

**VA RESEARCH: FOCUSING ON FUNDING, FINDINGS,
AND PARTNERSHIPS**

JOINT HEARING

BEFORE THE
SUBCOMMITTEE ON HEALTH
JOINT WITH
SUBCOMMITTEE ON OVERSIGHT & INVESTIGATIONS
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CONTENTS

Thursday, May 17, 2018

	Page
VA Research: Focusing On Funding, Findings, And Partnerships	1
OPENING STATEMENTS	
Honorable Neal Dunn, Acting Chairman	1
Honorable Julia Brownley, Ranking Member, Subcommittee on Health	2
WITNESSES	
Robin L. Rusconi J.D., Chair, Board of Directors, National Association of Veterans' Research & Education Foundations	4
Paul Klotman M.D., President, Chief Executive Officer, and Executive Dean, Baylor College of Medicine, On behalf of Association of American Medical Colleges	5
Carolyn Clancy M.D., Executive in Charge, Veterans Health Administration, U.S. Department of Veterans Affairs	7
Accompanied by:	
Rachel B. Ramoni D.M.D., Sc.D., Chief Research and Development Offi- cer, Veterans Health Administration, U.S. Department of Veterans Affairs	
STATEMENTS FOR THE RECORD	
Roger Murray Executive Director, the Coalition to Heal Invisible Wounds	37
Rick Weidman, Executive Director for Policy & Government Affairs, Vietnam Veterans of America (VVA)	41
Ms. Jacqueline Garrick, LCSW-C, Whistleblowers of America	43
National Association of Veterans' Research and Education Foundations (NAVREF)	48

VA RESEARCH: FOCUSING ON FUNDING, FINDINGS, AND PARTNERSHIPS

Thursday, May 17, 2018

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

The Subcommittees met, pursuant to notice, at 10:03 a.m., in Room 334, Cannon House Office Building, Hon. Neal Dunn presiding.

Present: Representatives Bergman, Dunn, Bost, Poliquin, Arrington, Higgins, Coffman, Brownley, Kuster, Rice, O'Rourke, Correa, and Lamb.

OPENING STATEMENT OF NEAL DUNN, ACTING CHAIRMAN

Mr. DUNN. This meeting has come to order. Good morning, I thank all of you for joining us today to discuss the Department of Veterans Affairs medical and prosthetic research program. Before I begin, I would like to ask unanimous consent for our friend and fellow Committee Member Congressman Coffman from Colorado to join us on the dais for today's proceeding, when he comes in we will seat him.

Without objection, that is ordered.

All right. Well, current law requires VA to conduct research in order to carry out more effectively the primary function of veteran's health administration in order to contribute to the Nation's knowledge about disease and disability. The VA research program has attracted high quality clinician researchers to VA medical centers and led to many important partnerships. This has resulted in discoveries that have benefitted everybody in this room. You will hear the VA tout some of these most notable discoveries this morning. They range from the pacemaker in 1959 to the shingles vaccine in 2006.

Despite these successes, the Committee has become increasingly concerned that the VA's research program is in need of refocusing in several important areas. First, it is not clear that the majority of the research that the VA conducts displays a concentrated focus on veteran specific conditions and concerns.

There are many valuable research topics such as obesity and heart disease that are very deserving of research dollars and attention. But the VA's research program is meant to support research on issues that are unique to or particularly prevalent among veterans, and may not be receiving the funding and attention they deserve by other research entities. And these issues are such as toxic

exposures, traumatic brain injuries, and post-traumatic stress disorder.

Secondly, there are concerns that VA medical facilities are not complying with the VA policy by administering grants from outside entities through VA non-profit research and education corporations to the extent that is possible. The vast majority of VA researchers are duly appointed at both a VA medical facility and a nearby academic affiliate, which can create conflicts of interest when it comes time to determine where our given grant is administered.

There are significant financial considerations inherent in that determination, and the VA has to make sure that the department is given due consideration and not leaving a cent of potential research funding on the table and out of the veterans reach. Finally, there are concerns that the VA's not getting a significant return on its investment in research overall.

A statement from the record from the Vietnam Veterans of America said it perhaps most succinctly. "How much of what VA research produced recently is of significant benefit to veterans?" And I have no doubt that the VA's researchers are leaders in their field, making great progress on a regular basis, but we are not sure that enough of what VA researchers are discovering is being translated efficiently and effectively into the VA medical centers and clinics to benefit veterans across the country.

I am grateful today for our witnesses for their attendance here this morning to discuss these issues with us. One thing I will note before yielding is that the Subcommittee on health will be holding another hearing on June 8th that will focus specifically on burn pit research. I am looking forward to that and diving deeper into that specific research efforts at that hearing and not today.

I will yield to Ranking Member Brownley for any opening statement that she may at this time. Thank you.

**OPENING STATEMENT OF JULIA BROWNLEY, RANKING
MEMBER, SUBCOMMITTEE ON HEALTH**

Ms. BROWNLEY. Thank you, Mr. Chairman. This morning this Subcommittee will delve into issues involving VA's mission to discover knowledge, develop researchers and health care leaders, and create innovations to advance health care for veterans and the Nation.

The successful advancement of this mission has positioned VA as the largest single provider of medical training in the United States. Today, over 70 percent of health care providers have received training through the VA. The partnerships VA has established with academic institutions and VA non-profit corporation have proven integral to VA's advancement of veteran-centric research.

VA's relationship to its academic affiliates is essential if VA is to provide the level of health care that we all expect for our veterans. This is why Congress, the VA, and its academic affiliates must work together to address areas that need improvement.

While our overall health care system reaps the benefits of VA inventions, VA also benefits by being able to rely on the high-quality providers and specialists that this type of research attracts. VA physicians are often on the leading edge of medical knowledge and leaders in their field of practice.

For instance, earlier this year the Minneapolis VA published a study that found that opioid pain killer are no more effective than safer alternatives in long-term treatment of patients with chronic pain. Not only is this information timely but it will likely shape Federal policies surrounding the prescribing of opioids in the future and save thousands of Americans from falling victim to opioid addiction.

Because of the important work VA's Office of Research and Development has accomplished, I wish to examine how we can better support VA research and research conducted by our academic affiliates in VA non-profit research corporations. I am concerned that VA's current research budget is not keeping pace with inflation. And if NIH awards significantly fewer research grants, this will have a negative effect on VA's ability to develop treatments for our veterans.

If funding for VA research continues to be lacking, I want to know about how VA can continue to leverage private investment in non-profit funding through our non-profit research corporations and through our academic affiliates to make up for Federal research funding shortfalls.

Finally, I want to continue to work with Ranking Member Kuster and our colleagues across the aisle to ensure VA is properly overseeing its research programs and the administration of NIH funded research through the VA's non-profits research corporations and its academic affiliates.

I would also like to better understand when it is appropriate for VA non-profit corporations and academic affiliates to administer NIH grants, and ensure VA is following its current policy directives. We need to come together to figure out the best way to ensure vital research to advance veterans health care needs is funded, and that it is administered properly so that this funding results in treatments that improve, and in some cases, save veterans lives. Educating our Nation's health care providers and developing medical breakthroughs to provide treatment to our veterans are part of VA's core mission. It is vital that we, as Members of Congress, support this mission.

So thank you, Mr. Chairman, Dr. Dunn. And I yield back the balance of my time.

Mr. DUNN. Thank you very much Representative Brownley.

I will make note that Chairman Bergman and Ranking Member Kuster will be making closing statements at the end of our hearing. And so I welcome our panel, and I will introduce you now.

First, we have Robin Rusconi, Chair of the Board of Directors for the National Association of Veterans' Research & Education Foundations. Next, we have Dr. Paul Klotman who is a nephrologist by training, the President and Chief Executive Officer, and Dean of Baylor College of Medicine, and here on behalf of the Association of American Medical Colleges. And I will make note that they are also the very first VA hospital ever.

Also, Dr. Carolyn Clancy, Executive in Charge of the Veterans Health Administration for the U.S. Department of Veteran Affairs, and who is accompanied also by Dr. Rachel Ramoni, VA's Chief Research and Development Officer. Welcome panel, we thank you all for being here with us this afternoon.

And, Mrs. Rusconi, I believe we will start with you. And you are now recognized for five minutes.

STATEMENT OF ROBIN RUSCONI

Ms. RUSCONI. Chairman Bergman and Dunn, Ranking Members Kuster and Brownley, distinguished Members of the Subcommittees, thank you for holding this important hearing.

VA research is an essential but under-publicized element of the VA health care system. It has a distinguished history of discovery and innovation that has benefitted veterans and the Nation for over 90 years. The Congressionally authorized VA affiliated non-profit corporations are proud to support and augment VA research.

My name is Robin Rusconi. Since 2014, I have been the executive director of the VA affiliated non-profit corporation located in Kansas City, Missouri. I am currently the chair of the Board of Directors for the National Association of Veterans' Research and Education Foundations, known as NAVREF.

As a child of two World War II veterans, I am proud to be supporting the VA research program and helping improve the lives of veterans. NAVREF's mission is simple, we exist to advance the success of the VA affiliated non-profit corporations. I am here today to tell you about the great work of our non-profits, our potential for greater contributions, and the progress made since last year's hearing.

We are pleased that the House Veterans Affairs Committee recognizes the importance of the non-profit corporations in the VA research enterprise. Over the last four years alone, the NPC's have administered over \$1 billion in support of the research and education activities at VA medical centers.

NAVREF and its members are excited too to support Dr. Ramoni's three strategic priorities for VA research; to provide greater access to clinical trials for veterans, to make VA data a national resource, and to achieve substantial real-world impact.

While NAV—excuse me—while NAVREF is proud of all the NPCs have accomplished, we feel they have the potential to make even greater contributions. In June 2017 the House Veterans Affairs Oversight and Investigations Subcommittee held a hearing about VA research that included testimony from NAVREF. During that testimony, NAVREF made several recommendations. I would like to update you on the progress made on two of those recommendations.

First of all, we were heartened to hear that the Office of Research and Development would engage an outside consultant to assess the need for VA to establish and enforce clear guidelines for administering Federal awards. Unfortunately, we are frustrated that the process has moved slowly, and we are concerned that the perspective of the non-profit corporation is not being fully investigated and appreciated.

We believe the VA should enforce clear guidelines for the administration of extramural research activities that offer the NPC right of first refusal for all research efforts when the majority of this work occurs physically within the VA.

Second, the VA's non-profit oversight board took several positive steps last October regarding the oversight reviews being conducted

by the non-profit program office. Specifically, the NPOB created a clear appeals process, established an anonymous survey tool to receive feedback, and ensured oversight review out briefs include the full board of directors and the executive director of the non-profit corporation.

Each of these changes have been in place for a short time, so it is too early to determine if they have been effectively communicated to local VA leadership and if they will have their intended impact. Additionally, we would like to see greater clarity on the scope of these reviews. Our members are all independent 501(c)3 corporations remain confused about what is subject to VA review and what may be out of scope.

Thank you again for your attention to these matters. We greatly appreciate your continuing support of the VA research program and your support of the VA affiliated non-profit corporations. We look forward to working with you to achieve our vision of a Nation in which veterans receive the finest care based on innovated research and education.

Mr. DUNN. Thank you very much, Ms. Rusconi.

Dr. Klotman, you are now recognized for five minutes.

STATEMENT OF PAUL KLOTMAN

Dr. KLOTMAN. Thank you, Dr. Dunn. I really appreciate the opportunity to testify in front of you today. In addition to the Baylor College of Medicine, I also represent the Association of American Medical Colleges, which is a non-profit organization comprised of all the U.S. medical schools and major teaching hospitals including many of the VA hospitals.

And I would like to thank the Full VA Committee for preserving the VA's clinical relationship with academic medicine in the VA mission act to ensure our Nation's veterans have access to clinical services at our institutions and receive the highest quality of health care.

For this hearing I will share information on the research enterprise and the VA academic relationship through my experience as a clinician and researcher. For you—you may not know this, but I began my career as a trainee clinician physician scientist at the VA, and I was also supported by the NIH. I was a staff physician at the Durham VA for 13 years while at the faculty at Duke Medical School. And both my wife and I are partially supported by Duke to work at the Durham VA. I have spent 17 years in civil service between my time at the VA and the NIH. And, by the way, I am the Dean, my wife is also the Dean at the Duke Medical School, we all started our careers at the VA.

The Michael DeBakey VA Medical Center in Houston was the first to affiliated with an academic partner, and has been affiliated with Baylor since 1949. Today, it is one of the VA's largest hospitals serving Harris County, Texas, in 27 surrounding counties.

Baylor physicians provide virtually 100 percent of the medical care at the DeBakey VA. The veterans from around the country are referred there, and Baylor physicians provide the clinical services often not available by other providers, same physicians at Baylor hospitals and the VA hospital.

Medical schools fully integrate research and education with patient care, and these are very interdependent, as many of you physicians know, and to split those apart would really jeopardize the quality of care. Interestingly, the VA medical centers share the same tripartite mission of education, research, and clinical care. And by working together, we enhance the care for veterans—research that provides new treatments and train the next generation of health care providers, many of whom are then attracted to have a career in the VA.

Our clinical research partnership has led to tremendous care for our Nation's veterans at the DeBakey VA. We have one of the ten VA trans-aortic valve replacements programs, it is only one of two in the country with expertise in bronchial stenting for patients with lung cancer and fibrosis, and is one of the few that has a designated stroke center.

The DeBakey VA is the hub of our VISN, but it also gets national referrals with complex cases, second opinions, we have people sent from all over the country to our VA. And we have launch centers of excellence in cancer and Parkinson's Disease, post-traumatic stress disorder, liver transplant, epilepsy, substance abuse, and rehabilitation for mild to traumatic brain injury.

Our faculty are absolutely passionate about improving quality of care for the veterans, as well as our other affiliated hospitals. As national leaders, they can rapidly implement new guidelines and best practice initiatives for medical conditions in the care of our veterans. This partnership has played an important role in the DeBakey VA achieving a four-star rating in just a six-month period of time.

Research leads to medical advances, and Baylor and DeBakey VA have supported collaborations leading to innovation in mental health and cancer treatment, and prevention of antibiotic resistant infections, and chronic obstruction lung disease and emphysema, as well as cardiac care.

Nationally, most VA researchers have joint appointments at the VA and the affiliated medical school, which to physician scientists views it as a huge advantage, and it is a real important recruiting tool. At DeBakey, VA researchers have faculty appointment at Baylor giving them access to all the resources at Baylor including core laboratory facilities, oversight committees, dedicated IRB to the VA clinical trials, accreditation for human and animal research, and pre-award management for all non-VA grants. And these resources can be prohibitively expensive for VA medical centers and their not-for-profit corporations to support if they were independent of the affiliate. Sharing with academic affiliates reduces unnecessary redundancies and maximizes the use of Federal dollars.

Each VA academic partnership is unique. For example, about 20 years ago Baylor and the DeBakey VA consulted with the VA, our non-for-profit organization, and HHS, and agreed that we should be reimbursed by NIH grants for the on-campus facility FNA. Baylor provides complete research oversight support and provides annual contributions to the non-for-profit corporation to support VA research. So money is flowing to the VA from us.

All other medical schools—at other medical schools, NIH grants are administered via VA researchers vary based on the amount of

infrastructure provided by the VA. Due to this variation in support that various VAs have for the research enterprise, the AAMC believes that administration of NIH grants should be determined at the local level by each VA medical center. A one-size fits all approach could hurt VA research programs as well as the collaborations with affiliates.

The DeBakey VA relationship with Baylor and the joint appointment of researchers also is an important tool for recruiting physicians and scientists to the VA and retaining high quality researchers. The VA affiliation also enhances the training quality of our programs, the Baylor programs. Our students and residents have the opportunity to work with veterans and learn about military health, which makes them better doctors.

There are additional recommendations in the written testimony, but if I leave you with one message today, it is without the synergistic 70-year partnership with academic medicine, the VA's ability to fulfil its mission of patient care, education, research would be limited.

I appreciate this opportunity again, and I look forward to answering any questions that you have.

Mr. DUNN. Thank you very much, Dr. Klotman.

Dr. Clancy, you are now recognized for five minutes.

STATEMENT OF CAROLYN CLANCY

Dr. CLANCY. Good morning, Chairman Dunn, Chairman Bergman, Ranking Members Brownley and Kuster, Members of the Subcommittee. I appreciate the opportunity to discuss VA's medical and prosthetic research program, and I am accompanied by Dr. Rachel Ramoni our chief research and development officer.

VA's Office of Research and Development has been improving the lives of veterans through health care innovation and discovery for more than 90 years. And in so doing, civilians have also benefitted from groundbreaking advances including the first successful liver transplant, and, as mentioned by the Chairman, the pacemaker, and the first shingles vaccine.

We continue to conduct cutting-edge research such as the development of a bionic ankle that helps propel users forward, the creation of the Million Veteran Precision Medicine Initiative, and groundbreaking work to repair severed spinal cords. In addition to the scientific merit of VA research, VA is also recognized for its ability to translate research findings into real-world benefits for our veterans.

I want to thank the Committee for the additional resources you provided in the omnibus. And, in fact, we have created a one-page summary of how we will prioritize that unexpected but very welcome investment of resources, which I would like to ask be entered into the record.

Mr. DUNN. Without objection, it is entered.

Dr. CLANCY. The non-profit research and education corporations, or NPCs, are an important part of the VA research partnership ecosystem, established in 1988 to serve as a flexible vehicle to receive the external funds that help drive VA innovation. For example, a recently announced multi-million-dollar interagency agree-

ment with the National Cancer Institute will be administered by the not-for-profit corporations.

VA's affiliations with our Nation's medical schools go back to 1946 when General Omar Bradley forged this pioneering partnership. Seventy-two years later, we are affiliated with well over 90 percent of medical and osteopathic schools, so these partnerships give us access to cutting-edge technology, expertise, and national research networks that would be difficult, costly, and wasteful to duplicate within VA. For example, the spinal cord repair program previously mentioned is the product of a very strong collaboration with the University of California system.

VA research is committed to supporting activities that improve the health and well-being of our veterans. Our office of research and development evaluates proposed research projects by conducting rigorous scientific peer review. Projects that are not veteran focused do not receive funding.

In addition, our research portfolio is continually rebalanced over time to meet our veterans most pressing needs. So, today, our five clinical priorities are post-traumatic stress disorder, traumatic brain injury, suicide prevention, opioids, and Gulf War illness.

While VA's medical and prosthetic research program focuses on benefitting current and future veterans, the output of our research ultimately benefits the Nation. For example, in 2017 VA launched a nationwide study of the health benefits of a robotic exoskeleton for veterans with spinal cord injury. VA research also has an impressive track record of transforming VA health care by bringing new evidence-based treatments and technologies into everyday clinical care.

Two key examples recently. First is the implementation of a new suicide prevention clinical initiative, this has been defused across our system. Based on predictive modeling and existing medical record data to identify veterans at the very highest risk of suicide so we can provide them with more intensive services and follow-up.

Veterans are now using the bionic LUKE arm as the result of our Office of Research's partnerships. The approval and delivery to veterans of the most advanced prosthetic arm ever created. This is an area upper limb prosthesis that has not seen advances in about 50 years.

VA's medical and prosthetic and research program has significantly improved the care and well-being of our veterans. These gains have been possible because of consistent congressional commitment in both the form of attention and financial resources. And we believe it is critical to continue to move forward with the current momentum and preserve the gains made thus far.

This concludes my testimony. My colleague and I are prepared to answer any questions.

Mr. DUNN. Thank you very much, Dr. Clancy.

We are going to take—go around the dais and have everybody five minutes to ask you questions. I am going to ask the panel to try to answer concisely. I know that it is hard sometimes, we ask vague questions. But since we each only have five minutes, it is a plus if we can be concise.

So I am going to yield myself five minutes now. And start with Dr. Clancy a question. Given the prevalence of the PTSD and TBI

among veterans, I would like to know a little bit more about this. These are prioritized treatments you have and technologies, what do we—what can we offer our veterans that we hadn't been offering?

Dr. CLANCY. To some extent we are looking at different and can offer now new medical treatments, and we are also looking at ways of how to delivery those treatments. For example, I am going to guess that you are aware that one-third of the veterans we serve live in rural areas, so they have got a pretty substantial distance to travel to get care. And we have recently tested and developed a telehealth approach so that veterans can get this care virtually. And as nearly as we can tell from published studies, this is just as effective as traveling that distance and coming in person.

Mr. DUNN. So you have got metrics on that?

Dr. CLANCY. Yes.

Mr. DUNN. We would love to have you share that with us.

Dr. CLANCY. Sure.

Mr. DUNN. Not right this minute, but that is something that would be of keen interest, I think, to everybody in this Committee.

Dr. Klotman, you mentioned not one size fits all, and one of the areas that we have had some interactive with, which IRB do we use?

Dr. KLOTMAN. So it depends on what institution. In our case, we have seven independent IRBs, but one of them is dedicated to the VA. So we can get very quick IRB approval for any clinical protocol.

Mr. DUNN. Is the VA IRB quick for you? Is it easy to use?

Dr. KLOTMAN. It is because it is run by Baylor.

Mr. DUNN. Oh, okay.

Dr. KLOTMAN. So we man—it is sort of outsourced to us, so we do it for—

Mr. DUNN. Do you think that that translates across the country to all the researchers, because we get the sense that maybe it isn't?

Dr. KLOTMAN. I would say one of the big problems, when talking to academic institutions, with their VA affiliate is getting clinical trials approved. And I think it would—it is worth exploring how to improve the IRBs to facilitate clinical research for veterans. Absolutely important.

Mr. DUNN. Okay. While I have got you there, Dr. Klotman, I am going to ask you about translation of VA research to the vet side. So that if a clinical translation, do you think that that is happening well? Do you think it is happening rapidly, or enough?

Dr. KLOTMAN. I think it is happening terrifically well. We respond, you know, scientists respond to funding opportunities. When you list five priorities, our scientists are focused on mental health, on opioid addiction, on PTSD, traumatic brain injury. We are trying to do AI, run facial recognition to pick up depression by telemedicine. So we are very focused on trying to translate our work directly to patient care. But that is a mission, you know, of the—you look at the top 30 or 40 medical schools that are into research, it is—we do translation research, that is what we are trying to do, and the VA does it very well.

Mr. DUNN. So if I am a medical student—I am not going to go back to medical school—if I was a medical student—

Dr. KLOTMAN. I would feel sorry for you.

Mr. DUNN [continued]. —you could have a—you have a syllabus for —and I think these three would fit—or four, top four priorities, or five, would fit together very neatly; PTSD, TBI, suicide, and opioids. I mean, that sounds like one chapter, get this, and read it twice. Is that—we have a syllabus for that?

Dr. KLOTMAN. Well, we don't have a syllabus per se, but we do encourage our students to do research with these investigators. One of the—we have a specialized center called iQuest, which is really around health and human services research, it is one of the biggest in the country. And we have 25 faculty and probably 40 trainees in that group all doing research appropriate for veterans. It is actually funded by the VA and the NIH, and it is a tremendous center. So we have direct access for our trainees and learners to get into issues related to veterans.

Mr. DUNN. Great.

Dr. Clancy, so the same question on translation. Can you address that from your point of view, or maybe Dr. Ramoni? You choose.

Dr. CLANCY. Well, research that we publish, and support is highly publicized within our own system. The next step is obviously to make sure that that is tightly linked with clinical operations. And I have to say that under Dr. Ramoni's leadership, there has been a much, much stronger partnership there between the research enterprise and the people who have got to worry every day about how to get this done.

We literally had all of our network leaders in town this week, and to say—and Dr. Ramoni was not actually there for the conversation—but to say they were excited about research, and to hear where they have taken money out of their own budgets to make sure that their veterans have access to the findings so that they can put them into practice was quite—

Mr. DUNN. I am running short on time—

Dr. CLANCY [continued]. —wonderful.

Mr. DUNN. —here, so I—and I want to be—I want to observe the limits so that I will be a good role model here. The ORIEN, Dr. Ramoni, are you using ORIEN for the total cancer care? Is that something that is?

Dr. RAMONI. We are not—sorry—we are not yet participating in ORIEN, and that is in part because ORIEN and APOLLO in which we are participating, both are seeking the same types of samples.

Mr. DUNN. Okay. You and I are going to talk offline. And I recognize my time has run out. I will yield to Ms. Brownley. Representative Brownley.

Dr. RAMONI. I look forward to that. Thank you.

Ms. BROWNLEY. Thank you very much. I have just sort of a general overall question as it relates to the research that VA is undertaking. So where does one go to find out where all of the research, you know, what are all of the research projects, you know, across the country, and where is that happening? You know, what are sort of the subject areas? Dr. Dunn just mentioned a couple in terms of opioid abuse or brain injuries, post-traumatic stress, et cetera. But where—I don't know kind of what is happening on a global sense in terms of the research.

Dr. CLANCY. It is a great, great question, and I am so glad you asked. We put out a lot of information in the form of quarterly updates and newsletters. And I will tell you if you run an organization, as I did for a number of years outside VA that funds a lot of research, it is a bit challenging to figure how do you put these into buckets together in a way that is very, very accessible.

I think we could do a better job. I think that in many ways some of the phenomenal research we are funding has become one of the world's best kept secrets, and we are working very hard to try to overcome that. Do you want to add to that?

We also have an external research advisory committee that meets four times a year. So they become a very important source of spreading our research. But we have a lot more to do.

Ms. BROWNLEY. Are they like an overseer, or?

Dr. CLANCY. They are an advisory group. I think it is fair to say that they do give a lot of advice. And one person's advice might feel like someone else's oversight. But four times a year I think is a pretty good rhythm, and they are pretty current on what is going on.

Dr. RAMONI. Hi. Thank you for your question. I would just like to add that all of the research we fund is available through ERA Commons, which is NIH reporter. So if you go to the NIH reporter Web site and you select VA, you can get a list of all the projects we fund.

Now, as Dr. Clancy said, I think we can do a better job of summarizing that because I doubt with your busy schedules that you have time to scroll through our 2,000 funded projects. But what we are—what our national research advisory committee has advised us is that we ought to, at least on a yearly basis, summarize the research impact so that we can share more broadly with others. And we do have a breakdown of where our funding is going in terms of types of research that we can certainly make available to you.

Ms. BROWNLEY. And is that found on a Web site somewhere as well in terms of the priorities and the amount of resources funding as priorities?

Dr. RAMONI. We can certainly direct you to those. I am not certain if they are listed on the Web site because as Dr. Clancy said, it can sometimes be a challenge to clearly convey the distinct categories. For instance, if you were looking at suicide risk amongst people with opioid substance use disorder, they would be classified under two sections. And so that is sometimes a challenge for us to present. But we would be happy to walk you through that orally as well in a briefing.

Ms. BROWNLEY. Yeah. And just as a, you know, a layperson looking into this, it seems—it just seems very complicated and complex in trying to, you know, pull the layers apart to kind of see what is there. And once you start doing that, it tends to get more confusing—to me, anyway—and more complicated as opposed to sort of understanding, you know, what are the broad strokes, and are we all in agreement in terms of where—what our priorities are in the areas in which we want to continue to explore. And so, anyway, it just is a general statement. I think for a layperson and for people to understand that we are actually doing research and pursuing in-

novations when we really can't translate to the public and to the communities so that people know that their tax dollars are going to a good purpose, and that we do want to resolve and solve some of these issues that particularly veterans are experiencing when they come home from the battlefield, so.

Dr. CLANCY. So I am going to take that as a charge that we need a greatest hits. To use an old analogy. No, but I mean, I am saying that with the upmost respect. It takes some thought and so forth to do that. But we should.

Ms. BROWNLEY. Very good. I see my time is out, so I will yield back.

Mr. DUNN. Thank you, Representative Brownley. And since you yield back ten seconds, I am going to say we would all like to see that list of, you know, sort of—not the all 2,000 but how you are prioritizing, where the resources are going, and sort of by subject matter what they are. So thank you very much for that.

We will now recognize Mr. Poliquin for five minutes.

Mr. POLIQUIN. Thank you, Mr. Chairman, I appreciate it. Thank you all very much. It is so important to make sure that our research goes on with our affiliates, our academic affiliates, in concert with VA to make sure that we do the best we can for our veterans. We owe them that responsibility to do that.

Dr. Klotman, I want to ask you a question. You mentioned a minute ago some of your research dealt with diabetes, and what have you. Why wouldn't the VA—why wouldn't all the research on behalf of our veterans focus on ailments and maladies that are specific to veterans like PTSD, and traumatic brain injury, and exposure to toxins, and so forth, so on? If you have all these other institutions around the country doing great work on cancer and diabetes, why would we spend tax payer dollars to do that when we can get that already?

Dr. KLOTMAN. So I think you have to look at the broad health of veterans throughout their entire life span. Yet there are things that are very specific to veterans, but there are also things that impact veterans' lives. If you look at, you know, the vast number of veterans that we are taking care of, their day-to-day problems are often common illnesses.

Mr. POLIQUIN. Yeah. We have research on most of those common ailments.

Dr. KLOTMAN. But breakthroughs come from all different places. It is really hard to, you know, to say, well, we are going to have a cure for diabetes that is NIH focused.

Mr. POLIQUIN. So we might be doing—

Dr. KLOTMAN. Another big breakthrough might come from—

Mr. POLIQUIN [continued]. —we might be spending tax payer—

Dr. KLOTMAN [continued]. —VA—

Mr. POLIQUIN [continued]. —we might be spending tax payer dollars working on diabetes for veterans where we are doing it at other research facilities around the country, and you don't think that is duplicative and wasteful?

Dr. KLOTMAN. No, I actually don't. I will tell you the vast majority of research that we do at the VA is very specific to veterans' problems. But—

Mr. POLIQUIN. The veterans—thank you, sir. Dr. Clancy—

Dr. KLOTMAN. Let me just say one thing, though. If you are taking care of a veterans for their entire life span and you are trying to have them have a, you know, good outcomes, you have to take care of all of their illnesses.

Mr. POLIQUIN. No, of course not. I am not talking about specific to a veteran, I am saying a malady that is specific to the veteran population, that is what I am referring to.

Dr. Clancy, the VBA, the Veterans Benefit Administration, collects mountains of data on the 7 million veterans we take care of now. Do we aggregate this data, and whiteout, of course, who the individuals are, but aggregate this data such that we can use it to determine where the research should go?

Dr. CLANCY. We have some people who are beginning to take a very hard look at that. I guess—

Mr. POLIQUIN. Do we aggregate the data, and do we use it to make decisions on where the research dollars should go for our veterans? Because anybody that collects that amount of data on the veterans certainly know what their problems are.

Dr. CLANCY. Yes, and we are certainly aware of where the greatest opportunities are in terms of—

Mr. POLIQUIN. Okay. So who is aggregating—

Dr. CLANCY [continued]. —how many people apply for benefits.

Mr. POLIQUIN. So who is aggregating that data?

Dr. CLANCY. We can take that for the record, and I will follow-up. It is not a routine function that feeds right into research priorities, but I—which is what I think you are suggesting.

Mr. POLIQUIN. If we are looking for research on veterans who have problems, and we have mountains of data on what their ailments are, it would make sense to me that we use that information. So our office will get back to you to see what a more complete answer would be, if that is okay.

Dr. CLANCY. Yes, that would be fine.

Mr. POLIQUIN. Great. Thanks. Today, Mr. Chairman, there is about \$600 million in the VA budget that is specifically earmarked for medical research that is conducted either at the VA medical facilities around the country, about 160 of them, but there is an additional \$1.2 billion each year, roughly, for veterans—for research for veteran health, and it comes mostly from the NIH and the Department of Defense, and they are issued by grants.

This research is either conducted at the VA or at medical institutions, affiliates, academic institutions, universities like Baylor, great universities like Baylor, across the country. Now there are, if I understand this correctly—and, Ms. Rusconi, you are going to correct me if I am wrong, I am sure—there are roughly 150 individuals across the country that make decisions where the administration of those research projects go.

Either through you folks, through the NPCs, or they are administered actually through the research organization themselves. I think they are called investigators. And I think, Ms. Ramoni, you came to us several months ago, and you used to be an investigator. And, Mr. Klotman, you might be one now, I don't know.

But my point being this. If an investigator is an employee of the VA, and also an employee of say Harvard—my alma mater, so I am not picking on Baylor—and they all of a sudden are an individual,

he or she, whose career is dependent upon how much tax payer dollars they can come to that institution, whether you are Baylor or Harvard, or Yale or Stanford, whatever it might be, but they are also in a position to determine who gets the administration dollars for that project. Now, up in Maine, where I come from, that is a conflict of interest. And here is why that matters.

Let's say you have a \$10 million grant from the NIH. The administration cost is an add-on to that grant. Now if I am not mistaken, over at the NPCs that were formed 30 years ago specifically for this reason, your add-on cost is roughly 25, 26 percent. So that is \$2-and-a-half million on a \$10 million grant to develop whatever it might be, a new prosthetic. However, now places like Harvard, my understanding—

Mr. DUNN. Mr. Poliquin.

Mr. POLIQUIN [continued]. —is that the add-on cost—

Mr. DUNN. Mr. Poliquin.

Mr. POLIQUIN [continued]. —is roughly 70 percent.

Mr. DUNN. Mr. Poliquin?

Mr. POLIQUIN. Yes, sir.

Mr. DUNN. Your time is expired, but I like your line of questioning. I encourage you to pursue that.

Mr. POLIQUIN. Great. Would you like to, or anybody else like to give their time to me? Mr. Chairman.

Mr. DUNN. I will give them their opportunity when your time comes. All right. So that will be the next.

Mr. POLIQUIN. Thank you, sir.

Mr. DUNN. Representative Kuster, you are recognized for five minutes.

Ms. KUSTER. Thank you very much, Mr. Chairman, I appreciate it. And thank you to all of our witnesses for being with us. I want to also thank you for mentioning the LUKE arm in your testimony, Dr. Clancy. We are very proud in New Hampshire of the development of the LUKE arm, and I have had a chance to see it in action, and it is really very impressive.

I wanted to hone in on the conversation about, our Chair today has mentioned PTSD, traumatic brain injury, opioid addiction. I am the Chair of a bipartisan task force in Congress, we now have 105 Members working together, Republicans and Democrats, on legislation to combat the opioid epidemic, and I know that there is research being conducted, Congressman Brownley referenced a study out of Minnesota. It would be very helpful for us, and I would even like to ask our Chairs of the Health Committee, and the Subcommittee, and the Oversight Subcommittee, if we could put together a session that I would be happy to organization with members from the task force to talk about lessons that can be learned to reduce the use of opioid medication.

But in that regard, can you talk a little bit more about how this research is getting from the lab to use across the VA? And then what we would like to do, I am working on legislation about a center of excellence, so that we can then take those lessons learned into the civilian population.

Dr. CLANCY. So it is a great question, and, frankly, we use any vehicle that we can. So, for example, in terms of treating chronic pain and the use opioids, we have an evidence-base guideline that

we develop in collaboration with the Department of Defense because it speaks to the unique injuries and experiences of active duty members as well as veterans.

So that becomes one—because those guidelines are updated almost continuously to make sure that they have all the current evidence, that becomes one great vehicle to incorporate our latest research. I think that your idea of having such a session would be phenomenal because there is a lot going on in three areas.

One is, what other alternatives do we have to opioids? A second is, what nonpharmacologic in terms of chronic pain management, which the whole country is struggling for, and a bigger problem for our veterans. And the third is, how do we help people who are addicted actually begin to return to a functional life?

Ms. KUSTER. And if I could just add to the list, a fourth would be the CDC has recognized that four out of five heroin users have co-occurring mental health issues—

Dr. CLANCY. Yes.

Ms. KUSTER [continued]. —and I think that veteran population, with the anxiety, depression, traumatic brain injury, we are finding in the civilian population trauma. For example, sexual assault, domestic violence trauma. So I think there is a lot to be learned, and you can tell from 105 Members of Congress coming and working together right now, this is very rare, and you can tell the urgency and the breadth of this problem across the country. So love to work with you on that.

I guess my other question, I am very familiar, Dartmouth Medical School is my district, I work a lot with them, and they are the academic affiliate for White River Junction VA and hope—we are working on an affiliation, hopefully, with our Manchester VA that has had some troubles. I am familiar in the private sector in the civilian world that we have, for example, the New England Journal of Medicine, that physicians can stay current on research that is published. Is there a corollary from VA research where physicians can stay current based upon research results that are published?

Dr. CLANCY. So we have a terrific dissemination center that is part of the Office of Research and Development, and they will routinely put out surveys of research, which is—not surveys, I am sorry, summaries of research that has just been published and so forth which is extremely helpful, they will usually give you the electronic link. So if the journal makes a free access, right then you have got it. And I was literally looking at one on the way over here.

Some of our work is also going to get into something at NIH called Medline Plus, which actually translates into something closer to plain language English, I don't want to over-state this, sort of abstracts of published studies and so forth. Whether we can and should do more, we share a lot of cutting-edge findings with our veteran's service organizations and so forth. But I am sure that there is more that we could do.

Ms. KUSTER. So my time is, but I think I would join my colleagues in saying that we would be very interested in accessing those preferably plain English versions to understand so that we can share with the tax payers the incredible advances that are coming out of the VA. And I yield back.

Mr. DUNN. I thank you very much, Ms. Kuster.

Representative Higgins, we recognize you for five minutes.

Mr. HIGGINS. Thank you, Mr. Chairman. I would like to yield a minute of my time to my colleague Mr. Poliquin.

Mr. DUNN. You are recognized.

Mr. POLIQUIN. Thank you, Mr. Higgins, very much, I appreciate it.

We have already determined that at NPCs the add-on cost for administration is roughly 25, 26 percent. Mr. Klotman, what is the add-on cost of Baylor?

Dr. KLOTMAN. 56.5 cents.

Mr. POLIQUIN. Say it again, sir.

Dr. KLOTMAN. 56.5 cents.

Mr. POLIQUIN. 56.5. Ms. Rusconi, what is the difference between the administrative functions you provide for research down at the VA and the administrative that the folks at Baylor do, or at Harvard, or Yale, or anybody else? Is the service essentially the same? Does it include doing the paperwork, and paying the bills, and ordering supplies? Do I have that right?

Ms. RUSCONI. For the most part I would agree. At our VA, our VA actually has—takes care of all of the RIB and all of the services that were described.

Mr. POLIQUIN. Thank you. Mr. Klotman, who determines whether it is 56 percent or 70 percent?

Dr. KLOTMAN. The NIH. The NIH comes—the HSS comes and does a very complete audit, which it is like everything—

Mr. POLIQUIN. So it is NIH?

Dr. KLOTMAN. Yes, it does.

Mr. POLIQUIN. Whoever awards the grant, they determine what you are going to get paid?

Dr. KLOTMAN. We negotiate with them every three years, and we show our costs. I mean, it is very rigorously reviewed, the costs of oversight and research. The differences are often what services you are providing. So we, you know, we provide IACUC, IRB, all those real—those are real costs that—

Mr. POLIQUIN. Ms. Rusconi, do you provide the same services they do at the academic affiliates?

Ms. RUSCONI. Actually, at the Kansas City VA we provide the IACUC, the IRB, and the R&D for our facility as well as the facility in Wichita, Kansas, and we provide—

Mr. POLIQUIN. Okay.

Ms. RUSCONI [continued]. —the IRB—

Mr. POLIQUIN. Okay.

Ms. RUSCONI [continued]. —and for—

Mr. POLIQUIN. Thank you. We are stewards of the tax payer dollars, we are \$21 trillion in debt, the interest payments on that debt are about \$240 billion a year, that exceeds our entire budget by the VA by about 40 percent. Every dollar counts.

Mr. DUNN. Mr. Poliquin.

Mr. POLIQUIN. What I am trying to determine is, we have got two folks—

Mr. DUNN. Mr. Higgins—

Mr. POLIQUIN [continued]. —providing the same service—

Mr. DUNN [continued]. —will you yield another minute—

Mr. POLIQUIN [continued]. —but one is—

Mr. DUNN [continued]. —to Mr. Poliquin?

Mr. POLIQUIN [continued]. —twice the cost of the other, and I am trying to figure out why.

Mr. HIGGINS. I already have.

Mr. POLIQUIN. Sorry, Clay. Thank you, Clay.

Mr. DUNN. One more minute.

Dr. KLOTMAN. I would just say, you should look at the services provided. I mean, this is a real menu of costs, these are not fictitious costs, they are real overhead. Just in the same way you come to this building—

Mr. POLIQUIN. And whoever issues the grant, NIH DoD, they determine what your costs will be in negotiate with you, correct?

Dr. KLOTMAN. Correct.

Mr. POLIQUIN. Okay.

Dr. KLOTMAN. And the grants—a point you made before about, it is the individual and the conflict of interest. The grants are administered to the institution not to the individual.

Mr. POLIQUIN. No, but the individual—

Dr. KLOTMAN. It is in the name of the institution.

Mr. POLIQUIN [continued]. —who's the investigator at the institution can also award the administration to you.

Dr. KLOTMAN. The—

Mr. POLIQUIN. Is that correct?

Dr. KLOTMAN. Well, that is not really accurate. For NIH it is the grant is awarded to the institution on behalf of the individual. The expectation is that the institution supervises and oversees the research, and that the spending is responsible within—

Mr. POLIQUIN. And who determines where that administration—administrative dollars go? Does the NIH or does the investigator?

Dr. KLOTMAN. The NIH determines where it goes, it is not the individual investigator. With an individual—

Mr. POLIQUIN. That is not what Dr. Clancy and Dr. Ramoni told me.

Dr. KLOTMAN. No, if there is an individual who has shared time, every two weeks they have to fill out their activities report, and if—the amount of time that is covered at the VA is covered by the VA, and the amount of time that is covered by the NIH is covered by the NIH. There is no overlap of the two.

Mr. POLIQUIN. Okay. So you don't think it is a—

Mr. DUNN. One moment, Mr. Poliquin. Representative Higgins, you have three minutes remaining. Do you—

Mr. HIGGINS. (Inaudible).

Mr. DUNN. Then you are recognized for three minutes, Representative Higgins.

Mr. HIGGINS. Thank you, Mr. Chairman. And God bless you my colleague, Bruce.

Dr. Clancy, you may recall, madam, we met in my office, and we briefly discussed inclusion of urgent care facilities as a means by which veterans could access care in their community. The VA mission act passed the House of Representatives yesterday. If signed into law, will this provision and the precedence set by the recent launch of urgent care access for veterans in Southern California, will that provide the VA adequate authority to expand access to

these walk-in urgent care facilities in other regions? I have been advised that it would. Thank you for that answer.

Dr. CLANCY. Yes.

Mr. HIGGINS. My larger question to you, Dr. Klotman, you mentioned some of the research being tele-medicine using facial recognition for depression. I have an overall concern about a culture of over prescription, of pharmaceuticals, for our veterans; opioids, anti-depressants. And when investing money that has been harvested from the people to pay for research, and I am a big supporter of tele-medicine, I think it is wonderful, I have large rural communities in my district, but facial recognition for depression, how would that determine the difference between temporary depression or normal moments of sadness, or reflection, a contemplative somber moment, how would that differentiate from the diagnosis of clinical depression which could lead to further over prescription of pharmaceuticals into our veterans population? I am very concerned—

Dr. KLOTMAN. No, I understand.

Mr. HIGGINS [continued]. —about the culture we have created within our veteran populations that our goal should be to get them back into a state of productive—

Dr. KLOTMAN. I agree.

Mr. HIGGINS [continued]. —participation in society, and yet we are building barriers for them to return to work, and return to society, as a productive citizen because of the pharmaceuticals that we prescribe.

Dr. KLOTMAN. Well, I think you have hit upon a national problem, you are absolutely right. The study that is currently ongoing is to do exactly what you said, can you sort out a situational—

Mr. HIGGINS. Are we working on non-medicinal treatment—

Dr. KLOTMAN. Oh, yeah.

Mr. HIGGINS [continued]. —research for PTSD, for instance?

Dr. KLOTMAN. Absolutely. Absolutely, yeah.

Mr. HIGGINS. Service dogs—

Dr. KLOTMAN. And the other thing—

Mr. HIGGINS [continued]. —exercise, group therapy, et cetera?

Dr. KLOTMAN. And it is hard for veterans sometimes to come to the VA. The whole purpose of this is getting more continuous follow-up so you can detect problems sooner. I mean, the idea is to improve their lives in ways that are not drug dependent. Absolutely.

Mr. HIGGINS. Thank you for your answer. And I would also like response, perhaps in writing, from my colleague brought up, Mr. Chairman, regarding where exactly can we observe what research is taking place across the country and what the nature of that research is. I yield back.

Mr. DUNN. Your question is noted, Representative Higgins.

Representative Lamb, you are recognized for five minutes.

Mr. LAMB. Thank you, Mr. Chairman.

Dr. Clancy, by way of greatest hits, I just wanted to note back in Pittsburgh in a VA that is not actually in my district, but it is near it, and it takes care of many of veterans from our district, we had the development of a pneumatic wheelchair powered by an air motor, Dr. Rory Cooper, we are very proud of that.

The chair only weighs 80 pounds, and it can be used—it is water-proof basically. So one of the things they have used it for is kids with disabilities go to water parks and they use it, veterans as well. So that was a great achievement by our VA research in Pittsburgh at the human engineering research lab. So I think that is a good one to highlight. It has made a big difference in people's lives. It is easier for family members to carry it around because it is so light.

One concern that I have heard expressed from folks back in Pittsburgh is that in the Office of Research and Development, there tends to be a lot of resources behind the research side of it and less behind the development side of it. So I will just throw it open, maybe either Dr. Clancy or Dr. Ramoni, have you heard that concern before from people within the system?

Dr. RAMONI. Thank you, Congressman Lamb. That is, as you heard, one of my three priorities is to increase the real-world impact of VA research. And, in fact, in collaboration with Dr. Rory Cooper's lab in Pittsburgh, and I had the pleasure of visiting it and using that pneumatic wheelchair which is really a remarkable invention, we are establishing a development pipeline with him.

Often the first step is producing enough of a thing such that you can get buy in to produce it more broadly. For instance, to have enough versions of that pneumatic wheelchair such that a company might want to pick it up and produce it and distribute it. So we are entering currently into a partnership with Dr. Cooper's lab in order to do that.

In addition, we are taking a number of other steps to ensure that we move from bench or lab to bedside more quickly. We are, in the basic science space, funding actual development dollars to conduct toxicology studies which are the gap between the bench research and moving into clinical trials. So we have a broad-based effort to take more of our in-lab developed innovations and move them out where veterans can benefit from them.

Mr. LAMB. What is kind of the number one thing that we can do to support that to make it easier?

Dr. RAMONI. Well, it is certainly companies—I would say one of our great challenges is that sometimes veterans have very specialized needs. And so, for instance, an upper limb prosthesis, some companies might not find it financially attractive to proceed in those spaces. And so any help that, frankly, and party can provide to us in helping to overcome that barrier would be wonderful.

As an alternative, we are looking at, in those cases, could we as a department, and obviously this would be outside of research and development, could we actually produce those items for our veterans if no for-profit company is willing to step into that space.

Mr. LAMB. In addition to just overall more funding for research, are there specific programs that could use a shot in the arm to improve that transition that you are talking about?

Dr. RAMONI. So in technology transfer, and, of course, people know a GAO report came out recently, and that is an area of intense focus for us, we are doing a fantastic job on getting invention disclosures. The machinery to then actually market those inventions to producers is something that we are building. And so that

area in particular will help us go from invention to actual real-world use by veterans.

Mr. LAMB. Great. And I yield back the remainder of my time, Mr. Chairman. Thank you.

Mr. DUNN. Thank you very much, Mr. Lamb.

Mr. Arrington, you are recognized for five minutes.

Mr. ARRINGTON. Thank you, Mr. Chairman.

I want to follow along the line of my colleague Mr. Lamb. I was former vice chancellor for research and technology commercialization at Texas Tech, believe it or not. It is complicated, and it is challenging to get an early-stage technology to market. It takes a lot of time, it takes a lot of capital, it takes an entrepreneurial team. Not many universities are culturally aligned with sort of this sort of entrepreneurial dynamics that exist in the marketplace. So you got to really wire it well. There are some sophisticated ecosystems at Stanford, and Boston, and some other places, but it is very, very difficult.

Personally, my take on this is get it out, get it out of the VA, for God's sake. And I am just saying that because it is a big bureaucracy, and it is not entrepreneurial or innovative, but there could be some great discovers. I think relatively speaking, it is just universities don't have that very well. The best way to commercialize it is get it to a start-up company, get it to an established industry partner and let them run with it, and make sure that we take a piece of the action to evergreen the research.

Speaking of that, what are the deals that we made? How many—you said disclosures have increase, so what about revenue from—what about license agreements? Are they going up or down? Sorry, you, Ms. Ramoni.

Dr. RAMONI. Rachel. Yes. So thank you for your question. It is an area that is a very high interest to me not only for the revenues but also because this means that these products are out there where veterans can benefit—

Mr. ARRINGTON. Exactly.

Dr. RAMONI [continued]. —from them.

Mr. ARRINGTON. But if there is no financial motive they won't do it. Just let's be clear.

Dr. RAMONI. Absolutely.

Mr. ARRINGTON. So how many license agreements? Are they going up or down, or are they flat?

Dr. RAMONI. They are going up. And I have the facts and figures in here. But I can tell you, in terms of royalties, and if you read the GAO report, it is a pretty stark description of where we are now, or where we were. Back in 2016, we just had \$300,000 in royalties. And I have to say, historically that—

Mr. ARRINGTON. 300, how much?

Dr. RAMONI. Thousand dollars in royalties.

Mr. ARRINGTON. That is it?

Dr. RAMONI. Yes. And that is what I am saying. It is a pretty stark—

Mr. ARRINGTON. How many annual disclosures do you get of potential IP—

Dr. RAMONI. We get hundreds—

Mr. ARRINGTON [continued]. —potential marketable product?

Dr. RAMONI. Over 500 disclosures.

Mr. ARRINGTON. Over 500?

Dr. RAMONI. That is right.

Mr. ARRINGTON. So I would say that is—

Dr. RAMONI. Yes. And I do want to add that—

Mr. ARRINGTON. How long have you been in this space of technology transfer within the VA?

Dr. RAMONI. Well, I have just been—

Mr. ARRINGTON. Not you personally, the VA in general.

Dr. RAMONI. So the VA, I think the—certainly the attention that the VA receive from the House Veterans Affairs Committee surrounding the Shanaze hepatitis C treatment brought greater attention, and we are grateful for Mr. Bergman having written to the Secretary to increase our number of staff in tech transfer. So it has been a relatively recent growth in our tech transfer team, and we got a new head of tech transfer—

Mr. ARRINGTON. I would outsource it.

Ms. RAMONI [continued]. —tech transfer team.

Mr. ARRINGTON. I would give it to a group that does that, that that is their core competency. They do that for a living. They have the connections with the money guys. They have the connections with the industry. They move at the speed of business. I just would do it.

I mean, I must say, 500 disclosures—

Ms. RAMONI. Yes.

Mr. ARRINGTON [continued]. —and \$300,000 in revenue—

Ms. RAMONI. Yeah, I know.

Mr. ARRINGTON [continued]. —is paltry.

Ms. RAMONI. I—

Mr. ARRINGTON. And it is—I am not blaming you. I just don't think it is aligned with the core mission.

Ms. RAMONI. Well—

Mr. ARRINGTON. We have got to have incentives to get these—this IP to—into the right hands, where they can raise the capital, take it to market, and make a difference. They will never make a difference, in my opinion, inside the VA culture. It is not wired for that. And it is—

Ms. RAMONI. Right.

Mr. ARRINGTON [continued]. —not an indictment on your skills and competency. It is just a culture reality.

Ms. RAMONI. I agree with you—

Mr. ARRINGTON. What is the—

Ms. RAMONI [continued]. —entirely.

Mr. ARRINGTON [continued]. —let me just jump to Clancy—for

Dr. Clancy. What do you—how do you measure success? And I am not trying to be rude. I just—it is time. We don't have a lot of time. So what—how do you measure success among your—the researchers that you give taxpayer money to, to discover?

Dr. CLANCY. Sure. So broadly, that would be publications, of course. It would be who else or what other entities have picked up those publications. So for example, if work published becomes part of a Medicare quality measure, that is going to have a big impact—

Mr. ARRINGTON. Does—

Dr. CLANCY [continued]. —and get out and so forth.

Mr. ARRINGTON [continued]. —transferring the technology, to commercializing the technology, is that a metric?

Dr. CLANCY. That has to be a metric.

Mr. ARRINGTON. Is it a metric of success? Do you—

Dr. CLANCY. Yes, yes.

Mr. ARRINGTON [continued]. —hold people accountable for that?

Dr. CLANCY. Do we hold them accountable? Not yet. I want to be clear. Under Rachel's leadership, just in the past two years, we are on an upward curved for sure. I would love to have the opportunity to follow up with you, your staff, about what might be some options for who else we could partner with to make this happen. Some parts of the government have small business innovation research, and a variety of mechanisms that we actually do not have.

But that is just one that occurs to the top of my brain. I am sure there is a variety of other mechanisms, and given your experience, I think it would be a great—

Mr. ARRINGTON. I would love to—

Dr. CLANCY [continued]. —opportunity to follow up on.

Mr. ARRINGTON [continued]. —sit down with you. I want it to be successful, and I am over my time.

If you have a second round, I am going to stick around.

Mr. DUNN. And to that point, we will have time for a second round. I encourage you to stick around and take advantage of that.

Mr. ARRINGTON. Thank you, Mr. Chairman.

Mr. DUNN. These are great questions.

Mr. ARRINGTON. Sorry to abuse my—

Mr. DUNN. But I will recognize now, for five minutes, Representative Rice.

Ms. RICE. Thank you, Mr. Chairman. The Vietnam Veterans of America's statement for the record raised an issue about limited VA funded research for certain health conditions that are of immediate consequence to veterans, citing the long-term effects of Agent Orange exposure as an example. That remains significant for Vietnam war veterans. And conditions stemming from military exposure, such as toxic substances from burn pits for Iraq and Afghanistan veterans.

This point relates to an issue that has been raised by veterans in my district, in New York, on Long Island, regarding exposure to liver fluke in Vietnam which is a parasite prevalent in Southeast Asia known to cause a certain type of cancer that can take, literally, decades for—I mean, I am telling you. You guys know this—for symptoms to appear.

The VAMC in Northport, which is further out on Long Island, conducted the first ever pilot study on liver fluke in Vietnam vets through a partnership with an academic medical center in South Korea, which was privately funded after the VA declined to fund the study. For veterans who are just starting to show the long-term effects of something that they were exposed to in Vietnam, this type of health condition, obviously, is of immediate concern.

So to any of the panel Members, this concern that the VA is not funding research for certain health issues that are of immediate consequence to veterans—and now, while I may admit that this—the effects of liver fluke might relate to a small population of vet-

erans, they still served this country, and are suffering this condition because of their service.

So if anyone can answer that question as to why the VA is not funding research for certain health issues that are, right now—and for that matter, the Iraq and Afghanistan veterans, that are of immediate consequence to veterans?

Dr. CLANCY. Well, thanks to your support—that is of the Congress, right? We are funding a burn pits registry, and I have been really seriously impressed by the enthusiastic response from veterans in terms of their enrolling in this. And one of Dr. Ramoni's five priority areas for the additional support we got through the omnibus is actually to focus on exposure to Agent Orange and the impacts among Blue Water Navy veterans.

The liver fluke issue is quite interesting. I would say it is fair to say that one can find lots of examples, not just at VA but elsewhere, where somebody turned down a very novel, kind of, research product at one point in time or in—what was something that in—overtime turned out to be very, very consequential.

The word is out among veterans. One of the challenges we have is that we do not, at this moment in time, as I understand it, have a commercially available test to be able to test for that. So many veterans are coming in to see their docs, saying “I want this test because I read about this research.” So we need to find out more about that, and we would be happy to follow up with you.

Ms. RICE. Well, thank you. I would ask—

Dr. CLANCY. And I know that Rick is very interested.

Ms. RICE. Yes, thank you. Final question, then I will give whatever time I have to Mr. Poliquin, if he wants it.

What steps can the VA take to standardize and eliminate delays associated with the ISO reviews, to advance clinical trials, and support successful research partnerships?

Dr. CLANCY. ISO with you.

Ms. RAMONI. Thank you for your question. As you might have heard, we held a summit on April 12th with a broad variety of stake holders to look at all the barriers that prevent us from starting up clinical trials, especially industry trials, efficiently.

One of those was the information security officer review, and I am very happy and proud to say that we now have three research specific information security officers—officers in place, and I have been receiving e-mails from the field that say that this transforms everything, and this, when we announced it at the summit, received a standing ovation. So

Ms. RICE. Well, that is great.

Ms. RAMONI. —we are pleased to have addressed that.

Ms. RICE. Great, great. That is great news. And I have 51 seconds for my friend Mr. Poliquin—

Mr. POLIQUIN. Thank you.

Ms. RICE [continued]. —with the Chairman's approval.

Mr. DUNN. You are recognized for 46 seconds.

Mr. POLIQUIN. Thank you very much, Congressman. I have in front of me the May report of the Inspector General at HHS. Let me read this to you, if I may.

“The Department of Health and Human Services, which is the parent organization for the National Institute of Health, and under

that is the Division of Financial Advisory Service, DFAS, is the Federal agency responsible for negotiating and establishing indirect cost rates, i.e. administrative rates, for non-profit organizations, our affiliates, academic affiliates, that receive the majority of the Federal awards from HHS.” And their conclusion in part, “DFAS did not always comply with Federal requirements for establishing indirect cost rates.”

So I am very suspect that the process that is used to determine the rates between our affiliates in the Federal government is up to snuff. But with that, thank you very much Congressman Rice. I know we are going to have a second round, if I am not mistaken, Mr. Chairman.

Mr. DUNN. There will be a second round.

Mr. POLIQUIN. Thank you.

Mr. DUNN. I now recognize General Bergman for five minutes.

Mr. BERGMAN. Thank you, Mr. Chairman. You know, we are overloaded with acronyms around here. We would like to give you a new one; RTR, Research to Results.

So having said that, as you look at where you are, because we see—I see a lot of familiar faces at the testimony table, and you see at the front end of the food chain with those doing the research, we see you all the time. Why don’t we see them? That is okay. It is a rhetorical question. I can tell, stunned.

No, the point is the—we have all played the game where you start the message around the room and by the time it gets back—and this Committee, you know, bipartisan, we want to get to the bottom line very quickly. Not that they have to come here and testify, but I would suggest to you that most of the Committee Members here would be more than willing to devote some time to walk right into a research lab because of the fact that we get to talk with the people right then, right there.

So when front end, those literally in the labs doing the research, to this end where we are doing, you know, the testimony if you will, as far as the results—again, I will just speak for myself. I like to see the amount of layers that this goes through, and where it gets scrubbed, where it gets, you know, redirected. So the point is, we can do better.

Dr. Clancy, do you think the VA, NIH, and possibly DoD are duplicating research?

Dr. CLANCY. Having run a research agency for a number of years, for HHS, I can assure that a very key part of all applications submissions is saying where else that you are funded, and if you are untruthful about that, that is fraud and a reason to withdraw support. So by and large—and we have people that check that all the time. So I don’t think that they are duplicating research.

What I worry about more is gaps, and that is where we have been reaching recently far more to the NIH, to Defense, and so forth, to figure out “Okay. Here is all this great stuff”—

Mr. BERGMAN. So the point is—

Dr. CLANCY. Yes.

Mr. BERGMAN [continued]. —if we were to say, “Okay. Can you give us an example over the last four or five years of where a—this review board or whoever the folks were, you could produce a list of said, “Okay? You know, Houston and New York are doing

this overlap, and we said no to one of them.” I mean, is there some kind of data that we could get?

Dr. CLANCY. In general, that is almost always going to be handled before it even gets to peer review by a scientific committee. If it doesn’t get handled then, it is going to get handled before—

Mr. BERGMAN. Are there records? I mean, of the peer—I mean, the bottom line is, when someone is sitting at a desk, is asked to look at a couple different proposals and says, “No, we are already doing it here,” is there data that we can pull up that says that?

Dr. CLANCY. If it looks—I can’t speak for NIH, but could find out for you, and I don’t know if we have that kind of record. I know that in general, we feel like the opportunities greatly exceed available resources, which is not intended to sound ungrateful. But it also means that—

Mr. BERGMAN. Well, that—but that is more of a reason—

Dr. CLANCY. Exactly.

Mr. BERGMAN [continued]. —because if you have more opportunities than you do have resources, we have to ensure everything—

Dr. CLANCY. Yes.

Mr. BERGMAN [continued]. —we do does not accidentally overlap something that is already being done, because we are dealing with finite resources here that we have to focus on that research that is going to directly benefit our veterans in the long term.

I would like to, just for a second here, to expand on Mr. Poliquin’s line of questioning. You know, Dr. Clancy, in many instances, a researcher who decides which entity, the VA or the affiliate, will administer the NIH or DoD grants. Do you think allowing the researcher to make the decision creates a conflict of interest? And if so, what can the VA do to eliminate that?

Dr. CLANCY. I think that it may be perceived as a conflict of interest, which the distinction between those two, I think, is negligible. At—

Mr. BERGMAN. A lot of cases, they have dual appointments. Do you think there is any pressure being put on, in some cases, because you have a dual appointment? You are basically working very hard, but you can only serve one master, but you might be serving two.

Dr. CLANCY. Whether people perceive that there is implicit pressure, for example in the form of promotions and tenure and things like that, I can’t say. I think the study we are doing now will shed some light on that in terms of how those decisions are made.

Mr. BERGMAN. When do you think that study will be done?

Dr. CLANCY. Rachel? When will the WESTAT study be done?

Ms. RAMONI. The WESTAT study will be complete by the end of September, sir.

Mr. BERGMAN. Great. I look forward to that. And I am going to give you back ten seconds, Mr. Chairman.

Mr. DUNN. Thank you very much, General Bergman. So we have finished the first round of questions. We are blessed to have some time left on the clock. We would like to go about around and allow additional questions. So in—clearly, there are passionate and interested people here on the dais. Representative Brownley, I recognize you for five minutes.

Ms. BROWNLEY. Thank you. Dr. Clancy, I wanted to ask you a question. Congress authorized two major medical leases at Heinz and Albuquerque focused on research activities. To date, neither lease appears to have been executed by the department, and in fact, VA has told stake holders that it is engaged in procuring a contract to re-examine the requirements for the Heinz location.

This is concerning because Heinz researchers are located, my understanding, in a century-old building. Additionally, in this year's President's Budget Submission, VA removed a request for a lease for a research facility in San Francisco. I am concerned that VA is not taking action to ensure that VA researchers and partners have access to modern facilities to conduct research which we know is a major plus in VA for recruiting clinicians.

Can you tell me what the status of the three leases, and what assistance you might need from Congress to move forward on these leases for which you clearly identified a need as recently as a year ago?

Dr. CLANCY. I will take that for the record and get back to you promptly. I don't know the status of the current leases. I do know that the San Francisco VA is now engaged in a partnership to move major chunks of their facility. So I can imagine that might have led to a delay or pause in the additional research space, but for Heinz and Albuquerque, I do not know.

I do note to Mr. Poliquin and the Chairman Bergman's questions that some of the issues around space and available research space have something to do, I believe, with where the indirect costs are actually administered on occasion. But we will get—

Ms. BROWNLEY. If you could get back—

Dr. CLANCY. Of course.

Ms. BROWNLEY [continued]. —to me on that, I would appreciate it very much.

And Dr. Klotman, in your testimony, you said “To duplicate services such as numerous oversight and review services, if NIH grants were to instead be managed by the NPC, would produce no additional value and be a wasteful use of tax dollars.” Can you expound on that?

Mr. KLOTMAN. Well, I think it depends and, again, each institution is a little bit different. We do—and in part because we were—we have this long relationship with the VA dating back to the, you know, mid-40s. A lot of the research infrastructure was generated on the Baylor College of Medicine side.

If, for some reason now, it was, “Well, let's have it all administered by the not-for-profit entity,” they would have to duplicate a lot of things that we are doing. They would have to—the Oversight Committees, the IRB, everything, including bringing on and recruiting faculty, and educating them as to, you know, ethical conduct of research. There is just a lot infrastructure that would have to be duplicated to do that, and that is why I think it is duplicative in our case, but not in all cases.

Ms. BROWNLEY. Yeah.

Mr. KLOTMAN. But in our case.

Ms. BROWNLEY. Ms. Rusconi, do you—would you like to comment?

Ms. RUSCONI. Yes, I would really like to respond to that. I applaud what they have going on down at Baylor. We absolutely would not ever want to upset a system that from all appearances is working very, very well, both for the VA, the non-profit, and for the affiliate. There is no reason to change that, but there are many, many other situations throughout the country where that is not happening, and that is part of our concern.

There are also other models besides what is happening at Baylor, like in California, where some of those services are split between the VA and the affiliate, and also where there is a different format for the submission of grants. If the predominance of the work is occurring at the VA, then the non-profit takes the lead. If the predominance of the work is taking place at the affiliate, then the affiliate takes the lead.

And that has worked out very well, and honestly, the most profitable—for the most part, the most profitable NPCs are actually on the West Coast and they benefit greatly from that, and their VAs benefit greatly from that. For instance, they get infrastructure and many other things, like buildings and all those other pieces that the non-profit can contribute to that VA.

Ms. BROWNLEY. Thank you for that, and I yield back.

Mr. DUNN. Thank you, Representative Brownley. Representative Poliquin, you are recognized for five minutes.

Mr. POLIQUIN. Thank you very much, Mr. Chairman. Ms. Rusconi, if the NPC in your case is awarded the administrative work for research done at the VA, if you don't use all those dollars in the administration of that project, does that go back to the VA?

Ms. RUSCONI. I don't think I understand the question.

Mr. POLIQUIN. If in the administration of the project or the project itself, the research project itself, if all the funds are not consumed for that project, where does the money go?

Ms. RUSCONI. If it is a Federal project, the way that it is done is we—the administrative body, whoever it is, whether—

Mr. POLIQUIN. Yeah.

Ms. RUSCONI [continued]. —it would be the affiliate or the NPC, they have to expend those costs first before they get reimbursed. And so we would not be able to draw down those funds. So that is—

Mr. POLIQUIN. So it stays in the VA?

Ms. RUSCONI. Well, it doesn't go to the VA. It would never leave the NIH. So if we had a researcher that had \$50,000 grant—

Mr. POLIQUIN. Okay. Thank you.

Ms. RUSCONI [continued]. —that is what would happen, but if—

Mr. POLIQUIN. Thank you. Dr. Clancy—and I don't want to be rude, Ms. Rusconi. We just have a limited amount of time.

Dr. Clancy, if Harvard—to pick on Harvard a little bit, my Alma Mater. They are a great school. If they win a—they apply for and receive a \$10 million grant from the NIH, they receive the money, they are doing the research, and they don't—and also, the investigator is working for the VA and for Harvard. So the investigator says, "No, we are going to do the administration also," which I think is an inherent conflict of interest. We have already discussed. Is that if—and that is—and their markup, I guess, is 70 percent.

So you are talking about \$10 million for the research, \$7 million for the add-on, administrative add-on.

If that money in either case is not used, does Harvard keep it? If the research project ends without spending the \$10 million, do they keep it, or do they return it to the VA, or to the NIH?

Dr. CLANCY. They do not keep it. I—

Mr. POLIQUIN. Where does it go?

Dr. CLANCY [continued]. —don't believe they return it.

Mr. POLIQUIN. They just don't draw it down; is that correct?

Ms. RAMONI. They do not draw it down—

Mr. POLIQUIN. Got it.

Ms. RAMONI [continued]. —Mr. Poliquin.

Mr. POLIQUIN. Thank you very much.

Ms. RAMONI. Also, I would like to point out that the off-site rate—so if the work were being done at the VA but run through Harvard, the off-site rate for that typically is around 20 percent, 25 percent. So pretty close to that of the NPC.

Mr. POLIQUIN. Ms. Rusconi?

Ms. RUSCONI. My question, when they are talking about the off-site rate for the affiliate, is if that work is happening at the VA, why would they be getting an indirect rate at that point? Because honestly, at that point, if the work is happening at the VA, there should be a subaward to the NPC.

Mr. POLIQUIN. You know what I would like to see? And I am going—we have subpoena power here, don't we?

Mr. Chairman? We have subpoena power here, don't we? Yeah, great. Okay. Here is what I would like to see.

It is going to be very simple, and I think I asked for it last time Dr. Clancy and Dr. Ramoni were here. It is very simply. What I would like to see is going back—take five years. We could probably go back 50, but let's take five years.

What I would like to see is every grant that was awarded by the VA, by the NIH, by the DoD, and any other large organizations that do that outside the VA. I think it is the NIH and DoD. Every grant, what it was used for, who it went to, what the amount was for, who did the administrative work, and what that amounted to? That would be really tell-tale. So we can see—and what—so we can determine what the rate is. So we can see where the taxpayer dollars are going.

This is supposed to be used for care of veterans. I am all for research. I love it. I want to make sure the taxpayers aren't getting ripped off, and I want to make sure that our veterans get maximum bang for their buck. And when you have a delta between 25 percent and 56 percent, or 70 percent, which was what was told last time, last July, if I understand this correctly, then something is wrong. I am missing something.

And so I want to get that data. So Dr. Clancy, how do we get that data?

Dr. CLANCY. We will take a first crack at assembling it for you.

Mr. POLIQUIN. No, we already have a study that we went—we started back in July or September, whatever it was, we are six- or nine-months in. It will be a year before we get the study. Is it going to have this data?

Dr. CLANCY. Rachel?

Ms. RAMONI. Mr. Poliquin, thank you for your question. As we discussed, both when you were kind enough to visit us, as well as with your staff—

Mr. POLIQUIN. No, not to visit you. I paid an unannounced house call because you folks weren't responsive to our staff in getting the data. So it wasn't a scheduled visit. I just showed up.

Ms. RAMONI. We appreciate that.

Mr. POLIQUIN. Well, I appreciate getting—

Ms. RAMONI. And—

Mr. POLIQUIN [continued]. —us this data. How do we get this data?

Ms. RAMONI. We explained to you at that point that that data currently is not in the VA's hands, that we had made efforts to—

Mr. POLIQUIN. So how do we get this data?

Ms. RAMONI. The NIH would have to cooperate with us in releasing those data which would require a Congressional request.

Mr. POLIQUIN. Okay. Good. And that data can be released directly, I think, Mr. Bergman, can't it to this Committee? Thank you very much. I yield back my time. I don't have any.

Mr. DUNN. Thank you Representative Poliquin. Representative Kuster.

Ms. KUSTER. Just a quick—

Mr. DUNN. You have five minutes.

Ms. KUSTER [continued]. —question, if I could. This is for

Dr. Ramoni. We have been talking about bridging the gap between basic research and clinical research, and my particular interest is brain health diagnostics.

The Director of National Institute of Mental Health, in 2013, stated "We must set our sights higher than a 19th century approach for mental health diagnosis." So physicians need more than the current symptom-based categories. Symptoms alone rarely indicate the best choice of treatment. My question to you is can the VA support bio-marker discovery and validation, and pursue the deployment of at least two additional brain health diagnostic measurements before 2023?

And if anyone else has any comment on that, I am happy to hear.

Ms. RAMONI. Thank you for that question. As you heard, several of my priorities touch on mental health, with PTSD, suicide prevention, TBI, opioid use disorder, and it is a high priority of ours to move from symptom-based diagnostics to bio-marker based diagnostics. Even our work in Gulf War illness, we are moving towards bio-marker based diagnostics.

To that end, we are developing road maps for a set of projects that are intended to lead to objective bio-marker diagnostics for both PTSD and TBI, and we are not doing this alone. We are working in collaboration with NIH, with DoD, and with co-inveterate bioscience and industry partners in order—that this should move forward as quickly as possible.

Ms. KUSTER. Great. Thank you very much, and I yield back.

Mr. DUNN. Thank you very much, Representative Kuster. Representative Arrington—

Mr. ARRINGTON. Thank you.

Mr. DUNN [continued]. —you are recognized for five minutes.

Mr. ARRINGTON. Thank you, Mr. Chairman. I, too, believe in research and the investment we make as a Federal government to discover, to solve problems, and I think that no place on planet Earth do we do that better than in the United States of America, and I think a part of that is the investment the Federal government makes.

But we have got to do it in a smart way, in a strategic way, in a cost-effective way. We have to know what our core competencies are and what we are not as competent in, where there is greater expertise in the marketplace. So I think my colleague, Mr. Poliquin is—I appreciate his passion for making sure this is working the way it is supposed to, and we have an oversight roll, obviously in that.

And I guess my first question is, what is the process by which we engage in the research agenda? When you set that agenda, and there have been questions about how do we prevent mission creep? How do we focus on our area of interest and impact, which is those things that affect the unique community of our veterans, as opposed to cancer and other areas of research that are important, but they affect everybody? But we are trying to get at those specific issues that plaque the veteran community.

What is the process? Do you all bring that to the VA Committee or some Subcommittee prior to the concrete drying on that agenda so that we can provide some input and challenge you on why you are focused on area X, Y, or Z?

Dr. Clancy?

Dr. CLANCY. In terms of setting priorities for the research overall, we have some broad frameworks, right, that this is important to veteran's health. We are not going to fund it unless it is a veteran focused project.

I think the trickiest part is the one that you and a couple of your colleagues have keyed in on. The distinction between conditions that we know to be unique to veterans and what they are suffering right now, and conditions that are common, very prevalent—

Mr. ARRINGTON. Right.

Dr. CLANCY [continued]. —among veterans but also among other Americans as well. Creating that bright line is sometimes harder than you might think. For example, when Mr. Poliquin was asking about learning from VBA claims, which I think is a great idea, there are some exposures that have a very long latency and we might not know without having done research.

In general, we are looking to our advisory committee, to researchers themselves, to lots and lots of stakeholders, veterans service organizations, and so forth. To the best of knowledge, we have not come to the Congress. We certainly give you reports on the other side. We could certainly make that part of a budget submission so that you would have a better sense, I think.

I am not sure how close you want to get to that. Some people might think that was politicizing things too much, as opposed to substantive interest, which has been very much the theme of today's conversation.

Mr. ARRINGTON. I think it is part of our oversight role. I mean, I don't—I think it is too late after we see the work that you are

doing to suggest that it is inside or outside the purview of the mission for research at the VA.

But nevertheless, I think I am interested in how we can improve that process, so we are better engaged on the front end. How much—what percentage of the research at the VA is translational versus fundamental? Is it 50/50, Dr. Ramoni?

Ms. RAMONI. So that is an area that I am, as you know, keenly focused on. Currently, the majority of our research is basic research, and some of that basic research, of course, is in veteran focused areas. For instance, a non-opioid pain medication is being researched in basic science, or traumatic brain injury—

Mr. ARRINGTON. Just in the interest of time—

Ms. RAMONI. Yes.

Mr. ARRINGTON [continued]. —and I know I keep cutting you off, and I do apologize, but—

Ms. RAMONI. But—

Mr. ARRINGTON [continued]. —I think it is an opportunity.

Ms. RAMONI. Yes.

Mr. ARRINGTON. If I were there with you, I would say what—where can we have a strategic—

Ms. RAMONI. I agree.

Mr. ARRINGTON [continued]. —advantage and focus given our strengths, et cetera, sort of SWAT analysis. I would say—

Ms. RAMONI. Right.

Mr. ARRINGTON [continued]. —we should be more translational, less basic. NIH can do basic, all these other institutes. Let's focus more on how we get at solving the problem, and a quicker way, and I would also say, "Can we use the inside of the Veteran Hospital System, Health System?"

Ms. RAMONI. Yes.

Mr. ARRINGTON. It is the largest in the country.

Ms. RAMONI. Okay.

Mr. ARRINGTON. How do we tap into that, like you did with tele-medicine. That is why you are leading in tele-medicine. That is a leadership role for the VA. How to use the patient material and all that you have, but with some flexibility that you don't have on the outside, that my friend from Baylor College of Medicine doesn't have because of restrictions, how do you tap into that, so we can translate therapies and devices, so we can save lives?

That is a question I have. I am out of time, but let's talk about that. Let—you all come over to the office. I will come see you, and let's see if we can't share some thoughts and ideas on how to—

Ms. RAMONI. I would welcome that.

Mr. ARRINGTON [continued]. —have a—

Dr. CLANCY. Mr. Chairman, could I make one quick point? One area where we do take great advantage of our system, and this is just getting started but very, very exciting. You may be aware that clinical trials are unbelievably expensive because effectively every study creates a separate infrastructure which is then disbanded.

Because of our integrated system and an electronic record, we are actually now funding some point-of-care studies where patients are randomized when they are being seen for care. We are collecting data from the electronic record which takes the cost of a

clinical trial and reduces it by orders of magnitude. So we are with you, and we would love some follow-up.

Mr. ARRINGTON. Thank you for that. Mr. Chairman, I yield back.

Mr. BERGMAN. [Presiding.] Thank you. I am going to yield myself five minutes. That will complete the second round. I think—Representatives Brownley and Kuster, you have no more questions. Mr. Poliquin, you would like one more round?

Mr. Arrington, would you like any more time?

Mr. ARRINGTON. I am going to reserve mine for a meeting—

Mr. BERGMAN. Okay.

Mr. ARRINGTON [continued]. —but then, I appreciate their comments.

Mr. BERGMAN. All right.

Dr. Clancy, just—if you could take for the record, I would really like to know how many dual appointment researchers we have across the spectrum. Okay? And if you can give me a number, I assume you can give us a name. Okay?

So a by name, which then would therefore assume a by location list, because I sense across the Committee that there is keen interest in the how things are getting done, and not that all of you don't have—you know all your data, you know, because you do. But it is important for us to hear it from boots on the ground as well. So I think that is going to be an important step going forward.

Dr. Ramoni, Mr. Poliquin brought up problems with data sharing between VHA and VBA. What are some of the impediments to working with VBA?

Ms. RAMONI. Thank you for your question. So I think the first impediment is simply an historical inertia. We simply haven't worked that much with VBA in the past, although some of our researcher now are beginning to use VBA data, for instance in our suicide prevention work and also in our evidence-based policy group.

What would need to happen is to have a data use agreement with VBA, and to have that prioritized in both on the ORD side, which it certainly would be, and also on the VBA side so that we can establish those relationships and also have that work properly staffed because sharing data takes curation. It takes explanations of the data. It takes having some understanding from the VBA side.

Mr. BERGMAN. Is there any ongoing institutional resistance based on the, you know, old “if not invented here” syndrome type of thing? I mean, is there—do we have any cultural barriers that we need to break down between VHA and VBA?

Dr. CLANCY. I don't think so.

Ms. RAMONI. I don't think there are cultural barriers. Again, it has been a sort of inertia that we both need—we need to work on both sides to break down, and I certainly am committed to do so. And as we proceed, we will, of course, keep this Subcommittee informed and should we encounter any of the barriers you mentioned, we are grateful for your support.

Mr. BERGMAN. Oh, we know that human behavior is such that everyone in a, if you will, in a chain of command or a food chain, they look up to see the behavior above them. And if the leadership at all levels is not having cross-talks, cooperating across whatever

boundaries might be there, the organization will emulate those qualities of their leadership, and that is why it is so important that—it is kind of like, I don't know if you any of you are parents, but you know, kids watch their parents. And if the parents are talking the kids pay attention. If the kids think the parents aren't talking, they are going to try to, you know, divide and conquer you.

But we are here together in this, and you know, not to overblow the family analogy, but we are a family. We are a family that is dedicated to the results for veterans, and that is pure and simple the mission of the family.

Dr. Ramoni, in NAVREF's testimony, you asked that the VA share the scope, criteria, and assessment for the Nonprofit Program Office's out brief reviews. Could you please provide those to the Committee as well? Second, are these out briefs something the VA is willing to share with NAVREF? I mean, again, in the spirit of sharing information?

Ms. RAMONI. Would the out briefs that—excuse me, sir. The out briefs at each NPC?

Mr. BERGMAN. At the reviews, at the review level?

Ms. RAMONI. Yes. We would leave it to the discretion of the local NPC to share those because not every NPC has a relationship with NAVREF, but we have no desire to not make those publically available. We would certainly make those available to NAVREF if we were given the permission of the NPC.

Mr. BERGMAN. Okay. Well, it is, you know, again it is going back to breaking down those barriers—

Ms. RAMONI. Right.

Mr. BERGMAN [continued]. —that inhibit the results and giving—

Ms. RAMONI. Right.

Mr. BERGMAN [continued]. —us the, you know, the outcomes that we all are striving for, and sometimes outcomes aren't—isn't a strong enough work. It means results—

Ms. RAMONI. That is right.

Mr. BERGMAN [continued]. —related to the veteran. So with that, I am going to yield back. Mr. Poliquin, you get the third and final strike.

Ms. RAMONI. Thank you, sir.

Mr. BERGMAN. Round, I am sorry.

Mr. POLIQUIN. Thank you, Mr. Chairman, very much. Appreciate if you set that clock to eight minutes, instead of five, but in any event.

Dr. Clancy, who oversees the investigators? My—the reason I ask that question is my understanding—correct me if I am mistaken, is that the investigators or researchers—I am using investigators because that is what—Dr. Ramoni taught me that word.

If these individuals, I believe, are hired by the local VA hospitals around the country, so they are employees of the VA, and at the same time they might work for a terrific medical institution like at Baylor, at Harvard, or at Case Western, whatever it might be. And they then have authority to apply for grants, get the grants, and then determine where the administrative dollars goes, notwithstanding what

Dr. Klotman said earlier.

So who is overseeing those investigators to make sure everything is going the way it should be?

Dr. CLANCY. Well, as Dr. Klotman pointed out earlier, there is a very careful time and attendance record. The VA— actually from the time of my earliest training with—

Mr. POLIQUIN. No, I am not really asking that,

Dr. Clancy. Thank you for that. What I am asking is, is there anybody looking over the investigator's shoulders to say, "You know, every time you apply for a grant, and I know you work at XYU, University," that that grant money goes to XYU because you are applying for that and you have to put it on the grant, but the administration is also done by that university. Is anybody serve as a check and balance to that individual?

Dr. CLANCY. Well, to some—

Mr. POLIQUIN. Or are we doing it now?

Dr. CLANCY [continued]. —extent, we would expect the NPCs to do that. I am going to guess that a fair amount of that is delegated to the discretion of the investigator—if I could just finish for a moment.

Mr. POLIQUIN. Sure.

Dr. CLANCY. If I am splitting my time five-eighths, three-eighths, that would be a very common break because you have to be five-eighths funded to get VA research funding. But if I can say on my three-eighths time "I am applying for a grant from NIH," that would be okay the way we have been doing business.

Mr. POLIQUIN. No, what I am looking for is if you have an investigator—and what Congressman Bergman asked is a really good one. Who are these people, where are they located? If you have 150—oh, I am just choosing a number. I think it is probably pretty close. Is that if you have 100 of them that are always doing the administrative work, where they work, not at the VA but at their research affiliate, their academic affiliation, that would be a concern of mine.

Dr. CLANCY. I would agree.

Mr. POLIQUIN. Okay. Good. So there is no one that oversees that except us, correct?

Dr. CLANCY. I think you have brought a unique lens—

Mr. POLIQUIN. Okay.

Dr. CLANCY [continued]. —and intensity to—

Mr. POLIQUIN. Okay.

Dr. CLANCY [continued]. —our focus—

Mr. POLIQUIN. Here is why this—

Dr. CLANCY [continued].—and we appreciate that.

Mr. POLIQUIN. —matters, Dr. Clancy, and everybody here. Is that we have a situation where there is an inherent conflict of interest, and we are looking at very big amounts of dollars. A lot of bacon.

You have \$1.2 billion, roughly, of grants that are provided by NIH, and the DoD, and others, in one year. And if you say "roughly," if we use our low-cost provider over here, the NPCs, right, at roughly 25 percent, that is roughly \$900 million of research, roughly, and about \$300 million in one year of administrative overhead and so forth and so on, to administrate those—oversee those grants, make sure that they get—research gets done.

Well, what if you are overpaying? What if it is not 25 percent, what if it is double that, like has been discussed here? What if it is more than that? That is another \$300 million a year. So you are getting less research and more overhead. We see that everywhere. Everywhere, frankly, in the non-profit sector. Not picking on anybody.

That is why I want to see the data. I want to see what grants were issued, who did the research, how much money for the research, how much money for the overhead, who these investigators are, and what their record is of awarding that administrative work?

And on top of that, you have the Inspector General's report that says, "This ain't going well," and that just came out. So I am not trying to pick on anybody. We are all responsible for taking care of our veterans. Thank you. We are not clinicians, but it is our responsibility to make sure that the dollars are going to the right place, and we are not overpaying. It is that simple. Yes?

Ms. RUSCONI. I would like to make a point of clarification which is I understand what Dr. Clancy is talking about, that the NPC might have an input into where someone, a PI, would submit the grant, but the reality is that throughout the country, there are lots of times that the NPC isn't even aware that that grant is being submitted. So there is absolutely no way that the NPC could be part of it.

Mr. POLIQUIN. But 30 years ago, you folks were created by Congress specifically to solve this problem, correct?

Ms. RUSCONI. Correct.

Mr. POLIQUIN. Well, I would like to know how much of the business you are getting, because you are the low-cost provider.

Ms. RUSCONI. We would also like to know.

Mr. POLIQUIN. Good. Pretty simple, Jack. Excuse me, Mr. Chairman. I yield back my time.

Mr. BERGMAN. Am I now Chairman Jack? Is that what it is? I am no longer General Jack?

Mr. POLIQUIN. It is whatever you would like, sir, as long as the—

Ms. KUSTER. I vote general.

Mr. POLIQUIN [continued]. —this summer.

Ms. KUSTER. Just for the record.

Mr. BERGMAN. Yeah, so. All right. Well, thank you to all the Committee Members for the—this has probably been one of the more focused and direct Subcommittee meetings and hearings that we have had. So I appreciate everybody's input, especially all of you at the testimony table, because together we do make a difference and we make a positive difference. And if it was all easy, it would all have been done long time ago and we would all be doing other things.

So I really appreciate your continued intellectual engagement here for our penchant for details now that big data allows us to get those details in a relatively expeditious and accurate manner. So our thanks to all the witnesses today. You are now excused. Ranking Member Kuster, would you like to make any comments before we close?

Ms. KUSTER. I have a brief closing statement, and one point I would like to leave the record open long enough for the VA to respond to the questions that have been asked today.

The perspectives we heard today are important points of view to consider as we ultimately have a dramatic impact on the quality of care to our veterans in New Hampshire and all across the country, and to community providers, and indeed, civilians across this country. While I appreciate the hard work and dedication of the witnesses and organizations that you represent, the testimony today does concern me. I appreciate the great work that the VA Non-Profit Research and Education Corporations, or NPCs, conduct to oversee crucial VA research with frugality. However, it is concerning that the availability of NPCs at all VA medical centers may be limited.

Likewise, I appreciate the robust academic affiliations the VA currently enjoys, and as I mentioned in my comments, Dartmouth College and Dartmouth Medical School has proven to be a wonderful partner in expanding and improving veterans' health care in rural New Hampshire. However, it concerns me that some academic institutions may charge more than necessary to administer Federal research grants, and insuring the most efficient system is crucial to maximizing resources this Congress provides to care for our veterans. And I think you have heard this as a bipartisan concern.

I recognize the VA has been unable to provide clear guidance in an expeditious manner as to how this research money is to be distributed, and I encourage the VA to vitalize this guidance as quickly as possible, and share that with this Committee. I believe there is a great opportunity here for all stakeholders to work together and insure that VA's research regime is efficient and effective.

To that end, I ask my colleagues to consider joining me in convening a roundtable of relevant stakeholders to further discuss these issues, and as I mentioned specifically, I would love to include the bipartisan Heroine Task Force, and both Committees to engage in this discussion.

Our experience with the opioid epidemic has made effective medical research, especially into pain management and substance use disorder, an acute concern of members across this country. We know the importance of getting new research on pain, addiction, and mental health is important. Veterans are uniquely impacted by the opioid epidemic because over 50 percent of veterans experience chronic pain. Our veterans need the latest in medical research to combat this problem, and I hope to advance legislation soon that would centralize and improve pain management at the VA by creating centers of excellence.

Of course, this is hardly the only area in need of additional research. I know veterans with upper body prosthetic needs experience a limited suite of options. Creation of a center of excellence on bionics or upper prosthetics is needed to further meet the needs of veterans. There is emerging research and technology, and as I appreciate your mention in your opening remarks, about the Luke arm, but assuring that the VA is adequately able to deploy the latest technology is crucial to improving our veterans' quality of life.

So this serves to underscore my commitment to delivering the highest quality of care to our veterans by ensuring that the VA remains a leader in medical research. I thank you for your time, and I yield back.

Mr. BERGMAN. Thank you, Ranking Member Kuster. It has been nearly one year after our research hearing last June, and it quite frankly, does not appear that the VA has made any improvements on its utilization of the NPCs. Budgets are still tight, yet we continue to find examples of VA not utilizing the available options for additional funds.

As we have heard, NPCs have contributed over two billion, that would be with a "B," to VA research over the past decade and could contribute more if they were to administer the grants for research projects conducted within VA. VA should not be paying overhead costs without getting the benefit of reimbursement.

It is also critical that the research office have access to VBA's data so that it may better meet its mission of veteran centric research. This data would be extremely beneficial in determining what diseases and disorders to examine and help guide ongoing projects.

I hope that our discussion will open the door to better communications because quite frankly, I am pretty tired, and I think we all are, of hearing about missed opportunities within VA due to one office not communicating with another. VA's research budget exceeds \$1 billion annually. So one would think that the accomplishments it has contributed to veterans and the American public would be many, but what we have heard here today is that that is not the case.

Certainly, VA can tout some major accomplishments over the past several years, but unfortunately, they are not necessarily in areas significant to veterans or related to their service. Moreover, many of these results are being implemented at only one medical center or one VISN which limits the benefits received by veterans across the country.

Simply put, VA research needs to be more focused on specific conditions prevalent among our Nation's veterans, and the department must follow through on projects so that there are actual clinical benefits to show for all of the funding the research program receives. So bang for the buck. It is past time to witness the urgency this long-standing problem deserves.

I ask unanimous consent that all Members have five legislative days to revise and extend their remarks, and include extraneous material. Without objection, so order.

I would once again like to thank all of our witnesses and audience members for joining in today's conversation. With that, this hearing is adjourned.

[Whereupon, at 11:51 a.m., the Subcommittees were adjourned.]

Statements For The Record

Submitted by the Coalition to Heal Invisible Wounds

Roger Murry, Executive Director

Chairman Wenstrup, Chairman Bergman, Ranking Member Brownley, Ranking Member Kuster, and Members of the Subcommittees:

On behalf of the Coalition to Heal Invisible Wounds, thank you for this opportunity to provide written testimony regarding the VA's research partnerships, priorities and the extent to which the VA effectively translates research findings to the clinical setting to the benefit of Veteran patients. We commend the Subcommittees' leadership in addressing these critical issues.

The Coalition to Heal Invisible Wounds was founded in February 2017 to advance policy reforms that widen and expedite the pipeline for new therapies and diagnostics for post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI). Coalition members innovate at all stages of the therapy development life-cycle and also serve Veterans who most urgently require mental health interventions.¹

According to the VA PTSD Psychopharmacology Working Group: "The urgent need to find effective pharmacologic treatments for PTSD should be considered a national mental health priority."² Despite the "high prevalence and costly impact" of PTSD in military personnel and Veterans, "most patients are treated with medications or combinations for which there is little empirical guidance regarding benefits and risks," and there is "no visible horizon for advancements in medications that treat symptoms or enhance outcomes in persons with a diagnosis of PTSD." The scenario is similar for TBI and these two conditions often coexist but may also occur independently in the VA population.

The Coalition believes that better diagnostics and therapies will spur more Veterans to seek care. According to a 2017 survey of over 4,000 Iraq and Afghanistan Veterans of America (IAVA) members, 46 percent report having PTSD, while 19 percent report having TBI.³ Only 16 percent of IAVA members believe troops and Veterans are getting the care they need for mental health injuries and stigma remains the top reason Service members and Veterans are not seeking care. A major reason why IAVA members stop seeking care is that they do not think that the treatment will work.

An implicit promise of world-class health care is a strong research function. Veterans have earned the right to world-class health care. Better research will lead to better care of our Veterans who suffer from PTSD, TBI, and other mental health conditions that are prevalent among the veteran population. We strongly believe that the VA can become a leading partner in delivering new therapies and diagnostics; it has many outstanding assets and institutional strengths, as well as the desire to overcome the institutional hurdles to establishing advanced research partnerships.

The Coalition seeks to advance discrete reforms at the VA to support cutting-edge research partnerships. We focus on enhancing big-data research partnerships, standardizing approval and oversight of multi-site clinical trials to accelerate the development of new therapies, and spurring the development of new brain health diagnostics for clinical use. Ultimately, the VA can align its management of clinical trials much closer to best practices, which will lead to increased clinical trial success rates and the accelerated development of new diagnostics and therapies for conditions that disproportionately impact Veterans. We believe that in 2018, with appropriate oversight from Congress, the VA can pursue several targeted reforms that would serve as significant first steps in this process:

1. Permit sponsors to use commercial IRBs accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP);
2. Clarify that the Central Office has the authority to determine all information security requirements for a multi-site trial, direct the VA to develop a central list of compliant vendors and direct the VA to staff the office appropriately;
3. Direct the VA to study the obstacles sponsors face in recruitment and develop a plan to support Veteran participation in clinical trials;
4. Develop a master plan to support clinical research; and,

¹The Coalition's members are Cohen Veterans Bioscience (co-chair), the Military Veterans Project, NAMI Montana, Otsuka America Pharmaceutical Inc. (co-chair), and Tonix Pharmaceuticals.

²John H. Krystal et al., It Is Time to Address the Crisis in the Pharmacotherapy of Posttraumatic Stress Disorder: A Consensus Statement of the PTSD Psychopharmacology Working Group, *J. Biological Psychiatry* (2017) [http://www.biologicalpsychiatryjournal.com/article/S0006-3223\(17\)31362-8/abstract](http://www.biologicalpsychiatryjournal.com/article/S0006-3223(17)31362-8/abstract)

³2017 Member Survey; Iraq and Afghanistan Veterans of America." Accessed May 9, 2018. <https://cultureondemand.github.io/iava-report/>

5. Direct the VA to work with pertinent Federal and non-governmental partners to deploy at least two additional brain health diagnostic measurements for clinical use at VA facilities before 2023.

We are grateful for the opportunity in this testimony to describe in more detail both these initial steps and the overall trajectory for reform.

A. Conduct and Support for VA's Research Partnerships

We support the work of the Subcommittees and the VA to bridge the gap between basic research and clinical research. This work complements ongoing examinations within the Office of Research and Development, at NAVREF and their member Non-profit Research and Education Corporations (NPC), and within the private-sector research community as to how the VA can help get more research into the clinic. Major stakeholders share an understanding that the current diagnostic and therapeutic options available to Veterans are not sufficient, and that creating a more predictable and streamlined research approval and oversight process at the VA will attract more investment to address conditions that are specific to or prevalent among the Veteran population. Enhancing research pathways also will help the VA deliver better care to Veterans.

An important place to begin bridging the gap is to standardize clinical trial reviews. While some VA clinics have been able to participate in multi-site clinical trials, sponsors report a widespread lack of standardization in the approval and oversight of sponsored clinical research at the VA. This delays VA trial site start dates, increases research costs, and discourages research sponsors from partnering with the VA. We encourage the Subcommittees to comprehensively review how the VA can streamline the approval process, identify and propagate best practices, and develop true continuity in the approval and administration of clinical trials. For 2018, three reforms, described below, are close at hand and would immediately draw more clinical research to the VA.

1. Institutional Review Boards (IRBs)

IRB reviews ensure that clinical trials abide by clear ethical guidelines and protect the well-being of research participants, but sponsors need the reviews to be prompt and consistent. Despite earnest efforts by many within the VA to standardize and improve the IRB process (namely, by standing up a central IRB), the IRB process continues to be a source of major delays for sponsors. In fact, despite a decade or more of work on the central IRB, some multi-site clinical research sponsors, due to frustrations with the central IRB, have reverted to using local IRBs. In light of the high-quality, private-sector options available, we do not advise further efforts to enhance the current IRB process as it relates to sponsored research. Instead, we recommend that the Subcommittees move to permit sponsors to use commercial IRBs accredited by the AAHRPP. Stakeholders within the NPC, industry and non-profit communities broadly support this proposal.

Allowing the use of accredited commercial IRBs would allow for predictable and frequent IRB review processes and timelines. In pursuing this reform, it is important to consider and account for, where relevant, how this step would impact the role of other review committees, VA requirements for education and training, VA-specific regulatory requirements related to human subjects research, and the workload for the local and NPC IRBs. We believe that each of these considerations can be adequately addressed.

2. Information Security Officer (ISO) Reviews

ISO reviews seek to ensure the safety of patient data. The reviews are often lengthy and unpredictable, leading to security requirements for the same study that can differ by VA clinic. Local ISOs are extremely busy and have variable knowledge of clinical research data storage and transfer requirements. Guidelines for ISOs can be unclear and outdated, while many ISOs feel organizational pressure to pursue the most conservative approach, and constrain the VA from participating in cutting-edge research. Further, there is no central list of compliant research vendors, so vendors are vetted and re-vetted by local ISOs.

A centralized information security review for multi-site clinical research would allow for a more thorough, standardized, and appropriate review process, while reducing delays that often occur at the local level. The VA has begun to move in this direction. The Central Office recently set up an office to assist local ISOs with reviews of multi-site research. However, the Central Office does not have clear authority to manage all information security requirements for a multi-site trial. Congress should clarify that the Central Office has the authority to determine all information security requirements for a multi-site trial, that it should develop a central list of

compliant vendors and direct the VA to staff the office appropriately. These steps would standardize the scope and timing of the ISO review process, as well as send positive signals to potential research sponsors.

3. Clinical Trial Recruitment

Veterans should have the right to be fully informed of all of their treatment options, including the potential benefits and risks of clinical trial participation. This allows Veterans the opportunity to benefit personally from cutting-edge research opportunities and assist the wider community as a whole through trial participation. In fact, in oncology and increasingly other areas of medicine, clinical trials are now the standard of care. Research sponsors report widely varying experiences recruiting research participants. Some VA sites, for example, maintain a database of VA patients that have indicated their desire to be contacted about new opportunities to participate in a study and allow sponsors to effectively recruit. Other VA sites do not offer this or other institutional supports for recruitment, leading to extended recruitment timelines and increased cost of the research. Some sponsors have been unable to fill the patient population needed for the trial, compromising the ability to understand the efficacy of the treatment being tested.

Recruitment problems are not unique to the VA. According to researchers at Vanderbilt and Duke Universities, nearly 1 in 5 clinical trials are either terminated for failed participant accrual, or are completed with less than 85 percent of the expected enrollment. Recruitment challenges increase the cost and reduce the speed with which advances in medicine reach Veterans and the general population.

VA research stakeholders have expressed an array of difficulties related to recruitment, but it is not yet clear what specific reforms the VA could undertake to best facilitate enrollment. We would advise that Congress direct the VA to study the obstacles sponsors face in recruitment and to develop a plan to support Veteran participation in clinical trials.

B. Translating Research Findings to the Clinical Setting to the Benefit of Veteran Patients.

1. Master Plan to Support Clinical Research

While improving clinical trial management will spur more private sector activity, the VA should also play a direct role in bridging the gap between basic research and clinical research. Today, grant money is divided across too many different projects, leaving each with too little money to appropriately design and run a clinical trial, and unable to lead to the next step of investigation. The VA should assess how federal agencies and the private sector are supporting clinical research into new diagnostics and therapies for conditions that disproportionately impact Veterans. The VA should then develop a master plan that provides for strategic support of clinical research, including for private sector activity, to speed developments that address those conditions. The plan should include innovation grants for external research, such as the Industry Innovation Competition, in which the VA spurs activity in the private sector to help solve VA's most pressing challenges. The plan should complement the comprehensive plan for biomarker discovery and validation described below.

2. Diagnostics Research Mandate

As our members engage every day with Veterans suffering from PTSD and TBI, they see an urgent need for mechanism-based diagnostic tools to precisely diagnose those conditions. Using symptom-based diagnostic tools alone diminishes the ability of physicians to effectively diagnose these multi-faceted disorders as well as overcome the known challenges of diagnosis such as stigma and delays in qualified clinical assessment. In 2013, while still serving as Director of the National Institute of Mental Health, Dr. Tom Insel stated that “the diagnostic system has to be based on the emerging research data, not on the current symptom-based categories,” and that “we must set our sights higher” than a 19th century approach.⁴ “Indeed, symptom-based diagnosis, once common in other areas of medicine, has been largely replaced in the past half century as we have understood that symptoms alone rarely indicate the best choice of treatment.” Clinicians need new tools to more precisely diagnose those suffering from PTSD and TBI, which requires the VA to effectively translate research findings to the clinical setting for the benefit of Veteran patients.

⁴“Post by Former NIMH Director Thomas Insel: Transforming Diagnosis.” NIMH Director’s blog. Posted April 29, 2013. Accessed May 9, 2018. <https://www.nimh.nih.gov/about/directors/thomas-insel/blog/2013/transforming-diagnosis.shtml>

Diagnostics are objective, measurable predictive factors that help doctors improve care. For example, the FDA recently approved a blood test to improve the diagnosis of concussions, which could eliminate the use of unneeded CT scans in at least a third of those with suspected brain injuries. Writing in the VA's PTSD Research Quarterly, VA researchers determined that "we appear to have reached a watershed in the development of biologically-based interventions for the prevention and treatment of PTSD."⁵ Further, understanding the multiple and interacting mechanisms of malfunction in each stress system will be critical to advance the diagnosis and treatment of trauma-related mental health disorders into the precision medicine era.

According to a recent literature search of PTSD biomarker discovery studies, researchers identified over 800 PTSD biomarker candidates, but none have been validated or approved by the FDA for clinical use. There are many reasons for the failure to validate PTSD candidate biomarkers to date, but most can be overcome by bringing together large data sets and standardization of research techniques. For example, targeted research based on big data analysis is more likely to direct researchers toward plausible candidates that can be replicated and validated. Given the state of the science, we believe this is not only possible but also probable by 2023.

To bridge the gap between basic research and the needs of Veterans and their doctors, Congress should require the VA to work with pertinent Federal and non-governmental partners to build a comprehensive plan for biomarker discovery and validation including the deployment of at least two additional brain health diagnostic measurements before 2023 for clinical use at VA facilities, and funding a broader long-term biomarker study through the Department of Defense (DOD). The statutory objective would help VA leadership marshal sufficient resources and implement administrative reforms to boost public-private partnerships and power the discovery of biomarkers.

C. Conclusion

The Coalition to Heal Invisible Wounds thanks the Subcommittees for its work to strengthen VA medical and prosthetic research program. We strongly believe that the VA has the potential to be a world-class research partner to the private sector, enabling better health care for Service members and Veterans, and the initiatives proposed above would provide significant initial progress toward that goal.

We encourage the Subcommittees to continue to engage with stakeholders to develop a multi-year plan that provides for continual improvements to data-sharing, clinical trials and therapy and diagnostics research. Comprehensive reforms would address the many other pacing limiters of clinical research, such as limitations on protected time for physician-researchers participating in sponsored research, and budget and Cooperative Research and Development Agreement (CRADA) negotiations. Comprehensive reform would also advance the best practices that have helped clinical trials succeed at the VA, such as the lead site model pioneered by several innovative NPCs.

Rick Weidman

Executive Director for Policy & Government Affairs

Regarding

Department of Veterans Affairs Medical and Prosthetic Research Program

Good morning, Dr. Wenstrup and General Bergman, and other distinguished members of these two very important Subcommittees. Vietnam Veterans of America (VVA) is pleased to have the opportunity to present for your consideration our Statement for the Record on the VA's medical and prosthetic research program. Also, for the record, we want you to know how much we appreciate the work you do for our nation's veterans.

As we all know, VA research is different from research sponsored by other federal research agencies. According to the VA it is focused entirely on veterans' needs. It is intramural, and more than 60 percent of VA researchers are also clinicians who provide direct patient care.

⁵"Biomarkers for Treatment and Diagnosis." PTSD Research Quarterly. Accessed May 9, 2018. <https://www.ptsd.va.gov/professional/newsletters/research-quarterly/V26N1.pdf>

In your letter to VVA you requested that we address three issues related to VA research, which we do in this statement. However, we would like to emphasize that our biggest issue with the Department's research program is that it does not fulfill, in our minds, the purpose for which it was established. And that is to conduct research that is focused entirely on veterans' needs. We would, therefore, request that you do a few things:

- Request a Government Accountability Report (GAO) that takes a comprehensive look at the VA research program, including projects funded, the amount of funding expended, the source of the funding and bench-to-bedside focused treatments and the reality of that goal in as much as it is accomplished by the VA.
- We ask that this be a report that takes a retrospective look over the last 5 to 15 years of the program.

Issue 1: Department of Veterans Affairs partnership with nonprofit research and education corporations, academic affiliates, and other entities regarding administration of research funding as well as to conduct and support research efforts.

The VA's total actual budgetary resources for Research & Development for Fiscal Year 2017 was \$1.8 billion, of which \$673 million was direct appropriations. VA's research program also relies on other sources of funding, non-federal as well as federal. For FY17, in addition to the direct appropriations, the department received \$535 million for Medical Care Support, \$425 million from other federal agencies, and \$170 million in non-federal funding. Though this pales when measured against federal research dollars for the National Institutes of Health, the Congressionally Directed Medical Research Programs of the Department of Defense, and the Centers for Disease Control and Prevention, it is certainly not insignificant.

VA proudly, and rightfully, points to some of the major accomplishments coming out of its research program, e.g., the heart pacemaker, the nicotine patch, the first successful liver transplant, improvements in wheelchair design. However, we must question: How much of what VA research has produced recently is of significant benefit to veterans?

Conceptually, VVA has no argument with enlisting outside researchers from not-for-profit research and educational corporations and academic affiliates. For several years now, we have proposed the creation of an external entity, headed by a qualified individual who would be confirmed by the Senate, which would engage independent scientists and medical researchers to conduct research on specific health conditions of immediate consequence to veterans, conditions stemming from battlefield trauma, e.g., the ingestion of toxic substances from burn pits in Afghanistan and Iraq, and other military exposures such as oil well fire, sulfur fire, sand, dust, and particulate matter.

We say this because for several years after the advent of the 21st century, it is our understanding that little or no research was conducted, for instance, on the long-term effects of exposure to Agent Orange and other toxins that were so liberally sprayed in South Vietnam. When the former head of the VA's Office of Research and Development was asked pointblank a few years ago if and when Agent Orange research would be funded, he replied with empty rhetoric and could not cite any specific research program then underway or being planned for the immediate future.

We would urge you to investigate how much money was expended on just what specific, peer-reviewed research was conducted that has been of salient benefit to our wounded warriors.

Finally, in brief response to the essence of the first question, VVA has no qualms about expanding and enhancing the universe of researchers who would respond to a Request for Proposal (RFP) for specific areas of research, as long as there is strict oversight by the appropriate staff at the VA and by you in Congress.

Issue 2: The extent to which VA's research projects and priorities display a concentrated focus on issues and conditions that are specific to or prevalent among the veterans population.

Much of our answer to this question is alluded to above. Basically, we have not seen any concentrated focus in this regard. Why? Because we believe VA researchers have been funded for the most part to conduct research in their individual areas of interest which are not always of relevance to specific health conditions unique to veterans exposed to the inherent dangers in a combat zone.

Issue 3: The extent to which VA effectively translates research findings to clinical settings to the benefit of veteran patients.

Again, the nugget of our comment here is in our responses to Issues 1 and 2. This is not to say that all research projects funded by the VA are of little consequence to veterans. Important research has been conducted in improving prosthetic arms and legs, for instance. But this is the exception, not the rule.

We thank you for the opportunity to submit for your consideration our Statement for the Record. Should you have any questions, we would of course be pleased to reply.

Whistleblowers of America

Jacqueline Garrick, LCSW-C

Dear Chairman Roe and Ranking Member Walz;

Whistleblowers of America (WoA) is submitting this statement because we are concerned about priorities for further research and the proper management of research funds at the Department of Veterans Affairs (VA). We are grateful for this opportunity to share VA insider information with you and the rest of the Committee.

Sentinel Events:

Sentinel events usually involve wrongful deaths, surgery on wrong patients or body part, loss of function, other surgical errors/retention of foreign body, treatment delays or complications, medication mismanagement, falls/injuries, suicides or overdoses of a patient in or at a facility, assaults and other crime. According to a study conducted by Johns Hopkins University in 2016¹, medical errors would actually be the third leading cause of death in the United States accounting for 220,000 to 440,000 annual deaths if the Centers for Disease Control and Prevention tracked those deaths using the same coding as the study.

VA does capture some data on sentinel events (also known as adverse events or medical errors) through its National Center for Patient Safety. However, VA insiders note that these events are supposed to undergo a root cause analysis (RCA) and other administrative reviews but are inconsistently conducted and can be more punitive in nature than corrective. Furthermore, these RCAs rarely generate adequate process improvement recommendations that can be monitored, shared and re-evaluated.

- Congress should require VA to replicate the study conducted by Johns Hopkins University and mandate that it provide an annual roll up report of its sentinel events and related research on the tools its uses to identify, manage, disclose, respond, remediate and re-evaluate these adversities that risk patient safety.

Opioids and Pain Management Research Translation:

WoA has provided previous testimony on the problems it sees with opioid use and pain management for veterans seeking care at VA. Our belief is that care should be holistic and utilize multiple tools and interventions. It should be driven by medical decisions not administrative policies. Those medical decisions should be evidence based and informed, which requires VA to engage in veteran-centric research and translational activities to bring research into the patient care environment. However translational research is often lacking, and policies made by non-clinical managers drive outcomes. VA research and development funding must give veterans, Service members and their families priority. These research dollars must be aligned to population data-driven needs.

WoA understands that pain cannot be managed to zero. However, pain as the 5th Vital Sign can be confusing to patients and needs research on alternative interventions to opioids to bridge gaps in prescribing practices. For example, Chronic Pain Syndrome can be managed with improved sleep hygiene, dietary changes, exercise (physical therapy, yoga, stretching), chiropractic therapy, orthotic intervention usage, as well as good calcium and Vitamin D levels. Strong occupational and physical therapy programs as well as dieticians are indicated in thorough pain management. However, these are all underfunded and under studied areas of intervention. The Department of Defense (DoD) has done some studies with Service members who have benefited from massage, Reiki, yoga, acupuncture, aqua therapy and the adaptive sports programs. In the private sector, pain management is an integral part of the care management team. This has not been the case with VA and military

¹Johns Hopkins Medicine, May 3, 2016 release

transitioning patients see the disparity in their treatment. VA needs to give more attention to these techniques to close the parity gap in pain management care.

WoA has met with the Veterans Cannabis Coalition because of our shared concerns in addressing the opioid epidemic in America and prescription drug use among VA patients. Regarding cannabis research studies, the National Academies of Sciences (NAS) found, in a 2017 review of 10,000 existing cannabis studies, conclusive or substantial evidence that cannabis is effective for the treatment of pain in adults and limited evidence that it can improve the symptoms of posttraumatic stress disorder (PTSD). The NAS report recommendations focus on the broad need for improvements to research processes and high-quality clinical trials. The VA is uniquely positioned to fully investigate the effects and potential applications of cannabis. The health care needs of veterans, particularly for alternatives to opioids for chronic pain management, should make cannabis research a top priority within the VA, and Congress should work to remove the existing barriers to research and stigma imposed by the National Institute for Drug Abuse (NIDA). As one physician noted to WoA, “over the years, my practice has changed, based on the changes in the medical literature. Cannabis research could someday potentially change what the current medical literature states is standard of care regarding pain management.”

As WoA has previously testified, the Federal Government has no Center Of Pain Management Excellence (COPE) but could greatly benefit from such a focus. Strategically located COPEs in partnership with DoD were recommended by a joint task force report issued by the Army Surgeon General in 2010². If this recommendation were instituted, VA and DoD could be leading the nation in responding to the opioid epidemic as required by President Trump. However, eight years later, we still do not have these Centers, proper toxicology or accountability for opioids, or standardized protocols for pain management that could come from the proper research. Congress should ask for an update on these recommendations, especially regarding the COPE.

- Congress should authorize VA to partner with DoD and other entities to establish a COPE.
- COPE should lead efforts to create, delegate, and integrate further studies on alternative to opioids for pain management, including cannabis.
- COPE should develop and institute plans and strategies to translate research into practice.

Mental Health, TBI, and Suicide Prevention:

Mental health is the bailiwick of VA, especially related to (PTSD). The VA had led the nation in researching PTSD and its treatment. It houses a body of knowledge through the National Center for PTSD that is unexceed anywhere else. However, as reported by the AFGE, there is a high turnover rate among VA providers, so there is a constant need for new clinicians to be supported and trained with innovative approaches and techniques, such as with Virtual Environments (VE). For example, these VE can help train providers to deal with difficult subjects to discuss, such as Military Sexual Trauma (MST) or sexual dysfunction, or suicidal ideation. Social Work students are already being trained in these environments as well as military personnel in leadership courses. These tools need further research and development for application in a VA environment, but could expand training capabilities and reduce long-term production costs.

Although VA collaborates with DoD on issues related to Traumatic Brain Injury (TBI) there are still gaps in its ability to understand and treat this range of brain damage, especially when there are co-morbid conditions present. For example, in accordance with the VA/DoD Treatment Practice Guidelines, “For patients with PTSD, we recommend individual, manualized trauma focused psychotherapies that have a primary component of exposure and/or cognitive restructuring to include Prolonged Exposure (PE), Cognitive Processing Therapy (CPT), Eye Movement Desensitization and Reprocessing (EMDR), specific cognitive behavioral therapies for PTSD, Brief Eclectic Psychotherapy (BEP), Narrative Exposure Therapy (NET), and written narrative exposure.” These are excellent standards of care but can be ineffective with patients who are cognitively impaired, such as those with TBI or Dementia. Thus, the above can leave veterans labeled “treatment resistant” as opposed to misdiagnosed. While VA spends on average \$30 million a year on brain research, DoD spends closer to \$80 million. Each agency has different populations it needs

²The Pain Management Task Force Report: Providing a Standardized DoD and VHA Vision and Approach to Pain Management to Optimize the Care for Warriors and their Families made 109 recommendations. The report was required by NDAA 2010.

to study, so researchers trying to deal with aging veterans find shortfalls in their capabilities, especially on brain studies involving women veterans, which is why Pink Concussion is seeking women veterans to donate their brains. In a 2018 OIG report, (15–01580–108) it found problems with providers who could not effectively diagnose TBI or differentiate it from PTSD, which negatively impacted veterans' ability to obtain proper service connection disability compensation and access medical care.

Investments should be made in exploring and testing some of the innovative neurotechnologies that are available for identifying brain functioning and treating or mitigating TBI impacts. Tools coming to the market include brain performance trackers and wearables, neuromonitoring, brain-computer interfaces, neuro-bio-feedback, and other cognitive aids that could also be explored for use in veteran populations.

Research has also already correlated PTSD and TBI to increased risks for dementia. Dementia onset also can stimulate new symptoms or exacerbate existing mental disorders as cognitive capabilities degenerate. As the veteran population with these conditions continue to age, new protocols are needed to support a healthy aging process that enhances the independence and integrity of the veteran while developing and testing tools that can better assist caregivers to allow veterans to age in place.

In 2013, VA, DoD and the Departments of Education and Health and Human Services issued a National Research Action Plan (NRAP) for Mental Health. Major commitments were made by all of the agencies and entities involved for enhanced research coordination and governance, prioritization, innovation and translational capabilities. However, over the last five years, there seems to be little reporting on the outcomes generated by the NRAP and its partners.

In July 2017, VA released data on veterans who have died by suicide. Although compelling, the problem with the data release was that it is not tied to any VA program outcome data or funding execution information. There is no indication that VA uses this report in any meaningful way to target its interventions or other approaches. In fact, there have been several OIG investigations that recommend that VA do more targeted outreach at the local levels. However, VA continues to fund national awareness campaigns that have no evidence of effectiveness. There is growing research that awareness campaigns do not work or could even have an adverse impact because they normalize the behavior they are trying to mitigate.³ Yet, in the last few years, VA has awarded almost \$100 million in contracts for “Make the Connection” and the “Veterans Crisis Line” campaigns instead of using those funds to address shortfalls at the call center, hire more mental health providers, expand peer support or conduct local outreach. Whistleblowers have noted that money gets spent on things like videos, posters, dashboards or SharePoint sites that could have been allocated for direct patient care, provider training or research.

Congress passed the Joshua Omvig, Clay Hunt, and the Chris Kirkpatrick Acts in attempts to mandate VA suicide prevention efforts. We lost Omvig, Hunt, and 20 other veterans a day, along with Dr. Kirkpatrick to suicide while VA has struggled to provide evidence-based interventions and support. Ongoing OIG and GAO investigations should prove fruitful in identifying suicide prevention improprieties and shortfalls along with recommendations for better practices.

- The Committee should hold a hearing to learn more about these mental health and brain treatment technologies to help prioritize their research value.
- Congress should require VA to lead an effort with its sister agencies to update the NRAP goals and objectives and document pertinent outcomes for veterans.
- Congress needs to hold VA accountable for how it uses the suicide population data it collects to inform the programs it creates and how it aligns appropriated funds for these purposes. The Committee should hold a hearing on suicide prevention funding to review OIG and GAO findings related to waste, fraud and abuse.

Research Treatment for Tinnitus:

Tinnitus and hearing loss are the primary service connected conditions adjudicated by the Veterans Benefits Administration. There are double the number of veterans who are service connected for tinnitus than there are for PTSD, yet the research funding for audiology is minimal.

Tinnitus, which is a constant ringing or buzzing in their ears, impacts so many aspects of a veterans' quality of life. It is often a side effect within the ear or brain from other conditions, environmental exposures (noise in a combat zone), or injury

³University of Michigan, School of Public Health

(TBI). Depression, anxiety, lack of sleep and difficulty focusing or concentrating are associated with tinnitus. Furthermore, tinnitus can exacerbate PTSD because of its sensory deprivation implications may impact memory imprints on the brain. A recent study⁴ looked at the relationship between Tinnitus and suicide.

Although symptoms can be managed, there is no cure. The National Center for Rehabilitative Auditory Research (NCRAR) at the VA Portland Health Care System has been involved with researching transcranial magnetic stimulation (TMS) that involves using magnets to nonsurgically penetrate the brain and affect the activity of neurons as a new treatment.

- Congress should request an update from the NCRAR for a status on its research portfolio and potential translation capabilities for TMS.

Homeless Veteran Program Data:

WoA is aware that VA administrators are intimidating VA employees to match homeless Veterans to housing that is grossly inadequate for the veteran and to underreport the number of homeless veterans who cannot maintain independent living. They are using the HUD vouchers to get homeless veterans into apartments, but then do not have the ability to furnish or provide supplies for them. Many of these veterans are chronically mentally ill and need more supervision than can be provided in an apartment. The veteran fails to conduct appropriate hygiene, so neighbors complain to landlords who evict these veterans. The VA case manager should be recording these veterans as homeless, but instead are told to document these veterans as transferring and not to report anything until they get the veteran into new housing. Additionally, over \$1 billion has been provided to community organizations via Supportive Services to Veterans Families (SSVF) grants, with little to no performance data produced.

There needs to be greater accountability for this highly vulnerable population.

- Congress should require VA to closely document the needs of each homeless veteran, match him or her with the appropriate type of facility, and enhance case manager assistance with ongoing issues while the veteran is transitioning from homelessness.
- VA should conduct a long-term “lifecycle” study on homeless veterans to identify challenges, complex medical/mental/dental needs and account for accurate touchpoints for interventions, services and outcomes of these engagements.
- VA should be required to report data regarding the number of veterans placed in transitional housing and the number who subsequently leave and the reasons why they left housing. It should also collect and report SSVF outcome data. Congress should authorize VA to conduct a comprehensive review of the Homeless Veteran population and a needs assessment.

Toxic Exposures and Environmental Hazards Research and Presumption:

Agent Orange: A primary source of concern for veterans that have contacted WoA has been related to toxic exposures and environmental hazards. There are still so many Vietnam-era Veterans with Agent Orange related issues that have not been appropriately recognized because of the shortfalls in the research, such as Blue Water Navy. For example, eye cancers are a continuous issue that lack research support. VA continues to deny claims for disability benefits, which in turn blocks veteran from accessing care. As the Vietnam generation ages and has more complex needs for care, the arguments over probable correlations need to be resolved before there is no one left for the science to help.

Gulf War Illness: Although it has been more than 25 years since the US invaded Iraq, the mysteries of Gulf War Illnesses haunt veterans while perplexing VA. A July 2017 GAO report concluded that VA is still inappropriately denying veterans claims. It found an 80 percent denial rate, which is three times greater than any other type of claim denials. Plus, it also took VA longer to adjudicate these benefits. This delay means that sick veterans are not fully eligible for VA health care. VA has promised better training and to develop a new plan for research.

Fort McClellan: When the Veterans Disability Benefits Commission (VDBC) issued its report,⁵ it included the Service members (mostly women) from Ft. McClellan, AL in its recommendation for a presumption framework. The VDBC made 20 recommendations for improvements to the VA presumption process, the creation of

⁴Martz et al. (2018)

⁵VDBC. Honoring the Call to Duty: Veterans Disability Benefits in the 21st Century. October 2007.

a scientific review board, and veteran health surveillance. Over 10 years later, the American Legion is still reporting on the “unknown toxic legacy” of Anniston and has resolutions that requires a toxic substance national research center, comprehensive examinations for environmental exposures, and improvement in these rules.⁶

Camp LeJeune: Due to the water contamination at the Marine Corps Base, Camp LeJeune, NC, increased reports of cancers in veterans and their families have been documented over the last several decades related to the cleaning solvents in the water. Referring to the previous notes on Ft. McClellan and the VDBC findings, VA would be better situated to address these issues if they were to have a standardized process and scientific review board.

Burn Pit Exposures: Similar to previous generations of veterans, those who have served in Afghanistan and Iraq since 9/11 were exposed to a concoction of burning substances on military installations that has caused them to raise health concerns from cancers to respiratory and gastrointestinal disorders. Although VA denies conclusive research for these conditions and does not have a presumption for burn pits, it has established a registry. However, this is an area yet again that the VDBC recommendation could be informative and assistive to veterans’ wellness if implemented. A registry alone assists no one.

- Mandate VA to establish a Scientific Review Board as described by the VDBC for use in considering presumptions related to exposures. A standard should be adapted for “causal effect” based on more likely than not broad spectrum of evidence that is either Sufficient, Equipose and above, Equipose and below, Against. This calculation should include relative risk assessment, epidemiology, registries, surveillance data, predictive algorithms and interfaces with DoD.

Research Waste, Fraud and Abuse:

WoA has reviewed complaints related to the waste, fraud and abuse of research program funds that have gone to universities and other private sector partners. In these cases, VA failed to provide proper oversight of government funds or property and could not account for items issued to non-government researchers or other staff. Property that should have been returned to the government was not and funds unexecuted were not returned.

Much of the \$1.9 billion of taxpayer funded VA Research falls outside of the realm of “Direct Veteran Patient Care.” There exist little or no oversight to monitor these VA funded research activities. VA Medical Centers Research dollars and facility resources are often redistributed towards gaps in Veteran care services, which leads to a disparaged and fractured research work environment. These are dedicated VA laboratory research spaces intended to support VA funded research that take place at more than 80 VA research facilities nationwide. The VA remedy is the wholesale issuance of “100% Off Site Waivers” to the Academic Affiliate.” VA Rules and Regulations stipulate that “All VA Funded Grant Activity must take place on VA owned property.” Local VA “Nonprofit research Corporations” (NPC’s) no longer route Veteran-centric research grant funding through VA and millions of dollars of research equipment and space are abandoned to sit fallow. As a result, a “Boondoggle” is created to support an illusion of “Activity and Accountability” as once noted by Congressman Mike Coffman. The end result is displaced VA equipment infrastructure, lost technology transfer opportunities, royalties and invention disclosure as reported in a recent GAO report.⁷

The OIG has conducted several investigations into VA research and development and has time and time again found mismanagement issues. For example, it investigated the development of a mobile application by VA and found that there were 80 potential contracts totaling over \$1 billion and VA did not “pick and stick” to the line item appropriation, thereby executing funds without the proper congressional authorities and confusing technology and patient care funds. In another investigation, the OIG found that VA did not have proper safeguards with its data when sharing information with external entities, such as universities.

- Considering these research deficits and the lack of VA’s accountability for mismanagement and mishandling of equipment and space in its research program, VA should immediately put forth a plan for research oversight and its ability to report on executed research funds.

⁶Olsen, K. the long shadow of Ft. McClellan. The American Legion Magazine. March 2018. Pgs. 22-28

⁷GAO-18-325: Published: Apr 25, 2018.

Jacqueline Garrick is a former Army social work officer who has worked in the Departments of Veterans Affairs and Defense as well as for the House Veterans Affairs Committee. She is a subject matter expert in mental health and program evaluation. She is an advocate for disabled veterans and the use of peer support to improve resilience in traumatized populations. She founded Whistleblowers of America in 2017 based on her experience reporting attempted fraud with DoD Suicide prevention funds.

Whistleblowers of America is a 501C3, EIN 82-3989539. Its mission is to provide peer support to employees and veterans who have reported wrongdoing and experienced retaliation.

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**National Association of Veterans' Research and Education Foundations
(NAVREF)**

May 23, 2018

US House of Representatives
House Committee on Veterans' Affairs
335 Cannon House Office Building
Washington, DC 20515

To the Committee Staff:

In regard to the hearing held May 17th on the Department of Veterans Affairs' medical and research prosthetic program, we would like to make an addition to the hearing record. Representative Poliquin asked Ms. Rusconi about the handling of unspent funds from an NIH research award. We would like to add the following statement to Ms. Rusconi's response:

It should be noted that funds drawn from an NIH or other federal grant by an NPC include the federally negotiated indirect rate to administer those funds. Those administrative funds are used to support the NPC, whose sole mission is to support VA research.

Thank you for holding this important hearing and giving NAVREF the opportunity to represent the perspective of the VA-affiliated nonprofit corporations.

Respectfully,
Richard P. Starrs
Chief Executive Officer
Robin Rusconi
Chairperson

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