

115TH CONGRESS
2D SESSION

H. R. 4825

To improve medical research on marijuana.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 18, 2018

Mr. BISHOP of Utah (for himself, Mr. CURTIS, Mr. STEWART, Mrs. LOVE, Mr. RASKIN, Ms. NORTON, Mr. POLIS, and Mr. BLUMENAUER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, 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 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 2018” 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—

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

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

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

7 “(2) Registration applications”;

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

11 (5) by striking “Article 7” and inserting the
12 following:

13 “(4) Article 7”; and

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

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

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

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

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

1 “(aa) the Secretary under section
2 505(i) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355(i)); or

4 “(bb) the National Institutes of
5 Health or another Federal agency that
6 funds scientific research; or

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

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

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

23 “(i) The applicant’s experience in dispensing, or
24 conducting research with respect to, controlled sub-
25 stances.

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

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

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

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

12 “(i) allows a researcher to voluntarily submit
13 the research protocol of the researcher for review
14 and approval; and

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

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

22 “(I) approve the application; or

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

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

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

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

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

18 “(I) change the type of drug, the source of the
19 drug, or the conditions under which the drug is
20 stored, tracked, or administered; or

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

22 “(ii) If an applicant amends or supplements the re-
23 search protocol under clause (i), the applicant shall, in
24 order to renew the registration under this paragraph, pro-
25 vide notice to the Attorney General of the amended or sup-

1 plemented research protocol in the applicant’s renewal ma-
2 terials.

3 “(iii)(I) If an applicant amends or supplements the
4 research protocol in a manner that involves a change to
5 the type of drug, the source of the drug, or conditions
6 under which the drug is stored, tracked, or administered
7 or otherwise increases the risk of diversion, the applicant
8 shall provide notice to the Attorney General not later than
9 30 days before proceeding on such amended or supple-
10 mental research protocol.

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

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

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

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

1 under subsection (a) or (b) for registration of manu-
2 facturers or distributors of controlled substances in
3 schedule I or II.

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

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

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

25 “(A) grant the application; or

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

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

12 “(6) RELATION TO THE SINGLE CONVENTION
13 ON NARCOTIC DRUGS.—

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

21 “(B) ARTICLE 28.—Article 28 of the Sin-
22 gle Convention on Narcotic Drugs shall not be
23 construed to prohibit, or impose additional re-
24 strictions upon, the manufacturing of mari-
25 juana that is conducted in accordance with

1 paragraph (1) or (2), as applicable, and other
2 applicable provisions of this title.”.

3 **SEC. 4. GOOD MANUFACTURING PRACTICES.**

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

10 **SEC. 5. QUOTAS.**

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

17 **SEC. 6. TERMINATION OF INTERDISCIPLINARY REVIEW**

18 **PROCESS FOR NON-NIH-FUNDED RESEARCH-**

19 **ERS.**

20 The Secretary of Health and Human Services may
21 not—

22 (1) reinstate the Public Health Service inter-
23 disciplinary review process described in the guidance
24 entitled “Guidance on Procedures for the Provision

1 of Marijuana for Medical Research” (issued on May
2 21, 1999); or

3 (2) create an additional review of scientific pro-
4 tocols that is conducted only for research on mari-
5 juana (as defined in section 102 of the Controlled
6 Substances Act (21 U.S.C. 802), as amended by sec-
7 tion 2(b)) other than the review of research proto-
8 cols performed at the request of a researcher con-
9 ducting nonhuman research that is not federally
10 funded, in accordance with section
11 303(f)(3)(A)(ii)(II) of the Controlled Substances Act
12 (21 U.S.C. 823(f)(3)(A)(ii)(II)), as amended by sec-
13 tion 2(a).

○