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Statement of

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On
VA Research: Focusing on Funding, Findings, and Partnerships

Before the
Committee on Veterans' Affairs
U.S. House of Representatives

May 17, 2018

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 2016[1], 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

[1] Johns Hopkins Medicine, May 3, 2016 release

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.**

<u>Opioids and Pain Management Research Translation:</u>

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 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

healthcare 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 2010[2]. 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.

[2] The *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.

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 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-biofeedback, 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 (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 study[4] looked at the relationship between Tinnitus and suicide.

[3] University of Michigan, School of Public Health
[4] Martz et al. (2018)

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 magnates 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 healthcare. 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 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 document 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, Equipoise and above, Equipoise and below,**

[5] VDBC. Honoring the Call to Duty: Veterans Disability Benefits in the 21st Century. October 2007.
[6] Olsen, K. the long shadow of Ft. McClellan. The American Legion Magazine. March 2018. Pgs. 22-28

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.**

[7] GAO-18-325: Published: Apr 25, 2018.

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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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