

117TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. TESTER (for himself and Mr. SULLIVAN) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To direct the Secretary of Veterans Affairs to carry out a series of clinical trials on the effects of cannabis on certain health outcomes of veterans 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 2021”.

1 **SEC. 2. DEPARTMENT OF VETERANS AFFAIRS CLINICAL**
2 **TRIALS ON THE EFFECTS OF CANNABIS ON**
3 **CERTAIN HEALTH OUTCOMES OF VETERANS**
4 **WITH CHRONIC PAIN AND POST-TRAUMATIC**
5 **STRESS DISORDER.**

6 (a) CLINICAL TRIALS REQUIRED.—

7 (1) IN GENERAL.—The Secretary of Veterans
8 Affairs shall carry out a series of clinical trials on
9 the effects of medical-grade cannabis on the health
10 outcomes of covered veterans diagnosed with chronic
11 pain and covered veterans diagnosed with post-trau-
12 matic stress disorder.

13 (2) REQUIRED ELEMENTS.—The clinical trials
14 required by paragraph (1) shall include—

15 (A) with respect to covered veterans diag-
16 nosed with chronic pain, an evaluation of the
17 effects of the use of cannabis on—

18 (i) osteopathic pain (including pain in-
19 tensity and pain-related outcomes);

20 (ii) the reduction or increase in opioid
21 use or dosage;

22 (iii) the reduction or increase in
23 benzodiazepine use or dosage;

24 (iv) the reduction or increase in alco-
25 hol use;

26 (v) inflammation;

- 1 (vi) sleep quality;
- 2 (vii) agitation; and
- 3 (viii) quality of life;

4 (B) with respect to covered veterans diag-
5 nosed with post-traumatic stress disorder, an
6 evaluation of the effects of the use of cannabis
7 on—

- 8 (i) the symptoms of post-traumatic
9 stress disorder (PTSD) as established by
10 or derived from the clinician administered
11 PTSD scale, the PTSD checklist, the
12 PTSD symptom scale, the post-traumatic
13 diagnostic scale, and other applicable
14 methods of evaluating symptoms of post-
15 traumatic stress disorder;
- 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
2 of nightmares and night terrors.

3 (3) OPTIONAL ELEMENTS.—The clinical trials
4 required by paragraph (1) may include an evaluation
5 of the effects of the use of cannabis to treat chronic
6 pain and post-traumatic stress disorder 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) intestinal inflammation;

14 (H) motor vehicle accidents;

15 (I) mania;

16 (J) psychosis;

17 (K) cognitive effects;

18 (L) cannabinoid hyperemesis syndrome;

19 (M) neuropathy; or

20 (N) spasticity.

21 (b) LONG-TERM OBSERVATIONAL STUDY.—The Sec-
22 retary may carry out a long-term observational study of
23 the participants in the clinical trials required by sub-
24 section (a).

25 (c) TYPE OF CANNABIS.—

1 (1) IN GENERAL.—In carrying out the clinical
2 trials required by subsection (a), the Secretary shall
3 study varying forms of cannabis, including whole
4 plant raw material and extracts.

5 (2) PLANT CULTIVARS.—Of the varying forms
6 of cannabis required under paragraph (1), the Sec-
7 retary shall study not fewer than seven unique plant
8 cultivars with ratios of tetrahydrocannabinol to
9 cannabidiol in each of the following categories:

- 10 (A) Less than 1:5.
11 (B) Between 1:2 and 1:5.
12 (C) Approximately 1:2.
13 (D) Approximately 1:1.
14 (E) Approximately 2:1.
15 (F) Between 2:1 and 5:1.
16 (G) More than 5:1.

17 (d) USE OF CONTROL AND EXPERIMENTAL
18 GROUPS.—The clinical trials required by subsection (a)
19 shall include both a control group and an experimental
20 group that shall—

- 21 (1) be of similar size and structure; and
22 (2) represent the demographics of the veteran
23 population, as determined by the most recent data
24 from the American Community Survey of the Bu-

1 reau of the Census that is available prior to the
2 commencement of the clinical trials.

3 (e) DATA PRESERVATION.—The clinical trials re-
4 quired by subsection (a) shall include a mechanism to en-
5 sure the preservation of all data, including all data sets,
6 collected or used for purposes of such trials in a manner
7 that will facilitate further research.

8 (f) IMPLEMENTATION.—Not later than 180 days
9 after the date of the enactment of this Act, the Secretary
10 shall—

11 (1) develop a plan to implement this section
12 and submit such plan to the Committee on Veterans’
13 Affairs of the Senate and the Committee on Vet-
14 erans’ Affairs of the House of Representatives; and

15 (2) issue any requests for proposals the Sec-
16 retary determines appropriate for such implementa-
17 tion.

18 (g) EFFECT ON OTHER BENEFITS.—The eligibility
19 or entitlement of a covered veteran to any other benefit
20 under the laws administered by the Secretary or any other
21 provision of law shall not be affected by the participation
22 of the covered veteran in a clinical trial under subsection
23 (a) or a study under subsection (b).

24 (h) PERIODIC REPORTS.—During the five-year pe-
25 riod beginning on the date of the enactment of this Act,

1 the Secretary shall submit periodically, but not less fre-
2 quently than annually, to the Committee on Veterans' Af-
3 fairs of the Senate and the Committee on Veterans' Af-
4 fairs of the House of Representatives reports on the imple-
5 mentation of this section.

6 (i) COVERED VETERAN DEFINED.—In this section,
7 the term “covered veteran” means a veteran who is en-
8 rolled in the patient enrollment system of the Department
9 of Veterans Affairs established and operated under section
10 1705(a) of title 38, United States Code.