that is not directly funded by the VA. So I have some serious concerns and maybe you might address some of those.

The National Institutes of Health, a major grant provider to the VA, does not provide any medical support funding for grants awarded to the VA. We must do something about that and hopefully we can make some progress. There are many unanswered questions about how these changes in funding research will occur.

I will be listening and hopefully we will be able to get some of those answers.

And, Dr. Wray, I understood also that you have been working in Houston, and I appreciate the fact that you have already some willingness in some bold initiatives. So I wanted you to maybe talk a little about those initiatives, especially as it deals with the order on stand-down for projects with the human subject research. So I look forward to your testimony in that area. I know you are in the midst of a 90-day review, and I want to know if you are now confident to move forward from that and, as you provide testimony, I look forward to those comments.

Thank you, Mr. Chairman, for having this meeting. I look forward to those comments.

[The prepared statement of Congressman Rodriguez appears on p. 43.]

Mr. SIMMONS. Thank you. I notice that our distinguished ranking member is here. Does he have an opening statement that he would like to offer to the subcommittee?

OPENING STATEMENT OF HON. LANE EVANS, RANKING DEMOCRATIC MEMBER, COMMITTEE ON VETERANS' AFFAIRS

Mr. EVANS. Yes, sir. And I welcome the veterans at the VA for their research efforts. They are unquestionably some of the best in academia and the practical sector as well. We must ensure that VA research continues to receive the full support it needs. VA research is unique. The purpose of VA research is to improve the care and quality of life of our veterans. The VA recently found, for example, that exercise and behavioral therapy can benefit veterans who have Gulf War illnesses. Imagine how this information might help currently deployed troops.

While veteran-focused, VA research has benefitted many others as well. For example, the VA is the world leader in PTSD research. VA PTSD research has benefitted countless veterans and untold victims of traumatic events.

I appreciate the opportunity to introduce my friend from Iowa City, Dr. Kevin Dellsperger. If he would stand up, we would like to give him a round of applause. (Applause.)

I know that we have worked directly with him in my Moline office and he does really good work for the Veterans' Advisory Committee that I have set up. So, thank you, doctor. He is a board-certified internist with a subspecialty in cardiovascular disease. He is the chief of staff at Iowa City and a researcher himself. With two current VA awards and numerous scientific publications, he also maintains active teaching and supervisory roles at the Iowa City hospitals and clinics. Iowa City's VA medical research program is one of the leading grant awardees within the system. It has made a significant contribution to the understanding of Gulf War illnesses, diabetes, heart research, and prostrate cancer. I thank my friend for participating today.

And thank you, Mr. Chairman, for giving me the opportunity to speak.

Mr. SIMMONS. Thank you. Without objection, what I would like to do is now go to our first panel, because Mr. Langevin has a time constraint. Before I do, I would like the subcommittee to know that

we invited Christopher Reeve to testify today. He was unable to because of his difficult schedule, but he did send a 2-page letter to the subcommittee. Without objection, I would like to enter it into the record of these proceedings. Hearing no objection, it is done.

(The provided material appears follows:)

CHRISTOPHER REEVE PARALYSIS FOUNDATION

a merger of the American Paralysis Association and the Christopher Reeve Foundation

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April 7, 2003

The Honorable Rob Simmons
Chairman Subcommittee on Health
House Committee on Veterans Affairs
United States House of Representatives
338 Cannon Building House Office Building
Washington, D.C. 20515

Dear Representative Simmons:

Thank you for holding an oversight hearing on biomedical research programs for the Department of Veterans Affairs, on Thursday, April 10, 2003. Although I will be unable to testify at the hearing, I wanted to share my experience of contributions made by the VA to medical research.

Last week, media attention throughout the world focused on my recent surgery to have electrodes implanted to assist and strengthen my breathing. Whenever such medical victories are reported, it seems important to appreciate that they do not come easily — either for the patient or for the clinicians. In the case of my surgery, the foundation for this procedure was laid back in the 1970's and nurtured over the years by federal research programs whose job it is to make investments in solid fundamental ideas today that promise clinical translation tomorrow.

The diaphragm pacing system is one of many research triumphs that have resulted from the often overlooked Department of Veterans Affairs Rehabilitation Research Program, collaborating with academic partners such as Case Western Reserve University School of Medicine and other Federal agencies. The VA has taken a leadership role in ensuring the continuity and progression of this research to the benefit of veterans and others with paralysis worldwide. Work of this caliber is a cooperative effort requiring the sustained effort of the researchers, the research participants, the institutions that sponsor the research programs, and the leadership of the federal agencies that provide the necessary vision and resources to achieve success.

The applications of electrical signals to muscles in order to control their function was initially supported as exploratory research by both VA and the National Institutes of Health in the early 1970's. As potential clinical applications emerged from this initial research, VA continued to support development and design of electrodes, surgical tools and methods, and pre-clinical testing to demonstrate the system's human potential. More recently, support has been provided by the Food and Drug Administration's Orphan

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Products Division to study the implementation of the system in human subjects. I am fortunate to have been selected as the third participant in this study.

In addition to diaphragm pacing, electrodes have the potential to affect bladder and bowel control, to prevent pressure sores, to support standing and transfer after spinal cord injury, and to improve walking following stroke. VA has funded research in the development of all these applications and provides a model for how clinical care and research can merge to provide a continuum of research that will benefit the healthcare of tomorrow.

Today research investments that began long ago are about to bear fruit. We are on the threshold of a number of clinical trials treating paralysis and spinal cord injuries. The VA system would be an excellent home for clinical trials for patients who have served their country, and most deserved to benefit from our nation's cutting edge research. In addition, the VA has identified standardized best practices and outcome measurements that will be required to translate research to therapies.

By recognizing the contributions of our entire medical research enterprise, we will ensure the future viability of research programs that offer hope to so many.

Thank you very much,

Christopher Reeve /acs

Christopher Reeve

The New York Times

March 25, 2003

To the Editor:

Re "Reeve Is Waking Up to Smell the Coffee Again, and More" (news article, March 14), about my surgery to have electrodes implanted to assist and strengthen my breathing:

Whenever such medical victories are reported, it is important to appreciate that they do not come easily.

In the case of my surgery, the foundation for this procedure was laid in the 1970's and nurtured over the years by federal research support from the Department of Veterans Affairs and other federal agencies in partnership with engineering and medical schools.

The diaphragm-pacing system is one of many research triumphs involving functional electrical stimulation that have resulted from the often overlooked V.A. rehabilitation research program, collaborating with academic partners like Case Western Reserve University, the National Institutes of Health and others.

Research investments that began long ago are about to bear fruit. We will ensure the viability of such programs that benefit so many only by recognizing the contributions of all.

CHRISTOPHER REEVE
Bedford, N.Y., March 21, 2003

Mr. SIMMONS. I would now like to introduce our first panel and panelist. Congressman Jim Langevin came into the Congress the same year and the same day I did. We are neighbors across the Connecticut/Rhode Island border. He had a distinguished career as a state representative, as Secretary of State of Rhode Island, I believe the youngest in its history and one of the youngest in the United States at the time. He serves with me on the Armed Services Committee. He is on the Select Committee on Homeland Security. He is co-chair of the Bipartisan Disabilities Caucus. And he is somebody who has a substantial amount of experience on spinal cord injuries, which we tend on this subcommittee to associate with military service, but these are of course injuries that affect many others around the country.

Congressman Langevin, we are prepared to hear your statement, and welcome.

STATEMENT OF HON. JAMES LANGEVIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF RHODE ISLAND

Mr. LANGEVIN. Thank you, Mr. Chairman. I appreciate the kind introduction, and it certainly is an honor for me to be here. I appreciate the invitation. I would just like to again personally commend you and recognize and thank you, Chairman Simmons and Ranking Member Rodriguez and Ranking Member Evans and the entire Subcommittee on Health, for convening today's hearing on biomedical research programs in the Department of Veterans Affairs.

The contributions made by the Department of Veterans Affairs to medical research are substantial, high caliber, and incredibly far-reaching. I want to commend VA's rehabilitation research and development services for their dedication to improving the quality of life for impaired and disabled veterans and the nation as a whole.

The VA has shown true leadership in forming partnerships with universities and other federal agencies to ensure their research reaches veterans and others who might benefit worldwide. Recently, a project initiated by the VA in collaboration with NIH led the development of a diaphragm pacing system. This generated national news when my friend, Christopher Reeve, underwent surgery to implant electrodes to stimulate muscles in his diaphragm, allowing him to breath without a ventilator for up to 15 minutes at a time. Just think for just a minute of how we take for granted how easy it is just to breathe, and yet this is something that Christopher Reeve and many others with his type of spinal cord injury, he had such a high-level injury, can't do on their own. What a wonderful thing it would be with the use of technology if something like this could be employed to allow them to be free of a cumbersome ventilator. This is just a fantastic breakthrough and development.

Electrode research has the potential to tremendously benefit persons living with paralysis, not only in the area of breathing but to prevent pressure sores, support standing, and transfer after spinal cord injury and to improve walking following stroke. As a person living with a spinal cord injury, I know firsthand the difference such research can make in the quality of life for an individual.

That particular project received a good deal of media coverage, but it should be noted that the VA is engaged in many more cutting-edge projects happening behind the scenes. Investigators are studying the use of anabolic pharmaceuticals, including anabolic steroids to treat secondary disabilities of spinal cord injury. A spinal cord injury which affects more than 40,000 veterans nationwide is often associated with problems related to muscular function, breathing, and cardiovascular health.

The innovative methods being developed and the rehabilitation research and the development centers of excellence are making a real difference in the quality of life of impaired and disabled veterans. In the process, they are reaching people all over the world. The VA researchers are breaking new ground in the areas of osteoporosis, lung injury, and chronic obstructive pulmonary disease. They are internationally recognized leaders in HIV/AIDS research and making important advances in studies of prostrate cancer. Indeed, this research will benefit all of us.

I also want to highlight the success the VA has had in rehabilitation and employment services for veterans. Since my arrival in Congress, I worked to bring attention to the issues of unemployment and under-employment in the disability community. There is an unemployment rate of 70 percent in the disability community. And this is a population that so much wants to work. With some basic supports, it can be done. And the VA has shown this by providing the supports to service-connected, disabled veterans from vocational counseling, and service members and veterans who have recently separated from active duty. This assistance can mean the difference between a life spent in isolation and a life spent actively participating in one's community. Or to look at it another way, a life spent receiving government assistant or a life spent in meaningful employment.

I look forward to continued work with the VA on the vocational education counseling programs. We have so much to learn from them, and I know we will. From their approved rehabilitation research projects, through evaluation and technology transferred to final clinical application, the VA has truly managed to attract the brightest minds from academia, industry, and medicine. The commitment to finding research solutions to the needs of veterans with disabilities will benefit all Americans.

I just want to close by thanking you, Mr. Chairman, for the opportunity to acknowledge these critical programs. And I look forward to our continued work together. And I would be happy to answer any questions. Thank you.

Mr. SIMMONS. Thank you, Jim. I have one question and then I will go to my colleagues here. I touched on it a moment ago. You were injured as a teenager as a consequence of a gunshot wound, as I understand.

Mr. LANGEVIN. I was a police cadet serving an Explorer Scout program and thought I was well on my way to a career in law enforcement when my life took a turn, and certainly my dream of entering law enforcement. But not in contributing in other ways.

Mr. SIMMONS. And you certainly have. It was a gunshot wound. It was not experienced as a consequence of military service or service in a combat zone, which is what we frequently encounter before

this subcommittee or before the Veterans' Affairs Committee. And yet, as I understand your testimony, the work of the VA, the work of the Veterans' Administration, in concert with certain federal agencies, in concert with certain academic institutions brings about developments in medical health care and research which have a direct impact on you and your life and those like you. Could you expand on that a little bit?

Mr. LANGEVIN. Absolutely. The kind of research that is done at VA, just in the area of spinal cord injuries by way of example, that could help paralyzed veterans will transfer out into the larger community as a whole. And certainly I would benefit directly from successful research in those fields, in the area of cardiovascular technologies to help improve muscle tone, in the area of this electrode research. I think about it from the personal terms in how exciting it would be just being able to, with the use of electrodes, be able to stand and maybe walk a few steps. I fly twice a week going back and forth between Washington.

Mr. SIMMONS. It is a wonderful lifestyle, isn't it?

Mr. LANGEVIN. Maybe for gypsies, but it is a challenging lifestyle, to say the least. I have to get transferred from my wheelchair going onto the plane. I go up to the door of the plane and then I have to get transferred into an aisle chair because the aisles are too narrow. So I get lifted out of the chair into an aisle chair and then backed into the plane and then get transferred from that aisle chair to the seat of the plane. How grateful I would be just to be able to, even with the use of electrodes, to be able to stand and walk the few feet into the plane and then sit in the seat and the reverse process coming out. How easy that would make my life. And it would be better for me health-wise.

So, again, the research that is being done at the VA will transcend beyond just assisting veterans. And it will help the 400 other or so thousand people who are living with spinal cord injuries.

Mr. SIMMONS. Thank you very much. Mr. Rodriguez. Mr. Strickland.

Mr. STRICKLAND. Mr. Chairman, I don't have a question, just a very, very brief comment. And that is I am well aware that the VA helps those other than veterans. Some of the most progressive research that has been done in this country in the area of breast cancer, for example, has come from the VA. And so I think all of us can be really proud of this wonderful research system that we have and commit ourselves to protecting it.

Thank you very much, Jim, for your testimony.

Mr. LANGEVIN. Thank you, sir.

Mr. SIMMONS. Thank you.

Dr. Snyder, have you prepared an opening statement and questions? That is a very good response.

Mr. Rodriguez?

Mr. RODRIGUEZ. Thank you, Mr. Chairman. Let me also—I know you mentioned in terms of the research, is that electrode research that you were talking about?

Mr. LANGEVIN. That is correct.

Mr. RODRIGUEZ. Do you know how much of that we are doing or whether we are putting efficient resources in that area and maybe

what other areas you think we ought to be concentrating on or how you would prioritize?

Mr. LANGEVIN. Well, I think, as often happens, the amount of progress we make is directly proportional to how much we are pouring in in terms of research dollars. So although progress has been made in this area of electrode research, there is still more work that needs to be done and it could be months or years often in development in perfecting the technologies, again depending on how much we are willing to put in resources and research. And I encourage us to look at these areas because they are wonderful investments not only in terms of improving someone's quality of life but also in avoiding the unintended consequences or the consequences of the various disabilities and how they affect health and preventing deterioration of health.

Mr. RODRIGUEZ. On this electrode that you talked about, are where there now—I am real naive about it. Is it working now in some cases?

Mr. LANGEVIN. Well, again, it is all experimental. Just by way of example, Christopher Reeve has to use a ventilator in order to breathe. And I can see how cumbersome it is and requires a battery. It is a cumbersome unit that has to go in the back of the wheelchair, which makes it harder to get around, in and out of vans or for travel and just daily living. And the electrodes that were implanted in his chest as part of the, again, experimental research and use of this technology, he is now able to breathe for a time on his own without the use of that ventilator. And it is expected that in time, as his body gets used to this, and they continue experimenting with his endurance with this electrode, that he will be able to be free from the ventilator completely.

So, again, that is something I know he is excited about. And that type of research will translate into other things. For example, allowing people with spinal cord injuries to stand and to walk. And they are already in many areas doing this kind of research. But the VA has certainly been a leader.

Mr. RODRIGUEZ. Thank you.

Mr. SIMMONS. Mr. Ryan.

Mr. RYAN. I just want to thank the gentleman for his leadership on this and your commitment. And it has been a pleasure to get to know you over the past few months, and we look forward to trying to help you here as much as we can. So keep up the good work.

Mr. LANGEVIN. Thank you, likewise.

Mr. SIMMONS. Dr. Snyder.

OPENING STATEMENT OF HON. VIC SNYDER

Dr. SNYDER. Thank you, Mr. Chairman. I will make a brief comment because this is—and I apologize for being late, but this is an area that I have had an interest in not just as a Member of Congress but as a family doctor who trained as a medical student in one VA hospital and then part of my training as a family practice resident in another. I think this research is very important.

Some of what we are talking about here today is potentially very dramatic in terms of its ability to help not only injured veterans but injured people all over the world. But a lot of the groundwork in research ain't sexy. You are talking about adequate square foot-

age. You are talking about adequate equipment. You are talking about making it a priority when it comes to funding. And we have really several years of difficulty with funding the VA budget just to meet the health care needs. And I think in order for the VA—which I think does spectacular research, some of the best in the world in some areas—if we don't fund it properly, you don't get the potential good out of it. I am sure that Mr. Langevin agrees with that, too. But that is one of the questions I am going to have for these subsequent witnesses as to where we are at in terms of prioritizing funding for VA research and infrastructure, equipment, and all those kinds of things.

Mr. LANGEVIN. Yes, I couldn't agree more with that statement. And it really is an investment that has—that pays off in dividends in so many ways.

Mr. SIMMONS. Thank you for that comment. Just as a note for the record, Chris Reeves in his letter explains that the original research on using electrical signals to the muscles goes back to VA/NIH studies in the early 1970s, but the application of this is relatively recent, I gather. And he is only the third participant in a study that has just been approved by the FDA Orphan Products Division. So the theory is fairly longstanding but the application is recent. And I would guess that there may be some risk involved with the application of this research.

So VA and the other participants in this ground-breaking initiative are taking risks. And I guess from my perspective I give them credit for that. If it works for Superman, I hope it works for everybody else.

Thank you, Jim, very much, for your testimony. And I think we have got you out of here right on time. Thank you.

Mr. LANGEVIN. Thank you, Mr. Chairman. Thank you, members of the committee.

Mr. SIMMONS. Our next panel is headed up by Dr. Nelda Wray, who is the Chief Research and Development Officer in the Veterans' Administration. My colleague has already praised her for her choice of geographic location, Houston, TX. We welcome her here today. She is joined by Dr. Mindy Aisen, who is the Director of Rehabilitation Research and Development; Dr. John Demakis, the Director of Health Services Research and Development; and Dr. Fred Wright, the Associate Chief of Staff for Research at the VA Connecticut Healthcare System. That was a random choice, I just want you all to know that.

It is terrific to have you here today. Unless my colleague has a comment to make, I would ask you to begin your testimony, and we will have questions after the testimony. Dr. Wray.

STATEMENT OF NELDA P. WRAY, CHIEF RESEARCH AND DEVELOPMENT OFFICER, OFFICE OF RESEARCH AND DEVELOPMENT, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY MINDY AISEN, DIRECTOR, REHABILITATION RESEARCH AND DEVELOPMENT; JOHN DEMAKIS, DIRECTOR, HEALTH SERVICES RESEARCH AND DEVELOPMENT; AND FRED WRIGHT, ASSOCIATE CHIEF OF STAFF FOR RESEARCH, VA CONNECTICUT HEALTHCARE SYSTEM

Dr. WRAY. Mr. Chairman and members of the subcommittee, I truly appreciate the opportunity to appear before you today. In fact, I consider it one of the great honors of my life to have the opportunity to discuss the Department of Veterans Affairs Medical and Prosthetic Research Program. After having spent just 3 months as VA's chief research and development officer, I can honestly say that I remain just as excited today as I did in January about this once in a lifetime opportunity to lead such a distinguished program.

One of my first activities was to come here even before I started and run a strategic planning meeting. And during that meeting, we developed a new vision for VA research. That vision statement is, "Today's VA research leading tomorrow's healthcare." I ask each of you to reflect on that compelling statement. To achieve it, not only must we continue to conduct outstanding laboratory studies that ask fundamental questions about diseases processes, but we must also expand our research efforts into two other critical areas. We must expand our clinical research portfolio to include issues that directly affect clinical practice with an emphasis on research that provides knowledge for the practice of evidence-based healthcare. In addition to increasing funding for clinical research studies, we will develop a new initiative to increase dramatically the number of individuals, that is physicians, with expertise and training in conducting clinical research.

However, as the Institute of Medicine Report, "Crossing the Quality Chasm," documents, the development of information through research does not necessarily mean that such information is given to patients at the bedside. Therefore, VA will expand research designed to identify the barriers to the rapid translation of research into clinical practice and to study new organizational structures with the potential to remove those barriers. By expanding our portfolio in such ways, I want this committee to know that the NIH may be their best long-term investment in improving health care and the way we do things by understand the gene and the gene therapy.

But the VA will be the greatest short-term investment for improving health care today and tomorrow. By expanding our portfolio in such ways, I am confident that VA's research program will be at the forefront of improving the quality of and developing the excellence of tomorrow's health care.

VA's Medical and Prosthetic Research Program has produced three Nobel laureates, pioneered tuberculosis treatment, developed the cardiac pacemaker, created the Seattle foot, and conducted the first successful drug treatments for high blood pressure and schizophrenia. Those are our successes of the past.

Let me cite just a few of our most recent, literally within the last 2 to 3 months, exciting developments. Researchers at the San Diego VA Medical Center, in collaboration with the U.S. Army, have developed an oral drug that halts the deadly action of smallpox in infected mice. We will work extremely hard to confirm these results in other animals and to get this oral drug approved for use in humans. As I am sure you all understand, the potential for developing an oral smallpox treatment in humans would be a major discovery.

Another exciting study, which received significant media attention recently, revealed that Gulf War-era veterans, who had unexplained chronic medical symptoms, such as pain, fatigue, and cognitive difficulties, experienced a statistically significant improvement in their symptoms when treated with a combination of aerobic exercise and cognitive behavioral therapy. While not everyone in the study was helped, the discovery is a major step in overcoming Gulf War illnesses.

VA continues to lead the way in treating post-traumatic stress disorder or PTSD. We are conducing a $5 million clinical trial in collaboration with the Department of Defense that will assess two interventions for women veterans with PTSD. The trial is the largest of its type, dedicated at women veterans, the fastest growing segment of the veteran population.

The devastating news that several of our brave service members have lost limbs as a result of combat operations in Iraq has greatly saddened all of us. Fortunately, VA researchers were already at work developing technologies that will enable these great Americans to lead more normal lives. Those technologies place VA at the forefront of osteo-integration research in the nation. Osteo-integration involves implanting at titanium rod directly into the bone of the limb. Once the limb has healed, a prosthesis is directly attached to the titanium rod, thereby preventing chronic wear and tear on the soft tissues of the amputated limb.

More recently, VA developed a technology which has enabled actor Christopher Reeve to begin to breath relatively normally for limited periods off a respirator. Investigators at the Cleveland VAMC discovered a method of electronically stimulating the phrenic nerves in the diaphragm muscle to restore more natural breathing.

In addition to all of the exciting developments I have just described, please let me assure you that VA investigators are busily exploring issues of the utmost importance to the nation's veterans, issues like mental illness, aging, heart disease, diabetes, and others. As you can see, this is an extremely exciting time for VA research. We truly are on our way to building the greatest healthcare research program in the country.

Mr. Chairman, this concludes my statement. I will now be happy to answer any questions that you or other members of the subcommittee might have.

[The prepared statement of Dr. Wray appears on p. 48.]

Mr. SIMMONS. Thank you. I have two questions, and I will ask them both up front. The first question goes to the issue of your testimony on page 1. You stated, "We must expand our clinical research portfolio," et cetera, et cetera. I guess that leads me to ask

what do you consider your top two or three goals for that portfolio over the next several years?

My second question goes to a situation that I understand exists. Let me give you a practical example. If Yale University, in my home state, gets a substantial grant from the Federal Government for healthcare research, and decides to give a portion of that grant to a member of either the Yale Hospital or the medical school there, that researcher can get up to 50 percent of the grant, I understand. But if a portion of that research goes to somebody over to the VA hospital, a VA principal investigator, he or she is not able to share financially in any way even though they may be colleagues and they may be closely associated. My second question is, should we work to re-institute indirect administrative grants to VA principal investigators?

Dr. WRAY. Let me answer the first question and then the second question, Mr. Chairman. First, regarding the goals of the portfolio. The goals of the portfolio for my clinical research endeavor are to study those entities which give the greatest—inflict the greatest damage to veterans and improve their health and health care. The studies will be immediately beneficial to these veterans.

Let me give some examples of what we are doing now, but we will greatly expand this. We recently published a study regarding care of diabetics. One-sixth of the veterans who we provide care to in the VA do suffer from diabetes. Diabetes is the leading cause for blindness, amputation, and chronic renal failure. We recently published a study on prophylactic care for diabetics' feet to prevent amputation. It turns out that in fact amputation is the surgical procedure in the VA with the highest mortality because of the degree of underlying chronic illness. It is immensely important that we look at what we can do to prevent amputation.

So that is one type of the clinical study. There are many others that I could go through. But, again, the goals of this clinical endeavor, the goals of my endeavor to when we once find what works, making sure it gets into place, is to improve the quality of care.

I have set up three blue ribbon commissions to advise me in this area. One is on the clinical research. One is on the translation or implementation research. And one is on how to measure quality. I want to know that when we have done this, we can in fact show that we have improved the quality of care.

Let me move now to the issue regarding NIH indirects. Let me take just a minute to explain what we are talking about, and then I will go into the history.

When researchers write a grant, we write a budget for what we refer to as the direct cost of that grant, what it takes to do the grant, my research assistant's salary, my supplies, if I need a computer, my computer, other equipment, other personnel costs. Those are all referred to as the direct cost of the grant.

There are then what is referred to as two big classifications of indirect costs. One type of indirect cost is literally the administration of the grant, who watches the books, who distributes payroll, who does purchasing, who does contracting, administrative charges for the grant. The other is referred to as the facility charge. Somebody has got to keep the lab clean. We have got to pay for the telephones, the electricity, air conditioning, heating, those are the facil-

ity charges. I am not talking about construction charges. I am literally talking about the maintenance of the facilities.

Universities negotiate with NIH an administrative charge and a facility charge. Most of VA grants, most grants VA investigators get from the NIH are individuals who are affiliated with an academic institution, and their grants are at that academic institution. The academic institution is allowed to charge and the NIH pays the indirect for the administrative charge. If I were at the private hospital affiliated—if I had my lab at the private hospital affiliated with that university or if I had my lab at the university, a facility charge would be added on. The administrative charge at the NIH is capped at 28 percent—I mean 26 percent and basically everybody's is 26 percent.

The facility charge across this country averages around 35 to 40 percent. If you are at the VA, the university gets the administrative charge and we are not allowed to charge the facility charge. We have approximately $400 million in NIH grants. We have paid an auditor who worked most of his life for the NIH to audit 85 VAs. And we have determined across those 85 VAs that our facility charge is 24 percent. Each year we donate $100 million to the NIH. Twenty-four percent of our $400 million. Our facilities and infrastructure are crumbling because we are not getting this. We got it before 1989. A policy decision since 1989, the NIH does not pay it.

I can try to answer any other question.

Mr. SIMMONS. My time has expired. I wish now to ask my colleague, Mr. Rodriguez.

Mr. RODRIGUEZ. Let me follow up on what you just indicated. Basically, what you are saying is that the NIH does not reimburse you for the utilization of our own labs. And what was the amount of money in that area? If we were compensated, how much are you talking about?

Dr. WRAY. It is approximately $100 million, Mr. Rodriguez.

Mr. RODRIGUEZ. One hundred million.

Dr. WRAY. Where I come up with that number is VA investigators have approximately $400 million in directs, in NIH grants. We paid an auditor who determined that on average, our facility charge is 24 percent, far below what the facility charges of universities are. Twenty-four percent or 25 percent of $400 million is approximately $100 million.

Mr. RODRIGUEZ. So we need to see maybe if we could ask or send a letter to NIH, either that and/or somehow we would need to come up with an additional $100 million just to talk about that aspect of the research?

Dr. WRAY. Yes, sir, I would point out that, for example, the NIH does pay an 8 percent rate to foreign governments even. So any assistance that you could help us in——

Mr. RODRIGUEZ. Have you all ever sat down and dialogued over this issue, do you recall?

Dr. WRAY. Not since I have been here, Mr. Rodriguez. Dr. Roswell has given testimony in front of the committee before. Tremendous discussions have gone on. We have not gotten to the point of negotiation. Congressman Udall did send a letter to Secretary Thompson last November or so. Dr. Zorini has been busy enough,

he has not been able to get me on his calendar since I have been in town.

Mr. RODRIGUEZ. I want to ask the chairman to see if later on there is some way that we could strategize as to how to deal with this.

Let me ask you another question. I know you have talked about the issue of stand-down, and I wanted to get a clarification on what that means?

Dr. WRAY. The term "stand-down," as you know in the military, usually has two components, the first of which is whatever the activity is that is of concern is stopped. So if we are concerned, and I must admit that Secretary Principi is the one who taught me this term, if we were concerned about Navy pilots—Secretary Principi, of course, is one—having too many accidents, we stop the flying.

So that is one part of the stand-down. The other part of the stand-down is we look closely in what we call root cause analysis, what were the problems here, what education needs to be done, how to get safety back at the forefront. The stand-down that I did of human studies did not include the first component. We did not stop any human subject studies. It did require the second component. That is a tense review. I didn't require the first——

Mr. RODRIGUEZ. So you didn't stop anything, you are just reviewing?

Dr. WRAY. That is correct, sir.

Mr. RODRIGUEZ. Is that still going on?

Dr. WRAY. I am sorry?

Mr. RODRIGUEZ. Is that still going on?

Dr. WRAY. Yes, sir, it was 90 days. It finishes June the 6th. The 90-day period, we have required the following to occur. First, that the top administration of the hospital, the director of the hospital, the chief of staff, look at their own IRB, look at their own research committee and ensure that it is functional. Second, we are putting in place an educational program that is not in fact required by any university. When this is done, we will have the highest level of education regarding human studies.

We are doing two types of education. It is IRB ethics training, which generally is required but it is generally only required of investigators. We are requiring it of all research coordinators, all research assistants, and, in fact, we simply only excluded secretaries. All administrators in research, the HUSA for research, the chief of staff, everyone will have to take that.

In addition, they are going to do what is good clinical practices. That is a course where we in fact require more stringent clinical practice for patients that are in studies than your doctor gives to you. For example, you may call your physician and say, "I have a headache." They may say, "Take two aspirin and call me back tomorrow." Good clinical practice says that if a patient on a research study calls, regardless of their complaint, they are asked to come in and be seen and be evaluated, because of the concern that it may be related to research.

That program has not been widely available. Some companies have made it. It costs $1,400, $1,500 a person on the Internet. I commissioned one of my clinical trials programs to immediately go to work on this. We have produced the software. It is available. I

will be happy to give it to you. It is up on the Internet. It cost us $25,000 to get it electronically put on to the Internet, but it is now totally available free to all investigators and they are all having to take that.

In addition, we are requiring that anyone involved in research be credentialed so that even those individuals who are without compensation will have to come in and have to be completely credentialed. The education program, the credentialing program, the insurance by the administration will be completed within 90 days.

Mr. RODRIGUEZ. Real quickly, I know I have only a little more time to ask you one last question. As it deals with the funding, I know that we have had some difficulties, and I was wondering if you could comment on it because we have talked about the importance. And I know that we have almost doubled the budget for NIH but we haven't done that for you. I wanted to see if you would maybe talk a little bit about that in terms of the impact that it is having to the VA?

Dr. WRAY. Let me just start by making a statement which I know you know and that is our 2 percent increase, which is in the 2004 budget, if you have a 4 percent COLA increase is a 2 percent cut. It is not a 2 percent increase. And so the funding——

Mr. RODRIGUEZ. Once again, what did you say?

Dr. WRAY. Well, if you give me a 2 percent raise and the COLA, cost of living, the federal employee cost of living is 4 percent, which it is on average in January, then instead of giving me a 2 percent raise, I have got a 2 percent reduction in absolute buying and purchasing power. If you look at the growth in the VA budget in absolute purchasing power, it has been virtually flat for the last few years.

Mr. SIMMONS. Mr. Strickland.

Mr. STRICKLAND. Thank you, Mr. Chairman. Dr. Wray, I want to thank you for what is very obvious to me, and that is your enthusiasm for your responsibilities and for the other doctors who are here. Thank you for what you do.

There is much that the VA does that is admirable. I worked in a maximum security prison before coming to Congress, and I was always struck by the number of veterans that we had in that prison. And many of them carrying the diagnosis of PTSD that had been perhaps unrecognized and untreated and other problems, drug addictions and the like. And they ended up, after serving our country, serving long prison sentences, perhaps unnecessarily.

But I know you have done great research in the area of mental health. But right now we are facing a current war, and it appears that perhaps last week some of our soldiers and even members of the press may have been exposed to sarin nerve gas. There have been reports that some troops came into contact with substances. They thereafter experienced symptoms of dizziness, vomiting, and skin rashes. There have been other reports of potential sarin and mustard gas presence. If these reports are confirmed, you may be receiving young Americans coming home in need of treatment for these kinds of exposures. And I would just like to know what has the VA learned about treating such exposures? And do you feel the

VA is ready at this point to be able to provide the kind of care and treatment that these individuals may need?

Dr. WRAY. Well, regarding the treatment, let me say that the first 20-odd-some years, I guess 27 years of my career, I was a physician in Houston. I am double board in internal medicine and pulmonary diseases. I ran the ICU for many years. The VA stands ready to do all that is known of benefit for these veterans. I met with Secretary Principi the week before last. I met with his chief of staff last week. He is extremely concerned about what is happening to our veterans—to our active military. And we stand ready to provide whatever care is necessary to these veterans when they return.

Regarding research into this area, as you know, we found out that ALS is in fact twice as common in deployed veterans as nondeployed veterans. As soon as that broke, Secretary Principi immediately made them available.

Mr. STRICKLAND. Can I say a word about that?

Dr. WRAY. Yes, sir.

Mr. STRICKLAND. Because it is one of the things that I am most proud of for what you have done. And I will just take a minute or two to tell you about a young man who came to my office, walked to my office a couple of years ago, and he had been diagnosed. He had been in Desert Storm. He was a man with three children. And unfortunately his wife had deserted him once he received the diagnosis. And I remember him just saying to me, "Congressman, I am not worried about myself. I want my children taken care of."

Over the months, he continued to come to see me. He is now confined to a wheelchair. He can barely speak. He needs 24-hour care. And a few days before Christmas he was informed that in fact he was receiving past compensation. And I just want to thank you. I know it was a major, major decision of the VA, but if it were only for that one young American and no others were involved, it was a decision that you ought to be very, very proud of. And I just want to thank you for that.

Dr. WRAY. Thank you, sir. I have been in the VA for 27 years, and we have never had a Secretary at the Department of Veterans Affairs, to my mind, that approaches the professionalism and the passion and commitment of our current Secretary. I am proud to have the opportunity to work for Secretary Principi.

Mr. STRICKLAND. Thank you. Thank you, Mr. Chairman.

Dr. WRAY. I would like to speak to the sarin gas, if I may.

Mr. STRICKLAND. Yes.

Dr. WRAY. Because of personal reasons, I am committed to a research endeavor that will do everything possible to limit the harm that these people experience, our brave Americans experience, when they return as veterans. I prepared for the committee, that is our oversight committee, that is chaired by Jim Bins, the first 3 days I was here. We just last week—there are researchers in Israel who have done very exciting work on asedocolin esteray system, that is the system that would be affected by these gases, exciting work, that they may explain some of the undefined symptoms of Gulf War illnesses. And I have committed the money and my research infrastructure to put the study in place, to have answers be-

fore October 1. So we potentially will have one of the most exciting studies to help explain Gulf War illness.

Mr. STRICKLAND. Thank you.

Mr. SIMMONS. Dr. Wray and panel, we have just been called to vote. It is a 15-minute vote, of which we have I think about 6 minutes left and another 5 minutes. So we will recess for 15 to 20 minutes.

[Recess.]

Mr. SIMMONS. The subcommittee will come to order. I welcome again our panel. I know that some members have some additional questions. Next on our list is Mr. Renzi.

OPENING STATEMENT OF HON. RICK RENZI

Mr. RENZI. Thank you, Mr. Chairman. Thank you for your testimony, and I am grateful that you have traveled today to be with us.

I just had two questions I wanted to ask you. I know prior to joining this panel a couple of years ago, we had an emotional debate over informed consent. And I would ask, if you don't mind, just to take the time to teach me a little bit. Prior to any volunteers getting involved in clinical studies, I think we all agree it is probably imperative that they have access to all the information as it relates to who is sponsoring it and what is included in it. Where are we right now on that emotional issue of informed consent and full disclosure?

Dr. WRAY. Let me say that the common rule is the document under which human studies is performed and guided in all federal institutions. The common rule is the rule that specifies an IRB, it specifies what an IRB membership should be, it specifies what an IRB should look at. I am sorry, Institute Review Board. The board that—the common rule specifies that before you can do human subjects studies, a board independent of the investigator must look at the study for certain things. The board must be made up of scientists. But it must also be made up of non-scientists, individuals like those that might enter into the study. It also must be both racially and gender diverse. It must be made up of local individuals so that issues regarding the local environment are taken into care.

So the common rule specifies what they have to look at, the risk/benefit ratio, the informed consent sheet, to make sure all the risks are put out.

The VA and NIH, NIH-funded sites, universities are all under the common rule and follow the common rule. The problem, however, is that the common rule doesn't do all we need for it to do. You all are aware of some of the problems we have had. They are very uncommon. We have over 15,000 studies, over 150,000 patients. These events are very uncommon.

But many of the events we have had and the full disclosure issue is not prevented or part of the common rule. We need to look at what else we need to do to create the state-of-the-art human studies program. The common rule doesn't say that investigators have to be credentialed to ensure they can do the study. The common rule doesn't say that investigators have to tell if they are going to receive some benefit from any drug. So the common rule, which we

all—everybody in government follows isn't as complete as it needs to be.

I am a professor of medicine, and I am a professor of medical ethics. I have had the pleasure in my career to work with the leading research ethicist in this country. I have commissioned Dr. Brody, Brook Brody, in Houston, he is a Leon Janwaski Endowed Chair professor of biomedical ethics, to do a content analysis of not only the common rule but the Helsinki Accord and other documents which are used in Europe and other parts of the country to oversee—and other parts of the world to oversee human studies and by August provide to me what would be a complete state-of-the-art human studies program.

So let me say what we are putting in place today, as I mentioned in my earlier testimony, is more rigorous than anybody at any university is currently doing. But it is only the common rule that we are putting in place. By August what we look to do is to go forward with even a more complete, more rigorous human studies oversight.

Mr. RENZI. Mr. Chairman, if I could follow up?

Mr. SIMMONS. Absolutely, the light is still green.

Mr. RENZI. Thank you. You mentioned that one of the preventative measures, I think one of the critical pieces of substance would be that the investigators would be certified, was that your words? Go ahead. You are saying that the investigators——

Dr. WRAY. What we have required in the stand-down, which we have put in place which is not really a stopping of human studies but a review, is that all investigators and all individuals in fact involved in research will be certified for having IRB ethics training and what we call good clinical practice training. IRB ethics training really looks at the issues of informed consent, the components that the IRB looks at, and why they are important.

Mr. RENZI. I want to get one more question in. Let me recommend that we get together, maybe with my staff, because I would like to look at possible areas of legislation to help in that, that is something I would like to be passionate about.

I am from Flagstaff, Arizona and we are thankful to be home for the pathogen study lab. As a matter of fact, all of the anthrax that killed the Americans, every American who was killed by anthrax after 9/11, that anthrax was identified at our university, Northern Arizona University in Flagstaff. The chairman took the time to teach me that one of the inequities that exist in the system right now is that when Veterans' Affairs receives grants like from NIH, that the hard costs aren't included. Has there been any kind of collaboration between the Veterans' Affairs and the universities in order to share those costs? And in particular as it relates to the chemical agents that we are not seeing as the major threat against Americans?

Dr. WRAY. The issue is not whether our universities would be willing to provide us the funding if the NIH would provide it to them. The issue is that since 1989, the NIH has precluded universities from putting on the grants which a VA investigator writes and puts through their university, they have precluded the ability to put on a facility charge to reimburse the VA for the expenditures for facilities maintaining the labs, such as the air conditioning, the cleaning, the telephones, the electricity. I said earlier we have au-

dited 85 of our VAs, and that is about a 24 percent charge, 24 percent of the directs would be that. We have about $400 million in NIH grants. So 25 percent of that would be about $100 million that we donate to the NIH each year.

Mr. RENZI. When you collaborate with the university——

Mr. SIMMONS. Now the light is red. Dr. Snyder.

Dr. SNYDER. Thank you, Mr. Chairman.

Dr. Wray, I read your written statement and listened to your opening statement. You gave such an upbeat assessment of research at the VA, I was tempted to ask you if we should look to your budget as a source of cutting funds to fund the President's tax cut or VA health care or the defense budget or something. But then you made a couple of comments in response to questions. One of them was—I believe I wrote it down exactly what you said—talking about NIH, referring to your facilities, "Our facilities are crumbling," I believe were your exact words. And then you also started talking about the reduction in purchasing power that comes along if your budget is raised only a little bit and yet your cost of living and expenses goes up more than that.

I would like to hear from all of you. If we could do this like a test. I have an M.D. You are all M.D.'s. And if you can take out a pencil and a piece of paper, and I would like to hear a letter grade of what grade you give the funding for research over the last 5 years? And I hope—you are all independent minds, I hope you won't be swayed by what OMB has told you or by what the person sitting in the classroom next to you says.

Why don't we start with you, Dr. Wright, and just go around the table. And any comments you want to make. Are we A, B, C, D or F on the level of funding for research?

Dr. WRIGHT. Well, I am not sure that I can place it in a letter grade, but it certainly is not A, B or C at our facility in West Haven. Our research—we have a large research program. Last year, we had about $30 million in direct cost funding for the research program. It is a combination of laboratory research and patient-oriented clinical research. Our laboratory facilities occupy about 60,000 square feet. Most of that space is in buildings that were constructed in 1918 as New Haven's Tuberculosis Hospital was opened as an Army hospital. We have renovated with sort of marginal funds over the years. One room or group of rooms at a time to make laboratory facilities. But it is a very inadequate facility.

About 10 years ago, we recognized this, had extensive talks with the school, with Yale University, and recognized that one of the things that was coming down the road was that Yale was embarking on its first large research laboratory building project in a long time. And so that we knew about 10 years down the road that the market for research space was going to change. And we had more space than people might be able to find at the medical school 10 years ago, we were going to have inferior quality space about now.

And, in fact, this spring the new research building at Yale is opening and it changes even the perception of the facilities that people work in. We in that 10 year period got help from the medical school to have an architect work with us to make a preliminary design for a research building. We had that finished in 1992, 1993.

But there has been no possibility during the 1990s to have research construction funds. And so we are sort of in the same position that we were 10 years ago, the space is 10 years older and the heating plant is 10 years older and so forth.

So we have modest plans in our going forward strategic planning currently to do small scale renovations of space that we can and it looks like we are going to be able to renovate maybe 5,000 or 10,000 square feet at most with resources that we can piece together. But it is not the kind of thing, that we really need to have a first-class research environment.

Dr. DEMAKIS. I am John Demakis. I have been in charge of health services research for the last 5 years. I am based here in Washington, Congressman. However, I will tell you I think our job is to do the best with what we have. And I think whatever budget we have, we will always give you the best. And I think you have heard many of the accomplishments just this year alone. If you went back many more years, you will hear the outstanding benefits VA research does and the value you are getting for your bucks.

Dr. SNYDER. I can interrupt you. I would hope that you would see as part of your duties also is to tell this committee when what you have is inadequate. I agree with you, you have got to do whatever you get from this Congress—from the American people through this Congress—you have got to do the best job that you can with. But if you don't think it is adequate, I think it is your responsibility to tell us.

Dr. DEMAKIS. We can always do better with more, Congressman.

Dr. SNYDER. I understand.

Dr. DEMAKIS. We do the best we can with what you give us. If you give us more—you see the value you get for your dollar now.

Dr. SNYDER. But you are not going to give me a letter grade, are you?

Dr. DEMAKIS. I will tell you I was in Chicago at the Heinz VA Hospital for 29 years before I came to Washington. That was the first VA hospital, by the way, chartered by the government. The building research was being done in was built in 1919 as a public health hospital. The plumbing was still intact. When I left there, they were tearing the asbestos out of the walls to make it safe. I think that should answer your question.

Dr. SNYDER. Yes. Dr. Wray.

Dr. WRAY. Well, I know it was not the direct responsibility of this committee but I also know you all voted, and I want to commend you for doubling the NIH budget over the prior 5 years. During that time, the VA budget has grown very small amounts. I would look forward in the future to working with this committee to look at a 15 percent increase each year for 5 years to double the VA budget.

Dr. SNYDER. Are you going to give me a letter grade?

Dr. WRAY. I think you get an "A+" for the NIH.

Dr. SNYDER. No, no, are you going to give us for the adequacy of funding over the last 5 years?

Dr. WRAY. I would give you an "F."

Dr. SNYDER. Am "F."

Dr. AISEN. We all support the President's budget, of course, but I think—I am from rehab research. And when I came to Washing-

ton 4 years ago, the rehab budget was $27 million per year. And that was the smallest budget in a very small budget. And I think that you can see what rehab has been able to achieve. I daresay many of the things that were highlighted today were efforts that rehab medicine has invested in, better prosthetics, electrical stimulation.

Now we are interested in things like micro-technology and neuroprostheses. Now under Dr. Wray's leadership, and under Dr. Foysner's, that budget has grown, but it is still minuscule and minuscule compared to what the Department of Education invests in rehab research and what the NIH is able to invest in rehab research. And I can tell you that there are an extraordinary number of unfunded opportunities in rehab research and throughout the whole ORD.

So I don't think I would be—I have been in Washington the past 5 years and I have seen good things happen. I wouldn't give you an "F," but I think maybe a "C."

Dr. SNYDER. A "C," thank you.

Well, Mr. Chairman, we have got Dr. Wright, who said he would not give us an "A," "B" or a "C" so that is either a "D" or an "F." And we got an "F" and we got a "C," and it is not looking very good. But I think the very practical thing is Dr. Wray's comment, 15 percent increase over 5 years seems like a reasonable and worthy goal.

Thank you all for your candor.

Mr. SIMMONS. Thank you, Dr. Snyder, for your questions and for your exam. In my experience as a college professor, from time to time we awarded incompletes, and let's hope that we can operate on an incomplete and finish up the business sooner rather than later.

That being said, we are on the second round of questions, if we want a second round. I will pass for purposes of timeliness but have some questions to submit for the record which follow up some of the questioning that we have already heard. I would like to remind the members that we do have another panel. With that, I defer to my ranking member.

Mr. RODRIGUEZ. I just have one additional question, because I know we have had calls here regarding the appropriation language that deals with—and I don't know if you can answer this or any of you can answer this—but we were contacted that the VA is requesting 5 percent of the medical research support cost be authorized for a transfer between both the medical care and medical research budget so that if there is a decision made that medical centers are either over or under, that you can utilize that or make that adjustment. Can you explain that?

Dr. WRAY. Yes, sir. For the first time this year, the dollars which were distributed by the VERA allocation system, that at the facilities were then used to support research will no longer be distributed through the medical care dollars. They will be distributed through the research budget.

Let me explain a little bit more. NIH grants, if I put in NIH grants, my salary, the position salary is on the NIH grant. In the Department of Veterans Affairs, because one of the four missions of the VA is to do research, physician salaries have not been paid

out of the research line. They have bene paid out of the medical line. But if that position, man or woman, spends 35 percent of their time doing research, that is in fact those medical care dollars are going 35 percent to research.

Mr. Principi, Dr. McKay felt it was best to align the dollars that are being spent for research into research. So if you look at our budget his year, as opposed to being somewhat less than $400 million in 2003, our budget is $812 million in 2004—I mean $820 million. But the reason for that is the 400 in 2003 got a 2 percent increase to 408 and 412 came out of the medical care dollars over to the research dollars.

I took that long time to say the following. No one knows how accurate the 412 is, the dollars that were previously medical care dollars spent for research. It is a rough estimate. There is a feeling that it may be an underestimate. So the legislation asks that we do the 412 but have a fudge factor in case that 412 is really far short of what we believe it to be. And I don't have the numbers right in front of me, but I believe the fudge factor is 10 percent. So that up to 10 percent could also be transferred.

Mr. RODRIGUEZ. And this only applies to the VERA monies?

Dr. WRAY. Yes, sir, the VA has the medical care line and its research line. And we are talking about the medical care VERA dollars that previously were used to fund research are now all in the research line. And what we are talking about is that was $412 million that was moved but there is concern that it wasn't estimated correctly. And so there is an asking that up to, I believe it is 10 percent, but up to 10 percent more or another $40 million could be transferred.

Mr. RODRIGUEZ. Thank you.

Dr. WRAY. And, likewise, if I don't spend it, I can send $40 million back to them this first year. So it can be an error in either direction.

Mr. RODRIGUEZ. You send it back to where?

Dr. WRAY. Back over to medical care dollars.

Mr. RODRIGUEZ. But it stays because the VERA money is supposed to follow the veteran in reference to the region, right?

Dr. WRAY. I just didn't hear you, sir?

Mr. RODRIGUEZ. Please tell me if I am wrong. And I am asking all the staff. My understanding is that VERA monies were supposed to follow the veterans in terms of those areas and regions where the numbers of veterans has increased, is that correct?

Dr. WRAY. That is absolutely correct.

Mr. RODRIGUEZ. So when you say it goes back, what does that mean?

Dr. WRAY. Exactly where the $40 million error will come from, I can't tell you. The 412 is going to come off the top, as I would refer to it. So that before monies are distributed by the VERA dollars out to the sites, this money in fact by legislation, when we get our appropriation, the research line will now have $820 million in it and the VERA dollars will be the $26 billion or whatever it is.

Mr. RODRIGUEZ. So there will be more money for research if that is what the expenditure is?

Dr. WRAY. We don't know whether it is more or not because we weren't sure exactly how much was spent out of VERA dollars. In

essence, it is an estimate that it would be the same amount out of VERA dollars this year with a slight increase compared to last year, a 2 percent increase. It certainly, I want to make clear, it is not a doubling of the research budget from $400 million to $812 million.

Mr. RODRIGUEZ. Thank you.

Mr. SIMMONS. Mr. Strickland, do you have a question for the second round?

Mr. STRICKLAND. Yes, just one quick question.

Mr. SIMMONS. Yes.

Mr. STRICKLAND. I want to go back to the fact that this decision was made by NIH that is depriving you of about 100 million estimated dollars. How was that decision made and what can be done to reverse that decision?

Dr. WRAY. It was a policy decision, and it would take a policy decision to reverse it. There is law passed, I am sorry—I may have the number here in my book—that makes clear that the NIH is responsible to provide indirects to VA hospitals consistent with the indirects that they pay to universities.

Mr. STRICKLAND. And to foreign governments?

Dr. WRAY. Yes.

Mr. STRICKLAND. And if I could just say to you, Mr. Chairman, I am just wondering if there is something that this committee could do by way of expressing an opinion to NIH that they reconsider this policy and perhaps reverse it. And with that, I yield back my time.

Mr. SIMMONS. To respond to your question, the issue has been a matter of concern on both sides of the aisle and has been explored fairly aggressively this afternoon I think, as well as in previous hearings. So the answer is yes.

Dr. Snyder?

Dr. SNYDER. Thank you, Mr. Chairman. Just one quick question, Dr. Wray.

Dr. WRAY. Yes, sir.

Dr. SNYDER. The process by which infrastructure projects are funded within the VA seems compared to most agencies to be relatively free of politics. You all have an internal system that makes decisions about what gets funded and what doesn't get funded. But the mention was made about—I forget, I guess it was you, Dr. Wright, about 5,000 square feet or so of new research space, which is about the size these days of a new home. It is not an extravagant amount of space. We have struggled with what is an adequate level of Veterans' health care budget and compensation budget and all these kinds of things. And it is always difficult to play one section of veterans' care against the other.

But what is your assessment of the fairness of the VA system in terms of making decisions about the order in which infrastructure projects will be funded for research?

Dr. WRAY. As far as I know, any infrastructure monies for improvement of research have come from research. I don't know the history of say four or 5 years ago, but I am just talking about in the recent past. We have teams that go and visit our research sites on a rotating basis. We try to see all sites every 3 years. There we do education and we look at the structures.

And it is that process that, when we see structures that really need a lot of help, we ask them to apply. Because our dollars have been so limited in the past, we have asked for matching dollars. So that, as Dr. Wright spoke, he patched together other dollars and then came to us.

Dr. SNYDER. So the decision with regard to the level of funding available for infrastructure for research is made when the pie is divided up under your section and within your section, your piece of the pie, you make the decision about how much money you have available for infrastructure.

So if I understand this right, a new VA hospital is not being played off against new infrastructure space. It is the overall number of funding for the research that may be played off against a new VA hospital somewhere.

Dr. WRAY. Let me make that clear. I think the Congressman spoke eloquently when he said, "Just to be able to get out of the chair would be wonderful." The researchers who are working with the instrument that was used, the pacemaker-like instrument that was used for Chris Reeve, have worked on that to help strengthen muscles, or at least to cause those muscles to contract so someone who has a normal upper body can walk with a walker.

They have a very vivid film of a woman who was to be married. And all she wanted to be able to do was to walk down the aisle with her husband and her father. And we were able to do that with her in a walker with this instrument. So I have to make a decision, am I going to change his heater out, okay, provide him new plumbing, or try to get a few more dollars over to do research. And it is simply the trade-off.

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

Mr. SIMMONS. Thank you. Are there any other questions for this panel? Hearing none, I want to thank you all for coming down.

Dr. WRAY. Thank you.

Mr. SIMMONS. I know some of you have traveled some distance, I really appreciate it and also commend you. As I went through the biographies last night, I noticed that some of the biographies or curriculum vitae were 15 and 20 pages long. I thought I was doing pretty good with three-quarters of a page. We thank you for your excellent work to improve health care, not just of our veterans but for all Americans. Thank you.

Dr. WRAY. Thank you.

Mr. SIMMONS. We will now move to the next panel, panel three.

I want to welcome our third panel. The panel consists of the Chairperson of the National Association of Veterans' Research and Education Foundations, which we call NAVREF, for those of you into acronyms. That is Dr. Eileen Lennon. And she is accompanied by Ms. Barbara West, the Executive Director of NAVREF.

We also have Dr. Ira Katz, a professor of psychiatry and the Director of Geriatric Psychiatry at the University of Pennsylvania Health System, who also serves as Director of the Mental Illness Research Education and Clinical Center of VA's VISN–4 in Philadelphia. He is somebody else who has a curriculum vitae that goes on and on and on, over 20 pages, as I recall.

And then Dr. Kevin Dellsperger, the Clinical Chief of staff at the Iowa City VA Medical Center.

I want to thank all four of you for being here today, for sitting through this hearing of the subcommittee. Why don't we begin with testimony from Dr. Lennon.

STATEMENT OF EILEEN LENNON, CHAIRMAN, NATIONAL ASSOCIATION OF VETERANS' RESEARCH AND EDUCATION FOUNDATION; ACCOMPANIED BY BARBARA WEST, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF VETERANS' RESEARCH AND EDUCATION FOUNDATIONS; IRA R. KATZ, PROFESSOR OF PSYCHIATRY, DIRECTOR, SECTION ON GERIATRIC PSYCHIATRY, UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM; AND KEVIN C. DELLSPERGER, CHIEF OF STAFF, ASSOCIATE DEAN OF VETERANS' AFFAIRS, IOWA CITY VA MEDICAL CENTER

Ms. LENNON. Thank you. Good afternoon, Mr. Chairman and members of the subcommittee. I am here today, as Congressman Simmons said, as the chair of the National Association of Veterans' Research and Education Foundations. This is a membership organization of the VA-affiliated nonprofit research and education corporations. Also, I am executive director of the Seattle Institute for Biomedical and Clinical Research, known as SIBCR.

There are 88 nonprofit research and education corporations affiliated with VA medical centers nationally. Each is an independent, state-chartered 501(c)(3) corporation. Their statutory purpose is to provide a flexible funding mechanism for the conduct of VA-approved research and education at the medical center.

In testimony presented before the Subcommittee on Oversight and Investigations last year, NAVREF discussed specific examples of how nonprofit expenditures benefit facility research programs. Because time is short, I will only discuss briefly what SIBCR does to support the VA Puget Sound Health Care System.

SIBCR administers funds related to over 20 percent of the active projects of VA Puget Sound, including hiring staff, payroll, accounting and financial reporting, and paying for all the direct costs of the research. In addition to these functions, the SIBCR board of directors has approved support to the VA Puget Sound Research and Development Program that totals over $200,000 annually.

I would like to give you one example of a project supported in part by SIBCR funds. A physician who works closely with Vietnam veterans was drawn into a serious problem of post-traumatic stress disorder nightmares and sleep disturbance. Many had not slept through the night in years. This had a negative impact on their ability to hold a job and interact socially. This investigator speculated that if he reduced the excess brain adrenaline response, it might prevent the PTSD nightmares. He obtained VA approval and tried a generic drug that has been used for years to treat high blood pressure and costs only a dollar for 3 months of treatment. It is safe and effective, and best of all, he found that it stopped the PTSD nightmares. The veterans slept better and improved their quality of life. SIBCR supported this pilot research and now the project is funded with the VA Merit Award. This is an exciting research endeavor, applicable to all veterans suffering from PTSD.

Now I would like to turn to national nonprofit issues. During the summer of 2002, the GAO and IG audited seven nonprofits. In Sep-

tember, they presented testimony before the Subcommittee on Oversight. Overall, the findings by both the IG and the GAO were supportive. Both acknowledged that the nonprofits provide significant benefit to VA research and validated that they were fulfilling their intended statutory mission. In their testimony, both the IG and GAO recommended ways to increase collection of data about the nonprofits and to improve accountability. Please be assured that NAVREF is committed to promoting the highest standards of nonprofit management. We have participated fully in developing measures to address the recommendations, including the new VA nonprofit program office, improved reporting by the nonprofits, and increased data collection by the VA.

Also, NAVREF supports improved accountability, such as requiring all the nonprofits to undergo audits in accordance with generally accepted government auditing standards.

That said, we will continue to recommend against imposing on the VA-affiliated nonprofits management and accounting practices not required of other U.S. nonprofits. In our view, efforts to make the nonprofits more like the government will undermine their statutory purpose and the clear intent of Congress that they should be different and separate from the government.

In conclusion, we encourage the subcommittee to move forward on two legislative requests submitted by NAVREF. The first would provide nonprofit research employees with protection against personal liability under the Federal Tort Claims Act. The second would approve the effectiveness of the nonprofits by providing the VA with mechanisms to use VA-appropriated funds to pay for services provided by the nonprofits.

It has been our pleasure to work with subcommittee staff to develop these initiatives, and we request enactment this year. Many field personnel view the nonprofits as the best thing that ever happened to VA research, and we thank Congress for its foresight in authorizing them. However, as the GAO pointed out in spoken testimony last September, with growth of the nonprofits comes increased potential risk. While we fully appreciate the importance of accountability and oversight, we want to ensure that the nonprofits retain the flexibility necessary to perform the mission for which to establish them. We appreciate that both this subcommittee and the VA have included NAVREF in deliberations over improvements, and we look forward to continue this collegial working relationship.

Thank you for considering our views. And I would be pleased to answer questions.

[The prepared statement of Ms. Lennon, with attachment, appears on p. 52.]

Mr. SIMMONS. Thank you. I think that what we might wish to do is hold the questions and ask Dr. Katz or any of the other panelists if they have a statement that they would like to make? I mention Dr. Katz because he has submitted a statement for the record. If so, please proceed.

Dr. KATZ. Thank you, Mr. Chairman and members of the subcommittee. I am here as a professor of psychiatry at the University of Pennsylvania, but I also serve as director of the VA Mental Illness Research Education and Clinical Center, the MIRECC for VISN–4, that serves Pennsylvania, Southern New Jersey, Dela-

ware, and West Virginia. I will be speaking about the MIRECCs as an important part of the VA mental health programs, an area that is critical because at least one in five veterans in our health system require mental health care.

Modeled after the geriatric centers, or GRECCs, MIRECCs were created by the 104th Congress to serve as scientific infrastructures and educational foundations for mental health programs in the VA and to support innovation by serving host facilities, VISNs, and the VA as a whole. There are currently MIRECCs in eight VISNs serving 27 states and the District of Columbia, all with specific themes that overlap enough to facilitate synergies but are distinct enough to cover the field.

The research components are designed to facilitate innovations directly related to patient care by maintaining infrastructures for research, including pilot programs and training for new investigators. They emphasize projects that will improve care sooner rather than later. Based on these activities, MIRECC clinicians and scientists apply for and obtain competitive grant support, leveraging the VA's investments and bringing in new resources.

I would like to provide some examples of recent research and to note that the MIRECCs and Research and Education Foundations share credit for a really significant advance in PTSD. In thinking about the war in Iraq, and those who will be our newest veterans, we must recognize that the wounds of war are increasingly a reflection of stress-related psychiatric disorders, such as Post-Traumatic Stress Disorder, as well as physical injuries. Recent research from the VISN–20 MIRECC has demonstrated that prazosin, a drug initially used for hypertension, can alleviate the nightmares and sleep disturbances that are major causes of suffering and disability in PTSD. Although the definitive clinical trials still need to be done, the research has already made a new, safe, and low-cost treatment available.

Another example is about naltrexone. It is an opiate-blocking drug that has been found to be useful in treating alcoholism through research at the Philadelphia and West Haven VAs. Recently, puzzled by findings from some studies that showed limited benefits from the drug, investigators from the VISN–1 and 4 MIRECCs showed that the response to naltrexone is affected by genetic variability in specific brain receptors. This advances care and shifts the question away from whether naltrexone works to who it works for. It provides an approach for matching individual veterans to the treatments that will work for them.

Other projects are even more related to clinical care. Investigators in the VISN–5 MIRECCs have conducted sophisticated research on behavioral treatment for patients with schizophrenia. And they are applying it to the rehabilitation of treatment-resistant patients who until now have required long-term hospitalization. My colleagues in VISN–4 and I have recognized that many veterans with depression and co-existing medical illnesses won't come to us. They prefer to have their depressions treated by primary care providers. We validated telephone-based care management strategies to support this and are now beginning to apply them on a routine basis at the Philadelphia VA and its community-based outpatient clinics. Here, the MIRECC is supporting novel

clinical activities that improve the process and outcomes of care by integrating mental health and other medical services.

I could go on with a number of similar success stories, but I would like to conclude by making three points. One, is that the MIRECCs are productive and successful in linking research education and clinical activities. And that in this they are fulfilling the vision of the 104th Congress that created them.

The second point is about the funding mechanism. MIRECCs are supported through special purpose funds set aside from clinical care dollars, appropriately so given their activities. There are ongoing discussions about whether the MIRECCs should be shifted to VERA-based funding as part of a sort block grant to the VISNs. However, those concerned about mental health care in the VA have major reservations about this. They are concerned that this type of change in funding would lead over time to an erosion of support and a sacrifice in the MIRECCs' ability to pursue their mission. This is especially important in the mental health field where there are ongoing concerns about maintaining capacity.

The third point is about added value. Given what the MIRECCs do and the magnitude of the needs they address, they are a good investment. The system needs additional MIRECCs, including two new centers in fiscal year 2004.

Thank you. I am pleased to answer any questions.

[The prepared statement of Dr. Katz appears on p. 63.]

Mr. SIMMONS. Thank you, Dr. Katz.

My first question is to Dr. Lennon. I have always been a believer that government works best when it works with private entities, whether they be educational or commercial, and the partnership is what it is all about. As I understand it, the GAO inquiries of the VA-affiliated nonprofit research and education corporations that took place resulted in certain findings. And I guess my question would be did those findings or did the problems that the GAO investigation focused on, were these problems of medical ethics or medical research or the management of medical health care or were these problems related more to administrative and financial activities within the organizations themselves? Could you clarify that for me?

Ms. LENNON. Well, actually, the GAO audited five of the seven last year. And, in fact, their report was fairly laudatory to the nonprofits. They found no management problems to speak of. They recognized all the expenditures were benefitting the research program. They felt it was highly—many of the nonprofits had gone to a great effort to develop conflict of interest programs, even over and above what was in existence so there wouldn't be a problem with any clinical studies or any research, that in full disclosure. And so I think when we got the GAO report, we were quite happy, to tell you the truth, because it sort of validated exactly that we were fulfilling our purpose.

Mr. SIMMONS. I thank you for that statement, and I appreciate that.

Dr. Katz, on the issue of Post-Traumatic Stress Syndrome, I am a Vietnam veteran, and I certainly appreciate the research that has been done in that area. I recall many years ago, in 1979, 1980, when that issue was first raised, that a Member of Congress, who

will remain nameless, told me, "Well, that was just a problem with a bunch of crybabies." I found it interesting that at the time the U.S. Government would go to extraordinary lengths to address what I call physical wounds of war in very dynamic ways but spent little, if any, time on what I call the mental wounds of war. Would you comment a little bit on how you and the MIRECCs have addressed Post-Traumatic Stress Syndrome and whether it is now treated in a fashion that the veteran himself or herself does not feel a stigma from this kind of treatment?

Dr. KATZ. Wow.

Mr. SIMMONS. In 5 minutes or less.

Dr. KATZ. Sure. This morning, Tom Insoll, the new director of VNIMH, made the point that 30 percent of Vietnam veterans had PTSD. And there are those who have calculated that more Vietnam veterans may have killed themselves since the war than died in the war. We can't afford another wall for those who are mentally scarred by their participation in battle and took their own lives. We have got to prevent that from happening in the future.

We hope that we can do it early on with our newest veterans. Our oldest ones and our aging ones are much more scarred. All too often PTSD leads to substance abuse when veterans have tried to use different drugs to treat themselves. This presents a chasm in which they can't get into PTSD programs because of substance abuse. And they can't deal with substance abuse programs because of PTSD. Several of the MIRECCs are working to overcome this gap. This is being done in VISN–4. I am very proud of this. And also in VISN–21, to coordinate mental health and substance abuse treatment to deal with this problem, to de-stigmatize and to really give and to really give new hope to these people.

Mr. SIMMONS. Thank you very much. I will have to excuse myself. I will ask Mr. Renzi if he could sit in the chair, and I ask my colleague and ranking member if he has questions?

Mr. RODRIGUEZ. Thank you very much. Let me follow-up again on the issue of mental illness because I know that—and I don't know what the percentage is for the VA, how much is spent in that area in comparison to others. But I do know that on anything else, usually what happens is MH, the mental illness is usually an after thought. We deal with everything else and then we think about the mentally health. I am just wondering whether we are doing sufficient in that area in proportion to what we are allocating and how much of that is going. And I really believe and I feel very strongly, and qualify my statement, in what you indicated because when people, whether they are veterans or not but more so veterans that have experienced war, when you go through any traumatic experience, such as the people in New York, the people at the Pentagon that went through that experience, there is no doubt that that has a direct impact on them. And sometimes even unconsciously, they are unaware of the impact.

And so I wanted to just get some feedback from anyone on the panel, whether we are spending sufficient resources in proportion to the other research items?

Dr. KATZ. The answer is of course not. But let me go on some more about that. And the issue is in terms of both clinical care, as well as research. The number of veterans that are served by pro-

grams directed towards those with chronic and severe disorders have gone up by about 5 percent in recent years. But the budget has gone down by about 15 percent. In a way this reflects the shift in mental health treatment away from the hospital into the community. Because of dramatic advances in medications, it is more possible than ever for people to leave the hospital. But the system, though it has done an excellent job at making new medications available, hasn't made enough rehabilitation available to allow these people to live in the community and return to productivity.

There are other issues about the medical care of people with chronic and severe medical illnesses. They are hard to treat clinically, and we need special mechanisms. Work in the VISN–1 MIRECCs has done a good job and others of us are emulating it in trying to design special medical care services for the mentally ill.

We can talk there about patients who have chronic and severe conditions who are recognized as people as psychiatric disorders but there is another whole family veterans with mental disorders, of new patients. If a middle-aged person were to get a heart attack and become depressed over it and start drinking to treat the depression, he would need care in three separate systems, even within the VA. We have to do more about integrating that. And depression is a big deal. Depression after a heart attack is a better predictor of mortality and a second heart attack than almost any other measure that my medical colleagues can do. We really have to invest, not just in treating the people we know to be patients with psychiatric disorders, but increasingly to work with the psychiatric components of medical illness. The mind and the body are one, and we have to integrate care.

Mr. RODRIGUEZ. Any of the others want to comment?

Dr. DELLSPERGER. This is Kevin Dellsperger. I would like to make a comment regarding the overall issue of funding. Certainly, I would agree that we are under-funding mental health research, but I am adamantly and strongly supporting that we are under-funding all research. The doubling of the NIH budget is just the beginning. The VA has not seen anywhere close to that impact. I am concerned that without substantial increases in funding, we will leave many doors unopened. When we look at good quality grants, we are funding in the 20 percent to 30 percent range. That means we open two to three out of 10 doors. We need to open eight to 10 out of 10 doors in order to find the discoveries that all of us want for our futures and the futures of our children.

When it comes to mental illness and co-morbidities, as a cardiologist, one of the worst things I see in patients is the depression following their heart attack. Treatment of their depression has only been available in the last few years because some of the newer drugs don't have the effects on the cardio-vascular system that older drugs had. But we have to have new systems in place to run our hospitals, infrastructure to support our research environments, and to grow and develop into the 21st century VA as we espouse to.

Under the guidance of Dr. Kaiser, we made great, great strides in improving the quality of care to our veterans. I hate to see us

lose ground as we under-fund important missions. And we need to take those strides now.

Mr. RODRIGUEZ. Thank you very much. I still see the light is yellow, so let me see if I can pull off another one. I just want to ask you maybe some quick feedback on nonprofits, as to what the VA can better work with you? I know you made a couple of recommendations but any others?

Ms. LENNON. Well, those are the two initiatives that we are trying to I guess get resolved. One of the issues is the contracting authority that would allow the VA to contract with the nonprofits. Right now, we can reimburse in VA for almost anything but if we provide a service for the VA, there is a very limited amount of what we can do and that would be like inter-personnel agreements or inter-personnel government agreements whereas a lot of services that are being provided by the nonprofits, either buying a large piece of equipment that would allow the VA researchers, as well as the nonprofit researchers or university researchers to only pay the direct cost of when they use that service.

And yet, if we were saying that, they wouldn't be able to reimburse us for that whereas it is a very big benefit. Or providing other core research. I think I was talking earlier that biostatisticians are a very important part of research programs but normally grants don't cover the cost of—they might cover 5 percent. But that is an example of something that can be provided as a core resource and have the skilled personnel hired by the nonprofit and possibly just charge it out to the indirect cost that we discuss so much lately or as a direct charge to that. But it would mean in some cases getting reimbursed from the VA from appropriated funds, which right now we are not able to do.

Mr. RENZI (presiding.) I thank the ranking member. Dr. Dellsperger, did you have a formal statement you wanted to submit to the record?

Dr. DELLSPERGER. Not a formal statement, but I would like to make a couple of informal comments, if you don't mind.

Mr. RENZI. Let me recognize you, thank you.

Dr. DELLSPERGER. Thank you, Mr. Chairman. I would like to first start off that the Iowa City VA has a 50-year tradition in research. We were built only 51 years ago, so we started very early in our being a research institution. We have celebrated the fact that we have been in the top 10 of the VA research programs in the country over the last several years and in many cases we rank in the top five of medical services research.

We enjoy one of the strongest affiliations with the University of Iowa. I and my staff are frequently invited to either chair or participate in review committees of affiliations and VAs having difficulty and hardship in their relationships, to try to give them advice and give them some insight into how to have a more harmonious relationship that is a win/win for both the academic environment, as well as the strength of the VA programs.

Our programs are broad and deep. We go all the way from the very basic research programs, where Jack Stapleton, one of our infectious disease staff physicians, works on the study of HIV and Hepatitis C co-infection, all the way to quality work led by Dr. Gary Rosenthal, as one of the VA quality scholars. We cover all of

the intermediate steps. In the clinical arena, Dr. Ken Follet, one of our neurosurgeons oversees the clinical cooperative study evaluating deep brain stimulators in the treatment of Parkinson's Disease. These studies are rich and deep, and they truly improve our environment.

I would like to leave the subcommittee with a couple of points. One is research is not a vacuum in an academic medical center. And I view our VA as an academic medical center. Having a strong research environment improves the education for our students and for our residents because we are able to share with them new breakthroughs in science and technology and improve their inquisitive minds, to ask us questions regarding what is the future going to be? We want to teach them not only the care of today but the care of the future so that all of us can benefit from that.

Secondly, access to specialists, especially for me in Iowa City, would be nearly impossible if it weren't for our close and integrated affiliation with the University of Iowa. These specialists provide extraordinary care to America's veterans. We receive referrals from all over the country for our nationally-designated kidney transplant center. It is because of that interaction with the university and the availability of VA research that I am able to attract and retain America's best physicians and specialists. I would not have neurosurgeons or orthopedists on staff if it weren't for strong research programs.

I implore the oversight committee to make as many recommendations as within your authority to improve the funding to the research programs throughout the VA. It is a dollar well spent and it is critically important that we solve the infrastructure issue. My Middleton Award winner of a few years ago, Dr. Gerald Deboma, is performing his studies in a renovated nursing dormitory. This dormitory has totally inadequate heating, ventilation, and air conditioning systems. As we were site visited, the site visit team asked why the windows were open. We sort of laughingly said, "That is part of the heating/ventilation/air conditioning system." It is not a way to have high quality, 21st century work done, and certainly we need to clearly address the infrastructure issues in our VA medical centers.

Thank you.

Mr. RENZI. Sir, thank you for your comments.

Mr. Strickland?

Mr. STRICKLAND. Thank you, Mr. Chairman. I think you have made convincing cases that we need more money for research. And I was just sitting here and contemplating the fact that a few minutes ago, an hour and a half or so ago, we held a support our troops rally over in the Capitol Building. And we are proud of our troops, and we grieve those who are lost and have been injured. But it is ironic that probably in a few hours we will be casting a vote in the House of Representatives to cut $28.3 billion out of VA health care and other benefits. It just seems inconsistent to me.

I mentioned earlier that I had worked in a prison, and I am wondering does the VA have any outreach program to incarcerated veterans who may be suffering as a result of war-related or service-related injuries? Once they are incarcerated, are they no longer a focus of the VA's attention, these individuals?

Dr. DELLSPERGER. I guess as a chief of staff I can answer that probably better than some of the other panel members. We are prohibited from caring for incarcerated veterans.

Mr. STRICKLAND. And I suspected that was the case. And, quite frankly, I think that is something that we ought to really look at, because if we understand the consequences of some of these illnesses and some of these addictions and some of these co-occurring conditions, and if we also understand that the onset of some of the most serious illnesses occurs at about the time that a young American is in fact a part of our armed services, in their late teens, early 20s.

And also, going beyond the incarcerated veteran, what about the homeless veteran? Are there any particular programs that are designed specifically to reach out to the homeless veteran who may be in need of help?

Dr. KATZ. Yes, these are important mental health issues. As the states have had less funds available for mental health care, the jails and prisons of America have become the new mental health institutions. They do a lousy job.

That is interesting, that is for young and middle-aged people. For older people, the nursing homes are the mental health institutions of America. And none of these institutions are designed to do their job.

Jail diversion projects have worked in community settings. And I honestly don't know if there are jail diversion projects in the VA, but there should be. Many people who were arrested because they are acting strangely or their judgment is so impaired that they get into trouble can be successfully treated and kept out of jail. It is an important issue for the VA.

The VA does much better at homelessness. I know that being a champion for these issues is something that Susan Edgerton has worked on so much over the last few years. We do better in that. At least half of homelessness is a mental health issue, at least. Substantial numbers of Vietnam veterans with PTSD are the homeless people of today.

With treatment and outreach and ability to deal with substance abuse and mental health together, we can really make an impact on this. And the VA is part of an ongoing consortium of agencies working hard to try to reduce, if not end, homelessness in America.

Mr. STRICKLAND. Just one other question, Mr. Chairman. Doctor, you mentioned that we are prohibited by law to providing services to incarcerated veterans. Where is that law? Could you——

Dr. DELLSPERGER. My general counsel has told me we are, so I rely upon her to tell me. Certainly, in the case of what Dr. Katz talked about, there are people who are released from the incarceration, let's say someone is arrested, this is an acute arrest, not a sentence to a prison, but someone is arrested. As long as they are released from that state of incarceration, and we do take care of them. And many of these patients that come into our medical center from the sheriff's office of various towns in eastern Iowa and western Illinois are mentally ill. And it is their mental illness that prompted their breaking the law.

Mr. STRICKLAND. You know, on Easter Sunday in Ohio we will celebrate a very tragic occurrence that occurred 10 years ago, and

that is when the Lucasville Southern Ohio Correctional Facility had a terrible riot that took the lives of several inmates and a correctional officer. Not long before that riot, a group of Vietnam veterans who were a part of that institution, who met regularly as veterans who had become stabilized and who were in my judgment the most responsible stable part of that institution and had considerable influence throughout the entire prison population, a decision was made to transfer those inmate veterans to lesser secure environments. And I have always wondered whether or not that riot would have occurred if in fact those veterans had remained in that prison because they, in my judgment, were a very stabilizing force. They were really nice people, in my judgment, who had received the help they needed while in the prison, were pursuing educations and so on and so forth.

Senator DeWine, my Republican colleague from Ohio, and myself, introduced legislation a couple of years ago to establish a grant program for mental health courts because, as you say, there are so many people who get caught up in the criminal justice system simply because they are suffering from untreated, sometimes undiagnosed mental illnesses. And, sadly, tragically, many of those folks are veterans, people who have served this country with honor and who have become ill and have somehow fallen through the cracks and end up in our prisons and jails.

So I want to thank you for what you do, for all of you. And keep doing it. Thank you.

Mr. Chairman, I yield back.

Mr. RENZI. Thank you, Mr. Strickland. Mr. Strickland makes a good point. I think last year, it was pointed out to me that Chairman Smith has taken up legislation, Public Law 107–95, which addresses many of the concerns that Mr. Strickland has brought up. It is legislation that provides new models in care for those in jails and in prisons. And the focus today that Mr. Strickland has put on it is certainly worthy.

Also, if I can for the record, if not the political record, since we are sitting in Mr. Simmons' committee, I want to be sure for the record those witnesses here today and for the members in the audience that we understand that the budget blueprint that was passed by the House of Representatives a couple of weeks ago, that at 2:30 in the morning, myself and Chairman Smith and Chairman Simmons were able to get a letter, a commitment in writing that called for there to be no cuts in the veterans' budget. In addition, we received a letter that gave us $1.8 billion above the President's numbers. And, as a minimum, we would get the Senate's numbers.

Now at 2:30 in the morning, you can't change the language that we are voting on, but it is a testimony to Mr. Smith, his leadership, and Mr. Simmons, who fought very, very hard under immense pressure. And while the gentleman does point out that the original intent of the Republicans was to cut, there are several who deserve the credit for fighting hard against their own team at times.

That said, let me move to Ms. West, if you don't mind, while I have my questioning time available. And we will finish up here. We know, Ms. West, that you have got real good recommendations, I know you have a great background, and some of the improvements that you have seen need to be made in the Torts Claim Act. In ad-

dition, you talked about collaboration and we talk about extending some kind of authority to help corporations trade with their host VA. And within that arena, the idea that we can work together and benefit from each others' strengths and the idea of what you can do that the VA can do, and what the VA can do that you might not be able to do but working together to overcome. What are your thoughts on any initiatives or programs that are going on, if you don't mind?

Ms. WEST. Well, very tough. I would like to say first that we have—really the nonprofits have very strong working relationships with their affiliated VA medical centers. The budget discussion here has been very interesting and the nonprofits have a vested interest in a very successful and well-funded VA research program because the principal investigators that do the nonprofit research are in fact, of course, VA employees who are attracted to the VA in the first place by the opportunity to conduct research. So it is a very synergistic relationship between the nonprofits and the VA.

In terms of specific programs, I think, as Eileen mentioned, the contractor reimbursement authority that we have suggested would greatly strengthen the partnership. It would allow a nonprofit to buy a piece of very expensive equipment that the VA facility might not otherwise be able to afford and then essentially bill the VA on an as-needed basis or per-use. So the only cost that VA would incur for that piece of equipment would be for its actual use. The nonprofit would underwrite the rest of that cost and perhaps bill the university or the nonprofit itself.

Mr. RENZI. Yes, the collaboration between university, VA and nonprofit, those three people teaming up, it feels to me just instinctively that we have got to be able to loosen the binds that don't allow this occur or aren't allowing it to occur as much as it should.

Ms. WEST. We would certainly welcome that. And we have always, right from the beginning when we proposed this possibility of the medical centers being allowed to use appropriated funds, we have encouraged that whatever mechanism is developed involves rigorous oversight. We want any contracts, any funds, any payments under this authority, whether it is contractor reimbursement, to be very carefully scrutinized for any potential for conflict of interest, make sure that the amounts are appropriate, all of that kind of thing.

If I could just mention one other possibility, is the Federal Tort Claims Act protection that you mentioned. Currently, there is a Department of Justice opinion that has thrown an unacceptable level of uncertainty on the possibility of Federal Tort Claims Act coverage for a without-compensation employee of the VA. That is somebody who is essentially a salaried employee of the nonprofit but a person who has a VA without-compensation appointment. And there is a certain amount of uncertainty as to whether that person would in fact be protected from personal liability under the Federal Tort Claims Act.

So we have suggested legislation that would make that more explicit. Of course, the person would still have to have a VAWC appointment, would have to be working only on VA-approved research, and also would have to be supervised by a VA salaried employee. They would have to meet those conditions.

Mr. RENZI. Acting their direct authority—or under a directive.

Ms. WEST. Right, exactly. Right, but in the absence of this coverage, some of the nonprofits are now looking at having to buy private sector medical malpractice coverage with premiums that begin at $10,000. And that is money that could otherwise be spent on research.

Mr. RENZI. Well said. We need to clarify that and work towards that. Mr. Strickland, are we good?

Mr. STRICKLAND. We are good, and I want to thank the witnesses and I want to thank you, Mr. Chairman.

Mr. RENZI. I want to thank all of you. We have got some written questions that will be submitted to this panel. Thank you very, very much for your testimony, extremely interesting, for the recommendations from all of you, for your passion in what you do for all of us. I believe that what we are trying to do day in and day out for our veterans is absolutely vital, particularly given the time that our nation is in. So I thank you all very much for attending.

We are adjourned.

[Whereupon, at 3:30 p.m., the subcommittee was adjourned.]

APPENDIX

PREPARED STATEMENT OF CHAIRMAN SIMMONS

This Committee is the jurisdictional committee in the Congress for the Department of Veterans Affairs (VA) health care system, a nationwide system of 1,300 clinics, hospitals, nursing homes and other health care facilities that provide care for nearly 6 million veterans, with 185,000 employees and a budget of $23.9 billion in 2003.

This Committee authorizes programs and facilities with legislation, holds public hearings and meetings and carries out other activities of oversight. This work is done to ensure that the Department of Veterans Affairs fulfills its mission of providing appropriate and safe health care to eligible veterans of service in our armed forces, of training the next generation of health care providers, of supporting America's military services at a time of war or national emergency, and of conducting a leading edge program of medical and prosthetic research. The Committee holds an important responsibility, and let me assure all present today that it is a serious and sobering responsibility for all our Members, especially in light of our current military deployment overseas. My primary interest in holding this particular hearing is to highlight the accomplishments of the medical and prosthetic research programs of the Department of Veterans Affairs, and to also review some of its current challenges.

VA carries out an extensive array of research and development as a complement to its affiliations with medical and health professions schools and colleges nationwide. While VA research is targeted directly to the needs of veterans, as it should be, also the work has defined new standards of care that benefit all Americans. Among the major emphases of VA research are aging, chronic diseases, mental illnesses, substance-use disorders, sensory losses, and trauma-related illnesses. VA's research programs are internationally recognized and have made important contributions in virtually every area of medicine, health, and health systems.

Each day we learn about extraordinary research advances that are made in medicine, and it is important for us to use this pulpit to broadcast the fact that many of these advances come from research that is conducted in VA programs across the nation. Just last week it was announced that research at the Minneapolis VA discovered that influenza shots may shield the elderly against future cardiac-related diseases.

Earlier this year VA researchers in Portland found that a certain combination of drugs can reduce the suffering and the length of hospital stays for schizophrenia patients. In Little Rock, Arkansas, VA researchers were the first to demonstrate that synthetic hormones can build bone without harming reproductive organs. This finding may lead to new treatments to prevent osteoporosis for veterans. These are just some of the most recent and remarkable advances that VA researchers are claiming.

In assessing these developments, the Subcommittee also wishes to help build a foundation to improve funding for VA's research programs. The President proposed an increase of only two percent in 2004 for this program. This Committee recommended an additional $52 million be added to the 2004 budget in order for VA research to keep pace with funding developments in the Federal biomedical research community. This is an important program and it needs to be reinforced and promoted and this Subcommittee is the place for this work. I am pleased to lead the charge for VA research.

I welcome all our witnesses, particularly our colleague in the House, the Honorable Jim Langevin, who represents the 2nd district of Rhode Island. Mr. Langevin serves on the Armed Services Committee with me and other colleagues here, and on the Select Committee on Homeland Security. He is also the Co-Chair for the Bipartisan Disabilities Caucus. Mr. Langevin has spent his time in office concentrat-

ing on health care and education issues and is well known on this Hill for being a hard working reformer who is committed to good government. A graduate of Harvard University, Mr. Langevin overcame a very serious physical challenge in his teens which left him paralyzed. Instead of allowing his disability to obstruct him from pursuing his dream of going into law enforcement, it helped inspire him to become a lawmaker. Jim's life is an inspiration to us all.

I also welcome representatives from the Office of Research and Development of VA, including Dr. Nelda Wray, Dr. Mindy Aisen, Dr. John Demakis, Dr. Fred Wright, and Dr. Kevin Dellsperger. Also I welcome the Chairman of the National Association of Veterans' Research and Education Foundations, Dr. Eileen Lennon and Ms. Barbara West. Finally I welcome the Committee's good friend, Dr. Ira Katz, professor of psychiatry and the Director of Geriatric Psychiatry at the University of Pennsylvania, who also serves as director of the Mental Illness Research, Education and Clinical Center of VA's VISN 4 in Philadelphia.

I look forward to hearing testimony from all of our witnesses today, and I look forward to asking questions of those involved, and to working together to ensure that quality medical care is provided to our veterans through the excellent research conducted in our VA medical facilities.

Research Highlights of the Department of Veterans Affairs' Office of Research and Development

Flu shots may also protect the elderly against heart disease and stroke
According to a study of more than 286,000 elderly people conducted at the Minneapolis VA medical center, hospital stays for heart disease and stroke during flu seasons are substantially reduced among those who receive flu shots. Results of the study demonstrate that elderly men and women over the age of 65 who receive a flu shot are protecting themselves against the flu, but also possibly, future cardiac-related illnesses.

Drug combination improves schizophrenia therapy
VA research at the Portland VA medical center reported earlier this year that decreased suffering and shorter hospital stays for schizophrenia patients can result when the anticonvulsive drug divalproex is combined with either of two commonly used antipsychotic drugs, olanzapine and risperidone. According to findings reported in *Neuropsychopharmacology,* patients responded to therapy much better after taking the combined drugs, with no additional side effects. *(Jan 2003)*

'BION' microchips may one day help patients regain muscular control (Multiple sites/work in progress)
VA Rehabilitation Research and Development is collaborating with the Alfred E. Mann Foundation to explore Bionic Neuron (BION) technology — wireless, implantable microchips about the size of a grain of rice that deliver regulated electrical pulses. The BIONs interact with muscles and activate nerves. This cutting-edge therapy could help improve functioning in veterans being treated for motor rehabilitation, bowel and bladder control, swallowing difficulties, and many other conditions. *(Nov. 2002)*

Study finds common knee surgery no better than placebo
Patients with osteoarthritis of the knee who underwent mock arthroscopic surgery were just as likely to report pain relief as those who received the real procedure, according to a VA study published in the *New England Journal of Medicine.* The results, which came out of the Houston VA medical center, challenge the usefulness of a common medical procedure on which Americans spend more than $3 billion each year. The researchers say the findings suggest that the money spent on such surgeries could be put to better use. *(July 2002)*

Quick blood test to diagnose heart failure in ER
In a trial of nearly 1,600 patients in the United States and Europe, a 15-minute blood test enabled emergency-room doctors to correctly diagnose congestive heart failure in 90 percent of cases—without relying on costly, time-consuming tests such as echocardiograms and chest X-rays. The study, led by a VA cardiologist at the San Diego VA medical center, appeared in the *New England Journal of Medicine.* The test, approved by the FDA and already in use in some hospitals, detects elevated levels in the blood of a specific hormone. The hormone is released by the heart ventricles when pressure rises, signaling a failing heart. Congestive heart failure affects nearly 5 million Americans, with more than 500,000 new cases each year. *(July 2002)*

Smaller aneurysms best left alone
Abdominal aortic aneurysms can be deadly if they rupture, but a VA study at the Minneapolis VA medical center found it is better not to correct the problem with surgery unless the aneurysm exceeds a certain size. The hazards of surgery can be the greater threat unless the aneurysm is larger than 5.5 centimeters in diameter, according to findings published in the *New England Journal of Medicine.* The

aorta is a major artery that delivers blood from the heart to internal organs in the lower part of the body. Aneurysms are blood-filled bulges in the weakened wall of the aorta. *(May 2002)*

New study promises safer hormone replacement therapy
VA scientists and colleagues at the Little Rock VA medical center have identified a synthetic compound that reverses bone loss in mice without affecting the reproductive system, as does conventional hormone replacement therapy. Reporting in *Science*, the researchers were the first to demonstrate that synthetic hormones can build bone without harming reproductive organs. The finding may lead to new treatments to prevent osteoporosis for millions of men and women and lead to safer alternatives to hormone treatments that have recently been shown to present greater risks than previously thought. *(October 2002)*

Changing bacteria produce persistent lung infections
Populations of bacteria may be changing constantly in the lungs of patients with chronic obstructive pulmonary disorder (COPD), which affect nearly 15 million people in the United States. VA doctors from the Buffalo VA medical center reported in *The New England Journal of Medicine* that the bacteria altered repeatedly over time, making it difficult for the body's immune system to respond effectively. The findings may explain why patients develop recurring infections and may allow researchers to develop vaccines that can keep pace with the changing strains of bacteria. COPD is the fourth leading cause of death in the United States. *(August 2002)*

Study questions widespread prescribing of diabetic footwear
Medicare pays for therapeutic footwear for thousands of people with diabetes each year. But VA researchers and colleagues from the Seattle VA medical center reported in the *Journal of the American Medical Association* that for many patients, ordinary good-quality shoes may work just as well to prevent foot ulcers. The study randomized patients with diabetes and a prior foot ulcer into three groups. One group wore extra-depth shoes with customized cork inserts. A second group wore therapeutic shoes with non-custom polyurethane inserts. The third group served as controls and wore their own shoes. After two years, ulcer rates were about the same in all three groups. The study did not include patients with special problems who may in fact benefit from custom-made footwear. *(May 2002)*

'Hunger hormone' may be key in weight loss
Gastric bypass surgery seems to achieve long-term weight loss when other methods fail. The reason for the difference may hinge on a recently discovered appetite-stimulating hormone, according to a VA-led study that appeared in the *New England Journal of Medicine*. The researchers at the Seattle VA medical center found dramatic differences in the levels of "ghrelin," a hormone secreted by the stomach, in blood samples from dieters and gastric-bypass patients. The new findings may explain why keeping off excess weight through dieting, exercise or even medication is often a constant uphill battle, whereas obese patients who lose up to 200 pounds or more through gastric bypass surgery tend to keep off the pounds permanently. *(May 2002)*

First oral drug to treat smallpox infection
VA researchers from San Diego are leading a team that developed an oral drug that halts the deadly action of smallpox and related viruses in lab tissue-culture cells and mice. The drug is now undergoing evaluation for use in humans. Researchers announced their discovery at the 15th International Conference on Antiviral Research in Prague. *(March 2002)*

CIRO RODRIGUEZ
DEMOCRATIC RANKING MEMBER
HEALTH SUBCOMMITTEE
COMMITTEE ON VETERANS AFFAIRS

MEDICAL AND PROSTHETIC RESEARCH PROGRAMS IN THE DEPARTMENT OF VETERANS AFFAIRS
Statement for the Record

APRIL 10, 2003

Good afternoon, Mr. Chairman. Thank you for holding this important hearing.

Research is a vital mission within VA that serves veterans as well as other Americans. But not only is research important in advancing clinical care, it is integral to our partnership with the Nation's medical schools and as an important recruitment and retention tool for health care providers in a highly competitive workforce market.

I want to welcome Dr. Nelda Wray, a fellow Texan with years of experience as a VA researcher, who will tell us about the many accomplishments of the VA medical and prosthetic research program over the years. I was particularly impressed by a recent article written by Dr. Wray identifying Racial and Ethnic Disparities in Healthcare as a priority for VA Research. I have a special interest in populations that are traditionally underserved by our nation's health care system. I might note that along with its many other research achievements, the San Antonio VA Medical Center operates a Mexican American Medical Treatment Effectiveness Research Center.

I am proud that San Antonio is a major VA research facility. It is currently involved in more than 500 research projects and has made significant strides in areas including aging, renal disease, diabetes, cancer and HIV/AIDS. I am looking forward to hearing from Dr. Lennon about the value of the research foundations. In San Antonio, the Biomedical Research Foundation of South Texas has been operating for more than a decade and research has benefited greatly from it.

I am concerned that a change in allocating medical support funding announced in the FY 04 budget has the potential of shortchanging San

Antonio and other research-intensive facilities, particularly if they're involved in a great deal of research that is not directly funded by VA. The National Institutes of Health, a major grant provider, does not provide any medical support funding to VA for its grants and VA does not completely fill this void—we must do something about this. There are many unanswered questions about how this change in funding researchers for their support costs will occur. I will be listening to our researchers in San Antonio and elsewhere in the field to hear if they believe they are being adequately supported.

Dr. Wray, I understand you are new to this position. I also appreciate the fact that you have already shown your willingness to take on some bold initiatives. I am curious about your thoughts regarding the changes proposed for the research support funding. In addition, I read the Washington Post article that discussed the "stand down" you have ordered for human subjects research. I know there were a few sensational events that precipitated this action—all of which occurred before your tenure began I might add—but, I want to know if you are now confident that there is an adequate oversight infrastructure at VA to support your efforts.

Finally, I am concerned about rumors I have heard that VA may have decided to pull back funding that was already committed to researchers through a peer-reviewed process. I want to understand if this is true and, if so, why this somewhat extraordinary step was taken.

The story of VA Research is mostly a happy one and I believe that VA is poised to keep making positive contributions to the health of veterans and all Americans. With troops once again on the battlefield, I am pleased VA has established the basis for research that may assist them as they, God willing, return to us safely.

I am pleased to have all of our witnesses here today and I look forward to your testimony.

PREPARED STATEMENT OF CONGRESSMAN GUTIERREZ

I thank Chairman Simmons and Ranking Member Rodriguez for holding this important hearing today. The research the VA conducts has been and will continue to be of great importance to the health care of deserving veterans.

I know that in the Chicago area, for example, Hines VA Hospital, North Chicago VA Medical Center, and local schools of medicine have a long and illustrious history of conducting research that has been of tremendous benefit to veterans and the entire population of the United States. VA has become a world leader in such research areas as aging, women veterans' health concerns, spinal cord injury, AIDS, post-traumatic stress disorder and assistive medical devices like the pacemaker and MRI.

Let us make no mistake, however. VA's revolutionary medical advances and stellar research program will be a thing of the past without proper funding. I am proud to have played a role with the help of my colleagues in acquiring almost $50 million in additional appropriations in the last Congress (FY02 and 03) for medical and prosthetic research. Last year, we secured an additional $29 million in funds for Fiscal Year 2003.

For the record, let me also say that the Administration's Fiscal Year 2004 request for a 2 percent increase in medical and prosthetic research is paltry at best. It is a bit disingenuous to boast about VA medical research and then not back up it up with actions to insure adequate funding.

Nevertheless, I continue to be extremely proud of the Committee on Veterans' Affairs and this Subcommittee for our unwavering and active support of the VA's research programs. I look forward to working together again this year to secure an additional $60 million dollars to fund medical and prosthetic research.

As we move forward in our efforts, let us be mindful of veterans themselves, whose health services should in no way be jeopardized—and in every way improved—by the very important innovations and advances of VA research.

I extend my appreciation to the panelists for being here today and look forward to their testimony. Thank you.

CONGRESSMAN JAMES LANGEVIN
TESTIMONY FOR THE COMMITTEE ON VETERANS AFFAIRS
SUBCOMMITTEE ON HEALTH
Oversight hearing on medical and prosthetic research programs in the Department of Veterans Affairs
April 10, 2003

I would like to thank Chairman Simmons, Ranking Member Rodriguez, and the entire Subcommittee on Health for convening today's hearing on biomedical research programs in the Department of Veterans Affairs. The contributions made by the Department of Veterans Affairs to medical research are substantial, high caliber, and incredibly far reaching. I want to commend VA's Rehabilitation Research and Development Services for their dedication to improving the quality of life for impaired and disabled veterans, and the nation as a whole.

The VA has shown true leadership in forming partnerships with universities and other federal agencies to ensure their research reaches veterans and others who might benefit worldwide. Recently, a project initiated by the VA in collaboration with NIH led to the development of a diaphragm pacing system. This generated national news when my friend Christopher Reeve underwent surgery to implant electrodes to stimulate muscles in his diaphragm, allowing him to breathe without a ventilator for up to 15 minutes at a time. Electrode research has the potential to tremendously benefit persons living with paralysis – not only in the area of breathing, but to prevent pressure sores, support standing and transfer after spinal cord injury and to improve walking following stroke. As a person living with spinal cord injury, I know firsthand the difference such research can make in the quality of life for an individual.

That particular project received a good deal of media coverage, but it should be noted that the VA is engaged in many more cutting edge projects happening behind the scenes. Investigators are studying the use of anabolic pharmaceuticals, including anabolic steroids, to treat secondary disabilities of spinal cord injury. Spinal cord injury, which affects more than 40,000 veterans nationwide, often is associated with problems related to muscular function, breathing, and cardiovascular health. The innovative methods being developed in the Rehabilitation Research & Development's Centers of Excellence are making a real difference in the quality of life of impaired and disabled veterans. In the process they are reaching people all over the world – the VA researchers are breaking new ground in the areas of osteoperosis, lung injury and Chronic Obstructive Pulmonary Disease. They are internationally recognized leaders in HIV/AIDS research, and making important advances in the studies of prostate cancer. Indeed, this research will benefit all of us.

I also want to highlight the success the VA has had in rehabilitation and employment services for veterans. Since my arrival in Congress, I have worked to bring attention to the issues of unemployment and underemployment in the disability community. There is an unemployment rate of 70% in the disability community, and this is a population that wants to work. With some basic supports, it can be done – the VA has shown this by providing the supports to service-connected disabled veterans from vocational counseling and service-members and veterans who have recently separated from active duty. This assistance can mean the difference between a life spent in isolation and a life spent actively participating in one's community – or to look at it another way, a life spent receiving government assistance and a life spent in meaningful employment. I look forward to continued work with the VA on their vocational education counseling programs – we have much to learn from them.

From their approved rehabilitation research projects, through evaluation and technology transfer to final clinical application, the VA has truly managed to attract the brightest minds from academia, industry, and medicine. Their commitment to finding research solutions to the needs of veterans with disabilities will benefit all Americans. I thank the Chairman for the opportunity to acknowledge these critical programs and look forward to our continued work together.

Statement
of
Nelda P. Wray, M.D., M.P.H.
Chief Research and Development Officer
Department of Veterans Affairs
On
Medical and Prosthetic Research Programs in the Department of Veterans Affairs
before the
Subcommittee on Health
of the
Committee on Veterans' Affairs
U.S. House of Representatives

April 10, 2003

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Mr. Chairman and Members of the Subcommittee, I truly appreciate the opportunity to appear before you today to discuss the Department of Veterans Affairs (VA) medical and prosthetic research program.

After having spent three months as VA's chief research and development officer, I can honestly say that I remain just as excited today as I was in January about this once-in-a-lifetime opportunity to lead such a distinguished program. One of my first activities was to work with the Office of Research and Development (ORD) to establish a new vision: *Today's VA research leading tomorrow's health care.*

To achieve it, not only must we expand the VA research portfolio and continue to conduct laboratory studies that ask fundamental questions about disease, but also we must expand our research efforts in two other areas.

We must expand our clinical research portfolio to include issues that directly affect clinical practice, with an emphasis on research that provides knowledge for the practice of evidence-based medicine. In addition to increasing funding for clinical research studies, we will develop a new initiative to dramatically increase our clinical research capacity.

However, as the Institute of Medicine report "Crossing the Quality Chasm" documents, the development of information through research does not necessarily mean that such information is applied at the bedside. Therefore, ORD will expand research designed to identify the barriers to the rapid translation of research into clinical practice and to study new organizational structures with the potential to remove those barriers.

By expanding our portfolio in such ways, I am confident that VA's research program will be at the forefront of tomorrow's health care. And what a research program it has been. VA's medical and prosthetic research program has produced three Nobel Prize winners, pioneered tuberculosis treatment, developed the cardiac pacemaker, created the Seattle Foot, and conducted the first successful drug treatments for high blood pressure and schizophrenia, and VA investigators continue their leadership in medical and prosthetic research. Let me cite several recent and exciting developments.

Chairman Smith responded to the homeland defense challenge by championing the "Department of Veterans Affairs Emergency Preparedness Act of 2002." ORD has also responded by soliciting and funding new research on emerging pathogens and bio-terrorism. Our primary areas of concern are vaccine development, bacteria, and DNA-based vaccination strategies. The reaction of VA investigators has been highly gratifying; in just a short time, their efforts have resulted in many critical discoveries. I would like to share one with you today.

Researchers at the San Diego VA Medical Center, in collaboration with scientists at the U.S. Army Medical Research Institute for Infectious Disease, have developed an oral drug that halts the deadly action of smallpox in infected mice. The drug blocks the activity of a variety of smallpox virus strains by halting their ability to replicate and to spread. We will work extremely hard to confirm those results in other animals and to get the oral drug approved for use in humans. As I'm sure you all understand, the potential for developing an oral smallpox treatment in humans would be a major discovery.

And while we here in the U.S. tackle difficult homeland security issues, the brave men and women of our military wage a much more difficult war overseas. I know that the thoughts and prayers of everyone in this room are with our brave soldiers in Iraq. Combat operations there and elsewhere underscore VA's critical mission of treating the Nation's veterans for any injury, be it bullet or environmental hazard that causes them harm. In addition to its significant studies into deployment-related health issues, VA, together with the Departments of Defense (DoD) and Health and Human Services, has invested almost a quarter of a billion dollars to fund research projects dedicated to deciphering the numerous undiagnosed symptoms related to Gulf War veterans' illnesses.

The results of a recently concluded trial offer hope to some veterans. That exciting study, which received significant media attention, revealed that Gulf War-era veterans who had unexplained chronic medical symptoms such as pain, fatigue, and cognitive difficulties experienced a statistically significant improvement in their symptoms when

treated with a combination of aerobic and cognitive behavior therapy. While not everyone in the study was helped, the discovery is a major step in helping Gulf War veterans with unexplained illnesses.

Additionally, VA continues to lead the way in treating Post-Traumatic Stress Disorder, or PTSD. Studies have shown that PTSD is a major complication of war, and studies of the Gulf War in particular have shown that women service members are susceptible to the disorder. VA is currently conducting a multimillion-dollar clinical trial to understand the determinants of that disease and explore effective therapies. The $5 million clinical trial will be conducted in collaboration with DoD and will assess two interventions for women veterans with PTSD who have been exposed to war-related or non-war related traumatic events. That trial is the largest of its type for women veterans, one of the two fastest growing segments of the veteran population.

The devastating news that several of our brave service members lost lower limbs as a result of combat operations in Iraq has greatly saddened all of us. The challenges that await those brave Americans are formidable. However, VA will ensure that those service members' lives are returned to normal as soon as possible by providing them the best prosthetic care available. Ongoing VA research promises to make more normal lives for our veterans a reality and not just a dream.

And, although VA has made incredible contributions to the lives of amputees, we will not rest on our laurels. Limitations to ambulation still remain, as does damage that occurs at the site of the prosthesis. VA stands at the forefront of osseointegration research in America. That procedure involves integrating a prosthetic device with a patient's natural bone. Osseointegration promises to increase the strength of the bone-prosthesis interface while reducing healing and recovery times.

Investigators at the San Diego VA Medical Center VA are studying this technique in the laboratory to answer fundamental questions about safety and infection rate. Another VA researcher has studied osseointegration surgical techniques and is prepared to use the procedure once it receives FDA approval. Amputees who have had successful experiences with the procedure report that they have greater comfort, a more natural gait, and fewer complications. Just last week I traveled to VA's 2003 Winter Sports Clinic in Colorado; I watched in inspired amazement as amputees skied downhill, and I can tell you that it was a truly gratifying experience.

More recently, VA developed technology that enabled actor Christopher Reeve to regain the ability to breathe on his own for limited periods. Severe spinal cord injuries block the brain signals that normally stimulate the nerves in the diaphragm necessary for breathing. When that happens, paralyzed patients must rely on mechanical

ventilators. VA investigators discovered a method of electrically stimulating the phrenic nerves in the diaphragm muscle to restore more natural breathing.

Mr. Reeve is only the third patient to have received the new procedure, and it will take months before we know for sure whether it will work as hoped. While Mr. Reeve can breathe on his own for only limited periods of time, his volunteer efforts already have helped researchers in their efforts to restore motor movement to thousands of veterans and Americans.

The restoration of motor function also remains a top priority for ORD. Pioneering efforts in functional electrical stimulation at the Cleveland VA Medical Center have led to FDA approval of a hand grasp system and commencement of clinical trials of an advanced bladder/bowel management system.

VA also continues to address the challenges of an increasingly older veterans population. Investigators are conducting myriad projects to improve the quality of life of our senior veterans, including the development of a shingles vaccine, prevention of falls and other injuries, and the use of folate and B-vitamins to lessen cardiovascular disease. Also noteworthy is VA's diabetes portfolio. That integrated research effort will improve glucose control, reduce blindness, and preserve the limbs of the elderly.

As I mentioned earlier, the science that our research produces can only benefit veterans if we put that science into practice. It can take years, however, before research results are turned into practical clinical tools that directly improve the quality of health care. We in ORD believe that that is simply too long. VA is the leader in trying to understand the barriers and impediments to the rapid translation of research into clinical practice. In 1998, ORD established the Quality Enhanced Research Initiative, or QuERI, to identify the best practices for getting research findings from the bench to the bedside. QuERI focuses on eight priority conditions, including mental health, spinal cord injury, chronic heart failure, ischemic heart disease, diabetes, substance abuse, colorectal cancer, and HIV/AIDS.

As you can see, this is an extremely exciting time for VA research. We truly are on our way to building the greatest health care research program in the country!

Mr. Chairman, this concludes my statement. I will now be happy to answer any questions that you and other members of the Subcommittee might have.

Testimony

Before the

Subcommittee on Health

Of the

Committee on Veterans Affairs

Regarding the

VA-Affiliated Nonprofit Research and

Education Corporations

April 10, 2003

Presented by

Eileen Lennon, Ph.D.

Chair

National Association of Veterans'

Research and Education Foundations (NAVREF)

Good afternoon, Mr. Chairman and members of the Subcommittee on Health of the Committee on Veterans Affairs. Thank you for the opportunity to present testimony on the VA-affiliated nonprofit research and education corporations. I am Eileen Lennon, Ph.D., executive director of the Seattle Institute for Biomedical and Clinical Research (SIBCR) and chair of the National Association of Veterans' Research and Education Foundations (NAVREF). NAVREF is the membership association of the VA-affiliated nonprofit research and education corporations. Its mission is to promote the interests of the VA nonprofits, and it does so through programs of education and advocacy. SIBCR is a member of NAVREF.

Background about the VA-Affiliated Nonprofits

Since 1988 when Congress passed the authorizing legislation, eighty-eight VA medical centers have established nonprofit research and education corporations. The statutory purpose of the nonprofits is to provide a flexible funding mechanism for the conduct of VA-approved research and education at the medical center. Each one is an independent, state-chartered 501(c)(3) organization. As mandated by Congress, senior facility executives serve on the board, and their officers, directors and employees are subject to federal regulations pertaining to conflicts of interest. Records of the nonprofits are available to the DVA Secretary, the Inspector General and the Comptroller General at any time. All research administered by the nonprofits must be VA approved and is subject to VA oversight and regulation.

While maintaining a close relationship with VA, Congress clearly intended for the nonprofits to be private sector organizations that are separate and different from VA. The nonprofits are a vehicle to accomplish objectives over and above what the VA can do itself, such as accepting and administering private sector and non-VA federal funds in support of research. The nonprofits can respond rapidly to the changing needs of research programs. However, the most important advantages of the nonprofits are that they bring additional resources to the VA research program, their expenditures benefit the research programs at their affiliated medical centers and they are flexible.

In reports submitted to VA in June 2002, the nonprofits reported total revenues of nearly $180 million supporting 4,700 research projects. While most of this funding was derived from private sector grants from pharmaceutical companies and other nonprofits, $57 million came from other federal agencies, including NIH, CDC and DOD. Federal funding is the fastest growing component of nonprofit revenues as more nonprofits begin assuming responsibility for administering NIH and other federal grants on behalf of VA investigators. Revenues from indirect cost rates associated with these federal grants benefit VA to an extent not possible when the grants are provided to affiliated universities, who generally do not provide resources from these funds to their affiliated VA.

In testimony presented before the Subcommittee on Oversight and Investigations last year, NAVREF discussed specific examples of how nonprofit expenditures benefit facility research programs. Appendix A of this statement provides current examples of nonprofit support for facility compliance programs to demonstrate the nonprofits' commitment to this important aspect of research. Because time is short, I will only discuss what SIBCR does to support the VA Puget Sound Health Care System in Seattle.

SIBCR administers funds related to about 20% of the 476 active projects at VA Puget Sound. These projects are funded by other nonprofit and voluntary health organizations as well as industry sources. SIBCR provides significant support to the projects it administers. This support includes hiring staff, payroll and benefits administration, negotiations with sponsors, preparing grant submissions, accounting and financial reporting, buying supplies and equipment and paying for the direct costs of the research, including clinical study services provided by the VA.

In addition to these functions, the SIBCR Board has approved support to the VA Puget Sound Health Care System Research and Development program including:

- Up to $50,000 per year to provide bridge and development funding to VA investigators who are between grants. As a result of the SIBCR funding, investigators are better able to submit competitive research proposals to VA or other funding sources.

- At an annual cost of over $100,000, provides 2.5 FTE for support of the research and development program including research administration and compliance management.
- With VA, co-funded the start up of a unit to support clinical research. This clinical research unit has 2.4 FTEs, including a nurse practitioner, a nurse and a research associate, to provide support to clinical research projects. The costs are defrayed from direct project charges, but SIBCR still covers over $50,000 a year in salary support.
- Annually, provides each VA funded investigator with a $500 allotment for travel. In view of the scarcity of VA travel funding, these small grants allow investigators to stay current in research in their fields by attending scientific meetings and presenting results of VA and non-profit funded research, all of which is approved by VA and relevant to veterans.

The pharmaceutical studies that SIBCR administers provide important benefits to veterans. For example, SIBCR is administering studies involving an approved new antibiotic known to be effective against antibiotic-resistant organisms. This drug costs $85-95 per day and is not on the VA formulary. But by participating in studies, our clinician-investigators obtain it for their patients at no charge to VA. Our studies are showing that the drug is an effective treatment for catheter infections, pneumonia and limb-threatening diabetic foot infections, all problems among the veteran population. Further, the drug can be taken orally so there is no need for hospitalization or complex IV therapy. As a result of these studies, veterans get an expensive drug at no cost, cutting edge treatment for their condition, and they benefit from the extra care provided by the nurse who was hired by SIBCR to help the physician run the study.

A second example was supported in part by SIBCR funds. A physician who works closely with a group of African-American Vietnam Veterans was drawn into the serious problem of Post Traumatic Stress Disorder (PTSD) nightmares and sleep disturbance. Many of the veterans had not slept through the night in years with a negative impact on their ability to hold a job and interact socially. The physician speculated that if he reduced the excess brain adrenaline response, it might prevent the PTSD nightmares. He obtained VA approval and tried a generic drug that has been used for years to treat high blood pressure and costs only $1 for 3 months treatment. It is safe and effective, and best of all, he found that it stopped the PTSD nightmares so the veterans slept better and improved their quality of life. SIBCR funds helped fund this pilot

research and now this project is funded with a VA merit award. This continues to be an exciting research endeavor applicable to all veterans suffering from PTSD as well as the many civilians who have had a traumatizing event precipitating PTSD.

2002 Oversight Hearings and GAO and IG Site Visits

Last year the VA-affiliated nonprofits were the subject of two hearings conducted by the Subcommittee on Oversight and Investigations. The first was a routine oversight hearing in May. I wish to emphasize that there was no precipitating event for this hearing. Unfortunately, misunderstandings about the functions of the nonprofits and their required reporting to VHA resulted in the subcommittee concluding that VA was not collecting sufficient information about the nonprofits. The subcommittee also determined that no one in VA was routinely looking critically at the information that was available. As a result, the IG and GAO were asked to investigate the nonprofits and to report their findings at a subsequent hearing.

During the summer of 2002, the GAO and IG audited 7 of the nonprofits and presented testimony before the Subcommittee on Oversight in September. Overall, the findings by both the IG and the GAO were supportive of the nonprofits. The GAO recognized that the nonprofits are integral to the VA research mission and that the growth of the nonprofits is directly related to a significant benefit to veterans. The GAO reported that "...expenditures were related to research or to running the nonprofit corporations and were consistent with its internal control procedures." The IG stated that "nothing came to our attention indicating that controls over expenditure and fund usage at these facilities were inadequate." Both acknowledged that the nonprofits provide significant benefit to VA research and validated that the nonprofits were fulfilling their intended statutory mission.

Response to GAO and IG Recommendations

In their testimony, both the IG and GAO recommended ways to increase collection of data about the nonprofits and to improve accountability. I will use the remainder of my time to address measures that are being taken to meet these objectives, and to provide our own

recommendations. NAVREF is committed to promoting the highest standards of fiscal and operational management of the nonprofit research and education corporations, and has participated fully in the development of these measures.

1. **Consistent with one of the IG's recommendations, NAVREF supported establishment of a new VA Nonprofit Program Office within VHA and the Office of Research and Development (ORD).** At ORD's invitation, NAVREF participated in discussions that helped shape the role and staffing of this office. We anticipate that the office will provide a degree of routine oversight by VHA that has been absent to date. We hope that this office also will work with NAVREF to be proactive in ensuring that VHA policies incorporate the nonprofits when appropriate, in communicating essential information that may not otherwise reach the executive directors, in assisting individual nonprofits in dealings with ORD, and in developing national solutions to common problems.

2. **Consistent with IG and GAO recommendations, and the objective of legislation that ultimately was not enacted by the 107th Congress, NAVREF supports improved accountability by the nonprofits.** While we had concerns about many of the specific IG recommendations and some provisions of this bill, last year we worked diligently with staff of this subcommittee and the Office of Research and Development to develop alternatives that would provide both VA and Congress with more meaningful information and an appreciable improvement in oversight. At the same time, our aim was to ensure that new requirements do not duplicate or conflict with standards already imposed on nonprofits by the Internal Revenue Service, the Federal Accounting Standards Board, the Office of Management and Budget and other federal, state and local oversight organizations. It is our understanding that new legislation will be introduced by this subcommittee next month that will contain mutually agreeable improvements in accountability including:

   - Requiring all nonprofits with revenues over $300,000 to undergo an annual audit in accordance with Generally Accepted Government Auditing Standards (GAGAS). Although this may double the cost of some nonprofits' audits, in our view the increased

scrutiny provided by a GAGAS audit, particularly in reviewing internal controls, justifies the additional expense.

- Developing a more meaningful annual report to VA and Congress. While the current report provides standardized financial information largely drawn from the IRS Form 990 each nonprofit must submit, it does not provide sufficient detail about nonprofit operations, and particularly fails to capture the many ways the nonprofits support facility research programs.
- Requiring the Inspector General to review annually 10% of the nonprofits' annual reports to VA.

That said, we will continue to recommend against imposing on the VA- affiliated nonprofits management and accounting practices not required of other US nonprofits. For example, VA nonprofits must retain the right to select their own fiscal year, methods of accounting (cash or accrual), accounting software and chart of accounts. In our view, efforts to make the nonprofits more like the government will undermine their statutory purpose as flexible funding mechanisms and the clear intent of Congress that they should be different and separate from the government. As stated in the authorizing legislation, the VA-affiliated nonprofits are "required to comply only with those Federal laws, regulations and executive orders and directives which apply generally to private nonprofit corporations" [38 USC 7361(a)].

3. **Also consistent with the recommendations of the *IG and GAO*, NAVREF supports improved reporting by the nonprofits and increased data collection by VA.** Current reporting is largely financial and fails to capture a true picture of the nonprofits and their value to VA. We have suggested that a more meaningful annual report is needed and have offered to work with the VA Nonprofit Program Office to develop a template. In addition, we have encouraged VA to collect from the IRS Form 990s submitted by the nonprofits the wealth of information that is not captured currently. At the same time, we recommend keeping the statutory reporting requirements to a minimum. Section 7366(a)(1)(A) of the nonprofit authorizing statute specifies that the records of a nonprofit shall be available to the Secretary. Consequently, additional statutory requirements for specific financial information

do not seem to be needed. The nonprofits are prepared to respond promptly to virtually any inquiry about their finances, if provided with reasonable response time to accumulate the data and assuming that the request does not entail undue cost and time commitments.

4. **Consistent with the IG's recommendation, NAVREF supports improved guidance to define research expenditures**. Although we were unaware of any confusion in this regard, we have no objection to clear guidance and have provided ORD with draft text that we suggest incorporating in the next version of Handbook 1200.17, the VA policy manual for the nonprofits. Our suggested wording goes further than the IG recommendation in that it also includes specific guidance on documenting the research relatedness of nonprofit expenditures.

NAVREF's Training and Standards Setting Initiatives

At the next meeting of the board of directors, NAVREF will continue its ongoing review of our mission as a forum for promoting the highest nonprofit management standards and ensuring that we provide outstanding educational programs to our members. The programs currently include:

- An annual conference that provides two days of training in nonprofit management that is specifically tailored for the staff of the VA-affiliated nonprofits;
- A second conference with two days devoted to a single operational topic such as human resource management or accounting;
- Best Practices Consultations designed to promote peer-to-peer sharing of "best practices" in nonprofit management conducted on site by experienced executive directors and NAVREF staff; and
- A new web based Best Practices Program that when complete, will provide comprehensive guidance on virtually all aspects on nonprofit management, with particular emphasis on compliance with VA policies.

During this same meeting, the board will also explore new educational initiatives, possibly involving "distance learning" opportunities over the Internet or during moderated conference

calls. And we look forward to re-scheduling the board training session we had planned to hold for hospital directors and chiefs of staff in conjunction with the VA Senior Management Conference.

Conclusion

I would like to conclude with three final NAVREF recommendations.

1. **We respectfully encourage this subcommittee to move forward on two legislative requests submitted by NAVREF.** The first would encode VA's intent that nonprofit employees with VA without compensation appointments shall be provided with protection against personal liability under the Federal Tort Claims Act. Due to a ruling by the Department of Justice such coverage is uncertain so a statutory clarification is required. The second would improve the effectiveness of the nonprofits by providing VA with a mechanism to use VA-appropriated funds to pay for services provided by nonprofits in support of VA research and education. NAVREF has no preference as to whether the solution is "contract" or "reimbursement" authority. We ask only that it serve the intended purpose and involve rigorous VA review and approval of all transactions. It has been our pleasure to work with subcommittee staff to develop these initiatives, and we request enactment this year.

2. **In our view, the Nonprofit Program Office staff should be strengthened by the addition of a full time VA attorney dedicated to nonprofit matters.** It is our understanding that ORD supports this step and has agreed to fund the necessary FTE.

3. **We encourage ORD and the Office of Academic Affiliations (OAA) to explore consolidating their respective data collection responsibilities within the VA Nonprofit Program Office.** In our view, it would be more efficient to make a single office responsible for collecting both research and education information and compiling a single, consistent report to Congress.

During the fifteen years since their inception, the nonprofits have become an integral and increasingly significant component of the VA research program. Many field personnel view the nonprofits as the best thing that ever happened to VA research, and we thank Congress for its foresight in authorizing them. However, as the GAO pointed out in spoken testimony last September, with growth comes increased potential for risk. While we fully appreciate the importance of accountability and oversight, we want to ensure that the nonprofits retain the flexibility necessary to perform the mission for which you established them. We appreciate that both this subcommittee and the VA have included individual nonprofits and NAVREF in deliberations over improvements and we look forward to continuing this working relationship.

Thank you for considering our views. I would be pleased to answer your questions.

Appendix A

Selected Examples of NPC Support for VA Research Compliance

Following are selected examples of NPC funds used in support of VA research compliance programs including support for VA R&D Committees and Institutional Review Boards (IRBs) as well as bio-safety and animal oversight programs. In many cases, these contributions are just a portion of total dollars donated in support of research at affiliated VA medical centers. Additional examples of NPC support for facility research programs include, but are not limited to salary support for research or animal staff, research and office equipment and maintenance costs, travel and meeting costs for research principal investigators and staff, publications, educational seminars, renovation of out-of date VA laboratory space, bridge funding, security, and young investigator grants.

Bronx Veterans' Medical Foundation, Inc. (NY): Provides salary support for two compliance officers, the IRB chair, and a secretary for the ACOS for Research and Development. Total Support: $167,000

McGuire Research Institute, Inc. (VA): Provides salary support for Human Research Protections Program (HRPP) staff, IRB members and Investigational Pharmacy. MRI also provides support for HRPP training, equipment, renovations, supplies, vendor costs and other miscellaneous expenses. Total Support: $697,100

Veterans Research Foundation of Pittsburgh (PA): Provides salary support for IRB staff and supports cost of IRB member honorariums. VRFP also provides support to HRPP through training, conference registration and education materials. Total Support: $67,100

The Bay Pines Foundation, Inc. (FL): Supported an IRB regulatory requirements seminar and HRPP training by paying for registrations and travel expenses. Total Support: $70,500

Brentwood Biomedical Research Institute (CA): Provides salary support for IRB staff and pharmacists. BBRI also supports VA research compliance by paying for travel, tuition and stipends for IRB and IACUC staff; volunteer and community members of the IRB and animal committees as well as salary for one full-time Clinical Research Center (CRC) coordinator: Total Support: $422,500

Tuscaloosa Research and Education Advancement Corporation (AL): Provided salary support to the VA IRB and R&D programs. In addition, TREAC recognizes the importance of current compliance information and therefore supported IRB staff and the committee chairman to attend the VA Day at the Public Responsibility in Medicine & Research and the Applied Research Ethics National Association conferences. Total Support: $43,600.

East Bay Institute for Research and Education, Inc. (CA): Paid HRPP salary expenses and loaned EBIRE employees to meet the immediate needs of the R&D office. EBIRE also contributes to the VA research program by absorbing administrative costs for employees. Total Support: $122,000.

Palo Alto Institute for Research and Education, Inc. (CA): Over the past two years PAIRE has contributed more than $150,000 for the development of a web based research application and management system to assist the R&D committee and subcommittees.

Baltimore Research and Education Foundation (MD): Provided funding for compliance costs for clinical studies and animal studies through support of IRB and IACUC expenses, consent form scanning into electronic media record and salary support for a quality assurance nurse. Total Support $153,900

STATEMENT OF IRA R. KATZ, M.D., PH.D.

Testimony before the US House of Representatives

Committee on Veterans' Affairs

Subcommitttee on Health

April 10, 2003

Mr. Chairman and Members of the Subcommittee:

I am Ira Katz, Professor of Psychiatry at the University of Pennsylvania and Director of the VISN 4 MIRECC. I am speaking today in my role as a member of the University of Pennsylvania faculty with expertise in clinical care, research, and teaching in psychiatry. However, I want to focus my remarks today on the VA's Mental Illness Research Education and Clinical Centers or MIRECCs.

Today, while our country is fighting in Iraq, it is important to remember that the wounds of combat affect the mind, brain, and spirit as well as the body and that, for today's heroes as well as yesterday's, stress-related conditions like post-traumatic stress disorder (PTSD) and depression can be among the most chronic and disabling of illnesses, Moreover, mental disorders such as PTSD and depression are common complications of injuries of all types, and they often represent significant barriers to rehabilitation and recovery as well as sources of suffering. These and related issues constitute the ongoing work of the MIRECCs.

The concept of the MIRECCs was derived from the Geriatric Research Education and Clinical Center (GRECC) program. In developing the model, the idea of translating from the field of aging to mental health was supported by recognition of the extraordinary activities of the National Center for PTSD. The MIRECC concept received growing support for a decade before they were authorized by the 104th Congress in Public Law 104-262 that created them to provide an intellectual infrastructure for the VA's mental health programs,

and to provide a mechanism for innovation. The first three MIRECC's were first funded in 1997, the second three in 1998, and the third set of two in 1999. Each became operational the following year.

According to 38 USC Sec 7320 (a) and (b), the purpose of the MIRECCs is to improve the provision of health care for veterans with mental illness (especially service-related disorders) through research, education, and improved clinical models. The goal of the MIRECC program is to generate new knowledge about the causes and treatments of mental disorders, apply it to model clinical programs, and widely disseminate it through educational outreach programs to improve the quality of veterans' lives and their daily functioning and to assist veterans in recovering from mental illness.

There are currently 8 MIRECCs within the VA, located in VISN 1, 3, 4, 5, 16, 20, 21, and 22. Together the MIRECCs directly serve 8 VISNs and 27 states as well as the District of Columbia. Programmatically, the MIRECCs cover a diverse set of foci, all responsive to the overall goals of the program. Through the impact of their research, education, and information dissemination activities they serve the VA system as a whole, and, in fact, provide leadership in improving mental health care for the nation.

The VA New England Healthcare System MIRECC (from VISN 1 serving the six New England states) focuses on veterans with combined mental illness and drug or alcohol dependence (dual diagnosis), an area that is significant because veterans with dual diagnosis constitute a major part of VA practice. In addition, they have special needs because having two types of illnesses makes it more difficult to recover from either one. The aim is to improve the treatment of dually-diagnosed veterans by developing innovative new treatments, devising more effective ways to deliver existing treatments, and creating better programs to train VA providers in therapies with proven efficacy.

The New York, New Jersey Veterans Healthcare Network MIRECC (from VISN 3 serving the New York metropolitan area, the Hudson Valley, and northern New Jersey) focuses on improving our understanding of the causes of serious mental illness and the development of effective treatments to better assist in the recovery and return of our veterans to the community. This is accomplished through the study of current practice, provider education, service delivery, neurobiology, and psychopharmacologic treatment of serious mental illness.

The Stars and Stripes Network MIRECC (from VISN 4 serving Pennsylvania, southern New Jersey, Delaware, and West Virginia) focuses on issues and problems related to comorbidity, the coexistence of psychiatric illnesses, substance abuse disorders, and/or medical conditions. Comorbidity is the rule rather than the exception in VA patients, in whom coexisting disorders complicate the diagnosis and treatment of individual patients and the operations of the programs and systems that serve their needs. The goal is to develop knowledge and programs to improve care and integrate mental health and general medical care services.

The Capitol Health Care Network MIRECC (from VISN 5 serving Maryland, the District of Columbia, Virginia, and West Virginia) focuses on improving the quality and cost-effectiveness of services for veterans with schizophrenia and their families through research on the nature and treatment of the illness, and education and clinical demonstration projects that promotes the translation of research findings into evidence-based practice. The primary concerns are in the areas of substance abuse, psychopharmacology, neurocognitive factors and rehabilitation, health behaviors, women with schizophrenia, and service delivery systems.

The South Central Network MIRECC (from VISN 16 serving Arkansas, Texas, Louisiana, Mississippi, Oklahoma, and Florida) focuses on "closing the gap" between what research demonstrates is

possible to achieve with mental health treatments and services, and what is actually achieved in day-to-day clinical practice. Its primary concerns are on four patient populations – patients with schizophrenia, PTSD, substance abuse, and the mental disorders of late life. By identifying opportunities to improve treatment adherence, the technical quality of mental health care provided and the service delivery system, this MIRECC aims to optimize the clinical outcomes of the mentally ill veterans that it serves.

The Northwest Network MIRECC (from VISN 20 serving Washington, Oregon, Idaho, and Alaska) focuses on discovering and disseminating new knowledge about the causes and treatments of major mental disorders afflicting veterans. In this, the primary concerns of MIRECC scientists, educators and clinicians are in schizophrenia, posttraumatic stress disorder, agitation and psychosis in Alzheimer's disease, and mental illness complicating chronic medical illness (including post-Gulf War related disorders).

The Sierra Pacific Network MIRECC (from VISN 21 serving California, Nevada, and Hawaii) focuses on veterans with dementias and behavioral problems due to dementia, and veterans with Posttraumatic Stress Disorder (PTSD). The aim of the MIRECC is to improve the treatment of these veterans by working toward better matching of veterans with the types of treatment that will provide them with the best treatment for their own personal situation.

The Desert Pacific Healthcare Network MIRECC (from VISN 22 serving California and Nevada) focuses on improving the long-term functional outcome of patients with chronic psychotic mental disorders, including schizophrenia, schizoaffective disorder and psychotic mood disorders. Each of these illnesses is characterized by psychosis during its most severe periods, and functional impairments that can lead to deterioration in social and vocational adjustment. Each is a chronic illness that usually appears during young adulthood and requires a long-term management strategy that includes pharmacological and psychosocial management.

The focus of each of the MIRECCs was proposed as part of the competitive application process on the basis of the strengths of the investigators, clinicians, and educators, and existing clinical programs, as well as needs, both locally and nationally. The areas of focus provide overlap enough to facilitate collaborations and synergies, but they are distinct enough so that the program as a whole covers a comprehensive range of content areas and methods. The MIRECCs interact extensively with each other, with the National Center for PTSD, and, in many cases with GRECCs and PADRECCs. Other MIRECC activities include service to their own VISNs and to the system as a whole including outreach to other VISNs through training, dissemination of best practices, and consultation. The research activities in MIRECCs are centered around infrastructure support, and pilot or seed support programs to enable the development of new research and new investigators. Thus, in their activities, the MIRECCs have major research enabling and facilitating roles. With the aid of these resources, MIRECC investigators compete for and are awarded research funds to study the complex phenomena of mental illness and brain diseases through the VA, NIH (primarily NIMH, NIAAA, and NIDA), foundations, and other sources. In this way, the MIRECCs leverage their resources, and bring new opportunities for research and program development to the VA and its patients. In addition, each of the MIRECC's have strong roles within their host medical centers, VISN's, and academic affiliates.

One key aspect of the added value that MIRECCS bring to the VA is linkage of research, educational, clinical, and clinical evaluation activities that, in other contexts, are often kept distinct from each other. This occurs in the translation from basic research to treatment development, from treatment development to a progression of clinical and efficacy trials, and from efficacious to effective treatments. The activities distinguish the MIRECC from business as usual with each of the domains in which they function, and serve to fulfill the vision of the authorizing legislation that they will serve as sources of innovation.

The value of the MIRECC's to the VA is best described by providing examples of current and recent activities:

PTSD Research: With the ongoing war in Iraq, we all want to focus on what we be able to do to help those who will be returning from combat. Through its education and information dissemination activities, the National Center for PTSD has been ensuring that evidence-based treatments are available to benefit veterans throughout the system at the same time that its research activities are developing and validating new approaches to care. Within the MIRECCs themselves, work at both VISN 20 and 21 has focused on the role of adrenaline-like transmitters as mediators of stress effects in the brain and has led to the hypothesis that adrenergic-blocking agents should be useful for treating at least some of the symptoms of PTSD. VISN 20 investigators have observed that the alpha-adrenergic blocking drug prazosin shows promise in treating the trauma-related nightmares and sleep disturbances that cause significant suffering and disability in these veterans. Other MIRECC clinicians and investigators have been concerned about the vicious cycle that occurs some people with PTSD turn to street drugs in an attempt to treat themselves. In many settings, the substance abuse can make people ineligible for standard mental health care for PTSD, but, at the same time, the PTSD can make them less able to benefit from substance abuse treatment. To address this problem, clinical investigators from both VISNs 4 and 21 are evaluating Seeking Safety, a novel psychological treatment that allows them to address both conditions. In the conduct of these initiatives, they are both advancing knowledge and providing new hope to many veterans who have had persistent and disabling symptoms. Finally, other research in VISN 21 is underlining the importance of recognizing and treating PTSD through research demonstrating that it can contribute to age-related neurodegeneration.

Cocaine abuse: There are programs of research focusing on substance abuse in several of the MIRECCs. Investigators in VISN 1 have been using genetics to study the problem of cocaine abuse and have found that

genes related to the functioning of dopamine-beta-hydroxylase, an enzyme involved in noradrenaline metabolism, are related to the likelihood that someone who uses cocaine will become drug dependent or experience paranoia. Following these findings, other VISN 1 investigators have been evaluating the effects of the dopamine-beta-hydroxylase inhibitor disulfiram on relapse rates after cocaine withdrawal, and have observed early positive and promising findings. Following a different line of research, investigators from VISN 4 have been studying the craving that occurs when people who were previously cocaine dependent are exposed to the sights and sounds that were associated with drug abuse. Not only do the cues induce the psychological symptoms of craving, they also induce related changes in brain activity that can be demonstrated with neuroimaging techniques. Having demonstrated that they can measure cue induced craving, both psychologically and through brain imaging, they then used these techniques to screen medications to evaluate which ones might be worth clinical studies to see if they could have enough of an effect on craving to be prevent relapse. So far, they have found that the drug baclofen, an analog of the neurotransmitter GABA shows promise.

Other investigators in VISNs 3 and 4 have been concerned about cocaine abuse as a complication and comorbidity of schizophrenia and have been evaluating approaches to combined treatment.

Alcoholism: The development of naltrexone as a treatment to prevent relapse in abstinent people with alcoholism was a significant contribution of VA investigators in Philadelphia and West Haven, from the time before the implementation of the MIRECCs at those sites. Although the effectiveness of naltrexone has been demonstrated in a number of studies, a recent large scale VA cooperative study did not find drug-placebo differences. However, this puzzling variability in responses may be related to evolving findings from MIRECC investigators from VISNs 1 and 4 who studied the genetics of the response to naltrexone, and observed that variability in brain receptors appear to have a major impact on whether or not naltrexone

prevents relapse. The next steps, currently being pursued, are to determine whether genetic tests can identify those who would benefit from naltrexone and those who should be receive other treatments.

Schizophrenia: There are a number of MIRECC activities that show promise toward advancing the care of veterans with schizophrenia and related disorders. One set of activities is approaching schizophrenia as a cognitive disorder. It is evaluating basic neural mechanisms in laboratory animals that advance the understanding of the neural pathways that are affected by schizophrenia and drug treatment, the value of basing rehabilitation on an understanding of the cognitive deficits associated with the disorder, and the importance of provider education on the ability to deliver effective rehabilitation in real world settings. In pursuing these areas, the MIRECCs in VISNs 3, 5, 16, 21, and 22 are develop new knowledge while at the same time improving the competencies of VA providers, and facilitating the delivery of state of the art care to substantial numbers of veterans.

Other findings related to schizophrenia are that use of clozapine, the most effective of the antipsychotic agents but the one with the most significant profile of adverse events, is low within the VA system. Accordingly, VISNs 3 and 16 have developed practice guidelines and educational programs to facilitate its optimal use.

There are also concerns about the medical care of veterans with schizophrenia. These have been intensified by findings from VISN 1 that most of the newer atypical antipsychotic agents can affect glucose tolerance and lead to diabetes. Related activities include quality initiatives from VISNs 3, 4, and 5 evaluating the recognition and control of diabetes in patients with serious mental illness. There are also initiatives from

VISNs 5 and 22 that are teaching behavioral strategies to veterans with schizophrenia to improve their management of diabetes and related conditions.

Depression: In the VA as elsewhere, depression is the most common of the mental disorders. It occurs in veterans who are otherwise healthy and as a complication of medical or neurological illnesses. Unlike the case with schizophrenia, or bipolar disorder that requires specialty care, there are evolving models for integrating the treatment of depression into primary care. MIRECC investigators are working to improve the recognition, diagnosis, and treatment within the primary care setting as well as within mental health services by developing new knowledge as well as strategies for facilitating the application of knowledge from the current evidence base. Ongoing initiatives include promising pharmacogenetic strategies to guide the choice of medications for individual patients (VISN 21), the development and dissemination of practice guidelines (VISN 16), use of tele-psychiatry for outreach to rural areas (VISN 16), and the use of disease management strategies and a clinical behavioral health laboratory to facilitate the integration of mental health services with primary care (VISN 4). The MIRECC program's activities related to depression include initiatives in primary care, CBOCs, rural areas, patients with lung disease, Parkinson's disease, and PTSD, and geriatric patients including those in nursing homes and those with Alzheimer's disease (VISNs 4, 16, 20).

Conclusions: My summary of the highlights of the MIRECC program is somewhat arbitrary. I could have focused more on other clinical and research programs, educational initiatives, or the development of new investigators. Instead of providing vignettes about research and clinical initiatives, I could have talked more about the added value of the MIRECCs to their host VISNs or the system as a whole. I am especially proud of the activities of the clinicians, scientists, and investigators with whom I work in VISN 4, and I may have emphasized our activities at the expense of others. However, the overall productivity of the MIRECCs as a whole, their commitment to improving the quality and effectiveness of care for veterans, and their

contributions to the VA and to the nation as a whole would emerge just as strongly from any review. Thus, the operations and activities of the MIRECCs have confirmed the wisdom of the authorizing legislation that created them to provide an intellectual infrastructure for the VA's mental health programs and a mechanism for innovation.

Although their support is derived primarily from clinical funds, the MIRECCs' missions include both education and research- facilitating and enabling activities such as the maintenance of infrastructures linking researchers with clinical care, pilot programs, and support for developing investigators. The linkage activities of the MIRECCs and the focus of their research on the development and application of knowledge directly related to clinical care provides a strong justification for the current funding mechanism.

Also, in considering the value of the MIRECCs to the VA, it is important to take a broad look at mental health programs during the era that led to the creation and operation of the MIRECCs. The VA Healthcare system as a whole has been under stress during this period, and mental health services were deeply affected. For example, from 1996 to 2000, programs for PTSD, homelessness, substance abuse, and serious mental illness grew by approximately 5.5% in the number of patients that they served, but they shrank by approximately 13.5% in their budgets. In a time marked by increasing needs, budgetary challenges, and emerging opportunities, mental health care within the VA needs the intellectual infrastructure and mechanism for innovation that the MIRECC provides. I urge you to maintain the current funding mechanism for the MIRECCs and to expand the program by creating additional centers.

WRITTEN COMMITTEE QUESTIONS AND THEIR RESPONSES

Questions for the Record
Honorable Rob Simmons, Chairman
Subcommittee on Health
Committee on Veterans' Affairs
April 14, 2003

Oversight Hearing on Medical and Prosthetic Research in the Department of Veterans Affairs

Additional questions for:
Fred S. Wright, MD
Associate Chief of Staff for Research
VA Connecticut Healthcare System
West Haven, CT 06516

1. Dr. Wright, please give the Subcommittee your insights as both a Yale professor of medicine and head of research at the VA of the value to the nation of having an integrated VA-academic partnership that focuses its attention on bio-medical research.

The strategic decision at the close of World War II, to expand and improve the VA hospital system by fostering affiliations with nearby medical schools, has had a very positive outcome. Today, VA medical centers affiliated with many of the nation's outstanding medical schools operate simultaneously, as inpatient and outpatient sites in VA health care networks providing high quality care to veterans, and as components of and partners in the university-affiliated academic medical center. The VA Connecticut Healthcare System (VACHS) for example includes a tertiary care hospital (at West Haven), out patient clinics providing both primary and specialty care (at West Haven and Newington), and community based primary care clinics at several locations throughout Connecticut. The VACHS Research program, located mainly on the West Haven campus, is vitally important to our hospital and to our ability to deliver high quality primary and specialty care to veterans. Because the West Haven medical center is closely affiliated with the Yale University School of Medicine, nearly all members of the VA medical staff have dual appointments as both VA physicians and Yale faculty members. In addition to their VA patient care activities, VACHS physicians have responsibilities in teaching and research. The VA-Yale affiliation provides benefits to both partners. The VACHS is important to Yale: the West Haven medical center is an important site for clinical rotations by Yale medical students, residents, and fellows in specialty training programs where they contribute to the care of VA patients and are taught by Yale faculty who are based at the VA. Yale is important to the VACHS: our ability to recruit physicians to the VACHS medical staff is greatly enhanced by the associated Yale faculty appointment and the opportunities to serve as a teacher for medical students and residents, and to carry out independent research in an environment enriched by the proximity of the medical school. When we recruit new members of the medical staff we seek individuals who have chosen to commit to a career that includes research and teaching and who qualify for a Yale faculty appointment. Yale assists in many recruitments by providing financial and other resources. The research programs of VACHS medical staff range from basic science (molecular biology, cell biology,

genetics) to clinical research (clinical trials, health services, epidemiology, rehabilitation). The research is all relevant to disease that affects the veteran population, but in my experience the particular type of research is less important than that the researchers are individuals who are committed to academic medicine and who are attracted to work in the VA because the combination of providing care for veterans, teaching Yale trainees, and conducting research in an environment enhanced by the resources of the nearby medical school. Without the VA Research program we would not be able to recruit the nationally recognized clinician investigators who serve as attending physicians, clinical leaders, and specialists consultants to whom our primary care physicians refer patients.

2. *I understand you chaired a group that developed the basic model of indirect Medical Care cost for support to VA research that VA has implemented. Now VA has proposed in the 2004 budget that VA's research "business line" incorporate both the direct research and the indirect Medical Care accounts into one consolidated mass. What are your views of taking what was basically an administrative allocation decision and introducing it into an appropriations arena? Is this next step a new problem or is it a continuation of the solution you developed?*

In early 2000 I co-chaired a workgroup, appointed by the VA Chief Financial Officer, that reported to a Committee of the VA Network Directors' Council. The workgroup included members with experience in either VA research or the VA financial system. The workgroup was tasked with developing an accounting system that could identify costs incurred in providing support to research activities in VA medical centers. Starting in 1997, and continuing to the present, the VA Medical Care appropriation has a component of the VERA system that is intended for support of research (facilities, administration, clinical services and paid time of clinician investigators). The research support funds allocated by this system are distributed to each medical center in amounts calculated to be proportional to the size of the research program (amount of research grant funds) at each medical center. The workgroup developed the VERA Research Support Cost Report and found that this report could identify research support costs, and could facilitate budgeting and tracking of these costs. An advantage of the present system for allocating funds in the Medical Care appropriation for research support, is that the costs are incurred by the medical center departments that are funded from the Medical Care appropriation (Facilities Management, Human Resources, Fiscal, clinical departments, etc.) A disadvantage of having research support funds in the Medical Care appropriation and distributed as part of the VISN and medical center budgets, is that they have not always been clearly identified as available for research support and tracked as having been used for research support. In my opinion this disadvantage can be overcome if medical centers establish a formal structure that requires regular discussions among medical center leaders (clinical, research and administration) to identify the appropriate costs and make research support funds available to pay them.

For the 2004 fiscal year VA has proposed that the funds to be used for research support (approximately $400 million nationwide) should be in the Research appropriation, along with the funds (also approximately $400 million) used to pay direct costs of research through VA research awards for projects. An advantage of this proposal

is that the funds for research support will be clearly identified for this purpose. A possible disadvantage is that at the present time the plans for how the funds will be distributed to the medical centers are still under discussion, and it is not certain that all of the necessary changes in systems for managing the funds will be in place by October 2003. In my view, either system for allocating and tracking research support funds can be effective. Whether the funds are allocated in the Medical Care appropriation or in the Research appropriation, the costs are incurred by the medical center and have traditionally been accounted for in the medical center budget. If the research support funds remain in the Medical Care appropriation, they need to be identified and then distributed to the medical centers, and then to the departments providing the support services to the Research program. If the research support funds are moved to the Research appropriation, a similar process of allocating the funds to the medical centers according to the size of their research programs, identifying the available funds, identifying the necessary support services, and transferring the costs between the medical center and the Research Office, requires the same planning and oversight by the same group of administrative, clinical and research leaders. In either case I believe that it is most important that the medical center leadership engage in regular discussions to identify the appropriate costs and to assign adequate amount of research support funds to pay them. At the VACHS we have recently formed a Research Support Committee in order to oversee the management of these research support funds.

3. *Over the past several years, Congress has invested substantial new appropriated funding in US bio-medical research, primarily by significantly increasing the research budgets of the National Institutes of Health, National Science Foundation, and Centers for Disease Control and Prevention. VA research has grown as well, but not nearly as much as these other federal programs. In your professional judgment, is VA research and development being left behind, and what are the implications of this development?*

During the past several years appropriations for the NIH have been increased to provide a "doubling" of the primary source of funds for the nation's biomedical research enterprise. The VA research program, which is small in comparison to the NIH budget, has not had its funding increased at the same rate. The VA research program is different not only in size from research supported by NIH. I view VA research funds as providing necessary core support for clinician-investigators who are based at the VA in order to serve as VA physicians providing care to veterans. The opportunity to carry out research and to teach in medical school-affiliated VA medical centers is critical to recruiting VA medical staff, particularly at hospitals offering advanced specialty services. If the VA Research appropriation had increased during the past several years along a trajectory similar to that of the NIH, the funds could have been well and responsibly spent to enhance a research program that has many opportunities to provide new knowledge as well as enable the recruitment of clinicians necessary for the delivery of high quality patient care. An example of the VA Research program "being left behind" is in the current state of facilities for conducting research. In the non-VA research world of public and private universities and medical schools, facilities for research (whether in laboratories, offices, or patient care settings) are maintained, replaced or expanded by a combination of funds from state governments, private philanthropy, and federal agencies such as the NIH. These sources of funds are not generally available to VA medical

centers, and maintenance and improvement of VA research facilities is a currently unmet need. Again, I can cite my own experience at VACHS. The laboratory facilities for our large research program are mostly located in buildings that were constructed in 1918. More than 10 years ago we recognized the need to replace these laboratories with space that would be structurally sound, adequately ventilated, and supplied with sufficient electricity. We worked with an architect, available through the generosity of the Yale Medical School, and completed a preliminary design for a research building to replace our outmoded laboratories. Unfortunately, we have not been able to secure the capital funds required to begin this kind of project. Thus, while the Yale Medical School has recently completed a large new research laboratory building on its campus, our VACHS laboratory facilities are 10 years older, and less attractive to clinician-investigators that we must recruit and retain to staff our medical center.

4. *Please provide the Subcommittee a synopsis of the VA research projects in which you and colleagues are engaged at the VA-Yale affiliation that would help inform the Subcommittee of the variety and potential of this work.*

At the present time the VACHS Research program has more than 380 active projects led by more than 130 principal investigators. Approximately two thirds of the projects are clinical research studies involving human subjects. Of the remainder, about half are investigations using animal subjects, and half involve data analysis or cell lines. Last year the competitively awarded funding for these projects totaled approximately $30 million. The majority of our investigators are clinicians who also provide patient care in either Internal Medicine, Mental Health, or Neurology. Medical specialties that are the focus of research at the VACHS include Oncology, where cancer researchers are conducting laboratory studies to develop new chemotherapy agents; Liver disease, where research is seeking treatments for the complications of cirrhosis; Cardiology, where investigators are using PET and SPECT imaging to explore the relation between cardiac disease and depression; Gastroenterology, where basic research is identifying the molecular basis of inflammation in the pancreas – how premature release of digestive enzymes causes pancreatitis. Also clinicians in Geriatrics, Rheumatology, Primary Care, and Infectious Disease are engaged in a wide range of Health Services research concerned with improving quality of care and the ability of patients to participate in decisions about their medical care. Clinicians in the Mental Health Services are working in an integrated group to bring several investigative approaches to bear on such problems as depression, anxiety (Post Traumatic Stress Disorder), schizophrenia, and substance abuse. The research includes clinical trials of new drugs, genetics studies seeking genes responsible for mental illness, and laboratory projects identifying roles of neurotransmitter chemicals in brain function. Health Services research in Mental Health is studying ways of integrating psychiatric and primary care, and of identifying patterns of practice to improve care of patients with serious mental illness, subtance abuse, and homelessness. The Neuroscience Research Center is a notable component of our program. It is a VA funded program pursuing basic research and rehabilitation applications to restore function and prevent disability from spinal cord injury and multiple sclerosis.

5. *Often research works on challenges today that may not bear fruit for many years. Can you give us some example of applications of research findings that occurred relatively quickly in the bio-medical arena?*

I agree with the main thrust of the question: that research is mostly a long and generally unglamorous journey, with the occasional finding that can quickly affect practice. I would prefer to make this the main thrust of my answer as well. In my own experience successful research requires the recognition and commitment of several parties to the proposition that research advances knowledge in small steps, with today's investigations following leads, ideas, and questions generated by yesterday's research. The several parties include the investigators who commit to a long period of education and training to learn techniques for conducting effective research, the institutions who employ them and are patient with the slow progress of most research, and the agencies that provide the monetary support, which is an investment in the unknown. Because the new knowledge that emerges from a healthy research program is often surprising and leads in new directions, it should not be expected that most research will produce a rapid succession of findings that fix the diseases that afflict us. Nevertheless, the VA Research program does seek to balance its portfolio by including efforts specifically aimed at identifying research results that can be put into practice and by conducting clinical trials of promising therapies. For example, investigators at the VACHS led a VA Cooperative Study to assess the health benefits and the cost-effectiveness of a new type of antipsychotic medication shortly after it was introduced. This study showed that use of the drug, although very expensive at that time, succeeded in reducing hospitalizations and other expensive requirements for managing a large group of seriously ill veterans.

Questions for the Record
Honorable Rob Simmons, Chairman
Subcommittee on Health
Committee on Veterans' Affairs
April 14, 2003

Oversight Hearing on Medical and Prosthetic Research in the Department of Veterans Affairs

1. Dr. Katz, with our troops overseas, this Subcommittee has been very concerned about force protections and post-deployment health. The Secretary of Veterans Affairs recently announced that VA is more ready today than ever in its history to care for those who have borne the battle. How do you assess the VA's readiness to deal with some of the wounds of war that might not be so visible—mental health issues in particular?

The wounds of war affect the mind and spirit as well as the body. In the aftermath of September 11, our country is beginning to recognize this. However, our veterans and our society are still not sure whether these injuries are "legitimate". A recent article from the New York Times (In Military Wards, Questions and Fears From the Wounded, front page, April 19,2003) makes this point clearly:

> BETHESDA, Md., April 18 - Lance Cpl. James Klingel of the Marines finds himself lost in thought these days when he is not struggling with the physical pain, his mind wandering from images of his girlfriend back in Ohio to the sight of an exploding fireball to the sounds of twisting metal.
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> Often, Corporal Klingel says, he is jolted from sleep at the National Naval Medical Center here, at times because of the aches and throbs in his right arm and right leg, and at other times because of the images of the Iraq war that the chaplains say will not likely go away soon.
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> More than two weeks after being seriously wounded by a rocket-propelled grenade that hit his armored vehicle, Corporal Klingel says he is glad to begin walking again, but disheartened because he will most likely limp the rest of his life and need to use a cane.
>
> In the worst moments, though, Corporal Klingel, a scout, said he questioned the legitimacy of his emotional pain as he considered the marine in the next bed, Staff Sgt. Eric Alva, a distance runner whose right leg was blown off by a land mine, or Seaman Brian Alaniz, a Navy medic down the hall who lost his right leg when a mine exploded under him as he rushed to aid Sergeant Alva.
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> ...
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> Corporal Klingel said he was cheered this week when President Bush and his wife, Laura, made the rounds, visiting dozens of wounded sailors and marines here and at the Walter Reed Army Medical Center, several miles south in Washington.
>
> Standing in front of a statue called "The Unspoken Bond," which shows a corpsman, as Navy medics are called, carrying an injured marine, Mr. Bush praised the heroism of the wounded and the work of the doctors here. But Corporal Klingel said that many here did not feel much like heroes. He said he went to visit a chaplain the next day because of the dreams he was wrestling with nightly.

> Early this week, Corporal Klingel was given a plane ticket, courtesy of a Navy charity, to fly to Harrisville Township, Ohio, to rest at his parents' house. He said he hoped that the nightmares would fade, but feared that he would have to live with them for a long time.
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> "The firefight scared the hell out of me," he said. "But this - moving forward - is just as scary."
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> After mentioning how much he looked forward to standing out on his parents' porch and staring into the wilderness, he added:
>
> "I am still looking over my shoulder. I am sure I will be standing on the back porch and worry about who might come shooting at me out of the bush. It's changed me."

Behavioral Health Services within the Veterans Health System have greater experience and expertise in dealing with these issues than anyone else. However, even in our system, there is a need to provide clinicians with updated knowledge, to inform them about the differences between the acute effects of stress that will be seen with those newly returned from battle and the more chronic effects of their current patients, and to help them key in to the experiences that are specific to the war in Iraq. In this, the National Center for PTSD has been serving as a national resource.

At the request of the Under Secretary for Health, the National Center has prepared an Iraq War Clinician Guide to assist VA clinicians in their efforts to help returnees cope with psychological and emotional issues resulting from their experiences during the Iraq War. The Guide, which has undergone several revisions, has specific chapters on psychological issues, clinical assessment, treatment, care of military evacuees with medical/surgical problems, treating PTSD in primary care settings, treating sexual trauma and interventions for traumatic grief. It is an important part of clinical preparedness that should help all providers in the VA system deal with Iraq War-related mental health problems.

In addition, the National Center's award-winning website www.ncptsd.org has added a great deal of new material for returning combatants, veterans and their families.

However, in spite of experience and expertise, there may be barriers to the delivery of care related to access and stigma. Behavioral Health Services within the VA may need additional resources to ensure timely access for those who seek care. In addition, the Department of Defense and the VA will need to work to reduce the stigma associated with seeking mental health services. From what the VA as a whole and the National Center for PTSD, in particular, have learned, more intense outreach will be important to help those in need accept and engage in treatment to facilitate readjustment, and to prevent the consequences of untreated stress-related disorders, including chronic mental illness, substance abuse, and suicide.

2. I understand that you have knowledge of some unique work now being done in the Air Force on the subject of suicide prevention. Please provide the Subcommittee with more extensive information on this matter.

The best contact person for information about this program is probably Colonel David Litts, but I can provide some basic information. During the early to mid 1990's the Air Force became aware that suicide rates were increasing among active duty personnel and that suicide had become the second leading cause of death in the service (after accidents). Early in 1996, the Air Force Chief of Staff commissioned the Surgeon General to work with Air Force personnel and other experts to evaluate the problem and recommend a strategy for prevention. This group identified risk factors for suicide that include mental health problems, trouble with the law, finances, intimate relationships, job performance, and alcohol and other forms of substance abuse. They also identified several factors that could be protective, including social support, coping skills, and policies and attitudes that encourage those in need to seek help. With the strong support of the Chief of Staff, the Air Force initiated a comprehensive, service-wide intervention that included encouraging personnel to get help at times of stress using resources in the community or within the military, requiring all Air Force personnel to receive training on suicide risk awareness and prevention, improving surveillance to identify emerging risk factors and clusters, establishing deployable critical incident stress-management teams, and supporting services to families. Together, these initiatives have had a dramatic effect in reducing suicide rates within the Air Force at a time when rates in other services remained more or less constant. See phs.os.dhhs.gov/BestPractice/USAF.pdf, www.e-publishing.af.mil./pubfiles/af/44/afpam44-160/afpam44-160.pdf

The Air Force program is a testament to what enlightened leadership can accomplish. It also demonstrates that interventions that destigmatize mental illness and improve access to mental health services can save lives. Given that the demographic characteristics of veterans place them at higher risk for suicide than the rest of the population, this can serve as an important model for the VA.

3. The Subcommittee is also concerned about the financial status of the Mental Illness Research, Education and Clinical Centers. We understand there may be a developing plan to blend their funding into the VERA system. Can you provide any information that would assist the Subcommittee in better understanding this plan and its implications?

Briefly, the basic issue is that the MIRECCs and the National Center for PTSD were authorized by Congress to address unmet needs in the Veterans Health System. These needs still exist. Protected funding of these Special Purpose programs was necessary when these programs were established to allow them to pursue their missions. It is just as important today.

The concept of MIRECCs was established in 1995, at the request of Congress and by the direction of the Under Secretary for Health. They were to support infrastructure for

research, innovations in clinical programs, and education to translate research findings to clinical practice. They were explicitly funded from Medical Care appropriations. In this, the MIRECCs and the National Center for PTSD are examples of programs that use Medical Care resources to provide infrastructure support for research, education and, of course, quality improvement and innovations in clinical practice. Although these programs could have been supplemented by Research appropriations, they never were.

It was clearly understood that the MIRECC's were not to be used for regular clinical care. It is for this reason that MIRECC Directors do not report to the Chief of Mental Health but to the Chief of Staff - or even higher, the VISN Clinical Manager. The funding for the MIRECC's was to be Specific Purpose funding i.e. "off the top" and the person responsible for the national systems of MIRECCs was the Chief Consultant for Mental Health. Both of these decisions were very appropriate, as the General Purpose distribution of VERA is tightly linked to a capitated (and somewhat case mix adjusted) workload - and clinical workload is not the desired output of the MIRECCs. If they were placed in General Purpose funding, they would become a burden on the host VAMCs and VISNs as they do not create workload yet consume resources. Moreover, if their direction was left entirely to local decision-makers, they would lose their national character, and their universal scientific accountability.

Finally, when Congress authorized these programs, and when the VA established them, no sunset provisions were provided for the system as a whole (although individual sites might lose their designation if they fail to maintain productivity.) Given the needs for innovation, and the exciting advances that are coming from these programs, a sunset provision would be as inappropriate as sunsetting the Research Appropriation or the ample research support derived from General Purpose VERA accounts for individual investigator awards or discontinuing the system of HSR&D Centers of Excellence.

Most specifically, the problem of blending MIRECC funding into VERA is that the VERA system was designed to reward the number and complexity of patients seen, while the MIRECCs were designed by Congressional intent to provide infrastructure support for innovations in psychiatric care through research, clinical demonstrations, and research. The effectiveness of the MIRECCs is not measurable by the number of new patients seen. The unfortunate result of merging the MIRECCs into VERA would be to burden the VISNs that host them with an annual cost of $1.5-1.6 million that, according to ongoing mechanisms for evaluation, would provide no return on VERA capitation. The result would be a perverse incentive to sacrifice the mission of the MIRECCs by redefining them over time as direct providers of clinical care.

4. Please provide the Subcommittee a synopsis of the VA mental illness research projects in which you and your colleagues are engaged at your VA-university affiliation that would help inform the Subcommittee of the variety and potential of this work.

The VISN 4 MIRECC, like each of the MIRECCs and the National Center for PTSD use the program's activities as a source of leverage to bring new resources to the VA. For our MIRECC, the other sources include NIH (primarily NIMH, NIDA, and NIAAA), private foundations, and corporate support (for example, from the pharmaceutical industry).

The theme of our MIRECC is comorbidity, the co-occurrence of medical illness, mental illness, and substance abuse disorders. This is a common problem, and one that provides major challenges for providers and systems. In general, when these disorders occur together, they amplify each others' effects, and complicate each others' treatment.

Our MIRECC provides infrastructure support for basic research on brain imaging and psychiatric genetics. The imaging lab is using these resources to develop ideas about novel treatments for cocaine abuse that are being translated into clinical trials. By focusing on what is happening within the brain during cocaine craving, they are working toward both preventing, and treating, addiction. The genetics lab has developed exciting findings about who is most likely to respond to naltrexone treatment for alcoholism; thus, their work is making existing treatments better.

Clinical research within the MIRECC has focused on a number of critical comorbidities, including alcohol abuse or dependence in depression, schizophrenia, and bipolar disorder; cocaine abuse in schizophrenia; depression in heart failure and Parkinson's disease; Hepatitis C and substance abuse; diabetes and chronic and severe mental disorders; substance abuse and PTSD; and the psychiatric complications of Alzheimer's disease.

Services-oriented research is learning how to overcome gaps within and between treatment systems, that is, about how to deliver mental health in nursing homes, combine treatment for substance abuse and other psychiatric disorders, and integrate mental health services into primary and specialty medical care settings.

Other initiatives are developing approaches for preventing suicide, involving both improving recognition and treatment of depression in primary care patients, and making treatments within behavioral health settings more responsive to veterans' needs.

In our educational programs, we are providing both conceptual and hands on information about issues of importance to providers. In this, the focus is increasingly on helping clinicians utilize the knowledge and tools developed through research, in the MIRECC and elsewhere. In addition, the interactions and outreach to front-line clinicians provides opportunities for clinical investigators to learn about "real life" problems and to develop strategies for addressing them.

The investigators in the MIRECC are intensely interested in basic neuro- and behavioral-science, as well as research designed specifically to improve clinical care. However, befitting our role at the intersection of the research, education, and clinical domains, the focus of the work support using the MIRECC's infrastructure resources and pilot research programs are designed specifically to improve access and outcomes for mental health care sooner rather than later.

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