

113TH CONGRESS  
1ST SESSION

# H. R. 2344

To direct the Secretary of Defense to carry out a pilot program for investigational treatment of members of the Armed Forces for traumatic brain injury and post-traumatic stress disorder.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 12, 2013

Mr. SESSIONS (for himself and Mr. THOMPSON of California) introduced the following bill; which was referred to the Committee on Armed Services

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## A BILL

To direct the Secretary of Defense to carry out a pilot program for investigational treatment of members of the Armed Forces for traumatic brain injury and post-traumatic stress disorder.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “TBI Treatment Act”.

1 **SEC. 2. PILOT PROGRAM FOR INVESTIGATIONAL TREAT-**  
2 **MENT OF MEMBERS OF THE ARMED FORCES**  
3 **FOR TRAUMATIC BRAIN INJURY AND POST-**  
4 **TRAUMATIC STRESS DISORDER.**

5 (a) PROCESS.—The Secretary of Defense shall carry  
6 out a five-year pilot program under which the Secretary  
7 shall establish a process through which the Secretary shall  
8 provide payment for investigational treatments (including  
9 diagnostic testing) of traumatic brain injury or post-trau-  
10 matic stress disorder received by members of the Armed  
11 Forces in health care facilities other than military treat-  
12 ment facilities. Such process shall provide that payment  
13 be made directly to the health care facility furnishing the  
14 treatment.

15 (b) CONDITIONS FOR APPROVAL.—The approval by  
16 the Secretary for payment for a treatment pursuant to  
17 subsection (a) shall be subject to the following conditions:

18 (1) Any drug or device used in the treatment  
19 must be approved or cleared by the Food and Drug  
20 Administration for any purpose and its use must  
21 comply with rules of the Food and Drug Administra-  
22 tion applicable to investigational new drugs or inves-  
23 tigational devices.

24 (2) The treatment must be approved by the  
25 Secretary following approval by an institutional re-  
26 view board operating in accordance with regulations

1 issued by the Secretary of Health and Human Serv-  
2 ices.

3 (3) The patient receiving the treatment must  
4 demonstrate an improvement under criteria ap-  
5 proved by the Secretary, as a result of the treatment  
6 on one or more of the following:

7 (A) Standardized independent pre-treat-  
8 ment and post-treatment neuropsychological  
9 testing.

10 (B) Accepted survey instruments including,  
11 such instruments that look at quality of life.

12 (C) Neurological imaging.

13 (D) Clinical examination.

14 (4) The patient receiving the treatment must be  
15 receiving the treatment voluntarily and based on in-  
16 formed consent.

17 (5) The patient receiving the treatment may not  
18 be a retired member of the Armed Forces who is en-  
19 titled to benefits under part A, or eligible to enroll  
20 under part B, of title XVIII of the Social Security  
21 Act.

22 (c) ADDITIONAL RESTRICTIONS AUTHORIZED.—The  
23 Secretary may establish additional restrictions or condi-  
24 tions for reimbursement as the Secretary determines ap-  
25 propriate to ensure the protection of human research sub-

1 jects, appropriate fiscal management, and the validity of  
2 the research results.

3 (d) AUTHORITY.—The Secretary shall make pay-  
4 ments under this section for treatments received by mem-  
5 bers of the Armed Forces using the authority in subsection  
6 (c)(1) of section 1074 of title 10, United States Code.

7 (e) AMOUNT.—A payment under this section shall be  
8 made at the equivalent Centers for Medicare and Medicaid  
9 Services reimbursement rate in effect for appropriate  
10 treatment codes for the State or territory in which the  
11 treatment is received. If no such rate is in effect, payment  
12 shall be made on a cost-reimbursement basis, as deter-  
13 mined by the Secretary, in consultation with the Secretary  
14 of Health and Human Services.

15 (f) DATA COLLECTION AND AVAILABILITY.—

16 (1) IN GENERAL.—The Secretary shall develop  
17 and maintain a database containing data from each  
18 patient case involving the use of a treatment under  
19 this section. The Secretary shall ensure that the  
20 database preserves confidentiality and that any use  
21 of the database or disclosures of such data are lim-  
22 ited to such use and disclosures permitted by law  
23 and applicable regulations.

24 (2) PUBLICATION OF QUALIFIED INSTITU-  
25 TIONAL REVIEW BOARD STUDIES.—The Secretary

1 shall ensure that an Internet website of the Depart-  
2 ment of Defense includes a list of all civilian institu-  
3 tional review board studies that have received a pay-  
4 ment under this section.

5 (g) ASSISTANCE FOR MEMBERS TO OBTAIN TREAT-  
6 MENT.—

7 (1) ASSIGNMENT TO TEMPORARY DUTY.—The  
8 Secretary of a military department may assign a  
9 member of the Armed Forces under the jurisdiction  
10 of the Secretary to temporary duty or allow the  
11 member a permissive temporary duty in order to  
12 permit the member to receive treatment for trau-  
13 matic brain injury or post-traumatic stress disorder,  
14 for which payments shall be made under subsection  
15 (a), at a location beyond reasonable commuting dis-  
16 tance of the permanent duty station of the member.

17 (2) PER DIEM.—A member who is away from  
18 the permanent station of the member may be paid  
19 a per diem in lieu of subsistence in an amount not  
20 more than the amount to which the member would  
21 be entitled if the member were performing travel in  
22 connection with a temporary duty assignment.

23 (3) GIFT RULE WAIVER.—The Secretary of De-  
24 fense may waive any rule of the Department of De-  
25 fense regarding ethics or the receipt of gifts with re-

1       spect to any assistance provided to a member of the  
2       Armed Forces for travel or per diem expenses inci-  
3       dental to receiving treatment under this section.

4       (h) MEMORANDA OF UNDERSTANDING.—The Sec-  
5       retary shall enter into memoranda of understandings with  
6       civilian institutions for the purpose of providing members  
7       of the Armed Forces with treatment carried out by civilian  
8       health care practitioners under treatment—

9               (1) approved by and under the oversight of ci-  
10       vilian institutional review boards; and

11              (2) that would qualify for payment under this  
12       section.

13       (i) OUTREACH.—The Secretary of Defense shall es-  
14       tablish a process to notify members of the Armed Forces  
15       of the opportunity to receive treatment pursuant to this  
16       section.

17       (j) REPORT TO CONGRESS.—Not later than 30 days  
18       after the last day of each fiscal year during which the Sec-  
19       retary is authorized to make payments under this section,  
20       the Secretary shall submit to Congress an annual report  
21       on the implementation of this section and any available  
22       results on investigational treatment studies authorized  
23       under this section.

1           (k) TERMINATION.—The authority to make a pay-  
2 ment under this section shall terminate on the date that  
3 is five years after the date of the enactment of this Act.

4           (l) AUTHORIZATION OF APPROPRIATIONS.—There is  
5 authorized to be appropriated to carry out this section  
6 \$10,000,000 for each fiscal year during which the Sec-  
7 retary is authorized to make payments under this section.

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