S. 179

To direct the Secretary of Veterans Affairs to carry out a clinical trial of the effects of cannabis on certain health outcomes of adults with chronic pain and post-traumatic stress disorder, and for other purposes.

IN THE SENATE OF THE UNITED STATES

January 17, 2019

Mr. Tester (for himself and Mr. Sullivan) introduced the following bill; which was read twice and referred to the Committee on Veterans' Affairs

A BILL

- To direct the Secretary of Veterans Affairs to carry out a clinical trial of the effects of cannabis on certain health outcomes of adults with chronic pain and post-traumatic stress disorder, and for other purposes.
 - 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 "VA Medicinal Cannabis
 - 5 Research Act of 2019".

| 1 | SEC. 2. DEPARTMENT OF VETERANS AFFAIRS CLINICAL |
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| 2 | TRIAL OF THE EFFECTS OF CANNABIS ON |
| 3 | CERTAIN HEALTH OUTCOMES OF ADULTS |
| 4 | WITH CHRONIC PAIN AND POST-TRAUMATIC |
| 5 | STRESS DISORDER. |
| 6 | (a) CLINICAL TRIAL REQUIRED.— |
| 7 | (1) IN GENERAL.—The Secretary of Veterans |
| 8 | Affairs shall carry out a double-blind randomized |
| 9 | controlled clinical trial of the effects of medical- |
| 10 | grade cannabis on the health outcomes of covered |
| 11 | veterans diagnosed with chronic pain and covered |
| 12 | veterans diagnosed with post-traumatic stress dis- |
| 13 | order. |
| 14 | (2) Required elements.—The clinical trial |
| 15 | required by paragraph (1) shall include— |
| 16 | (A) with respect to covered veterans diag- |
| 17 | nosed with chronic pain, an evaluation of the |
| 18 | effects of the use of cannabis on— |
| 19 | (i) neuropathic pain (including pair |
| 20 | intensity and pain-related outcomes); |
| 21 | (ii) the reduction or increase in opioid |
| 22 | use or dosage; |
| 23 | (iii) the reduction or increase in |
| 24 | benzodiazepine use or dosage; |
| 25 | (iv) the reduction or increase in alco- |
| 26 | hol use; |

| 1 | (v) inflammation; |
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| 2 | (vi) sleep quality; |
| 3 | (vii) spasticity; |
| 4 | (viii) agitation; and |
| 5 | (ix) quality of life; and |
| 6 | (B) with respect to covered veterans diag- |
| 7 | nosed with post-traumatic stress disorder |
| 8 | (PTSD), an evaluation of the effects of the use |
| 9 | of cannabis on— |
| 10 | (i) the symptoms of PTSD (based on |
| 11 | the Clinician Administered PTSD Scale, |
| 12 | the PTSD checklist, the PTSD symptom |
| 13 | scale, the posttraumatic diagnostic scale, |
| 14 | and other applicable methods of evaluating |
| 15 | PTSD symptoms); |
| 16 | (ii) the reduction or increase in |
| 17 | benzodiazepine use or dosage; |
| 18 | (iii) the reduction or increase in alco- |
| 19 | hol use; |
| 20 | (iv) mood; |
| 21 | (v) anxiety; |
| 22 | (vi) social functioning; |
| 23 | (vii) agitation; |
| 24 | (viii) suicidal ideation; and |

| 1 | (ix) sleep quality, including frequency |
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| 2 | of nightmares and night terrors. |
| 3 | (3) Optional elements.—The clinical trial |
| 4 | required by paragraph (1) may include an evaluation |
| 5 | of the effects of the use of cannabis to treat chronic |
| 6 | pain and PTSD on— |
| 7 | (A) pulmonary function; |
| 8 | (B) cardiovascular events; |
| 9 | (C) head, neck, and oral cancer; |
| 10 | (D) testicular cancer; |
| 11 | (E) ovarian cancer; |
| 12 | (F) transitional cell cancer; |
| 13 | (G) motor vehicle accidents; |
| 14 | (H) mania; |
| 15 | (I) psychosis; |
| 16 | (J) cognitive effects; or |
| 17 | (K) cannabinoid hyperemesis syndrome. |
| 18 | (b) COVERED VETERANS.—In this section, the term |
| 19 | "covered veteran" means a veteran who is enrolled in the |
| 20 | patient enrollment system of the Department of Veterans |
| 21 | Affairs under section 1705 of title 38, United States Code. |
| 22 | (c) Long-Term Observational Study.—The Sec- |
| 23 | retary may carry out a long-term observational study of |
| 24 | the participants in the clinical trial required under sub- |
| 25 | section (a). |

| 1 | (d) Type of Cannabis.—In carrying out the clinical |
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| 2 | trial required by subsection (a), the Secretary shall |
| 3 | study— |
| 4 | (1) varying forms of cannabis, including— |
| 5 | (A) full plants and extracts; and |
| 6 | (B) at least three different strains of can- |
| 7 | nabis with significant variants in phenotypic |
| 8 | traits and various ratios of tetrahydrocannabi- |
| 9 | nol and cannabidiol in chemical composition; |
| 10 | and |
| 11 | (2) varying methods of cannabis delivery, in- |
| 12 | cluding combustible and non-combustible inhalation |
| 13 | and ingestion. |
| 14 | (e) Use of Control and Experimental |
| 15 | GROUPS.—The clinical trial required by subsection (a) |
| 16 | shall include both a control group and an experimental |
| 17 | group which shall— |
| 18 | (1) be of similar size and structure; and |
| 19 | (2) represent the demographics of the veteran |
| 20 | population, as determined by the most recent data |
| 21 | from the American Community Survey that is avail- |
| 22 | able prior to the commencement of the clinical trial. |
| 23 | (f) Data Preservation.—The clinical trial required |
| 24 | by subsection (a) shall include a mechanism to ensure the |
| 25 | preservation of all data, including all data sets, collected |

- 1 or used for purposes of the research required by sub-
- 2 section (a) in a manner that will facilitate further re-
- 3 search.
- 4 (g) Implementation.—Not later than 180 days
- 5 after the date of the enactment of this Act, the Secretary
- 6 shall—
- 7 (1) develop a plan to implement this section
- 8 and submit such plan to the Committees on Vet-
- 9 erans' Affairs of the House of Representatives and
- the Senate; and
- 11 (2) issue any requests for proposals the Sec-
- retary determines appropriate for such implementa-
- tion.
- 14 (h) Effect on Other Benefits.—The eligibility
- 15 or entitlement of a covered veteran to any other benefit
- 16 under the laws administered by the Secretary or any other
- 17 provision of law shall not be affected by the participation
- 18 of the covered veteran in a clinical trial or study under
- 19 this section.
- 20 (i) Reports.—During the five-year period beginning
- 21 on the date of the enactment of this Act, the Secretary
- 22 shall submit periodically, but not less frequently than an-
- 23 nually, to the Committees on Veterans' Affairs of the

- 1 House of Representatives and the Senate reports on the
- $2 \ \ {\rm implementation} \ {\rm of} \ {\rm this} \ {\rm section}.$

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