

AMENDMENT TO RULES COMMITTEE PRINT 119-8
OFFERED BY MRS. TRAHAN OF MASSACHUSETTS

At the end of subtitle C of title VII, add the following new section:

1 **SEC. 7____. PILOT PROGRAM TO FACILITATE DEVELOP-**
2 **MENT OF CERTAIN TRAUMATIC BRAIN IN-**
3 **JURY DIAGNOSTICS FOR MEMBERS OF THE**
4 **ARMED FORCES.**

5 (a) PILOT PROGRAM.—Not later than 180 days after
6 the date of enactment of this Act, the Secretary of De-
7 fense, acting through the Assistant Secretary of Defense
8 for Health Affairs, shall establish a pilot program to—

9 (1) assess the feasibility and advisability of pro-
10 viding support to eligible entities engaged in the re-
11 search, development, test, evaluation, or production
12 of covered diagnostic technologies that may be pro-
13 cured by the Secretary and used in the diagnosis of
14 traumatic brain injuries among members of the
15 Armed Forces in connection with operational deploy-
16 ments, including in combat zones;

17 (2) assess covered diagnostic technologies to de-
18 termine—

1 (A) whether such technologies are capable
2 of distinguishing mild traumatic brain injury
3 from moderate or severe traumatic brain injury;

4 (B) how such technologies may be used
5 with other diagnostics or diagnostic aids for
6 traumatic brain injury (including neuroimaging
7 biomarkers used in computed tomography, mag-
8 netic resonance imaging or molecular imaging,
9 blood-based biomarkers, electrophysiological bio-
10 markers, oculomotor tracking systems, and en-
11 vironmental sensors);

12 (C) how such technologies may be inte-
13 grated with the detection of other indicators of
14 physiological deficit, to enhance the health, sur-
15 vival, and long-term prognosis of members of
16 the Armed Forces;

17 (D) how such technologies may improve
18 military readiness through the improved brain
19 health of members of the Armed Forces; and

20 (E) the extent to which such technologies
21 may address concerns regarding the growing
22 medical burden of traumatic brain injury by
23 more accurately assessing and quantifying acute
24 exposure; and

1 (3) facilitate the research, development, test,
2 evaluation, and production of safe and effective cov-
3 ered diagnostic technologies, including by facilitating
4 the research and development of new or updated
5 manufacturing processes for such technologies and
6 the transitioning of such technologies from the
7 prototyping phase to the production phase.

8 (b) DESIGNATION.—The pilot program established
9 under paragraph (a) shall be known as the “Warfighter
10 Traumatic Brain Injury Diagnostics Project” (in this sec-
11 tion referred to as the “pilot program”).

12 (c) ACTIVITIES.—The pilot program shall include—

13 (1) the conduct of research studies to make the
14 assessments specified in subsection (a), including
15 studies conducted by, or in consultation with—

16 (A) trauma, primary care, and traumatic
17 brain injury experts of the Department of De-
18 fense;

19 (B) emergency medical technicians of the
20 Department;

21 (C) members of the Armed Forces diag-
22 nosed with traumatic brain injuries; and

23 (D) personnel of the Department who are
24 experts in the covered diagnostic technologies
25 assessed under such studies; and

1 (2) such activities as the Secretary determines
2 may be necessary to incentivize participation in such
3 studies by military medical treatment facilities, units
4 of the United States Special Operations Command,
5 civilian level one trauma centers, and such other en-
6 tities as the Secretary determines appropriate.

7 (d) GRANTS.—

8 (1) AWARD OF GRANTS.—In carrying out the
9 pilot program, the Secretary of Defense may award
10 a grant to an eligible entity engaged in the research,
11 development, test, evaluation, or production of cov-
12 ered diagnostics, consistent with subsection (a)(3).

13 (2) PRIORITY OF AWARDS.—In awarding grants
14 under paragraph (1), the Secretary shall give pref-
15 erence to an eligible entity that the Secretary deter-
16 mines meets one or more of the following criteria:

17 (A) The eligible entity has a demonstrated
18 history of researching, developing, testing, eval-
19 uating, or producing a covered diagnostic tech-
20 nology.

21 (B) The eligible entity has a demonstrated
22 history of researching, developing, testing, eval-
23 uating, or producing a covered diagnostic tech-
24 nology or other related capability in the na-
25 tional technology and industrial base (as such

1 term is defined in section 4801 of title 10,
2 United States Code).

3 (C) The covered diagnostic technology re-
4 searched, developed, tested, evaluated, or pro-
5 duced by such eligible entity provides
6 modularity to support diverse applications.

7 (3) USE OF GRANT AMOUNTS.—An eligible enti-
8 ty awarded a grant under paragraph (1) may only
9 use such grant amounts to carry out one or more of
10 the following activities:

11 (A) Conducting research, development,
12 testing, or evaluation activities to validate a
13 covered diagnostic technology (including
14 through experimentation, prototyping, or adapt-
15 ing such technology), to determine or improve
16 the potential operational use to the Department
17 of Defense of such technology, or to integrate
18 such technology with other technologies and
19 systems, including with respect to new or exist-
20 ing pathways of care.

21 (B) Addressing manufacturing or other
22 production challenges relating to a covered di-
23 agnostic technology.

24 (C) Providing commercially available cov-
25 ered diagnostic technologies to any Secretary of

1 a military department, or commander of a com-
2 batant command, to support use assessments or
3 other testing by members of the Armed Forces.

4 (D) Building or strengthening relation-
5 ships with nontraditional defense contractors in
6 the technology industry that may be capable of
7 providing unused or underused solutions to spe-
8 cific operational challenges of the Department
9 relating to traumatic brain injury diagnostics
10 technology.

11 (e) REPORT.—Not later than 90 days after the date
12 on which the pilot program terminates under subsection
13 (f), the Secretary of Defense shall submit to the congres-
14 sional defense committees a report on the results of the
15 pilot program. Such report shall include—

16 (1) a summary of the results of the pilot pro-
17 gram;

18 (2) a determination of the Secretary regarding
19 whether to procure and adopt covered diagnostic
20 technologies in addition to tools already used by
21 medical providers of the Department of Defense to
22 screen for traumatic brain injury at the point of in-
23 jury; and

24 (3) any recommendations of the Secretary re-
25 garding necessary steps to promote the use of cov-

1 ered diagnostic technologies that meet the needs of
2 the Armed Forces, including any legislative solutions
3 that may be necessary.

4 (f) TERMINATION.—The authority to carry out the
5 program shall terminate on the date that is two years after
6 the date of the establishment of the pilot program.

7 (g) DEFINITIONS.—In this section:

8 (1) The term “covered diagnostic technology”
9 means a device that aids in the diagnosis of trau-
10 matic brain injury, including by assisting clinicians
11 in making such a diagnosis.

12 (2) The term “civilian level one trauma center”
13 has the meaning given that term in section 708 of
14 the National Defense Authorization Act for Fiscal
15 Year 2017 (Public Law 114–328; 10 U.S.C. 1071
16 note).

17 (3) The term “eligible entity” means—

18 (A) any entity organized under the laws of
19 the United States or any jurisdiction within the
20 United States; or

21 (B) any entity that is owned by an entity
22 described in subparagraph (A).

1 (4) The term “nontraditional defense con-
2 tractor” has the meaning given that term in section
3 3014 of title 10, United States Code.

