



UNDER SECRETARY OF DEFENSE  
4000 DEFENSE PENTAGON  
WASHINGTON, DC 20301-4000

PERSONNEL AND  
READINESS

OCT 28 2014

The Honorable Carl Levin  
Chairman  
Committee on Armed Services  
United States Senate  
Washington, DC 20510

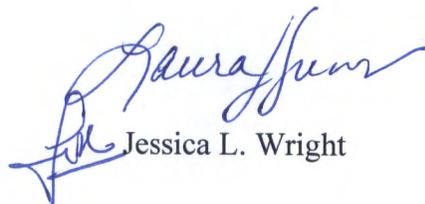
Dear Mr. Chairman:

The enclosed report provides the Department's initial response to Public Law 113-66, the National Defense Authorization Act for Fiscal Year 2014, section 704, "Pilot Program on Investigational Treatment of Members of the Armed Forces for Traumatic Brain Injury [TBI] and Post-Traumatic Stress Disorder [PTSD]." Section 704 requires the Secretary of Defense to carry out a pilot program to establish a process for randomized placebo-controlled clinical trials of investigational treatments of TBI or PTSD received by members of the Armed Forces in health care facilities other than military treatment facilities.

This report describes the initial actions taken by the Department of Defense toward the development and publication of a program announcement seeking submissions of randomized placebo-controlled clinical trials of investigational treatment proposals from non-military medical treatment or research institutions for research that can be made available to Active Duty members of the Armed Forces for their voluntary participation as research subjects. We will submit annual updates through December 2018.

A similar letter is being sent to the Chairman of the House Armed Services Committee. Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,



Jessica L. Wright

Enclosure:  
As stated

cc:  
The Honorable James M. Inhofe  
Ranking Member



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4000 DEFENSE PENTAGON  
WASHINGTON, DC 20301-4000

PERSONNEL AND  
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OCT 28 2014

The Honorable Howard P. "Buck" McKeon  
Chairman  
Committee on Armed Services  
U.S. House of Representatives  
Washington, DC 20515

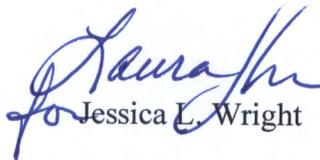
Dear Mr. Chairman:

The enclosed report provides the Department's initial response to Public Law 113-66, the National Defense Authorization Act for Fiscal Year 2014, section 704, "Pilot Program on Investigational Treatment of Members of the Armed Forces for Traumatic Brain Injury [TBI] and Post-Traumatic Stress Disorder [PTSD]." Section 704 requires the Secretary of Defense to carry out a pilot program to establish a process for randomized placebo-controlled clinical trials of investigational treatments of TBI or PTSD received by members of the Armed Forces in health care facilities other than military treatment facilities.

This report describes the initial actions taken by the Department of Defense toward the development and publication of a program announcement seeking submissions of randomized placebo-controlled clinical trials of investigational treatment proposals from non-military medical treatment or research institutions for research that can be made available to Active Duty members of the Armed Forces for their voluntary participation as research subjects. We will submit annual updates through December 2018.

A similar letter is being sent to the Chairman of the Senate Armed Services Committee. Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,

  
for Jessica L. Wright

Enclosure:  
As stated

cc:  
The Honorable Adam Smith  
Ranking Member

## **REPORT TO CONGRESS**

**The National Defense Authorization Act for Fiscal Year 2014,  
Section 704, (P.L. 113-66)**

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



The estimated cost of report for the Department of Defense is approximately  
\$400 in Fiscal Year 2014.

This includes \$300 in expenses and \$100 in DoD labor.

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## **Summary:**

Public Law 113-66, the National Defense Authorization Act for Fiscal Year 2014, section 704, “Pilot Program on Investigational Treatment of Members of the Armed Forces for Traumatic Brain Injury and Post-Traumatic Stress Disorder,” states that:

*“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 that:

*“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 directs the Secretary of Defense to provide to the Committees on Armed Services of the Senate and the House of Representatives a report not later than 30 days after the last day of each fiscal year, on the implementation of this section and any available results on investigational treatment clinical trials authorized under this section during such fiscal year.

This report describes the progress, to date, by the Department of Defense towards development and publication of a program announcement seeking submissions of randomized placebo-controlled clinical trials of investigational treatment proposals from non-military medical treatment or research institutions for research that can be made available to active duty members of the Armed Forces for their voluntary participation as research subjects.

## **Implementation Status:**

In response to the requirements of section 704, the Department has directed the development of a clinical trial research program announcement (PA) to be executed through the military medical research community.

The Deputy Assistant Secretary of Defense for Force Health Protection and Readiness directed the Director, Defense Health Agency (DHA), to implement section 704 as part of the fiscal year 2014 research program guidance. To implement, the U.S. Army Medical Research and Materiel Command will publish a research PA to address section 704, including clinical trials and database development related to traumatic brain injury and posttraumatic stress disorder. The DHA has allocated \$5 million from the Defense Health Program Research, Development, Test, and Education appropriation for this effort and the PA was released in September 2014.

All research applications received in response to this PA will undergo a scientific peer review and programmatic review. Scientific peer review is conducted by an external panel of expert scientists, clinicians, and specific research topic area advocates. Following peer review, a separate panel of scientific and military research subject matter experts will conduct a programmatic review to make funding recommendations. Awards from this PA will be made no later than September 30, 2015. We will submit annual updates through December 31, 2018.