II

114TH CONGRESS
2D SESSION

S. 3077

To improve medical research on marijuana.

IN THE SENATE OF THE UNITED STATES

JUNE 20, 2016

Mr. SCHATZ (for himself, Mr. HATCH, Mr. TILLIS, and Mr. COONS) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

To improve medical research on marijuana.

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 ''Marijuana Effective Drug Studies Act of 2016'' or the ''MEDS Act''.

SEC. 2. 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'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

''(iii) 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, Federal, or local laws relating to controlled substances.

''(iv) Such other conduct by the applicant that may threaten the public health and safety.

''(C) Not later than 90 days after the date of enactment of this paragraph, 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 later 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—

''(I) approve the application; or

''(II) serve an order to show cause upon the applicant in accordance with section 304(c).

''(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.

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

''(ii) Any other security measures required by the Attorney General under this paragraph to safeguard against diversion shall be consistent with those required for practitioners conducting research on other controlled substances in schedules I and 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 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 in the applicant's renewal materials.

''(iii)(I) If an applicant amends or supplements the research protocol in a manner that 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 protocol.

''(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 protocol.

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

''(G) Article 28 of the Single Convention on Narcotic Drugs shall not be construed to prohibit, or impose additional restrictions upon, research involving marijuana that is conducted in accordance with this paragraph and other applicable provisions of this title.

''(H) If marijuana or a compound of marijuana is listed on a schedule other than schedule I—

''(i) the provisions of this subsection that apply to research with a controlled substance in the applicable schedule shall apply to research with marijuana or that compound, as applicable; and

''(ii) subparagraphs (A) through (G) of this paragraph shall not apply to research with marijuana or that compound, as applicable.''.

(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. 3. MANUFACTURING OF MARIJUANA FOR CLINICAL USE.

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

''(j) REGISTRATION OF PERSONS TO MANUFACTURE AND DISTRIBUTE MARIJUANA.—

''(1) MANUFACTURE AND DISTRIBUTION FOR USE IN RESEARCH.—The Attorney General shall register an applicant to manufacture or distribute marijuana on behalf of the Federal Government to the extent that the marijuana is intended to be used exclusively for legitimate research and scientific uses, in accordance with the applicable requirements under subsection (a) or (b) of this section for registration of manufacturers or distributors of controlled substances in schedule I or II.

''(2) MANUFACTURE AND DISTRIBUTION FOR COMMERCIAL PRODUCTION OF FDA-APPROVED DRUGS.—The Attorney General shall register an applicant to manufacture or distribute marijuana on behalf of the Federal Government exclusively for the purpose of commercial production of a drug containing or derived from marijuana that is approved by the Secretary under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), in accordance with the applicable requirements under subsection (a) or (b) of this section for registration of manufacturers or distributors of controlled substances in schedule I or II.

''(3) NO LIMIT ON NUMBER OF MANUFACTURERS AND DISTRIBUTORS.—The Attorney General shall not impose a limit on the number of applicants eligible to be registered under paragraph (1) or (2).

''(4) TIMING.—Not later than 30 days after the date on which the Attorney General receives an application for registration under paragraph (1) or (2), the Attorney General shall—

''(A) grant the application; or

''(B) serve an order to show cause upon the applicant in accordance with section 304(c).

''(5) DETERMINATION OF SUPPLY.—In considering the factors under subsection (a) or (b), as applicable, for the purposes of registering an applicant eligible under paragraph (1) or (2) of this subsection, the Attorney General shall consider the demand from researchers for an adequate and uninterrupted supply of specific strains of marijuana and for marijuana grown pursuant to specific manufacturing processes.

''(6) RELATION TO THE SINGLE CONVENTION ON NARCOTIC DRUGS.—

''(A) CONSTRUCTIVE POSSESSION AND CONTROL.—The registration of manufacturers and distributors of marijuana under paragraphs (1) and (2) shall constitute constructive possession and control by the Federal Government for the purposes of the obligations under the Single Convention on Narcotic Drugs.

''(B) ARTICLE 28.—Article 28 of the Single Convention on Narcotic Drugs shall not be construed to prohibit, or impose additional restrictions upon, the manufacturing of marijuana that is conducted in accordance with paragraph (1) or (2), as applicable, and other applicable provisions of this title.''.

SEC. 4. GOOD MANUFACTURING PRACTICES.

Not later than 180 days after the date of enactment of this Act, the National Institute for Drug Abuse shall develop and publish recommendations for good manufacturing practices for growing and producing marijuana (as defined in section 102 of the Controlled Substance Act (21 U.S.C. 802), as amended by this Act) for research.

SEC. 5. QUOTAS.

Section 306(e) of the Controlled Substances Act (21 U.S.C. 826(e)) is amended in the third sentence by striking ''exceeds the aggregate of the quotas of all registrants under this section'' and inserting ''should be increased to meet the changing medical, scientific, and industrial needs for the controlled substance''.

SEC. 6. 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 conducted only for research on mari-

juana (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802), as amended by section 2(b)) 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 2(a).

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