116TH CONGRESS 1ST SESSION H.R. 712

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 HOUSE OF REPRESENTATIVES

JANUARY 23, 2019

Mr. CORREA (for himself and Mr. HIGGINS of Louisiana) introduced the following bill; which was 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
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 pain
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;
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

3

1	(ix) sleep quality, including frequency
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).

4

(d) TYPE OF CANNABIS.—In carrying out the clinical
 trial required by subsection (a), the Secretary shall
 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 9 tetrahydrocannabinol and cannabidiol in chem-10 ical composition; and

(2) varying methods of cannabis delivery, including combustible and non-combustible inhalation
and ingestion.

(e) USE OF CONTROL AND EXPERIMENTAL
GROUPS.—The clinical trial required by subsection (a)
shall include both a control group and an experimental
group which shall—

18 (1) be of similar size and structure; and

(2) represent the demographics of the veteran
population, as determined by the most recent data
from the American Community Survey that is available prior to the commencement of the clinical trial.
(f) DATA PRESERVATION.—The clinical trial required
by subsection (a) shall include a mechanism to ensure the
preservation of all data, including all data sets, collected

or used for purposes of the research required by sub section (a) in a manner that will facilitate further re 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 Vet9 erans' Affairs of the House of Representatives and
10 the Senate; and

(2) issue any requests for proposals the Secretary determines appropriate for such implementation.

(h) EFFECT ON OTHER BENEFITS.—The eligibility
or entitlement of a covered veteran to any other benefit
under the laws administered by the Secretary or any other
provision of law shall not be affected by the participation
of the covered veteran in a clinical trial or study under
this section.

(i) REPORTS.—During the five-year period beginning
on the date of the enactment of this Act, the Secretary
shall submit periodically, but not less frequently than annually, to the Committees on Veterans' Affairs of the

- 1 House of Representatives and the Senate reports on the
- $2 \hspace{0.1in} \text{implementation of this section.}$