

116TH CONGRESS
1ST SESSION

H. R. 3797

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

IN THE HOUSE OF REPRESENTATIVES

JULY 17, 2019

Mr. BLUMENAUER (for himself, Mr. HARRIS, Ms. LOFGREN, Mr. GRIFFITH, Mr. BISHOP of Utah, and Mrs. DINGELL) 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 amend the Controlled Substances Act to make marijuana accessible for use by qualified marijuana researchers for medical purposes, and for other purposes.

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 “Medical Marijuana Re-
5 search Act of 2019”.

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

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

4 (1) until the date on which the Secretary deter-
5 mines that manufacturers and distributors (other
6 than the Federal Government) can ensure a suffi-
7 cient supply of marijuana for qualified marijuana re-
8 searchers intended for medical research, shall—

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

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

14 (i) to all qualified marijuana research-
15 ers who submit a request for such plants
16 or seeds to engage in research pursuant to
17 the section 303(f)(3) of the Controlled
18 Substances Act, as amended by section 3;
19 and

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

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

1 (b) REQUIREMENT TO VERIFY REGISTRATION.—Be-
2 fore supplying marijuana to any person through the Na-
3 tional Institute on Drug Abuse Drug Supply Program, the
4 Secretary of Health and Human Services shall—

5 (1) require the person to submit documentation
6 demonstrating that the person is a qualified mari-
7 juana researcher seeking to conduct research pursu-
8 ant to section 303(f)(3) of the Controlled Substances
9 Act, as amended by section 3; and

10 (2) not later than 30 days after receipt of such
11 documentation, review such documentation and
12 verify that the marijuana will be used for such re-
13 search (and for no other purpose authorized pursu-
14 ant to this Act).

15 (c) GUIDELINES ON PRODUCTION.—The Commis-
16 sioner of Food and Drugs, in consultation with the Direc-
17 tor of the National Institute on Drug Abuse, shall—

18 (1) not later than 180 days after the date of
19 enactment of this Act, issue guidelines on the pro-
20 duction of marijuana by qualified marijuana re-
21 searchers pursuant to subsection (a)(1)(B); and

22 (2) encourage researchers and manufacturers
23 that are authorized to produce or manufacture mari-
24 juana pursuant to section 303 of the Controlled
25 Substances Act (21 U.S.C. 823), as amended by this

1 Act, to comply with such guidelines to the extent ap-
2 plicable.

3 (d) DEFINITION.—In this section:

4 (1) The term “immature marijuana plant”
5 means a marijuana plant with no observable flowers
6 or buds.

7 (2) The term “qualified medical marijuana re-
8 searcher” means a researcher who is registered to
9 conduct research with marijuana under section
10 303(f)(3) of the Controlled Substances Act, as
11 amended by section 3.

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

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

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

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

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

21 “(2) Registration applications”;

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

1 (5) by striking “Article 7” and inserting the
2 following:

3 “(4) Article 7”; and

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

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

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

12 “(ii) the applicant is only using marijuana man-
13 ufactured by a person registered under subsection
14 (l);

15 “(iii) the applicant’s research protocol—

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

17 “(aa) the Secretary under section
18 505(i) of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 355(i)); or

20 “(bb) the National Institutes of
21 Health or another Federal agency that
22 funds scientific research; or

23 “(II) in the case of nonhuman research
24 that is not federally funded, has been volun-
25 tarily submitted by the applicant to, and ap-

1 proved by, the National Institutes of Health;
2 and

3 “(iv) the applicant has demonstrated that there
4 are effective procedures in place to adequately safe-
5 guard against diversion of the marijuana from legiti-
6 mate medical or scientific use, in accordance with
7 subparagraph (E).

8 “(B) The Attorney General shall grant an application
9 for registration under this paragraph unless the Attorney
10 General determines that the issuance of the registration
11 would be inconsistent with the public interest. In deter-
12 mining the public interest, the following factors shall be
13 considered:

14 “(i) The applicant’s experience in dispensing, or
15 conducting research with respect to, controlled sub-
16 stances.

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

20 “(iii) Compliance with applicable State or local
21 laws relating to controlled substance misuse or diver-
22 sion.

23 “(C) Not later than 90 days after the date of enact-
24 ment of the Medical Marijuana Research Act of 2019, for

1 purposes of subparagraph (A)(ii)(II), the National Insti-
2 tutes of Health shall establish a process that—

3 “(i) allows a researcher to voluntarily submit
4 the research protocol of the researcher for review
5 and approval; and

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

9 “(D)(i) Not later than 60 days after the date on
10 which the Attorney General receives a complete applica-
11 tion for registration under this paragraph, the Attorney
12 General shall approve or deny the application.

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

17 “(iii) In the case of a denial under clause (i), the At-
18 torney General shall provide a written explanation of the
19 basis for the denial and a description of any curative steps
20 that may be taken for such request to be approved.

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

24 “(ii) Except as provided in clause (i), any security
25 measures required by the Attorney General for practi-

1 tioners conducting research with marijuana pursuant to
2 a registration under this paragraph shall be consistent
3 with the security measures for practitioners conducting re-
4 search on other controlled substances in schedule II that
5 have a similar risk of diversion and abuse.

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

10 “(I) change the type of drug, the source of the
11 drug, or the conditions under which the drug is
12 stored, tracked, or administered; or

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

14 “(ii) If an applicant amends or supplements the re-
15 search protocol or initiates research on a new research
16 protocol under clause (i), the applicant shall, in order to
17 renew the registration under this paragraph, provide no-
18 tice to the Attorney General of the amended or supple-
19 mented research protocol or any new research protocol in
20 the applicant’s renewal materials.

21 “(iii)(I) If an applicant amends or supplements a re-
22 search protocol and the amendment or supplement in-
23 volves a change to the type of drug, the source of the drug,
24 or conditions under which the drug is stored, tracked, or
25 administered or otherwise increases the risk of diversion,

1 the applicant shall provide notice to the Attorney General
2 not later than 30 days before proceeding on such amended
3 or supplemental research or new research protocol, as the
4 case may be.

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

9 “(iv) The Attorney General may object to an amend-
10 ed or supplemental protocol or a new research protocol
11 under clause (i) or (iii) only if additional security meas-
12 ures are needed to safeguard against diversion or abuse.

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

20 (b) CONFORMING AMENDMENT.—Section 102(16) of
21 the Controlled Substances Act (21 U.S.C. 802(16)) is
22 amended by inserting “or ‘marijuana’” after “The term
23 ‘marihuana’”.

1 **SEC. 4. MANUFACTURE AND DISTRIBUTION OF MARIJUANA**
2 **FOR USE IN LEGITIMATE, MEDICAL RE-**
3 **SEARCH.**

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

7 “(1) REGISTRATION OF PERSONS TO MANUFACTURE
8 AND DISTRIBUTE MARIJUANA FOR USE IN LEGITIMATE,
9 MEDICAL RESEARCH.—

10 “(1) REGISTRATION OF MANUFACTURERS.—Be-
11 ginning not later than the day that is 1 year after
12 the date of enactment of the Medical Marijuana Re-
13 search Act of 2019, the Attorney General shall reg-
14 ister an applicant to manufacture marijuana to the
15 extent the marijuana will be used exclusively by
16 qualified marijuana researchers for research pursu-
17 ant to subsection (f)(3), unless the Attorney General
18 determines that the issuance of such registration is
19 inconsistent with the public interest. In determining
20 the public interest, the Attorney General shall—

21 “(A) take into consideration—

22 “(i) maintenance of effective controls
23 against diversion of marijuana and any
24 controlled substance compounded there-
25 from into other than legitimate medical,
26 scientific, or research channels;

1 “(ii) compliance with applicable State
2 and local laws relating to controlled sub-
3 stance misuse and diversion; and

4 “(iii) prior conviction record of the
5 applicant under Federal or State laws re-
6 lating to the manufacture, distribution, or
7 dispensing of such substances; and

8 “(B) not take into consideration any fac-
9 tors other than the factors listed in subpara-
10 graph (A).

11 “(2) REGISTRATION OF DISTRIBUTORS.—Begin-
12 ning not later than the day that is 1 year after the
13 date of enactment of the Medical Marijuana Re-
14 search Act of 2019, the Attorney General shall reg-
15 ister an applicant to distribute marijuana that is in-
16 tended to be used exclusively by qualified medical
17 marijuana researchers for research pursuant to sub-
18 section (f)(3), unless the Attorney General deter-
19 mines that the issuance of such registration is incon-
20 sistent with the public interest.

21 “(3) PUBLIC INTEREST.—In determining the
22 public interest under paragraph (2), the Attorney
23 General shall—

24 “(A) take into consideration—

1 “(i) maintenance of effective controls
2 against diversion of marijuana and any
3 controlled substance compounded there-
4 from into other than legitimate medical,
5 scientific, or research channels;

6 “(ii) compliance with applicable State
7 and local law;

8 “(iii) prior conviction record of the
9 applicant under Federal or State laws re-
10 lating to the manufacture, distribution, or
11 dispensing of such substances; and

12 “(iv) past experience in the distribu-
13 tion of controlled substances, and the exist-
14 ence in the establishment of effective con-
15 trols against diversion; and

16 “(B) not take into consideration any fac-
17 tors other than the factors listed in subpara-
18 graph (A).

19 “(4) NO LIMIT ON NUMBER OF MANUFACTUR-
20 ERS AND DISTRIBUTORS.—Notwithstanding any
21 other provision of law, the Attorney General shall
22 not impose or implement any limit on the number of
23 persons eligible to be registered to manufacture or
24 distribute marijuana pursuant to paragraph (1) or
25 (2).

1 “(5) REQUIREMENT TO VERIFY USE FOR LE-
2 GITIMATE, MEDICAL RESEARCH.—As a condition on
3 registration under this section to manufacture or
4 distribute marijuana, the Attorney General shall re-
5 quire the registrant—

6 “(A) to require any person to whom the
7 marijuana will be supplied to submit docu-
8 mentation demonstrating that the marijuana
9 will be used exclusively by qualified medical
10 marijuana researchers for research pursuant to
11 subsection (f)(3);

12 “(B) in the case of distribution, to com-
13 plete, with respect to that distribution, the
14 DEA Controlled substance order form (DEA
15 222) (or a successor form) and the DEA Cer-
16 tificate of Registration (DEA Form 223) (or a
17 successor form) and to upload such forms to
18 the system used by the Drug Enforcement
19 Agency for such distribution;

20 “(C) to include in the labeling of any mari-
21 juana so manufactured or distributed—

22 “(i) the following statement: ‘This
23 material is for medical and scientific re-
24 search purposes only.’; and

1 “(ii) the name of the requestor of the
2 marijuana; and

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

8 “(6) TIMING.—Not later than 30 days after re-
9 ceipt of a request for registration under this sub-
10 section to manufacture or distribute marijuana, the
11 Attorney General shall—

12 “(A) grant or deny the request; and

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

17 “(7) DEEMED APPROVAL.—If the Attorney
18 General fails to grant or deny a request for registra-
19 tion under this subsection to manufacture or dis-
20 tribute marijuana within the 30-day period referred
21 to in paragraph (5), such request is deemed ap-
22 proved.

23 “(8) DEFINITION.—For purposes of this sub-
24 section, the term ‘qualified medical marijuana re-
25 searcher’ means a researcher who is registered to

1 conduct research with marijuana under subsection
2 (f)(3).”.

3 **SEC. 5. TERMINATION OF INTERDISCIPLINARY REVIEW**
4 **PROCESS FOR NON-NIH-FUNDED RESEARCH-**
5 **ERS.**

6 The Secretary of Health and Human Services may
7 not—

8 (1) reinstate the Public Health Service inter-
9 disciplinary review process described in the guidance
10 entitled “Guidance on Procedures for the Provision
11 of Marijuana for Medical Research” (issued on May
12 21, 1999); or

13 (2) create an additional review of scientific pro-
14 tocols that is only conducted for research on mari-
15 juana other than the review of research protocols
16 performed at the request of a researcher conducting
17 nonhuman research that is not federally funded, in
18 accordance with section 303(f)(3)(A)(ii)(II) of the
19 Controlled Substances Act (21 U.S.C.
20 823(f)(3)(A)(ii)(II)), as amended by section 3.

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

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

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

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

6 (2) submit a report to the Congress on the re-
7 sults of such review; and

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

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

18 Section 306 of the Controlled Substances Act (21
19 U.S.C. 826) is amended by adding at the end the fol-
20 lowing:

21 “(j) The Attorney General may only establish a quota
22 for production of marijuana that is manufactured and dis-
23 tributed in accordance with the Medical Marijuana Re-
24 search Act of 2019 that meets the changing medical, sci-

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

3 **SEC. 8. ARTICLE 28 OF THE SINGLE CONVENTION ON NAR-**
4 **COTIC DRUGS.**

5 Article 28 of the Single Convention on Narcotic
6 Drugs shall not be construed to prohibit, or impose addi-
7 tional restrictions upon, research involving marijuana, or
8 the manufacture, distribution, or dispensing of marijuana,
9 that is conducted in accordance with the Controlled Sub-
10 stances Act (21 U.S.C. 801 et seq.), this Act, and the
11 amendments made by this Act.

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

13 The Attorney General of the United States, and any
14 officer or employee of the Department of Justice, shall not
15 interfere with the production, distribution, and sale of
16 marijuana in accordance with this Act and the amend-
17 ments made by this Act.

18 **SEC. 10. DEFINITION.**

19 In this Act, the term “marijuana” has the meaning
20 given to the term “marihuana” in section 102 of the Con-
21 trolled Substances Act (21 U.S.C. 802).

○