

114TH CONGRESS
2D SESSION

H. R. 5549

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 21, 2016

Mr. HARRIS (for himself, Mr. BLUMENAUER, Mr. GRIFFITH, and Mr. FARR) 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 medical marijuana researchers, 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 2016”.

6 **SEC. 2. PRODUCTION AND SUPPLY.**

7 (a) IN GENERAL.—The Secretary of Health and
8 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 for qualified medical mari-
5 juana researchers, shall—

6 (A) continue to produce marijuana through
7 the National Institute on Drug Abuse (NIDA)
8 Drug Supply Program; and

9 (B) offer for sale immature marijuana
10 plants and the seeds of marijuana—

11 (i) to all qualified medical marijuana
12 researchers who submit a request for such
13 plants or seeds to engage in research pur-
14 suant to the section 303(f)(3) of the Con-
15 trolled Substances Act, as amended by sec-
16 tion 3; and

17 (ii) in quantities sufficient to produce
18 an adequate supply of marijuana for such
19 research; and

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

23 (b) REQUIREMENT TO VERIFY REGISTRATION.—Be-
24 fore supplying marijuana to any person through the Na-

1 tional Institute on Drug Abuse Drug Supply Program, the
2 Secretary of Health and Human Services shall—

3 (1) require the person to submit documentation
4 demonstrating that the person is a qualified medical
5 marijuana researcher seeking to conduct research
6 pursuant to the section 303(f)(3) of the Controlled
7 Substances Act, as amended by section 3; and

8 (2) not later than 30 days after receipt of such
9 documentation, review such documentation and
10 verify that the marijuana will be used for such re-
11 search.

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

15 (1) not later than 180 days after the date of
16 enactment of this Act, issue guidelines on the pro-
17 duction of marijuana by qualified medical marijuana
18 researchers pursuant to subsection (a)(1)(B); and

19 (2) encourage researchers and manufacturers
20 that are authorized to produce or manufacture mari-
21 juana pursuant to section 303 of the Controlled
22 Substances Act (21 U.S.C. 823), as amended by this
23 Act, to comply with such guidelines to the extent ap-
24 plicable.

25 (d) DEFINITION.—In this section:

1 (1) The term “immature marijuana plant”
2 means a marijuana plant with no observable flowers
3 or buds.

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

9 **SEC. 3. FACILITATING MARIJUANA RESEARCH.**

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

12 (1) by redesignating paragraphs (1) through
13 (5) 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
21 inserting “schedule I, except marijuana,”;

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

24 “(4) Article 7”; and

1 (6) by inserting before paragraph (4), as so
2 designated, 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 sub-
7 stances in schedules II, III, IV, and V under the
8 laws of the State in which the applicant practices;

9 “(ii) the applicant’s research protocol—

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

11 “(aa) the Secretary under section
12 505(i) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 355(i)); or

14 “(bb) the National Institutes of
15 Health or another Federal agency that
16 funds scientific research; or

17 “(II) in the case of nonhuman research
18 that is not federally funded, has been volun-
19 tarily submitted by the applicant to, and ap-
20 proved by, the National Institutes of Health;
21 and

22 “(iii) the applicant has demonstrated that there
23 are effective procedures in place to adequately safe-
24 guard against diversion of the marijuana from legiti-

1 mate medical or scientific use, in accordance with
2 subparagraph (E).

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

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

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

15 “(iii) Compliance with applicable State, Fed-
16 eral, or local laws relating to controlled substances.

17 “(iv) Such other conduct by the applicant that
18 may threaten the public health and safety.

19 “(C) Not later than 90 days after the date of enact-
20 ment of the Medical Marijuana Research Act of 2016, for
21 purposes of subparagraph (A)(ii)(II), the National Insti-
22 tutes of Health shall establish a process that—

23 “(i) allows a researcher to voluntarily submit
24 the research protocol of the researcher for review
25 and approval; and

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

4 “(D)(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 “(E)(i) A researcher registered under this paragraph
13 shall store marijuana to be used in research in a securely
14 locked, substantially constructed cabinet.

15 “(ii) Except as provided in clause (i), any security
16 measures required by the Attorney General for practi-
17 tioners conducting research with marijuana pursuant to
18 a registration under this paragraph shall be consistent
19 with the security measures for practitioners conducting re-
20 search on other controlled substances in schedule II that
21 have a similar risk of diversion and abuse.

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

1 “(I) change the type of drug, the source of the
2 drug, or the conditions under which the drug is
3 stored, tracked, or administered; or

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

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

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

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

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

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

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

16 **SEC. 4. MANUFACTURE AND DISTRIBUTION OF MARIJUANA**
17 **FOR USE IN LEGITIMATE, MEDICAL RE-**
18 **SEARCH.**

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

22 “(k) REGISTRATION OF PERSONS TO MANUFACTURE
23 AND DISTRIBUTE MARIJUANA FOR USE IN LEGITIMATE,
24 MEDICAL RESEARCH.—

1 “(1) REGISTRATION OF MANUFACTURERS.—Be-
2 ginning not later than the day that is 1 year after
3 the date of enactment of the Medical Marijuana Re-
4 search Act of 2016, the Attorney General shall reg-
5 ister an applicant to manufacture marijuana to the
6 extent the marijuana will be used exclusively by
7 qualified medical marijuana researchers for research
8 pursuant to subsection (f)(3), unless the Attorney
9 General determines that the issuance of such reg-
10 istration is inconsistent with the public interest. In
11 determining the public interest, the Attorney Gen-
12 eral shall—

13 “(A) take into consideration—

14 “(i) maintenance of effective controls
15 against diversion of marijuana and any
16 controlled substance compounded there-
17 from into other than legitimate medical,
18 scientific, or research channels;

19 “(ii) compliance with applicable State
20 and local law; and

21 “(iii) prior conviction record of the
22 applicant under Federal or State laws re-
23 lating to the manufacture, distribution, or
24 dispensing of such substances; and

1 “(B) not take into consideration any fac-
2 tors other than the factors listed in subpara-
3 graph (A).

4 “(2) REGISTRATION OF DISTRIBUTORS.—Begin-
5 ning not later than the day that is 1 year after the
6 date of enactment of the Medical Marijuana Re-
7 search Act of 2016, the Attorney General shall reg-
8 ister an applicant to distribute marijuana that is in-
9 tended to be used exclusively by qualified medical
10 marijuana researchers for research pursuant to sub-
11 section (f)(3), unless the Attorney General deter-
12 mines that the issuance of such registration is incon-
13 sistent with the public interest. In determining the
14 public interest, the Attorney General shall—

15 “(A) take into consideration—

16 “(i) maintenance of effective controls
17 against diversion of marijuana and any
18 controlled substance compounded there-
19 from into other than legitimate medical,
20 scientific, or research channels;

21 “(ii) compliance with applicable State
22 and local law;

23 “(iii) prior conviction record of the
24 applicant under Federal or State laws re-

1 lating to the manufacture, distribution, or
2 dispensing of such substances; and

3 “(iv) past experience in the distribu-
4 tion of controlled substances, and the exist-
5 ence in the establishment of effective con-
6 trols against diversion; and

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

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

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

22 “(A) to require any person to whom the
23 marijuana will be supplied to submit docu-
24 mentation demonstrating that the marijuana
25 will be used exclusively by qualified medical

1 marijuana researchers for research pursuant to
2 subsection (f)(3); and

3 “(B) 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 “(5) 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 “(6) DEFINITION.—For purposes of this sub-
16 section, the term ‘qualified medical marijuana re-
17 searcher’ means a researcher who is registered to
18 conduct research with marijuana under subsection
19 (f)(3).”.

20 **SEC. 5. TERMINATION OF INTERDISCIPLINARY REVIEW**
21 **PROCESS FOR NON-NIH-FUNDED RESEARCH-**
22 **ERS.**

23 The Secretary of Health and Human Services may
24 not—

1 (1) reinstate the Public Health Service inter-
2 disciplinary review process described in the guidance
3 entitled “Guidance on Procedures for the Provision
4 of Marijuana for Medical Research” (issued on May
5 21, 1999); or

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

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

15 Immediately upon the approval by the Food and
16 Drug Administration of an application for a marijuana-
17 based drug under section 505 of the Federal Food, Drug,
18 and Cosmetic Act (21 U.S.C. 355), and (irrespective of
19 whether any such approval is granted) not later than the
20 date that is 5 years after the date of enactment of this
21 Act, the Secretary of Health and Human Services shall—

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

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

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

9 **SEC. 7. NO PRODUCTION QUOTAS FOR MARIJUANA GROWN**
10 **FOR LEGITIMATE, MEDICAL RESEARCH.**

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

14 “(i) The Attorney General may only establish a quota
15 for production of marijuana that is manufactured and dis-
16 tributed in accordance with the Medical Marijuana Re-
17 search Act of 2016 that meets the changing medical, sci-
18 entific, and industrial needs for marijuana.”.

19 **SEC. 8. ARTICLE 28 OF THE SINGLE CONVENTION ON NAR-**
20 **COTIC DRUGS.**

21 Article 28 of the Single Convention on Narcotic
22 Drugs shall not be construed to prohibit, or impose addi-
23 tional restrictions upon, research involving marijuana, or
24 the manufacture, distribution, or dispensing of marijuana,
25 that is conducted in accordance with the Controlled Sub-

1 stances Act (21 U.S.C. 801 et seq.), this Act, and the
2 amendments made by this Act.

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

4 The Attorney General of the United States, and any
5 officer or employee of the Department of Justice, shall not
6 interfere with the production, distribution, and sale of
7 marijuana in accordance with this Act and the amend-
8 ments made by this Act.

9 **SEC. 10. DEFINITION.**

10 In this Act, the term “marijuana” has the meaning
11 given to that term in section 102 of the Controlled Sub-
12 stances Act (21 U.S.C. 802).

○