AMENDMENT TO RULES COMMITTEE PRINT 117–13

OFFERED BY MR. CORREA OF CALIFORNIA

Add at the end of title LX the following new section:

SEC. 60___. DEPARTMENT OF VETERANS AFFAIRS CLINICAL TRIAL OF THE EFFECTS OF CANNABIS ON CERTAIN HEALTH OUTCOMES OF ADULTS WITH CHRONIC PAIN AND POST-TRAUMATIC STRESS DISORDER.

(a) CLINICAL TRIAL REQUIRED.—

(1) IN GENERAL.—The Secretary of Veterans Affairs shall carry out a double-blind randomized controlled clinical trial of the effects of medical-grade cannabis on the health outcomes of covered veterans diagnosed with chronic pain and covered veterans diagnosed with post-traumatic stress disorder.

(2) REQUIRED ELEMENTS.—The clinical trial required by paragraph (1) shall include—

(A) with respect to covered veterans diagnosed with chronic pain, an evaluation of the effects of the use of cannabis on—

(i) neuropathic pain (including pain intensity and pain-related outcomes);

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

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

(iv) the reduction or increase in alcohol use;

(v) inflammation;

(vi) sleep quality;

(vii) spasticity;

(viii) agitation; and

(ix) quality of life; and

(B) with respect to covered veterans diagnosed with post-traumatic stress disorder (PTSD), an evaluation of the effects of the use of cannabis on—

(i) the symptoms of PTSD (based on the Clinician Administered PTSD Scale, the PTSD checklist, the PTSD symptom scale, the posttraumatic diagnostic scale, and other applicable methods of evaluating PTSD symptoms);

(ii) the reduction or increase in benzodiazepine use or dosage;

(iii) the reduction or increase in alcohol use;

(iv) mood;

(v) anxiety;

(vi) social functioning;

(vii) agitation;

(viii) suicidal ideation; and

(ix) sleep quality, including frequency of nightmares and night terrors.

(3) OPTIONAL ELEMENTS.—The clinical trial required by paragraph (1) may include an evaluation of the effects of the use of cannabis to treat chronic pain and PTSD on—

(A) pulmonary function;

(B) cardiovascular events;

(C) head, neck, and oral cancer;

(D) testicular cancer;

(E) ovarian cancer;

(F) transitional cell cancer;

(G) motor vehicle accidents;

(H) mania;

(I) psychosis;

(J) cognitive effects; or

(K) cannabinoid hyperemesis syndrome.

(b) COVERED VETERANS.—In this section, the term ''covered veteran'' means a veteran who is enrolled in the patient enrollment system of the Department of Veterans Affairs under section 1705 of title 38, United States Code.

(c) LONG-TERM OBSERVATIONAL STUDY.—The Secretary may carry out a long-term observational study of the participants in the clinical trial required under subsection (a).

(d) TYPE OF CANNABIS.—In carrying out the clinical trial required by subsection (a), the Secretary shall study—

(1) varying forms of cannabis, including—

(A) full plants and extracts; and

(B) at least three different strains of cannabis with significant variants in phenotypic traits and various ratios of tetrahydrocannabinol and cannabidiol in chemical 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—

(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 subsection (a) in a manner that will facilitate further research.

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

(1) develop a plan to implement this section and submit such plan to the Committees on Veterans' Affairs of the House of Representatives and 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 House of Representatives and the Senate reports on the implementation of this section.

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