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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Cannabis Research Act of 2018''.

SEC. 2. INCREASING THE NUMBER OF FEDERALLY-REGISTERED MANUFACTURERS OF CANNABIS FOR LEGITIMATE RESEARCH PURPOSES.

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

(1) by redesignating subsection (k) as subsection (l); and

(2) by inserting after subsection (j) the following:

''(k) REGISTRATION OF MANUFACTURERS OF CANNABIS FOR LEGITIMATE RESEARCH PURPOSES.—

''(1) IN GENERAL.—Any manufacturer of cannabis for research shall obtain a separate registration under this subsection for that purpose—

''(A) annually; or

''(B) for a longer period as determined necessary by the Attorney General to supply cannabis for the full duration of a particular multi-year study for legitimate research purposes.

''(2) ADEQUATE AND UNINTERRUPTED SUPPLY.—

''(A) ANNUAL ASSESSMENT.—On an annual basis, the Attorney General shall assess whether there is an adequate and uninterrupted supply of cannabis for legitimate research purposes.

''(B) INITIAL YEAR.—Not later than 1 year after the date of enactment of the Medical Cannabis Research Act of 2018, of the applicants meeting the requirements of this Act, the Attorney General shall register under subsection (a) and this subsection at least 2 applicants to manufacture cannabis for legitimate research purposes in addition to any manufacturers that are registered under subsection (a) to manufacture cannabis as of the date of enactment of the Medical Cannabis Research Act of 2018.

''(C) SUBSEQUENT YEARS.—For calendar year 2019 and each subsequent calendar year, of the applicants meeting the requirements of this Act, the Attorney General shall register (including any registration renewal) under subsection (a) and this subsection at least 3 appli-

cants to manufacture cannabis for legitimate research purposes.

''(3) REQUIREMENTS.—A manufacturer registered under this subsection shall—

''(A) comply with all applicable requirements of this Act;

''(B) limit the transfer and sale of any cannabis manufactured pursuant to this section—

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

''(ii) for purposes of use in preclinical research or in a clinical investigation pursuant to an investigational new drug exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act;

''(C) transfer or sell any cannabis manufactured pursuant to this section only with prior, written consent for the transfer or sale by the Attorney General;

''(D) have completed the application and review process under subsection (a) for the bulk manufacture of controlled substances in schedule I;

''(E) have established and begun operation of a process for storage and handling of controlled substances in schedule I, including for inventory control and monitoring security;

''(F) have the ability to provide at least 10 unique plant cultivars to ensure plant diversity and scale up to produce bulk plant material on an uninterrupted basis sufficient to supply forecasted demand;

''(G) be licensed, by each State in which the manufacturer conducts its operations pursuant to this subsection, to manufacture cannabis;

''(H) have completed a criminal background check for all personnel involved in the operations of the manufacturer pursuant to this subsection to confirm that such personnel have no conviction for a felony or drug-related misdemeanor;

''(I) have a letter of reference affirming the manufacturer's good standing from each of the applicable State health care and law enforcement authorities in each jurisdiction of the manufacturer's operations pursuant to this subsection; and

"(J) have the ability to test for and isolate at least 12 cannabinoids for the purposes of producing specific products for specific studies by compounding pharmacists or others, labeling, and chemical consistency.

"(4) APPLICATION CONTENTS.—As part of an application to be registered under this subsection, an applicant shall include a written explanation of how the applicant's proposed manufacture of cannabis would augment the Nation's supply of cannabis for legitimate research purposes.

"(5) PROCESS.—Not later than 1 year after the date on which the Attorney General receives an application to be registered under this section to manufacture cannabis for research, the Attorney General shall—

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

"(B) request supplemental information from the applicant.

"(6) RULE OF CONSTRUCTION ON REGISTRATION FOR PURPOSES OTHER THAN RESEARCH.—Nothing in this subsection shall be construed to affect the provisions of this section prohibiting or otherwise pertaining to registration of manufacturers of

cannabis for purposes other than research, including for purposes of strictly commercial endeavors funded by the private sector and aimed at drug product development.

''(7) NO DISCRIMINATORY TREATMENT BY FEDERAL GOVERNMENT.—Notwithstanding any other provision of law, no Federal department or agency shall deny or limit any funding, other assistance, licensing, or other privilege with respect to any person on the basis that such person is, or is legally receiving cannabis from, a manufacturer of cannabis that is—

''(A) registered under this subsection; and

''(B) in compliance with the requirements of this Act.

''(8) SPECIAL RULE.—If cannabis, or any component thereof, is placed in a schedule other than schedule I, the Attorney General may, as the Attorney General determines appropriate—

''(A) treat the reference to 'subsection (a)' in paragraph (2)(C) of this subsection as a reference to subsection (d); and

''(B) treat the references to schedule I in paragraph (3) as references to the appropriate schedule.

''(9) DEFINITION.—In this subsection, the term 'legitimate research purposes' has the meaning given to such term for purposes of subsection (a)(1).''.

(b) TRANSITIONAL PROVISIONS.—

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

(2) PENDING APPLICATIONS.—The Attorney General of the United States shall grant or deny, in accordance with section 303 of the Controlled Substances Act (21 U.S.C. 823), as amended by subsection (a), each application to manufacture cannabis to supply researchers in the United States that was submitted—

(A) pursuant to the policy statement entitled ''Applications To Become Registered Under the Controlled Substances Act To Manufacture Marijuana To Supply Researcher in the United States'' published by the Drug Enforcement

Administration in the Federal Register on August 12, 2016 (81 Fed. Reg. 53846); and

(B) before February 12, 2017.

(c) TECHNICAL AMENDMENT.—Section 102(16) of the Controlled Substances Act (21 U.S.C. 802(16)) is amended by inserting after ''The term 'marihuana' '' the following: ''or 'marijuana' or 'cannabis' ''.

SEC. 3. PROVISION BY DEPARTMENT OF VETERANS AFFAIRS HEALTH CARE PROVIDERS OF INFORMATION REGARDING VETERAN PARTICIPATION IN FEDERALLY-APPROVED CANNABIS CLINICAL TRIALS.

(a) PROVISION OF INFORMATION AND FORMS.—Notwithstanding any other provision of law, health care providers of the Department of Veterans Affairs may—

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

(2) complete forms relating to such participation.

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

Controlled Substances Act (21 U.S.C. 801 et seq.) to conduct research with controlled substances in schedule I of section 202(c) of such Act (21 U.S.C. 812(c)).

(c) RESEARCH.—The Secretary of Veterans Affairs may conduct research on cannabis if the employees of the Department who are conducting such research are researchers registered under the Controlled Substances Act (21 U.S.C. 801 et seq.) to conduct research with controlled substances in schedule I of section 202(c) of such Act (21 U.S.C. 812(c)).

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