UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

JUL 2 8 2021

The Honorable Jack Reed
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The Department's response to section 704 of the National Defense Authorization Act for Fiscal Year 2014 (Public Law 113−66), "Pilot Program on Investigational Treatment of Members of the Armed Forces for Traumatic Brain Injury and Post-Traumatic Stress Disorder," is enclosed. Due to managing coronavirus disease 2019 priorities within the Office of the Assistant Secretary of Defense for Health Affairs, this sixth and final report is late. However, the information contained in this report is up to date.

This report describes the Department's progress to date for the two recommended research projects responsive to this legislative request, currently awarded with funding totaling $5.45M. Each study entails the development and maintenance of a database that will include data from every patient receiving treatment. During the past year, both studies observed increased recruitment, screening, and participation consent from subjects, following implementation of mitigation plans to address slow recruitment and enrollment.

Thank you for your continued strong support for our Service members and families. I am sending a similar letter to the Committee on Armed Services of the House of Representatives.

Sincerely,

Virginia S. Penrod

Virginia S. Penrod
Acting

Enclosure:
As stated

cc:
The Honorable James M. Inhofe
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

JUL 2 8 2021

The Honorable Adam Smith
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The Department's response to section 704 of the National Defense Authorization Act for Fiscal Year 2014 (Public Law 113-66), "Pilot Program on Investigational Treatment of Members of the Armed Forces for Traumatic Brain Injury and Post-Traumatic Stress Disorder," is enclosed. Due to managing coronavirus disease 2019 priorities within the Office of the Assistant Secretary of Defense for Health Affairs, this sixth and final report is late. However, the information contained in this report is up to date.

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Sincerely,

Virginia S. Penrod

Virginia S. Penrod
Acting

Enclosure:
As stated

cc:
The Honorable Mike D. Rogers
Ranking Member

REPORT TO THE COMMITTEES ON ARMED SERVICES OF THE SENATE AND HOUSE OF REPRESENTATIVES

Section 704 of the National Defense Authorization Act for Fiscal Year 2014 (Public Law 113–66)

Pilot Program on Investigational Treatment of Members of the Armed Forces for Traumatic Brain Injury and Post-Traumatic Stress Disorder

Sixth and Final Report

July 2021

The estimated cost of this report or study for the Department of Defense (DoD) is approximately $410 in Fiscal Year 2019. This includes $150 in expenses and $260 in DoD labor.

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Summary:

Section 704 of the National Defense Authorization Act for Fiscal Year (FY) 2014 (Public Law 113–66), Pilot Program on Investigational Treatment of Members of the Armed Forces for Traumatic Brain Injury (TBI) and Post-Traumatic Stress Disorder (PTSD), states:

> The Secretary of Defense shall carry out a pilot program under which the Secretary shall establish a process for randomized placebo-controlled clinical trials of investigational treatments (including diagnostic testing) of traumatic brain injury or post-traumatic stress disorder received by members of the Armed Forces in health care facilities other than military treatment facilities;
>
> and,
>
> The Secretary shall develop and maintain a database containing data from each patient case involving the use of a treatment under this section. The Secretary shall ensure that the database preserves confidentiality and that any use of the database or disclosures of such data are limited to such use and disclosures permitted by law and applicable regulations.

In addition, section 704 requires the Secretary of Defense to provide to the Committees on Armed Services of the Senate and the House of Representatives a report, no later than 30 days after the last day of each FY, on the implementation of this section and any available results on investigational treatment clinical trials authorized under this section during the FY. While the Secretary of Defense's authority to carry out the pilot program terminated on December 31, 2018, the Director, Defense Health Agency (DHA), under authority delegated by the Secretary, elected to continue the current clinical trials under the pilot program until their completion, in accordance with section 704's original intent. Although not required, the Department has chosen to provide periodic reports to Congress until conclusion of the clinical trials. This is the sixth and final report to Congress.

This report describes the details and progress, to date, by the Department of Defense following development and publication of a 2014 program announcement requesting proposals for clinical trials and database development related to TBI and PTSD. The Department initially awarded a total of $4.76M in funding for two projects, with current funding totaling $5.45M. Applicants received notification in June 2015, and awards were made in September 2015. From each study, a database including data from each patient receiving treatment will be developed and maintained.

Implementation Status:

In response to the requirements of section 704, the Department directed the development of a clinical trial research program announcement to be executed through the military medical research community. The Joint Program Committee-5 (Military Operational Medicine Research Program) and Joint Program Committee-6 (Combat Casualty Care Research Program) worked with the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army

Medical Research and Development Command (USAMRDC) to publish a program announcement to address section 704. This solicitation requested proposals for clinical trials and database development related to TBI and PTSD. DHA allocated $5M from the Defense Health Program Research, Development, Test, and Evaluation appropriation for this effort. The FY 2014 Investigational Treatments for TBI and PTSD Clinical Trial Award program announcement was released on September 18, 2014.

A total of 56 pre-applications were received in November 2014 and reviewed by a programmatic panel of scientific and military research subject matter experts. Based on the pre-application selection criteria published in the program announcement, 11 investigators were invited to submit applications. Nine compliant applications were received by the January 23, 2015 deadline. The applications underwent a scientific peer review in March 2015, conducted by an external panel of expert scientists, clinicians, and specific research topic area advocates. In May 2015, the programmatic panel conducted a programmatic review of the nine applications according to the published application evaluation criteria. The panel recommended funding two of the nine applications for a total of $4,761,697. The Commanding General, USAMRDC, and the Director of the DHA Research and Development Directorate (J-9) approved funding for the applications recommended during programmatic review. Applicants received notification of their funding recommendation status in June 2015, and awards were made in September 2015. From each study, a database including data from each patient receiving treatment is being developed and maintained. A summary of the funded projects follows.

Brief Treatment for PTSD – Enhancing Treatment Engagement and Retention:

- **Awardee:** Boston VA Research Institute, Inc.
  (CDMRP Log # PT140164; Award # W81XWH-15-1-0391)
- **Awarded Amount:** $2,268,872 (initial); $2,705,003 (current)
- **Description:** This study will examine whether a brief, five-session narrative therapy approach, called Written Exposure Therapy (WET), is efficacious in the treatment of military-related PTSD. If proven effective, WET could provide an alternative to existing evidence-based forms of PTSD treatment. It would require less time, and potentially be more appealing and accessible to many Service members who have avoided or discontinued other treatments.
- **Current Status:** The WET project continues to screen, consent, and randomize participants; provide treatment; and conduct follow-up assessments. To alleviate slow recruitment and enrollment, a supplement of $184,903 was provided in June 2017 to support a second clinical site located outside of Fort Hood in Killeen, Texas. This study received a 1-year extension with funds in June 2019 in the amount of $251,228 to continue enrollment and reach the target sample size of 150 participants. During the last year, recruitment, screening, and consent of subjects for the study have increased. The WET project is leveraging resources with three additional clinical trials to pre-screen potential participants. To date, 206 individuals consented to the study, of which 151 were randomized. Although the study met its recruitment goal, it is continuing to recruit participants to accommodate for those who were randomized, but did not attend a single treatment session.

The Efficacy of 90-Minute vs. 60-Minute Sessions of Prolonged Exposure for PTSD – A Randomized Control Trial in Active Duty Military Personnel:

- **Awardee:** University of Pennsylvania
  (CDMRP Log # PT140178; Award # W81XWH-15-1-0555)
- **Awarded Amount:** $2,492,825 (initial); $2,742,625 (current)
- **Description:** This study will test the efficacy and efficiency of 90-minute versus 60-minute prolonged exposure therapy for combat-related PTSD in active duty military personnel. The results will inform dissemination efforts of evidence-based treatment in the military, as well as in the public sector, and help identify mechanisms for how prolonged exposure therapy might be improved to better reduce PTSD symptoms.
- **Current Status:** The prolonged exposure therapy project team implemented a mitigation plan to alleviate slow recruitment and enrollment into the study. A modification to the assistance agreement was made in October 2017 to allow the University of Pennsylvania to change subcontractors at no additional cost, and thus, change recruitment sites from the greater San Antonio area to the area surrounding Marine Corps Air Station Beaufort and Charleston, South Carolina. As a result, recruitment and enrollment have increased, but remain behind schedule. As of October 2019, 149 individuals were screened and consented. Of those, 124 were randomized into the study to help meet the study target of 160 participants. A supplement of $249,800 was provided in September 2018 to support additional personnel to provide care to the unexpectedly large number of Service members in need of treatment at the new recruitment site. Due to the delayed study timeline, a second 1-year extension was approved and received in September 2019 to continue enrollment and reach the target sample size.