

118TH CONGRESS
1ST SESSION

S. 326

To direct the Secretary of Veterans Affairs to carry out a study and 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

FEBRUARY 9, 2023

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 study and 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 2023”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

1 (1) COVERED VETERAN.—The term “covered
2 veteran” means a veteran who is enrolled in the pa-
3 tient enrollment system of the Department of Vet-
4 erans Affairs established and operated under section
5 1705(a) of title 38, United States Code.

6 (2) SECRETARY.—The term “Secretary” means
7 the Secretary of Veterans Affairs.

8 **SEC. 3. DEPARTMENT OF VETERANS AFFAIRS LARGE-**
9 **SCALE, MIXED METHODS, RETROSPECTIVE**
10 **QUALITATIVE STUDY ON THE EFFECTS OF**
11 **CANNABIS ON CERTAIN HEALTH OUTCOMES**
12 **OF VETERANS WITH CHRONIC PAIN AND**
13 **POST-TRAUMATIC STRESS DISORDER.**

14 (a) STUDY REQUIRED.—

15 (1) IN GENERAL.—The Secretary, through the
16 Office of Research and Development of the Depart-
17 ment of Veterans Affairs, shall carry out a large-
18 scale, mixed methods, retrospective, and qualitative
19 study on the effects of cannabis on the health out-
20 comes of covered veterans diagnosed with chronic
21 pain and covered veterans diagnosed with post-trau-
22 matic stress disorder.

23 (2) OBSERVATIONAL STUDY.—The study re-
24 quired by paragraph (1) shall be conducted as an

1 observational study on the effects of cannabis use on
2 the health of covered veterans.

3 (3) ELEMENTS.—

4 (A) IN GENERAL.—The study required by
5 paragraph (1) shall—

6 (i) triangulate a range of data
7 sources;

8 (ii) compare the positive and negative
9 health outcomes of covered veterans who
10 use cannabis, utilizing outcomes that can
11 be measured in an electronic health record
12 of the Department and through data sets
13 of the Department relating to claims for
14 benefits under the laws administered by
15 the Secretary;

16 (iii) elicit the positive and negative
17 outcomes of cannabis use for covered vet-
18 erans through semi-structured interviews;

19 (iv) estimate current and future
20 health system needs to address positive
21 and negative outcomes of cannabis use for
22 covered veterans;

23 (v) include a qualitative, open-ended
24 survey provided to covered veterans who
25 have sought care from the Department for

1 chronic pain or post-traumatic stress dis-
2 order during the five-year period preceding
3 the survey; and

4 (vi) include an assessment of—

5 (I) all records within the Vet-
6 erans Health Administration for cov-
7 ered veterans participating in the
8 study; and

9 (II) all records within the Vet-
10 erans Benefits Administration for cov-
11 ered veterans participating in the
12 study.

13 (B) HEALTH OUTCOMES.—A comparison
14 of health outcomes under subparagraph (A)(ii)
15 shall include an assessment of the following:

16 (i) The reduction or increase in opiate
17 use or dosage.

18 (ii) The reduction or increase in
19 benzodiazepine use or dosage.

20 (iii) The reduction or change in use of
21 other types of medication.

22 (iv) The reduction or increase in alco-
23 hol use.

24 (v) The reduction or increase in the
25 prevalence of substance abuse disorders.

- 1 (vi) Sleep quality.
- 2 (vii) Osteopathic pain (including pain
- 3 intensity and pain-related outcomes).
- 4 (viii) Agitation.
- 5 (ix) Quality of life.
- 6 (x) Mortality and morbidity.
- 7 (xi) Hospital readmissions.
- 8 (xii) Any newly developed or exacer-
- 9 bated health conditions, including mental
- 10 health conditions.

11 (b) IMPLEMENTATION.—Not later than 180 days
 12 after the date of the enactment of this Act, the Secretary
 13 shall commence the implementation of the study required
 14 by subsection (a)(1).

15 (c) DURATION OF STUDY.—The study required by
 16 subsection (a)(1) shall be carried out for an 18-month pe-
 17 riod.

18 (d) REPORT.—

19 (1) IN GENERAL.—Not later than 90 days after
 20 the completion of the study required by subsection
 21 (a)(1), the Secretary shall submit to the Committee
 22 on Veterans' Affairs of the Senate and the Com-
 23 mittee on Veterans' Affairs of the House of Rep-
 24 resentatives a report on the study.

1 (2) ABILITY TO CONDUCT CLINICAL TRIALS.—
 2 The Secretary shall include in the report required by
 3 paragraph (1) an assessment of whether the Sec-
 4 retary is able to meet the criteria necessary to con-
 5 duct the clinical trials required under section 4, in-
 6 cluding consideration of subsection (e)(1) of such
 7 section.

8 **SEC. 4. DEPARTMENT OF VETERANS AFFAIRS CLINICAL**
 9 **TRIALS ON THE EFFECTS OF CANNABIS ON**
 10 **CERTAIN HEALTH OUTCOMES OF VETERANS**
 11 **WITH CHRONIC PAIN AND POST-TRAUMATIC**
 12 **STRESS DISORDER.**

13 (a) CLINICAL TRIALS REQUIRED.—

14 (1) IN GENERAL.—If the Secretary indicates in
 15 the report required by section 3(d) that the Sec-
 16 retary is able to meet the criteria necessary to pro-
 17 ceed to clinical trials, commencing not later than
 18 180 days after the submittal of that report, the Sec-
 19 retary shall carry out a series of clinical trials on the
 20 effects of cannabis appropriate for investigational
 21 use, as determined by the Food and Drug Adminis-
 22 tration under section 505(i) of the Federal Food,
 23 Drug, and Cosmetic Act (21 U.S.C. 355(i)), on the
 24 health outcomes of covered veterans diagnosed with

1 chronic pain and covered veterans diagnosed with
 2 post-traumatic stress disorder.

3 (2) CONSIDERATIONS.—The clinical trials re-
 4 quired by paragraph (1) shall include, as appro-
 5 priate, an evaluation of key symptoms, clinical out-
 6 comes, and conditions associated with chronic pain
 7 and post-traumatic stress disorder, which may in-
 8 clude—

9 (A) with respect to covered veterans diag-
 10 nosed with chronic pain, an evaluation of the
 11 effects of the use of cannabis on—

12 (i) osteopathic pain (including pain in-
 13 tensity and pain-related outcomes);

14 (ii) the reduction or increase in opioid
 15 use or dosage;

16 (iii) the reduction or increase in
 17 benzodiazepine use or dosage;

18 (iv) the reduction or increase in alco-
 19 hol use;

20 (v) the reduction or increase in the
 21 prevalence of substance use disorders;

22 (vi) inflammation;

23 (vii) sleep quality;

24 (viii) agitation;

25 (ix) quality of life;

1 (x) exacerbated or new mental health
 2 conditions; and

3 (xi) suicidal ideation.

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) the reduction or increase in the
 21 prevalence of substance use disorders;

22 (v) mood;

23 (vi) anxiety;

24 (vii) social functioning;

25 (viii) agitation;

- 1 (ix) suicidal ideation; and
- 2 (x) sleep quality, including frequency
- 3 of nightmares and night terrors.

4 (3) OPTIONAL ELEMENTS.—The clinical trials
 5 required by paragraph (1) may include, as appro-
 6 priate, an evaluation of the effects of the use of can-
 7 nabis to treat chronic pain and post-traumatic stress
 8 disorder on other symptoms, clinical outcomes, and
 9 conditions not covered by paragraph (2), which may
 10 include—

- 11 (A) pulmonary function;
- 12 (B) cardiovascular events;
- 13 (C) head, neck, and oral cancer;
- 14 (D) testicular cancer;
- 15 (E) ovarian cancer;
- 16 (F) transitional cell cancer;
- 17 (G) intestinal inflammation;
- 18 (H) motor vehicle accidents; or
- 19 (I) spasticity.

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

24 (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, and may study
5 varying routes of administration.

6 (2) PLANT CULTIVARS.—Of the varying forms
7 of cannabis required under paragraph (1), the Sec-
8 retary shall study plant cultivars with varying ratios
9 of tetrahydrocannabinol to cannabidiol.

10 (d) IMPLEMENTATION.—Not later than 18 months
11 after the date of the enactment of this Act, the Secretary
12 shall—

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

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

20 (e) TERMINATION OF CLINICAL TRIALS.—

21 (1) CLINICAL GUIDELINE REQUIREMENTS OR
22 EXCESSIVE RISK.—The Secretary may terminate the
23 clinical trials required by subsection (a) if the Sec-
24 retary determines that the Department of Veterans
25 Affairs is unable to meet clinical guideline require-

1 ments necessary to conduct such trials or the clinical
2 trials would create excessive risk to participants.

3 (2) COMPLETION UPON SUBMITTAL OF FINAL
4 REPORT.—The Secretary may terminate the clinical
5 trials required by subsection (a) upon submittal of
6 the final report required under subsection (f)(2).

7 (f) REPORTS.—

8 (1) PERIODIC REPORTS.—During the five-year
9 period beginning on the date of the commencement
10 of clinical trials required by subsection (a), the Sec-
11 retary shall submit periodically, but not less fre-
12 quently than annually, to the Committee on Vet-
13 erans' Affairs of the Senate and the Committee on
14 Veterans' Affairs of the House of Representatives
15 reports on the implementation of this section.

16 (2) FINAL REPORT.—Not later than one year
17 after the completion of the five-year period specified
18 in paragraph (1), the Secretary shall submit to the
19 Committee on Veterans' Affairs of the Senate and
20 the Committee on Veterans' Affairs of the House of
21 Representatives a final report on the implementation
22 of this section.

23 **SEC. 5. ADMINISTRATION OF STUDY AND CLINICAL TRIALS.**

24 (a) DEMOGRAPHIC REPRESENTATION.—In carrying
25 out the study required by section 3 and the clinical trials

1 required by section 4, the Secretary shall ensure represen-
2 tation in such study and trials of demographics that rep-
3 resent the population of veterans in the United States, as
4 determined by the most recently available data from the
5 American Community Survey of the Bureau of the Census.

6 (b) DATA PRESERVATION.—The Secretary shall en-
7 sure that the study required by section 3 and the clinical
8 trials required by section 4 include a mechanism to en-
9 sure—

10 (1) the preservation of all data, including all
11 data sets and survey results, collected or used for
12 purposes of such study and trials in a manner that
13 will facilitate further research; and

14 (2) registration of such data in the database of
15 privately and publicly funded clinical studies main-
16 tained by the National Library of Medicine (or suc-
17 cessor database).

18 (c) ANONYMOUS DATA.—The Secretary shall ensure
19 that data relating to any study or clinical trial conducted
20 under this Act is anonymized and cannot be traced back
21 to an individual patient.

22 (d) EFFECT ON OTHER BENEFITS.—The eligibility
23 or entitlement of a covered veteran to any other benefit
24 under the laws administered by the Secretary or any other
25 provision of law shall not be affected by the participation

1 of the covered veteran in the study under section 3, a clin-
2 ical trial under section 4(a), or a study under section 4(b).

3 (e) EFFECT ON OTHER LAWS.—Nothing in this Act
4 shall affect or modify—

5 (1) the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 301 et seq.);

7 (2) section 351 of the Public Health Service
8 Act (42 U.S.C. 262); or

9 (3) the authority of the Commissioner of Food
10 and Drugs and the Secretary of Health and Human
11 Services—

12 (A) under—

13 (i) the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 301 et seq.); or

15 (ii) section 351 of the Public Health
16 Service Act (42 U.S.C. 262); or

17 (B) to promulgate Federal regulations and
18 guidelines pertaining to cannabidiol, marijuana,
19 or other subject matter addressed in this Act.

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