

116<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 3797

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IN THE SENATE OF THE UNITED STATES

DECEMBER 10, 2020

Received

DECEMBER 18, 2020

Read twice and referred to the Committee on the Judiciary

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## AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medical Marijuana Re-  
3 search Act”.

4 **SEC. 2. FACILITATING MARIJUANA RESEARCH.**

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

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

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

21 (B) not later than one year after the date  
22 of enactment of this Act, act jointly with the  
23 Attorney General of the United States to estab-  
24 lish and implement a specialized process for  
25 manufacturers and distributors, notwith-  
26 standing the registration requirements of sec-

1           tion 303 of such Act (21 U.S.C. 823), to supply  
2           qualified marijuana researchers with marijuana  
3           products—

4                   (i) available through State-authorized  
5                   marijuana programs; and

6                   (ii) consistent with the guidance  
7                   issued under subsection (c); and

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

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

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

17                   (B) to implement such specialized process.

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

24                   (1) require the person to submit documentation  
25                   demonstrating that the person is a qualified mari-

1       juana researcher seeking to conduct research pursu-  
2       ant to section 303(f)(3) of the Controlled Substances  
3       Act, as added by subsection (d) of this section, or  
4       a manufacturer duly registered under section 303(l)  
5       of the Controlled Substances Act, as added by sec-  
6       tion 3 of this Act; and

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

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

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

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

23               (2) by striking “(f) The Attorney General” and  
24               inserting “(f)(1) The Attorney General”;

1           (3) by striking “Registration applications” and  
2 inserting the following:

3           “(2) Registration applications”;

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

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

9           “(4) Article 7”; and

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

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

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

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

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

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

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

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

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

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

21                   “(i) The applicant’s experience in dispensing, or  
22           conducting research with respect to, controlled sub-  
23           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 or local  
5           laws relating to controlled substance misuse or diver-  
6           sion.

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

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

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

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

1 juana, the source of the marijuana, or the conditions  
2 under which the marijuana is stored, tracked, or adminis-  
3 tered.

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

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

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

23       “(iv) The Attorney General may object to an amend-  
24 ed or supplemental protocol or a new research protocol



1 under clause (i) or (iii) only if additional security meas-  
2 ures are needed to safeguard against diversion or abuse.

3 “(G) If marijuana is listed on a schedule other than  
4 schedule I, the provisions of paragraphs (1), (2), and (4)  
5 that apply to research with a controlled substance in the  
6 applicable schedule shall apply to research with marijuana  
7 or that compound, as applicable, in lieu of the provisions  
8 of subparagraphs (A) through (F) of this paragraph.

9 “(H) Nothing in this paragraph shall be construed  
10 as limiting the authority of the Secretary under section  
11 505(i) of the Federal Food, Drug, and Cosmetic Act or  
12 over requirements related to research protocols, including  
13 changes in—

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

15 “(ii) the dosing of marijuana; and

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

18 **SEC. 3. MANUFACTURE AND DISTRIBUTION OF MARIJUANA**

19 **FOR USE IN LEGITIMATE RESEARCH.**

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

23 “(1) REGISTRATION OF PERSONS TO MANUFACTURE  
24 AND DISTRIBUTE MARIJUANA FOR USE IN LEGITIMATE  
25 RESEARCH.—

1 “(1) REGISTRATION OF MANUFACTURERS.—

2 “(A) IN GENERAL.—Beginning not later  
3 than the day that is 1 year after the date of en-  
4 actment of the Medical Marijuana Research  
5 Act, the Attorney General, pursuant to sub-  
6 section (f)(3) and subject to subparagraph (B)  
7 of this paragraph, shall register an applicant to  
8 manufacture marijuana (including any deriva-  
9 tive, extract, preparation, and compound there-  
10 of) that is intended for—

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

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

19 “(B) PUBLIC INTEREST.—The Attorney  
20 General shall register an applicant under sub-  
21 paragraph (A) unless the Attorney General de-  
22 termines that the issuance of such registration  
23 is inconsistent with the public interest. In deter-  
24 mining the public interest, the Attorney General  
25 shall 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 laws relating to controlled sub-  
8           stance misuse and diversion;

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

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

15          “(2) REGISTRATION OF DISTRIBUTORS.—

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

1 by a duly registered manufacturer for use by  
2 qualified marijuana researchers for research  
3 pursuant to such subsection, unless the Attor-  
4 ney General determines that the issuance of  
5 such registration is inconsistent with the public  
6 interest.

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

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

13 “(ii) past experience in the distribu-  
14 tion of controlled substances, and the exist-  
15 ence of effective controls against diversion.

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

23 “(4) REQUIREMENT TO VERIFY USE FOR LE-  
24 GITIMATE RESEARCH.—As a condition of registra-  
25 tion under this section to manufacture or distribute

1 marijuana, the Attorney General shall require the  
2 registrant—

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

14 “(B) in the case of distribution, to com-  
15 plete, with respect to that distribution, the ap-  
16 propriate order form in accordance with section  
17 308 and to upload such forms to the system  
18 used by the Drug Enforcement Administration  
19 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 biomedical and scientific re-  
24 search purposes only.’; and

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

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

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

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

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

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

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

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

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

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

12           The Secretary of Health and Human Services may  
13 not—

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

19           (2) create an additional review of scientific pro-  
20           tocols that is only conducted for research on mari-  
21           juana other than the review of research protocols  
22           performed at the request of a qualified marijuana  
23           researcher conducting nonhuman research that is  
24           not federally funded, in accordance with section

1       303(f)(3)(A) of the Controlled Substances Act, as  
2       added by section 2 of this Act.

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

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

18           (3) include in such report whether, taking into  
19       consideration the factors listed in section 201(e) of  
20       the Controlled Substances Act (21 U.S.C. 811(c)),  
21       as well as any potential for medical benefits, any  
22       gaps in research, and any impacts of Federal restric-  
23       tions and policy on research, marijuana should be  
24       transferred to a schedule other than schedule I (if  
25       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.

