[115H3391]

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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

# H. R. _____

To amend the Controlled Substances Act to make marijuana accessible for use by qualified marijuana researchers for medical purposes, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Mr. BLUMENAUER introduced the following bill; which was referred to the Committee on _____

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# A BILL

To amend the Controlled Substances Act to make marijuana accessible for use by qualified marijuana researchers for medical purposes, 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 Marijuana Research Act of 2019''.

**SEC. 2. PRODUCTION AND SUPPLY.**

(a) IN GENERAL.—The Secretary of Health and Human Services—

(1) until the date on which the Secretary determines that manufacturers and distributors (other than the Federal Government) can ensure a sufficient supply of marijuana for qualified marijuana researchers intended for medical research, shall—

(A) continue to produce marijuana through the National Institute on Drug Abuse (NIDA) Drug Supply Program; and

(B) offer for sale immature marijuana plants and the seeds of marijuana—

(i) to all qualified marijuana researchers who submit a request for such plants or seeds to engage in research pursuant to the section 303(f)(3) of the Controlled Substances Act, as amended by section 3; and

(ii) in quantities sufficient to produce an adequate supply of marijuana for such research; and

(2) beyond the date specified in paragraph (1), may, at the Secretary's discretion, continue to so produce and supply marijuana.

(b) REQUIREMENT TO VERIFY REGISTRATION.—Before supplying marijuana to any person through the Na-

tional Institute on Drug Abuse Drug Supply Program, the Secretary of Health and Human Services shall—

(1) require the person to submit documentation demonstrating that the person is a qualified marijuana researcher seeking to conduct research pursuant to section 303(f)(3) of the Controlled Substances Act, as amended by section 3; and

(2) not later than 30 days after receipt of such documentation, review such documentation and verify that the marijuana will be used for such research (and for no other purpose authorized pursuant to this Act).

(c) GUIDELINES ON PRODUCTION.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institute on Drug Abuse, shall—

(1) not later than 180 days after the date of enactment of this Act, issue guidelines on the production of marijuana by qualified marijuana researchers pursuant to subsection (a)(1)(B); and

(2) encourage researchers and manufacturers that are authorized to produce or manufacture marijuana pursuant to section 303 of the Controlled Substances Act (21 U.S.C. 823), as amended by this Act, to comply with such guidelines to the extent applicable.

(d) DEFINITION.—In this section:

(1) The term ''immature marijuana plant'' means a marijuana plant with no observable flowers or buds.

(2) The term ''qualified medical marijuana researcher'' means a researcher who is registered to conduct research with marijuana under section 303(f)(3) of the Controlled Substances Act, as amended by section 3.

**SEC. 3. FACILITATING MARIJUANA RESEARCH.**

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

(1) by redesignating paragraphs (1) through (5) as subparagraphs (A) through (E), respectively;

(2) by striking ''(f) The Attorney General'' and inserting ''(f)(1) The Attorney General'';

(3) by striking ''Registration applications'' and inserting the following:

''(2) Registration applications'';

(4) in paragraph (2), as so designated, by striking ''schedule I'' each place that term appears and inserting ''schedule I, except marijuana,'';

(5) by striking ''Article 7'' and inserting the following:

''(4) Article 7''; and

(6) by inserting before paragraph (4), as so designated, the following:

''(3)(A) The Attorney General shall register a practitioner to conduct research with marijuana if—

''(i) the applicant is authorized to dispense, or conduct research with respect to, controlled substances in schedules II, III, IV, and V under the laws of the State in which the applicant practices;

''(ii) the applicant is only using marijuana manufactured by a person registered under subsection (l);

''(iii) the applicant's research protocol—

''(I) has been reviewed and allowed by—

''(aa) the Secretary under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)); or

''(bb) the National Institutes of Health or another Federal agency that funds scientific research; or

''(II) in the case of nonhuman research that is not federally funded, has been voluntarily submitted by the applicant to, and approved by, the National Institutes of Health; and

''(iv) the applicant has demonstrated that there are effective procedures in place to adequately safeguard against diversion of the marijuana from legitimate medical or scientific use, in accordance with subparagraph (E).

''(B) The Attorney General shall grant an application for registration under this paragraph unless the Attorney General determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

''(i) The applicant's experience in dispensing, or conducting research with respect to, controlled substances.

''(ii) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

''(iii) Compliance with applicable State or local laws relating to controlled substance misuse or diversion.

''(C) Not later than 90 days after the date of enactment of the Medical Marijuana Research Act of 2019, for purposes of subparagraph (A)(ii)(II), the National Institutes of Health shall establish a process that—

''(i) allows a researcher to voluntarily submit the research protocol of the researcher for review and approval; and

''(ii) provides a researcher described in clause (i) with a decision not less than 30 days after the date on which the research protocol is submitted.

''(D)(i) Not later than 60 days after the date on which the Attorney General receives a complete application for registration under this paragraph, the Attorney General shall approve or deny the application.

''(ii) For purposes of clause (i), an application shall be deemed complete when the applicant has submitted documentation showing that the requirements under subparagraph (A) are satisfied.

''(iii) In the case of a denial under clause (i), the Attorney General shall provide a written explanation of the basis for the denial and a description of any curative steps that may be taken for such request to be approved.

''(E)(i) A researcher registered under this paragraph shall store marijuana to be used in research in a securely locked, substantially constructed cabinet.

''(ii) Except as provided in clause (i), any security measures required by the Attorney General for practitioners conducting research with marijuana pursuant to a registration under this paragraph shall be consistent

with the security measures for practitioners conducting research on other controlled substances in schedule II that have a similar risk of diversion and abuse.

''(F)(i) If the Attorney General grants an application for registration under this paragraph, the applicant may amend or supplement the research protocol without reapplying if the applicant does not—

''(I) change the type of drug, the source of the drug, or the conditions under which the drug is stored, tracked, or administered; or

''(II) otherwise increase the risk of diversion.

''(ii) If an applicant amends or supplements the research protocol or initiates research on a new research protocol under clause (i), the applicant shall, in order to renew the registration under this paragraph, provide notice to the Attorney General of the amended or supplemented research protocol or any new research protocol in the applicant's renewal materials.

''(iii)(I) If an applicant amends or supplements a research protocol and the amendment or supplement involves a change to the type of drug, the source of the drug, or conditions under which the drug is stored, tracked, or administered or otherwise increases the risk of diversion, the applicant shall provide notice to the Attorney General not later than 30 days before proceeding on such amended

or supplemental research or new research protocol, as the case may be.

''(II) If the Attorney General does not object during the 30-day period following a notification under subclause (I), the applicant may proceed with the amended or supplemental research or new research protocol.

''(iv) The Attorney General may object to an amended or supplemental protocol or a new research protocol under clause (i) or (iii) only if additional security measures are needed to safeguard against diversion or abuse.

''(G) If marijuana or a compound of marijuana is listed on a schedule other than schedule I, the provisions of paragraphs (1), (2), and (4) that apply to research with a controlled substance in the applicable schedule shall apply to research with marijuana or that compound, as applicable, in lieu of the provisions of subparagraphs (A) through (G) of this paragraph.''.

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

**SEC. 4. MANUFACTURE AND DISTRIBUTION OF MARIJUANA FOR USE IN LEGITIMATE, MEDICAL RESEARCH.**

Section 303 of the Controlled Substances Act (21 U.S.C. 823), as amended by section 3, is further amended by adding at the end the following:

''(l) REGISTRATION OF PERSONS TO MANUFACTURE AND DISTRIBUTE MARIJUANA FOR USE IN LEGITIMATE, MEDICAL RESEARCH.—

''(1) REGISTRATION OF MANUFACTURERS.—Beginning not later than the day that is 1 year after the date of enactment of the Medical Marijuana Research Act of 2019, the Attorney General shall register an applicant to manufacture marijuana to the extent the marijuana will be used exclusively by qualified marijuana researchers for research pursuant to subsection (f)(3), unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the Attorney General shall—

''(A) take into consideration—

''(i) maintenance of effective controls against diversion of marijuana and any controlled substance compounded therefrom into other than legitimate medical, scientific, or research channels;

''(ii) compliance with applicable State and local laws relating to controlled substance misuse and diversion; and

''(iii) prior conviction record of the applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances; and

''(B) not take into consideration any factors other than the factors listed in subparagraph (A).

''(2) REGISTRATION OF DISTRIBUTORS.—Beginning not later than the day that is 1 year after the date of enactment of the Medical Marijuana Research Act of 2019, the Attorney General shall register an applicant to distribute marijuana that is intended to be used exclusively by qualified medical marijuana researchers for research pursuant to subsection (f)(3), unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest.

''(3) PUBLIC INTEREST.—In determining the public interest under paragraph (2), the Attorney General shall—

''(A) take into consideration—

''(i) maintenance of effective controls against diversion of marijuana and any controlled substance compounded therefrom into other than legitimate medical, scientific, or research channels;

''(ii) compliance with applicable State and local law;

''(iii) prior conviction record of the applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances; and

''(iv) past experience in the distribution of controlled substances, and the existence in the establishment of effective controls against diversion; and

''(B) not take into consideration any factors other than the factors listed in subparagraph (A).

''(4) NO LIMIT ON NUMBER OF MANUFACTURERS AND DISTRIBUTORS.—Notwithstanding any other provision of law, the Attorney General shall not impose or implement any limit on the number of persons eligible to be registered to manufacture or distribute marijuana pursuant to paragraph (1) or (2).

''(5) REQUIREMENT TO VERIFY USE FOR LEGITIMATE, MEDICAL RESEARCH.—As a condition on registration under this section to manufacture or distribute marijuana, the Attorney General shall require the registrant—

''(A) to require any person to whom the marijuana will be supplied to submit documentation demonstrating that the marijuana will be used exclusively by qualified medical marijuana researchers for research pursuant to subsection (f)(3);

''(B) in the case of distribution, to complete, with respect to that distribution, the DEA Controlled substance order form (DEA 222) (or a successor form) and the DEA Certificate of Registration (DEA Form 223) (or a successor form) and to upload such forms to the system used by the Drug Enforcement Agency for such distribution;

''(C) to include in the labeling of any marijuana so manufactured or distributed—

''(i) the following statement: 'This material is for medical and scientific research purposes only.'; and

"(ii) the name of the requestor of the marijuana; and

"(D) not later than 30 days after receipt of such documentation, and before supplying the marijuana to such person, to review such documentation and verify that the marijuana will be so used.

"(6) TIMING.—Not later than 30 days after receipt of a request for registration under this subsection to manufacture or distribute marijuana, the Attorney General shall—

"(A) grant or deny the request; and

"(B) in the case of a denial, provide a written explanation of the basis for the denial and a description of any curative steps that may be taken for such request to be approved.

"(7) DEEMED APPROVAL.—If the Attorney General fails to grant or deny a request for registration under this subsection to manufacture or distribute marijuana within the 30-day period referred to in paragraph (5), such request is deemed approved.

"(8) DEFINITION.—For purposes of this subsection, the term 'qualified medical marijuana researcher' means a researcher who is registered to

conduct research with marijuana under subsection (f)(3).''.

**SEC. 5. TERMINATION OF INTERDISCIPLINARY REVIEW PROCESS FOR NON-NIH-FUNDED RESEARCHERS.**

The Secretary of Health and Human Services may not—

(1) reinstate the Public Health Service interdisciplinary review process described in the guidance entitled ''Guidance on Procedures for the Provision of Marijuana for Medical Research'' (issued on May 21, 1999); or

(2) create an additional review of scientific protocols that is only conducted for research on marijuana other than the review of research protocols performed at the request of a researcher conducting nonhuman research that is not federally funded, in accordance with section 303(f)(3)(A)(ii)(II) of the Controlled Substances Act (21 U.S.C. 823(f)(3)(A)(ii)(II)), as amended by section 3.

**SEC. 6. CONSIDERATION OF RESULTS OF RESEARCH.**

Immediately upon the approval by the Food and Drug Administration of an application for a marijuana-based drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and (irrespective of

whether any such approval is granted) not later than the date that is 5 years after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) conduct a review of existing medical and other research with respect to marijuana;

(2) submit a report to the Congress on the results of such review; and

(3) include in such report whether, taking into consideration the factors listed in section 201(c) of the Controlled Substances Act (21 U.S.C. 811(c)), as well as any potential for medical benefits, any gaps in research, and any impacts of Federal restrictions and policy on research, marijuana should be transferred to a schedule other than schedule I (if marijuana has not been so transferred already).

**SEC. 7. NO PRODUCTION QUOTAS FOR MARIJUANA GROWN FOR LEGITIMATE, SCIENTIFIC RESEARCH.**

Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended by adding at the end the following:

''(j) The Attorney General may only establish a quota for production of marijuana that is manufactured and distributed in accordance with the Medical Marijuana Research Act of 2016 that meets the changing medical, sci-

entific, and industrial needs for marijuana (as defined by the National Institute on Drug Abuse).''.

**SEC. 8. ARTICLE 28 OF THE SINGLE CONVENTION ON NARCOTIC DRUGS.**

Article 28 of the Single Convention on Narcotic Drugs shall not be construed to prohibit, or impose additional restrictions upon, research involving marijuana, or the manufacture, distribution, or dispensing of marijuana, that is conducted in accordance with the Controlled Substances Act (21 U.S.C. 801 et seq.), this Act, and the amendments made by this Act.

**SEC. 9. NO INTERFERENCE BY DEPARTMENT OF JUSTICE.**

The Attorney General of the United States, and any officer or employee of the Department of Justice, shall not interfere with the production, distribution, and sale of marijuana in accordance with this Act and the amendments made by this Act.

**SEC. 10. DEFINITION.**

In this Act, the term ''marijuana'' has the meaning given to the term ''marihuana'' in section 102 of the Controlled Substances Act (21 U.S.C. 802).