

117TH CONGRESS
2^D SESSION

H. R. 9679

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

DECEMBER 22, 2022

Mr. GAETZ 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medical Cannabis Re-
3 search Act of 2022”.

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

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

9 (1) by redesignating subsections (k) and (l) as
10 subsections (l) and (m), respectively; and

11 (2) by inserting after subsection (j) the fol-
12 lowing:

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

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

18 “(A) annually; or

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

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

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

6 “(B) INITIAL YEAR.—Not later than 1
7 year after the date of enactment of the Medical
8 Cannabis Research Act of 2022, of the appli-
9 cants meeting the requirements of this Act, the
10 Attorney General shall register under sub-
11 section (a) and this subsection at least 3 appli-
12 cants to manufacture cannabis for legitimate
13 research purposes in addition to any manufac-
14 turers that are registered under subsection (a)
15 to manufacture cannabis as of the date of en-
16 actment of the Medical Cannabis Research Act
17 of 2022.

18 “(C) SUBSEQUENT YEARS.—For calendar
19 year 2023 and each subsequent calendar year,
20 of the applicants meeting the requirements of
21 this Act, the Attorney General shall register
22 (including any registration renewal) under sub-
23 section (a) and this subsection at least 4 appli-
24 cants to manufacture cannabis for legitimate
25 research purposes.

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

3 “(A) comply with all applicable require-
4 ments of this Act;

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

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

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

16 “(C) have completed the application and
17 review process under subsection (a) for the bulk
18 manufacture of controlled substances in sched-
19 ule I;

20 “(D) have established and begun operation
21 of a process for storage and handling of con-
22 trolled substances in schedule I, including for
23 inventory control and monitoring security;

24 “(E) have the ability to provide at least 10
25 unique plant cultivars to ensure plant diversity

1 and scale up to produce bulk plant material on
2 an uninterrupted basis sufficient to supply fore-
3 casted demand;

4 “(F) be licensed, by each State in which
5 the manufacturer conducts its operations pursu-
6 ant to this subsection, to manufacture cannabis;

7 “(G) have completed a criminal back-
8 ground check for all personnel involved in the
9 operations of the manufacturer pursuant to this
10 subsection to confirm that such personnel have
11 no conviction for a violent felony; and

12 “(H) have the ability to test for and isolate
13 at least 12 cannabinoids for the purposes of
14 producing specific products for specific studies
15 by compounding pharmacists or others, label-
16 ing, and chemical consistency.

17 “(4) APPLICATION CONTENTS.—As part of an
18 application to be registered under this subsection, an
19 applicant shall include a written explanation of how
20 the applicant’s proposed manufacture of cannabis
21 would augment the Nation’s supply of cannabis for
22 legitimate research purposes.

23 “(5) PROCESS.—Not later than 1 year after the
24 date on which the Attorney General receives an ap-
25 plication to be registered under this section to man-

1 manufacture cannabis for research, the Attorney General
2 shall—

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

5 “(B) request supplemental information
6 from the applicant.

7 “(6) RULE OF CONSTRUCTION ON REGISTRA-
8 TION FOR PURPOSES OTHER THAN RESEARCH.—
9 Nothing in this subsection shall be construed to af-
10 fect the provisions of this section prohibiting or oth-
11 erwise pertaining to registration of manufacturers of
12 cannabis for purposes other than research, including
13 for purposes of strictly commercial endeavors funded
14 by the private sector and aimed at drug product de-
15 velopment.

16 “(7) NO DISCRIMINATORY TREATMENT BY FED-
17 ERAL GOVERNMENT.—Notwithstanding any other
18 provision of law, no Federal department or agency
19 shall deny or limit any funding, other assistance, li-
20 censing, or other privilege with respect to any person
21 on the basis that such person is, or is legally receiv-
22 ing cannabis from, a manufacturer of cannabis that
23 is—

24 “(A) registered under this subsection; and

1 “(B) in compliance with the requirements
2 of this Act.

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

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

10 “(B) treat the references to schedule I in
11 paragraph (3) as references to the appropriate
12 schedule.

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

16 (b) TRANSITIONAL PROVISIONS.—

17 (1) CURRENT REGISTRANTS.—Notwithstanding
18 paragraph (1) of section 303(k) of the Controlled
19 Substances Act, as added by subsection (a), any
20 manufacturer that is registered under section 303(a)
21 of the Controlled Substances Act (21 U.S.C. 823(a))
22 to manufacture cannabis as of the date of enactment
23 of this Act shall not be required to obtain a separate
24 registration under such section 303(k) for the 1-year
25 period following the date of enactment of this Act.

1 (2) PENDING APPLICATIONS.—Except as pro-
2 vided in paragraph (1), the Attorney General of the
3 United States shall grant or deny, in accordance
4 with section 303 of the Controlled Substances Act
5 (21 U.S.C. 823), as amended by subsection (a), each
6 application to manufacture cannabis to supply re-
7 searchers in the United States that was submitted—

8 (A) pursuant to the policy statement enti-
9 tled “Applications To Become Registered Under
10 the Controlled Substances Act To Manufacture
11 Marijuana To Supply Researchers in the United
12 States” published by the Drug Enforcement
13 Administration in the Federal Register on Au-
14 gust 12, 2016 (81 Fed. Reg. 53846); and

15 (B) before the date of enactment of this
16 Act.

17 (c) TECHNICAL AMENDMENT.—Section 102(16) of
18 the Controlled Substances Act (21 U.S.C. 802(16)) is
19 amended by striking “and ‘marijuana’” and inserting
20 “‘marijuana’, and ‘cannabis’”.

1 **SEC. 3. PROVISION BY DEPARTMENT OF VETERANS AF-**
2 **FAIRS HEALTH CARE PROVIDERS OF INFOR-**
3 **MATION REGARDING VETERAN PARTICIPA-**
4 **TION IN FEDERALLY APPROVED CANNABIS**
5 **CLINICAL TRIALS.**

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

9 (1) provide information to veterans regarding
10 participation in federally approved cannabis clinical
11 trials; and

12 (2) complete forms relating to such participa-
13 tion.

14 (b) **RECEIPT OF INFORMATION.**—Health care pro-
15 viders and other employees of the Department may accept
16 information regarding federally approved cannabis clinical
17 trials provided by individuals who are not employed by the
18 Department who are researchers registered under the
19 Controlled Substances Act (21 U.S.C. 801 et seq.) to con-
20 duct research with controlled substances in schedule I of
21 section 202(c) of such Act (21 U.S.C. 812(c)).

22 (c) **RESEARCH.**—The Secretary of Veterans Affairs
23 may conduct research on cannabis if the employees of the
24 Department who are conducting such research are re-
25 searchers registered under the Controlled Substances Act
26 (21 U.S.C. 801 et seq.) to conduct research with con-

1 trolled substances in schedule I of section 202(e) of such
2 Act (21 U.S.C. 812(e)).

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