

Union Calendar No. 508

116TH CONGRESS
2D SESSION

H. R. 3797

[Report No. 116–619, Part I]

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

DECEMBER 7, 2020

Additional sponsors: Mr. GAETZ, Mrs. RODGERS of Washington, Mr. STEWART, Ms. NORTON, Ms. TITUS, Ms. LEE of California, Mr. GRIJALVA, Mr. CORREA, Mrs. HARTZLER, Mr. WALDEN, Mr. SMUCKER, Mr. CARTER of Georgia, Ms. BLUNT ROCHESTER, Mr. CURTIS, Mr. STEIL, and Mr. CASTEN of Illinois

DECEMBER 7, 2020

Reported from the Committee on Energy and Commerce with an amendment
[Strike out all after the enacting clause and insert the part printed in italic]

DECEMBER 7, 2020

Committee on the Judiciary discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on July 17, 2019]

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”.*

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

7 *(a) PRODUCTION AND SUPPLY.—The Secretary of*
8 *Health and Human Services—*

9 *(1) until the date on which the Secretary deter-*
10 *mines that manufacturers and distributors (other*
11 *than the Federal Government) can ensure a sufficient*
12 *supply of marijuana (as defined in section 102 of the*
13 *Controlled Substances Act (21 U.S.C. 802), as amend-*
14 *ed by section 8) intended for medical research for*
15 *qualified marijuana researchers registered pursuant*
16 *to paragraph (3) of section 303(f) of the Controlled*
17 *Substances Act (21 U.S.C. 823(f)), as added by sec-*
18 *tion 3, shall—*

19 *(A) continue, through grants, contracts, or*
20 *cooperative agreements, to produce marijuana*
21 *through the National Institute on Drug Abuse*
22 *Drug Supply Program; and*

23 *(B) offer to qualified marijuana researchers*
24 *marijuana products available through State au-*
25 *thorized marijuana programs that are consistent*

1 *with the guidance issued under subsection (c);*
2 *and*

3 *(2) beyond the date specified in paragraph (1),*
4 *may, at the Secretary's discretion, continue through*
5 *grants, contracts, or cooperative agreements, to so*
6 *produce and supply marijuana.*

7 ***(b) REQUIREMENT TO VERIFY REGISTRATION.***—*Before*
8 *supplying marijuana to any person through the National*
9 *Institute on Drug Abuse Drug Supply Program or from*
10 *State authorized marijuana programs, the Secretary of*
11 *Health and Human Services shall—*

12 *(1) require the person to submit documentation*
13 *demonstrating that the person is a qualified mari-*
14 *juana researcher seeking to conduct research pursuant*
15 *to section 303(f)(3) of the Controlled Substances Act,*
16 *as added by subsection (e) of this section; and*

17 *(2) not later than 60 days after receipt of such*
18 *documentation, review such documentation and verify*
19 *that the marijuana will be used for such research*
20 *(and for no other purpose authorized pursuant to this*
21 *Act).*

22 ***(c) GUIDANCE ON USE OF STATE AUTHORIZED MARI-***
23 ***JUANA PROGRAMS.***—*Not later than 180 days after the date*
24 *of the enactment of this Act, the Secretary of Health and*
25 *Human Services shall issue guidance related to the use of*

1 *marijuana from State authorized marijuana programs, in-*
2 *cluding necessary quality or production standards for*
3 *marijuana intended for use in medical research.*

4 *(d) COMPLIANCE WITH GUIDANCE.—The Secretary of*
5 *Health and Human Services, acting through the Commis-*
6 *sioner of Food and Drugs, shall ensure that a qualified*
7 *marijuana researcher is in compliance with guidance issued*
8 *by the Food and Drug Administration related to botanical*
9 *drug development.*

10 *(e) RESEARCH.—Section 303(f) of the Controlled Sub-*
11 *stances Act (21 U.S.C. 823(f)) is amended—*

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

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

16 *(3) by striking “Registration applications” and*
17 *inserting the following:*

18 *“(2) Registration applications”;*

19 *(4) in paragraph (2), as so designated, by strik-*
20 *ing “schedule I” each place that term appears and in-*
21 *serting “schedule I, except marijuana,”;*

22 *(5) by striking “Article 7” and inserting the fol-*
23 *lowing:*

24 *“(4) Article 7”; and*

1 (6) by inserting before paragraph (4), as so des-
2 ignated, the following:

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

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

9 “(ii) the applicant’s research protocol has been
10 reviewed and approved by the Secretary under section
11 505(i) of the Federal Food, Drug, and Cosmetic Act;
12 and

13 “(iii) the Secretary has determined the applicant
14 is qualified to conduct bona fide research.

15 A practitioner so registered shall be referred to in this Act
16 as a ‘qualified marijuana researcher’.

17 “(B)(i) Not later than 60 days after the date on which
18 the Attorney General receives a complete application for
19 registration under this paragraph, the Attorney General
20 shall approve or deny the application.

21 “(ii) For purposes of clause (i), an application shall
22 be deemed complete when the applicant has submitted docu-
23 mentation showing that the requirements under subpara-
24 graph (A) are satisfied.

1 “(iii) In the case of a denial under clause (i), the At-
2 torney General shall provide a written explanation of the
3 basis for the denial.

4 “(C) The Attorney General shall grant an application
5 for registration under this paragraph unless the Attorney
6 General determines that the issuance of the registration
7 would be inconsistent with the public interest. In deter-
8 mining the public interest, the following factors shall be
9 considered:

10 “(i) The applicant’s experience in dispensing, or
11 conducting research with respect to, controlled sub-
12 stances.

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

16 “(iii) Compliance with applicable State or local
17 laws relating to controlled substance misuse or diver-
18 sion.

19 “(D)(i) A qualified marijuana researcher shall store
20 marijuana to be used in research in a securely locked, sub-
21 stantially constructed cabinet.

22 “(ii) Except as provided in clause (i), any security
23 measures required by the Attorney General for practitioners
24 conducting research with marijuana pursuant to a registra-
25 tion under this paragraph shall be consistent with the secu-

1 rity measures for practitioners conducting research on other
2 controlled substances in schedule II that have a similar risk
3 of diversion and abuse.

4 “(E)(i) If the Attorney General grants an application
5 for registration under this paragraph, the applicant may
6 amend or supplement the research protocol without re-
7 applying if the applicant does not change the type of mari-
8 juana, the source of the marijuana, or the conditions under
9 which the marijuana is stored, tracked, or administered.

10 “(ii) If an applicant amends or supplements the re-
11 search protocol or initiates research on a new research pro-
12 tocol under clause (i), the applicant shall, in order to renew
13 the registration under this paragraph, provide notice to the
14 Attorney General of the amended or supplemented research
15 protocol or any new research protocol in the applicant’s re-
16 newal materials.

17 “(iii)(I) If an applicant amends or supplements a re-
18 search protocol and the amendment or supplement involves
19 a change to the type of marijuana, the source of the mari-
20 juana, or conditions under which the marijuana is stored,
21 tracked, or administered or otherwise increases the risk of
22 diversion, the applicant shall provide notice to the Attorney
23 General not later than 30 days before proceeding on such
24 amended or supplemental research or new research protocol,
25 as the case may be.

1 “(II) If the Attorney General does not object during
2 the 30-day period following a notification under subclause
3 (I), the applicant may proceed with the amended or supple-
4 mental research or new research protocol.

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

9 “(F) If marijuana or a compound of marijuana is list-
10 ed on a schedule other than schedule I, the provisions of
11 paragraphs (1), (2), and (4) that apply to research with
12 a controlled substance in the applicable schedule shall apply
13 to research with marijuana or that compound, as applica-
14 ble, in lieu of the provisions of subparagraphs (A) through
15 (E) of this paragraph.

16 “(G) Nothing in this paragraph shall be construed as
17 limiting the authority of the Secretary under section 505(i)
18 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 355(i)) or over requirements related to research protocols,
20 including changes in—

21 “(i) the method of administration of marijuana;

22 “(ii) the dosing of marijuana; and

23 “(iii) the number of individuals or patients in-
24 volved in research.”.

1 **SEC. 3. 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 2, is further amended*
6 *by adding at the end the following:*

7 *“(l) 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, the Attorney General shall register an ap-*
14 *plicant to manufacture marijuana (including any de-*
15 *rivative, extract, preparation, and compound thereof)*
16 *that is intended for the ultimate and exclusive use by*
17 *qualified marijuana researchers for research pursuant*
18 *to subsection (f)(3), unless the Attorney General deter-*
19 *mines that the issuance of such registration is incon-*
20 *sistent with the public interest. In determining the*
21 *public interest, the Attorney General shall take into*
22 *consideration—*

23 *“(A) maintenance of effective controls*
24 *against diversion of marijuana and any con-*
25 *trolled substance compounded therefrom into*

1 *other than legitimate medical, scientific, or re-*
2 *search channels;*

3 “(B) *compliance with applicable State and*
4 *local laws relating to controlled substance misuse*
5 *and diversion; and*

6 “(C) *prior conviction record of the appli-*
7 *cant under Federal or State laws relating to the*
8 *manufacture, distribution, or dispensing of such*
9 *substances.*

10 “(2) *REGISTRATION OF DISTRIBUTORS.—Begin-*
11 *ning not later than the day that is 1 year after the*
12 *date of enactment of the Medical Marijuana Research*
13 *Act, the Attorney General shall register an applicant*
14 *to distribute marijuana (including any derivative, ex-*
15 *tract, preparation, and compound thereof) that is in-*
16 *tended for the ultimate and exclusive use by qualified*
17 *marijuana researchers for research pursuant to sub-*
18 *section (f)(3), unless the Attorney General determines*
19 *that the issuance of such registration is inconsistent*
20 *with the public interest.*

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

24 “(A) *the factors specified in subparagraphs*
25 *(A), (B), and (C) of such paragraph; and*

1 “(B) past experience in the distribution of
2 controlled substances, and the existence of effec-
3 tive controls against diversion.

4 “(4) NO LIMIT ON NUMBER OF MANUFACTURERS
5 AND DISTRIBUTORS.—Notwithstanding any other pro-
6 vision of law, the Attorney General shall not impose
7 or implement any limit on the number of persons eli-
8 gible to be registered to manufacture or distribute
9 marijuana pursuant to paragraph (1) or (2).

10 “(5) REQUIREMENT TO VERIFY USE FOR LEGITI-
11 MATE, MEDICAL RESEARCH.—As a condition on reg-
12 istration under this section to manufacture or dis-
13 tribute marijuana, the Attorney General shall require
14 the registrant—

15 “(A) to require any person to whom the
16 marijuana will be supplied to submit docu-
17 mentation demonstrating that the marijuana
18 (including any derivative, extract, preparation,
19 and compound thereof) will be ultimately used
20 exclusively by qualified marijuana researchers
21 for research pursuant to subsection (f)(3);

22 “(B) in the case of distribution, to complete,
23 with respect to that distribution, the DEA Con-
24 trolled substance order form in accordance with
25 section 308 and to upload such forms to the sys-

1 *tem used by the Drug Enforcement Agency for*
2 *such distribution;*

3 “(C) to include in the labeling of any mari-
4 *juana so manufactured or distributed—*

5 “(i) the following statement: ‘This ma-
6 *terial is for biomedical and scientific re-*
7 *search purposes only.’; and*

8 “(ii) the name of the requestor of the
9 *marijuana;*

10 “(D) to limit the transfer and sale of any
11 *marijuana manufactured under this sub-*
12 *section—*

13 “(i) to researchers who are registered
14 *under this Act to conduct research with*
15 *marijuana; and*

16 “(ii) for purposes of use in preclinical
17 *research or in a clinical investigation pur-*
18 *suant to an investigational new drug ex-*
19 *emption under 505(i) of the Federal Food,*
20 *Drug, and Cosmetic Act (21 U.S.C. 355(i));*
21 *and*

22 “(E) to transfer or sell any marijuana
23 *manufactured under this subsection only with*
24 *prior, written consent for the transfer or sale by*
25 *the Attorney General.*

1 “(6) *TIMING.*—Not later than 60 days after re-
2 *ceipt of a request for registration under this sub-*
3 *section to manufacture or distribute marijuana, the*
4 *Attorney General shall—*

5 “(A) *grant or deny the request; and*

6 “(B) *in the case of a denial, provide a writ-*
7 *ten explanation of the basis for the denial.*

8 “(7) *DEEMED APPROVAL.*—*If the Attorney Gen-*
9 *eral fails to grant or deny a request for registration*
10 *under this subsection to manufacture or distribute*
11 *marijuana within the 60-day period referred to in*
12 *paragraph (5), such request is deemed approved.”.*

13 **SEC. 4. TERMINATION OF INTERDISCIPLINARY REVIEW**
14 **PROCESS FOR NON-NIH-FUNDED QUALIFIED**
15 **MARIJUANA RESEARCHERS.**

16 *The Secretary of Health and Human Services may*
17 *not—*

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

23 (2) *create an additional review of scientific pro-*
24 *ocols that is only conducted for research on mari-*
25 *juana other than the review of research protocols per-*

1 formed at the request of a qualified marijuana re-
2 searcher conducting nonhuman research that is not
3 federally funded, in accordance with section
4 303(f)(3)(A)(iii)(II) of the Controlled Substances Act,
5 as added by section 2 of this Act.

6 **SEC. 5. CONSIDERATION OF RESULTS OF RESEARCH.**

7 Immediately upon the approval by the Food and Drug
8 Administration of an application for a drug that contains
9 marijuana under section 505 of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 355), and (irrespective of
11 whether any such approval is granted) not later than the
12 date that is 5 years after the date of enactment of this Act,
13 the Secretary of Health and Human Services shall—

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

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

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

1 **SEC. 6. PRODUCTION QUOTAS FOR MARIJUANA GROWN FOR**
2 **LEGITIMATE, SCIENTIFIC RESEARCH.**

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

5 *“(j) The Attorney General may only establish a quota*
6 *for production of marijuana that is manufactured and dis-*
7 *tributed in accordance with the Medical Marijuana Re-*
8 *search Act that meets the changing medical, scientific, and*
9 *industrial needs for marijuana.”.*

10 **SEC. 7. ARTICLE 28 OF THE SINGLE CONVENTION ON NAR-**
11 **COTIC DRUGS.**

12 *Article 28 of the Single Convention on Narcotic Drugs*
13 *shall not be construed to prohibit, or impose additional re-*
14 *strictions upon, research involving marijuana, or the man-*
15 *ufacture, distribution, or dispensing of marijuana, that is*
16 *conducted in accordance with the Controlled Substances Act*
17 *(21 U.S.C. 801 et seq.), this Act, and the amendments made*
18 *by this Act.*

19 **SEC. 8. DEFINITIONS.**

20 (a) **QUALIFIED MARIJUANA RESEARCHER.**—*In this*
21 *Act, the term “qualified marijuana researcher” has the*
22 *meaning given the term in section 303(f)(3) of the Con-*
23 *trolled Substances Act, as added by section 2(d) of this Act.*

24 (b) **UPDATING TERM.**—*Section 102(16) of the Con-*
25 *trolled Substances Act (21 U.S.C. 802(16)) is amended—*

1 (1) *in subparagraph (A), by striking “the term*
2 *‘marihuana’ means” and inserting “the terms ‘mari-*
3 *huana’ and ‘marijuana’ mean”;* and

4 (2) *in subparagraph (B), by striking “The term*
5 *‘marihuana’ does not” and inserting “The terms*
6 *‘marihuana’ and ‘marijuana’ do not”.*

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