

114TH CONGRESS  
2D SESSION

# S. 3077

To improve medical research on marijuana.

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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.

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 “Marijuana Effective  
5 Drug Studies Act of 2016” or the “MEDS Act”.

6 **SEC. 2. MARIJUANA RESEARCH.**

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

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

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

3           (3) by striking “Registration applications” and  
4           inserting the following:

5           “(2) Registration applications”;

6           (4) in paragraph (2), as so designated, by strik-  
7           ing “schedule I” each place that term appears and  
8           inserting “schedule I, except marijuana,”;

9           (5) by striking “Article 7” and inserting the  
10          following:

11          “(4) Article 7”; and

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

14          “(3)(A) The Attorney General shall register a practi-  
15          tioner to conduct research with marijuana if—

16                  “(i) the applicant is authorized to dispense, or  
17                  conduct research with respect to, controlled sub-  
18                  stances in schedules II, III, IV, and V under the  
19                  laws of the State in which the applicant practices;

20                  “(ii) the applicant’s research protocol—

21                          “(I) has been reviewed and allowed by—

22                                  “(aa) the Secretary under section  
23                                  505(i) of the Federal Food, Drug, and  
24                                  Cosmetic Act (21 U.S.C. 355(i)); or

1                   “(bb) the National Institutes of  
2                   Health or another Federal agency that  
3                   funds scientific research; or

4                   “(II) in the case of nonhuman research  
5                   that is not federally funded, has been volun-  
6                   tarily submitted by the applicant to, and ap-  
7                   proved by, the National Institutes of Health;  
8                   and

9                   “(iii) the applicant has demonstrated that there  
10                  are effective procedures in place to adequately safe-  
11                  guard against diversion of the marijuana from legiti-  
12                  mate medical or scientific use, in accordance with  
13                  subparagraph (E).

14                 “(B) The Attorney General shall grant an application  
15                 for registration under this paragraph unless the Attorney  
16                 General determines that the issuance of the registration  
17                 would be inconsistent with the public interest. In deter-  
18                 mining the public interest, the following factors shall be  
19                 considered:

20                 “(i) The applicant’s experience in dispensing, or  
21                 conducting research with respect to, controlled sub-  
22                 stances.

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

1           “(iii) Compliance with applicable State, Fed-  
2           eral, or local laws relating to controlled substances.

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

5           “(C) Not later than 90 days after the date of enact-  
6           ment of this paragraph, for purposes of subparagraph  
7           (A)(ii)(II), the National Institutes of Health shall estab-  
8           lish a process that—

9           “(i) allows a researcher to voluntarily submit  
10          the research protocol of the researcher for review  
11          and approval; and

12          “(ii) provides a researcher described in clause  
13          (i) with a decision not later than 30 days after the  
14          date on which the research protocol is submitted.

15          “(D)(i) Not later than 60 days after the date on  
16          which the Attorney General receives a complete applica-  
17          tion for registration under this paragraph, the Attorney  
18          General shall—

19                 “(I) approve the application; or

20                 “(II) serve an order to show cause upon the ap-  
21          plicant in accordance with section 304(c).

22          “(ii) For purposes of clause (i), an application shall  
23          be deemed complete when the applicant has submitted  
24          documentation showing that the requirements under sub-  
25          paragraph (A) are satisfied.

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

4       “(ii) Any other security measures required by the At-  
5 torney General under this paragraph to safeguard against  
6 diversion shall be consistent with those required for practi-  
7 tioners conducting research on other controlled substances  
8 in schedules I and II that have a similar risk of diversion  
9 and abuse.

10       “(F)(i) If the Attorney General grants an application  
11 for registration under this paragraph, the applicant may  
12 amend or supplement the research protocol without re-  
13 applying if the applicant does not—

14               “(I) change the type of drug, the source of the  
15 drug, or the conditions under which the drug is  
16 stored, tracked, or administered; or

17               “(II) otherwise increase the risk of diversion.

18       “(ii) If an applicant amends or supplements the re-  
19 search protocol under clause (i), the applicant shall, in  
20 order to renew the registration under this paragraph, pro-  
21 vide notice to the Attorney General of the amended or sup-  
22 plemented research protocol in the applicant’s renewal ma-  
23 terials.

24       “(iii)(I) If an applicant amends or supplements the  
25 research protocol in a manner that involves a change to

1 the type of drug, the source of the drug, or conditions  
2 under which the drug is stored, tracked, or administered  
3 or otherwise increases the risk of diversion, the applicant  
4 shall provide notice to the Attorney General not later than  
5 30 days before proceeding on such amended or supple-  
6 mental research protocol.

7 “(II) If the Attorney General does not object during  
8 the 30-day period following a notification under subclause  
9 (I), the applicant may proceed with the amended or sup-  
10 plemental research protocol.

11 “(iv) The Attorney General may object to an amend-  
12 ed or supplemental research protocol under clause (i) or  
13 (iii) if additional security measures are needed to safe-  
14 guard against diversion or abuse.

15 “(G) Article 28 of the Single Convention on Narcotic  
16 Drugs shall not be construed to prohibit, or impose addi-  
17 tional restrictions upon, research involving marijuana that  
18 is conducted in accordance with this paragraph and other  
19 applicable provisions of this title.

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

22 “(i) the provisions of this subsection that apply  
23 to research with a controlled substance in the appli-  
24 cable schedule shall apply to research with mari-  
25 juana or that compound, as applicable; and



1           “(2) MANUFACTURE AND DISTRIBUTION FOR  
2           COMMERCIAL PRODUCTION OF FDA-APPROVED  
3           DRUGS.—The Attorney General shall register an ap-  
4           plicant to manufacture or distribute marijuana on  
5           behalf of the Federal Government exclusively for the  
6           purpose of commercial production of a drug con-  
7           taining or derived from marijuana that is approved  
8           by the Secretary under section 505 of the Federal  
9           Food, Drug, and Cosmetic Act (21 U.S.C. 355), in  
10          accordance with the applicable requirements under  
11          subsection (a) or (b) of this section for registration  
12          of manufacturers or distributors of controlled sub-  
13          stances in schedule I or II.

14          “(3) NO LIMIT ON NUMBER OF MANUFACTUR-  
15          ERS AND DISTRIBUTORS.—The Attorney General  
16          shall not impose a limit on the number of applicants  
17          eligible to be registered under paragraph (1) or (2).

18          “(4) TIMING.—Not later than 30 days after the  
19          date on which the Attorney General receives an ap-  
20          plication for registration under paragraph (1) or (2),  
21          the Attorney General shall—

22                  “(A) grant the application; or

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

1           “(5) DETERMINATION OF SUPPLY.—In consid-  
2           ering the factors under subsection (a) or (b), as ap-  
3           plicable, for the purposes of registering an applicant  
4           eligible under paragraph (1) or (2) of this sub-  
5           section, the Attorney General shall consider the de-  
6           mand from researchers for an adequate and uninter-  
7           rupted supply of specific strains of marijuana and  
8           for marijuana grown pursuant to specific manufac-  
9           turing processes.

10           “(6) RELATION TO THE SINGLE CONVENTION  
11           ON NARCOTIC DRUGS.—

12           “(A) CONSTRUCTIVE POSSESSION AND  
13           CONTROL.—The registration of manufacturers  
14           and distributors of marijuana under paragraphs  
15           (1) and (2) shall constitute constructive posses-  
16           sion and control by the Federal Government for  
17           the purposes of the obligations under the Single  
18           Convention on Narcotic Drugs.

19           “(B) ARTICLE 28.—Article 28 of the Sin-  
20           gle Convention on Narcotic Drugs shall not be  
21           construed to prohibit, or impose additional re-  
22           strictions upon, the manufacturing of mari-  
23           juana that is conducted in accordance with  
24           paragraph (1) or (2), as applicable, and other  
25           applicable provisions of this title.”.

1 **SEC. 4. GOOD MANUFACTURING PRACTICES.**

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

8 **SEC. 5. QUOTAS.**

9 Section 306(e) of the Controlled Substances Act (21  
10 U.S.C. 826(e)) is amended in the third sentence by strik-  
11 ing “exceeds the aggregate of the quotas of all registrants  
12 under this section” and inserting “should be increased to  
13 meet the changing medical, scientific, and industrial needs  
14 for the controlled substance”.

15 **SEC. 6. TERMINATION OF INTERDISCIPLINARY REVIEW**  
16 **PROCESS FOR NON-NIH-FUNDED RESEARCH-**  
17 **ERS.**

18 The Secretary of Health and Human Services may  
19 not—

20 (1) reinstate the Public Health Service inter-  
21 disciplinary review process described in the guidance  
22 entitled “Guidance on Procedures for the Provision  
23 of Marijuana for Medical Research” (issued on May  
24 21, 1999); or

25 (2) create an additional review of scientific pro-  
26 tocols that is conducted only for research on mari-

1       juana (as defined in section 102 of the Controlled  
2       Substances Act (21 U.S.C. 802), as amended by sec-  
3       tion 2(b)) other than the review of research proto-  
4       cols performed at the request of a researcher con-  
5       ducting nonhuman research that is not federally  
6       funded,       in       accordance       with       section  
7       303(f)(3)(A)(ii)(II) of the Controlled Substances Act  
8       (21 U.S.C. 823(f)(3)(A)(ii)(II)), as amended by sec-  
9       tion 2(a).

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