



(Original Signature of Member)

117TH CONGRESS  
1ST SESSION

**H. R.**

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

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IN THE HOUSE OF REPRESENTATIVES

Mr. BLUMENAUER introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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**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—

1           (1) until the date on which the Secretary deter-  
2 mines that manufacturers and distributors (other  
3 than the Federal Government) can ensure a suffi-  
4 cient supply of marijuana (as defined in section 102  
5 of the Controlled Substances Act (21 U.S.C. 802),  
6 as amended by section 8) intended for research by  
7 qualified marijuana researchers registered pursuant  
8 to paragraph (3) of section 303(f) of the Controlled  
9 Substances Act (21 U.S.C. 823(f)), as added by sec-  
10 tion 3, shall—

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

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

24           (i) available through State-authorized  
25 marijuana programs; and

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

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

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

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

12 (B) to implement such specialized process.

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

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

1 of the Controlled Substances Act, as added by sec-  
2 tion 3 of this Act; and

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

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

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

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

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

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

23 “(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.