

115TH CONGRESS
2D SESSION

H. R. 5634

To increase the number of manufacturers registered under the Controlled Substances Act to manufacture cannabis for legitimate research purposes, to authorize health care providers of the Department of Veterans Affairs to provide recommendations to veterans regarding participation in federally-approved cannabis clinical trials, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 26, 2018

Mr. GAETZ (for himself, Mr. BISHOP of Utah, Mr. SWALWELL of California, Mr. RUTHERFORD, Mr. TAYLOR, Mr. GARRETT, Mr. RASKIN, Mr. BLUMENAUER, Mr. JOYCE of Ohio, Mr. BUCK, Mrs. HANDEL, Mr. CURBELO of Florida, Mr. SOTO, Mr. POLIS, Mr. DENHAM, Ms. ROS-LEHTINEN, Mr. SANFORD, Mr. CICILLINE, Ms. LEE, Mr. ISSA, Mr. ROHRABACHER, Mr. GOODLATTE, Mr. MCCLINTOCK, Mr. HASTINGS, Mr. COHEN, Ms. TITUS, Ms. LOFGREN, and Mr. CORREA) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, and Veterans' Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To increase the number of manufacturers registered under the Controlled Substances Act to manufacture cannabis for legitimate research purposes, to authorize health care providers of the Department of Veterans Affairs to provide recommendations to veterans regarding participation in federally-approved cannabis clinical trials, 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 “Medical Cannabis Re-
5 search Act of 2018”.

6 **SEC. 2. INCREASING THE NUMBER OF FEDERALLY-REG-**
7 **ISTERED MANUFACTURERS OF CANNABIS**
8 **FOR LEGITIMATE RESEARCH PURPOSES.**

9 (a) IN GENERAL.—Section 303 of the Controlled
10 Substances Act (21 U.S.C. 823) is amended—

11 (1) by redesignating subsection (k) as sub-
12 section (l); and

13 (2) by inserting after subsection (j) the fol-
14 lowing:

15 “(k) REGISTRATION OF MANUFACTURERS OF CAN-
16 NABIS FOR LEGITIMATE RESEARCH PURPOSES.—

17 “(1) IN GENERAL.—Any manufacturer of can-
18 nabis for research shall obtain a separate registra-
19 tion under this subsection for that purpose—

20 “(A) annually; or

21 “(B) for a longer period as determined
22 necessary by the Attorney General to supply
23 cannabis for the full duration of a particular
24 multi-year study for legitimate research pur-
25 poses.

1 “(2) ADEQUATE AND UNINTERRUPTED SUP-
2 PLY.—

3 “(A) ANNUAL ASSESSMENT.—On an an-
4 nual basis, the Attorney General shall assess
5 whether there is an adequate and uninterrupted
6 supply of cannabis for legitimate research pur-
7 poses.

8 “(B) INITIAL YEAR.—Not later than 1
9 year after the date of enactment of the Medical
10 Cannabis Research Act of 2018, of the appli-
11 cants meeting the requirements of this Act, the
12 Attorney General shall register under sub-
13 section (a) and this subsection at least 2 appli-
14 cants to manufacture cannabis for legitimate
15 research purposes in addition to any manufac-
16 turers that are registered under subsection (a)
17 to manufacture cannabis as of the date of en-
18 actment of the Medical Cannabis Research Act
19 of 2018.

20 “(C) SUBSEQUENT YEARS.—For calendar
21 year 2019 and each subsequent calendar year,
22 of the applicants meeting the requirements of
23 this Act, the Attorney General shall register
24 (including any registration renewal) under sub-
25 section (a) and this subsection at least 3 appli-

1 cants to manufacture cannabis for legitimate
2 research purposes.

3 “(3) REQUIREMENTS.—A manufacturer reg-
4 istered under this subsection shall—

5 “(A) comply with all applicable require-
6 ments of this Act;

7 “(B) limit the transfer and sale of any
8 cannabis manufactured pursuant to this sec-
9 tion—

10 “(i) to researchers who are registered
11 under this Act to conduct research with
12 controlled substances in schedule I; and

13 “(ii) for purposes of use in preclinical
14 research or in a clinical investigation pur-
15 suant to an investigational new drug ex-
16 emption under 505(i) of the Federal Food,
17 Drug, and Cosmetic Act;

18 “(C) transfer or sell any cannabis manu-
19 factured pursuant to this section only with
20 prior, written consent for the transfer or sale by
21 the Attorney General;

22 “(D) have completed the application and
23 review process under subsection (a) for the bulk
24 manufacture of controlled substances in sched-
25 ule I;

1 “(E) have established and begun operation
2 of a process for storage and handling of con-
3 trolled substances in schedule I, including for
4 inventory control and monitoring security;

5 “(F) have the ability to provide at least 10
6 unique plant cultivars to ensure plant diversity
7 and scale up to produce bulk plant material on
8 an uninterrupted basis sufficient to supply fore-
9 casted demand;

10 “(G) be licensed, by each State in which
11 the manufacturer conducts its operations pursu-
12 ant to this subsection, to manufacture cannabis;

13 “(H) have completed a criminal back-
14 ground check for all personnel involved in the
15 operations of the manufacturer pursuant to this
16 subsection to confirm that such personnel have
17 no conviction for a felony or drug-related mis-
18 demeanor;

19 “(I) have a letter of reference affirming
20 the manufacturer’s good standing from each of
21 the applicable State health care and law en-
22 forcement authorities in each jurisdiction of the
23 manufacturer’s operations pursuant to this sub-
24 section; and

1 “(J) have the ability to test for and isolate
2 at least 12 cannabinoids for the purposes of
3 producing specific products for specific studies
4 by compounding pharmacists or others, label-
5 ing, and chemical consistency.

6 “(4) APPLICATION CONTENTS.—As part of an
7 application to be registered under this subsection, an
8 applicant shall include a written explanation of how
9 the applicant’s proposed manufacture of cannabis
10 would augment the Nation’s supply of cannabis for
11 legitimate research purposes.

12 “(5) PROCESS.—Not later than 1 year after the
13 date on which the Attorney General receives an ap-
14 plication to be registered under this section to man-
15 ufacture cannabis for research, the Attorney General
16 shall—

17 “(A) grant, or initiate proceedings under
18 section 304(c) to deny, the application; or

19 “(B) request supplemental information
20 from the applicant.

21 “(6) RULE OF CONSTRUCTION ON REGISTRA-
22 TION FOR PURPOSES OTHER THAN RESEARCH.—
23 Nothing in this subsection shall be construed to af-
24 fect the provisions of this section prohibiting or oth-
25 erwise pertaining to registration of manufacturers of

1 cannabis for purposes other than research, including
2 for purposes of strictly commercial endeavors funded
3 by the private sector and aimed at drug product de-
4 velopment.

5 “(7) NO DISCRIMINATORY TREATMENT BY FED-
6 ERAL GOVERNMENT.—Notwithstanding any other
7 provision of law, no Federal department or agency
8 shall deny or limit any funding, other assistance, li-
9 censing, or other privilege with respect to any person
10 on the basis that such person is, or is legally receiv-
11 ing cannabis from, a manufacturer of cannabis that
12 is—

13 “(A) registered under this subsection; and

14 “(B) in compliance with the requirements
15 of this Act.

16 “(8) SPECIAL RULE.—If cannabis, or any com-
17 ponent thereof, is placed in a schedule other than
18 schedule I, the Attorney General may, as the Attor-
19 ney General determines appropriate—

20 “(A) treat the reference to ‘subsection (a)’
21 in paragraph (2)(C) of this subsection as a ref-
22 erence to subsection (d); and

23 “(B) treat the references to schedule I in
24 paragraph (3) as references to the appropriate
25 schedule.

1 “(9) DEFINITION.—In this subsection, the term
2 ‘legitimate research purposes’ has the meaning given
3 to such term for purposes of subsection (a)(1).”.

4 (b) TRANSITIONAL PROVISIONS.—

5 (1) CURRENT REGISTRANTS.—Notwithstanding
6 paragraph (1) of section 303(k) of the Controlled
7 Substances Act, as added by subsection (a), any
8 manufacturer that is registered under section 303(a)
9 of the Controlled Substances Act (21 U.S.C. 823(a))
10 to manufacture cannabis as of the date of enactment
11 of this Act shall not be required to obtain a separate
12 registration under such section 303(k) for the 1-year
13 period following the date of enactment of this Act.

14 (2) PENDING APPLICATIONS.—The Attorney
15 General of the United States shall grant or deny, in
16 accordance with section 303 of the Controlled Sub-
17 stances Act (21 U.S.C. 823), as amended by sub-
18 section (a), each application to manufacture can-
19 nabis to supply researchers in the United States that
20 was submitted—

21 (A) pursuant to the policy statement enti-
22 tled “Applications To Become Registered Under
23 the Controlled Substances Act To Manufacture
24 Marijuana To Supply Researcher in the United
25 States” published by the Drug Enforcement

1 Administration in the Federal Register on Au-
2 gust 12, 2016 (81 Fed. Reg. 53846); and

3 (B) before February 12, 2017.

4 (c) TECHNICAL AMENDMENT.—Section 102(16) of
5 the Controlled Substances Act (21 U.S.C. 802(16)) is
6 amended by inserting after “The term ‘marihuana’” the
7 following: “or ‘marijuana’ or ‘cannabis’”.

8 **SEC. 3. PROVISION BY DEPARTMENT OF VETERANS AF-**
9 **FAIRS HEALTH CARE PROVIDERS OF INFOR-**
10 **MATION REGARDING VETERAN PARTICIPA-**
11 **TION IN FEDERALLY-APPROVED CANNABIS**
12 **CLINICAL TRIALS.**

13 (a) PROVISION OF INFORMATION AND FORMS.—Not-
14 withstanding any other provision of law, health care pro-
15 viders of the Department of Veterans Affairs may—

16 (1) provide information to veterans regarding
17 participation in federally-approved cannabis clinical
18 trials; and

19 (2) complete forms relating to such participa-
20 tion.

21 (b) RECEIPT OF INFORMATION.—Health care pro-
22 viders and other employees of the Department may accept
23 information regarding federally-approved cannabis clinical
24 trials provided by individuals who are not employed by the
25 Department who are researchers registered under the

1 Controlled Substances Act (21 U.S.C. 801 et seq.) to con-
2 duct research with controlled substances in schedule I of
3 section 202(c) of such Act (21 U.S.C. 812(c)).

4 (c) RESEARCH.—The Secretary of Veterans Affairs
5 may conduct research on cannabis if the employees of the
6 Department who are conducting such research are re-
7 searchers registered under the Controlled Substances Act
8 (21 U.S.C. 801 et seq.) to conduct research with con-
9 trolled substances in schedule I of section 202(c) of such
10 Act (21 U.S.C. 812(c)).

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