

117TH CONGRESS
1ST SESSION

H. R. 5657

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

OCTOBER 21, 2021

Mr. BLUMENAUER (for himself, Mr. HARRIS, Ms. NORTON, Mrs. DINGELL, Mr. COHEN, Mr. GRIFFITH, Ms. LEE of California, and Mr. CASE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, and the Budget, 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”.

1 **SEC. 2. FACILITATING MARIJUANA RESEARCH.**

2 (a) PRODUCTION AND SUPPLY.—The Secretary of
3 Health and 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 (as defined in section 102
8 of the Controlled Substances Act (21 U.S.C. 802),
9 as amended by section 8) intended for research by
10 qualified marijuana researchers registered pursuant
11 to paragraph (3) of section 303(f) of the Controlled
12 Substances Act (21 U.S.C. 823(f)), as added by sec-
13 tion 3, shall—

14 (A) continue, through grants, contracts, or
15 cooperative agreements, to produce marijuana
16 through the National Institute on Drug Abuse
17 Drug Supply Program;

18 (B) not later than one year after the date
19 of enactment of this Act, act jointly with the
20 Attorney General of the United States to estab-
21 lish and implement a specialized process for
22 manufacturers and distributors, notwith-
23 standing the registration requirements of sec-
24 tion 303 of such Act (21 U.S.C. 823), to supply
25 qualified marijuana researchers with marijuana
26 products—

1 (i) available through State-authorized
2 marijuana programs; and

3 (ii) consistent with the guidance
4 issued under subsection (c); and

5 (C) not later than 60 days after the date
6 of enactment of this Act, jointly convene with
7 the Attorney General a meeting to initiate the
8 development of the specialized process described
9 in subparagraph (B); and

10 (2) beyond the date specified in paragraph (1),
11 may, at the Secretary's discretion, continue—

12 (A) through grants, contracts, or coopera-
13 tive agreements, to so produce marijuana; and

14 (B) to implement such specialized process.

15 (b) REQUIREMENT TO VERIFY REGISTRATION.—Be-
16 fore supplying marijuana to any person through the Na-
17 tional Institute on Drug Abuse Drug Supply Program or
18 through implementation of the specialized process estab-
19 lished under subsection (a)(1)(B), the Secretary of Health
20 and Human Services shall—

21 (1) require the person to submit documentation
22 demonstrating that the person is a qualified mari-
23 juana researcher seeking to conduct research pursu-
24 ant to section 303(f)(3) of the Controlled Substances
25 Act, as added by subsection (d) of this section, or

1 a manufacturer duly registered under section 303(l)
2 of the Controlled Substances Act, as added by sec-
3 tion 3 of this Act; and

4 (2) not later than 60 days after receipt of such
5 documentation, review such documentation and
6 verify that the marijuana will be used for such re-
7 search (and for no other purpose authorized pursu-
8 ant to this Act or the amendments made by this
9 Act).

10 (c) GUIDANCE ON USE OF STATE-AUTHORIZED
11 MARIJUANA PROGRAMS.—Not later than 180 days after
12 the date of the enactment of this Act, the Secretary of
13 Health and Human Services shall issue guidance related
14 to marijuana from State-authorized marijuana programs
15 for research.

16 (d) RESEARCH.—Section 303(f) of the Controlled
17 Substances Act (21 U.S.C. 823(f)) is amended—

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

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

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

24 “(2) Registration applications”;

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

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

6 “(4) Article 7”; and

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

9 “(3)(A) The Attorney General shall register the ap-
10 plicant to conduct research with marijuana if—

11 “(i) the applicant is authorized to dispense, or
12 conduct research with respect to, controlled sub-
13 stances in schedule I, II, III, IV, or V;

14 “(ii) the applicant is compliant with, and au-
15 thorized to conduct the activities described in clause
16 (i) under, the laws of the State in which the appli-
17 cant practices; and

18 “(iii) in the case of an applicant pursuing clin-
19 ical research, the applicant’s clinical research pro-
20 tocol has been reviewed and authorized to proceed by
21 the Secretary under section 505(i) of the Federal
22 Food, Drug, and Cosmetic Act.

23 “(B) An applicant registered under subparagraph (A)
24 shall be referred to in this section as a ‘qualified mari-
25 juana researcher’.

1 “(C)(i) Not later than 60 days after the date on
2 which the Attorney General receives a complete applica-
3 tion for registration under this paragraph, the Attorney
4 General shall approve or deny the application.

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

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

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

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

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

1 “(iii) Compliance with applicable State or local
2 laws relating to controlled substance misuse or diver-
3 sion.

4 “(iv) Such other conduct which may threaten
5 the public health and safety.

6 “(E)(i) A qualified marijuana researcher shall store
7 marijuana to be used in research in a securely locked, sub-
8 stantially constructed cabinet.

9 “(ii) Except as provided in clause (i), any security
10 measures required by the Attorney General for applicants
11 conducting research with marijuana pursuant to a reg-
12 istration under this paragraph shall be consistent with the
13 security measures for applicants conducting research on
14 other controlled substances in schedule II that have a
15 similar risk of diversion and abuse.

16 “(F)(i) If the Attorney General grants an application
17 for registration under this paragraph, the applicant may
18 amend or supplement the research protocol and proceed
19 with the research under such amended or supplemented
20 protocol, without additional review or approval by the At-
21 torney General or the Secretary of Health and Human
22 Services if the applicant does not change the type of mari-
23 juana, the source of the marijuana, or the conditions
24 under which the marijuana is stored, tracked, or adminis-
25 tered.

1 “(ii) If an applicant amends or supplements the re-
2 search protocol or initiates research on a new research
3 protocol under clause (i), the applicant shall, in order to
4 renew the registration under this paragraph, provide no-
5 tice to the Attorney General of the amended or supple-
6 mented research protocol or any new research protocol in
7 the applicant’s renewal materials.

8 “(iii)(I) If an applicant amends or supplements a re-
9 search protocol and the amendment or supplement in-
10 volves a change to the type of marijuana, the source of
11 the marijuana, or conditions under which the marijuana
12 is stored, tracked, or administered, the applicant shall pro-
13 vide notice to the Attorney General not later than 30 days
14 before proceeding on such amended or supplemental re-
15 search or new research protocol, as the case may be.

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

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

24 “(G) If marijuana is listed on a schedule other than
25 schedule I, the provisions of paragraphs (1), (2), and (4)

1 that apply to research with a controlled substance in the
2 applicable schedule shall apply to research with marijuana
3 or that compound, as applicable, in lieu of the provisions
4 of subparagraphs (A) through (F) of this paragraph.

5 “(H) Nothing in this paragraph shall be construed
6 as limiting the authority of the Secretary under section
7 505(i) of the Federal Food, Drug, and Cosmetic Act or
8 over requirements related to research protocols, including
9 changes in—

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

11 “(ii) the dosing of marijuana; and

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

14 **SEC. 3. MANUFACTURE AND DISTRIBUTION OF MARIJUANA**
15 **FOR USE IN LEGITIMATE RESEARCH.**

16 Section 303 of the Controlled Substances Act (21
17 U.S.C. 823), as amended by section 2, is further amended
18 by adding at the end the following:

19 “(1) REGISTRATION OF PERSONS TO MANUFACTURE
20 AND DISTRIBUTE MARIJUANA FOR USE IN LEGITIMATE
21 RESEARCH.—

22 “(1) REGISTRATION OF MANUFACTURERS.—

23 “(A) IN GENERAL.—Beginning not later
24 than the day that is 1 year after the date of en-
25 actment of the Medical Marijuana Research

1 Act, the Attorney General, pursuant to sub-
2 section (f)(3) and subject to subparagraph (B)
3 of this paragraph, shall register an applicant to
4 manufacture marijuana (including any deriva-
5 tive, extract, preparation, and compound there-
6 of) that is intended for—

7 “(i) the ultimate and exclusive use by
8 qualified marijuana researchers for re-
9 search pursuant to subsection (f)(3); or

10 “(ii) subsequent downstream manu-
11 facture by a duly registered manufacturer
12 for the ultimate and exclusive use by quali-
13 fied marijuana researchers for research
14 pursuant to subsection (f)(3).

15 “(B) PUBLIC INTEREST.—The Attorney
16 General shall register an applicant under sub-
17 subparagraph (A) unless the Attorney General de-
18 termines that the issuance of such registration
19 is inconsistent with the public interest. In deter-
20 mining the public interest, the Attorney General
21 shall take into consideration—

22 “(i) maintenance of effective controls
23 against diversion of marijuana and any
24 controlled substance compounded there-

1 from into other than legitimate medical,
2 scientific, or research channels;

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

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

10 “(iv) such other conduct which may
11 threaten the public health and safety.

12 “(2) REGISTRATION OF DISTRIBUTORS.—

13 “(A) IN GENERAL.—Beginning not later
14 than the day that is 1 year after the date of en-
15 actment of the Medical Marijuana Research
16 Act, the Attorney General shall register an ap-
17 plicant to distribute marijuana (including any
18 derivative, extract, preparation, and compound
19 thereof) that is intended for the ultimate and
20 exclusive use by qualified marijuana researchers
21 for research pursuant to subsection (f)(3) or in-
22 tended for subsequent downstream manufacture
23 by a duly registered manufacturer for use by
24 qualified marijuana researchers for research
25 pursuant to such subsection, unless the Attor-

1 ney General determines that the issuance of
2 such registration is inconsistent with the public
3 interest.

4 “(B) PUBLIC INTEREST.—In determining
5 the public interest under subparagraph (A), the
6 Attorney General shall take into consider-
7 ation—

8 “(i) the factors specified in clauses (i),
9 (ii), (iii), and (iv) of paragraph (1)(B); and

10 “(ii) past experience in the distribu-
11 tion of controlled substances, and the exist-
12 ence of effective controls against diversion.

13 “(3) NO LIMIT ON NUMBER OF MANUFACTUR-
14 ERS AND DISTRIBUTORS.—Notwithstanding any
15 other provision of law, the Attorney General shall
16 not impose or implement any limit on the number of
17 persons eligible to be registered to manufacture or
18 distribute marijuana pursuant to paragraph (1) or
19 (2).

20 “(4) REQUIREMENT TO VERIFY USE FOR LE-
21 GITIMATE RESEARCH.—As a condition of registra-
22 tion under this section to manufacture or distribute
23 marijuana, the Attorney General shall require the
24 registrant—

1 “(A) to require any person to whom the
2 marijuana will be supplied to submit docu-
3 mentation demonstrating that the marijuana
4 (including any derivative, extract, preparation,
5 and compound thereof) will be ultimately used
6 exclusively by qualified marijuana researchers
7 for research pursuant to subsection (f)(3) or for
8 subsequent downstream manufacture by a duly
9 registered manufacturer for use by qualified
10 marijuana researchers for research pursuant to
11 such subsection;

12 “(B) in the case of distribution, to com-
13 plete, with respect to that distribution, the ap-
14 propriate order form in accordance with section
15 308 and to upload such forms to the system
16 used by the Drug Enforcement Administration
17 for such distribution;

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

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

23 “(ii) the name of the requestor of the
24 marijuana;

1 “(D) to limit the transfer and sale of any
2 marijuana under this subsection—

3 “(i) to researchers who are registered
4 under this Act to conduct research with
5 marijuana or to manufacturers duly reg-
6 istered under this subsection; and

7 “(ii) for purposes of use in preclinical
8 research or in a clinical investigation pur-
9 suant to an investigational new drug ex-
10 emption under 505(i) of the Federal Food,
11 Drug, and Cosmetic Act or for the pur-
12 poses of further manufacturing of mari-
13 juana; and

14 “(E) to transfer or sell any marijuana
15 manufactured under this subsection only with
16 prior, written consent for the transfer or sale by
17 the Attorney General.

18 “(5) TIMING.—Not later than 60 days after re-
19 ceipt of a request for registration under this sub-
20 section to manufacture or distribute marijuana, the
21 Attorney General shall—

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

23 “(B) in the case of a denial, provide a
24 written explanation of the basis for the denial.

1 “(6) DEEMED APPROVAL.—If the Attorney
2 General fails to grant or deny a request for registra-
3 tion under this subsection to manufacture or dis-
4 tribute marijuana within the 60-day period referred
5 to in paragraph (5), such request is deemed ap-
6 proved.”.

7 **SEC. 4. TERMINATION OF INTERDISCIPLINARY REVIEW**
8 **PROCESS FOR NON-NIH-FUNDED QUALIFIED**
9 **MARIJUANA RESEARCHERS.**

10 The Secretary of Health and Human Services may
11 not—

12 (1) reinstate the Public Health Service inter-
13 disciplinary review process described in the guidance
14 entitled “Guidance on Procedures for the Provision
15 of Marijuana for Medical Research” (issued on May
16 21, 1999); or

17 (2) create an additional review of scientific pro-
18 tocols that is only conducted for research on mari-
19 juana other than the review of research protocols
20 performed at the request of a qualified marijuana
21 researcher conducting nonhuman research that is
22 not federally funded, in accordance with section
23 303(f)(3)(A) of the Controlled Substances Act, as
24 added by section 2 of this Act.

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

2 Immediately upon the approval by the Food and
3 Drug Administration of an application for a drug that
4 contains marijuana (as defined in section 102 of the Con-
5 trolled Substances Act (21 U.S.C. 802), as amended by
6 section 8 of this Act) under section 505 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355), and (irre-
8 spective of whether any such approval is granted) not later
9 than the date that is 5 years after the date of enactment
10 of this Act, the Secretary of Health and Human Services
11 shall—

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

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

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

1 **SEC. 6. PRODUCTION QUOTAS FOR MARIJUANA GROWN**
2 **FOR 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 fol-
5 lowing:

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

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

13 Article 28 of the Single Convention on Narcotic
14 Drugs shall not be construed to prohibit, or impose addi-
15 tional restrictions upon, research involving marijuana, or
16 the manufacture, distribution, or dispensing of marijuana,
17 that is conducted in accordance with the Controlled Sub-
18 stances Act (21 U.S.C. 801 et seq.), this Act, and the
19 amendments made by this Act.

20 **SEC. 8. DEFINITIONS.**

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

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

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

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

9 **SEC. 9. DETERMINATION OF BUDGETARY EFFECTS.**

10 The budgetary effects of this Act, for the purpose of
11 complying with the Statutory Pay-As-You-Go Act of 2010,
12 shall be determined by reference to the latest statement
13 titled “Budgetary Effects of PAYGO Legislation” for this
14 Act, submitted for printing in the Congressional Record
15 by the Chairman of the House Budget Committee, pro-
16 vided that such statement has been submitted prior to the
17 vote on passage.

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