

116TH CONGRESS
1ST SESSION

S. 2032

To expand research on the cannabidiol and marihuana.

IN THE SENATE OF THE UNITED STATES

JUNE 27, 2019

Mrs. FEINSTEIN (for herself, Mr. GRASSLEY, Mr. SCHATZ, Mr. DURBIN, Ms. KLOBUCHAR, Mr. TILLIS, Mr. KAINE, Ms. ERNST, and Mr. CRAMER) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To expand research on the cannabidiol and marihuana.

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Cannabidiol and Marihuana Research Expansion Act”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Definitions.

TITLE I—REGISTRATIONS FOR MARIHUANA RESEARCH

Sec. 101. Marihuana research applications.
Sec. 102. Research protocols.
Sec. 103. Applications to manufacture marihuana for research.

Sec. 104. Adequate and uninterrupted supply.

Sec. 105. Security requirements.

Sec. 106. Prohibition against reinstating interdisciplinary review process for non-NIH funded researchers.

TITLE II—DEVELOPMENT OF FDA-APPROVED DRUGS USING
CANNABIDIOL AND MARIHUANA

Sec. 201. Medical research on cannabidiol.

Sec. 202. Registration for the commercial production and distribution of Food and Drug Administration approved drugs.

Sec. 203. Importation of cannabidiol for research purposes.

TITLE III—DOCTOR-PATIENT RELATIONSHIP

Sec. 301. Doctor-patient relationship.

TITLE IV—FEDERAL RESEARCH

Sec. 401. Federal research.

1 **SEC. 2. DEFINITIONS.**

2 In this Act—

3 (1) the term “appropriately registered” means
4 that an individual or entity is registered under the
5 Controlled Substances Act (21 U.S.C. 801 et seq.)
6 to engage in the type of activity that is carried out
7 by the individual or entity with respect to a con-
8 trolled substance on the schedule that is applicable
9 to cannabidiol or marihuana, as applicable;

10 (2) the term “cannabidiol” means—

11 (A) the substance, cannabidiol, as derived
12 from marihuana that has a tetrahydrocan-
13 nabinol level that is greater than 0.3 percent;
14 and

15 (B) the synthetic equivalent of the sub-
16 stance described in subparagraph (A);

1 (3) the terms “controlled substance”, “dis-
2 pense”, “distribute”, “manufacture”, “marihuana”,
3 and “practitioner” have the meanings given such
4 terms in section 102 of the Controlled Substances
5 Act (21 U.S.C. 802), as amended by this Act;

6 (4) the term “covered institution of higher edu-
7 cation” means an institution of higher education (as
8 defined in section 101 of the Higher Education Act
9 of 1965 (20 U.S.C. 1001)) that—

10 (A)(i) has highest or higher research activ-
11 ity, as defined by the Carnegie Classification of
12 Institutions of Higher Education; or

13 (ii) is an accredited medical school or an
14 accredited school of osteopathic medicine; and

15 (B) is appropriately registered under the
16 Controlled Substances Act (21 U.S.C. 801 et
17 seq.);

18 (5) the term “drug” has the meaning given the
19 term in section 201(g)(1) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 321(g)(1));

21 (6) the term “medical research for drug devel-
22 opment” means medical research that is—

23 (A) a preclinical study or clinical investiga-
24 tion conducted in accordance with section
25 505(i) of the Federal Food, Drug, and Cos-

1 metec Act (21 U.S.C. 355(i)) or otherwise per-
 2 mitted by the Department of Health and
 3 Human Services to determine the potential
 4 medical benefits of marihuana or cannabidiol as
 5 a drug; and

6 (B) conducted by a covered institution of
 7 higher education, practitioner, or manufacturer
 8 that is appropriately registered under the Con-
 9 trolled Substances Act (21 U.S.C. 801 et seq.);
 10 and

11 (7) the term “State” means any State of the
 12 United States, the District of Columbia, and any
 13 territory of the United States.

14 **TITLE I—REGISTRATIONS FOR**
 15 **MARIHUANA RESEARCH**

16 **SEC. 101. MARIHUANA RESEARCH APPLICATIONS.**

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

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

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

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

25 “(2)(A) Registration applications”;

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

3 “(3) Article 7”; and

4 (5) by inserting after paragraph (2)(A), as so
5 designated, the following:

6 “(B)(i) The Attorney General shall register a practi-
7 tioner to conduct research with marihuana if—

8 “(I) the applicant’s research protocol—

9 “(aa) has been reviewed and allowed—

10 “(AA) by the Secretary of Health and
11 Human Services under section 505(i) of
12 the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 355(i));

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

17 “(CC) pursuant to sections 1301.18
18 and 1301.32 of title 21, Code of Federal
19 Regulations, or any successors thereto; and

20 “(II) the applicant has demonstrated to the At-
21 torney General that there are effective procedures in
22 place to adequately safeguard against diversion of
23 the controlled substance for legitimate medical or
24 scientific use pursuant to section 105 of the
25 Cannabidiol and Marihuana Research Expansion

1 Act, including demonstrating that the security meas-
2 ures are adequate for storing the quantity of mari-
3 huana the applicant would be authorized to possess.

4 “(ii) The Attorney General may deny an application
5 for registration under this subparagraph only if the Attor-
6 ney General determines that the issuance of the registra-
7 tion would be inconsistent with the public interest. In de-
8 termining the public interest, the Attorney General shall
9 consider the factors listed in—

10 “(I) subparagraphs (B) through (E) of para-
11 graph (1); and

12 “(II) subparagraph (A) of paragraph (1), if the
13 applicable State requires practitioners conducting re-
14 search to register with a board or authority de-
15 scribed in such subparagraph (A).

16 “(iii)(I) Not later than 60 days after the date on
17 which the Attorney General receives a complete applica-
18 tion for registration under this subparagraph, the Attor-
19 ney General shall—

20 “(aa) approve the application; or

21 “(bb) request supplemental information.

22 “(II) For purposes of subclause (I), an application
23 shall be deemed complete when the applicant has sub-
24 mitted documentation showing that the requirements
25 under clause (i) are satisfied.

1 “(iv) Not later than 30 days after the date on which
2 the Attorney General receives supplemental information as
3 described in clause (iii)(I)(bb) in connection with an appli-
4 cation described in this subparagraph, the Attorney Gen-
5 eral shall approve or deny the application.

6 “(v) If an application described in this subparagraph
7 is denied, the Attorney General shall provide a written ex-
8 planation of the basis of denial to the applicant.”.

9 **SEC. 102. RESEARCH PROTOCOLS.**

10 (a) IN GENERAL.—Paragraph (2)(B) of section 303
11 of the Controlled Substances Act (21 U.S.C. 823(f)), as
12 amended by section 101 of this Act, is further amended
13 by adding at the end the following:

14 “(vi)(I) If the Attorney General grants an application
15 for registration under clause (i), the registrant may amend
16 or supplement the research protocol without reapplying if
17 the registrant does not change—

18 “(aa) the quantity or type of drug;

19 “(bb) the source of the drug; or

20 “(cc) the conditions under which the drug is
21 stored, tracked, or administered.

22 “(II)(aa) If a registrant under clause (i) seeks to
23 change the type of drug, the source of the drug, or condi-
24 tions under which the drug is stored, tracked, or adminis-
25 tered, the registrant shall notify the Attorney General via

1 registered mail, or an electronic means permitted by the
2 Attorney General, not later than 30 days before imple-
3 menting an amended or supplemental research protocol.

4 “(bb) A registrant may proceed with an amended or
5 supplemental research protocol described in item (aa) if
6 the Attorney General does not explicitly object during the
7 30-day period beginning on the date on which the Attorney
8 General receives the notice under item (aa).

9 “(cc) The Attorney General may only object to an
10 amended or supplemental research protocol under this
11 subclause if additional security measures are needed to
12 safeguard against diversion or abuse.

13 “(dd) If a registrant under clause (i) seeks to address
14 additional security measures identified by the Attorney
15 General under item (cc), the registrant shall notify the At-
16 torney General via registered mail, or an electronic means
17 permitted by the Attorney General, not later than 30 days
18 before implementing an amended or supplemental research
19 protocol.

20 “(ee) A registrant may proceed with an amended or
21 supplemental research protocol described in item (dd) if
22 the Attorney General does not explicitly object during the
23 30-day period beginning on the date on which the Attorney
24 General receives the notice under item (dd).

1 “(III) If a registrant under clause (i) seeks to change
2 the quantity of marihuana needed for research, the change
3 shall be deemed approved by the Attorney General on the
4 date on which the registered mail return receipt is re-
5 turned to the registrant, or the date on which the elec-
6 tronic notification, as permitted by the Attorney General,
7 is received, if the registrant submits to the Attorney Gen-
8 eral—

9 “(aa) the Drug Enforcement Administration
10 registration number of the registrant;

11 “(bb) the quantity of marihuana already ob-
12 tained; and

13 “(cc) the quantity of additional marihuana
14 needed to complete the research.

15 “(IV) Nothing in this clause shall limit the authority
16 of the Secretary of Health and Human Services over re-
17 quirements related to research protocols, including
18 changes in—

19 “(aa) the method of administration of mari-
20 huana;

21 “(bb) the dosing of marihuana; and

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

24 (b) REGULATIONS.—Not later than 1 year after the
25 date of enactment of this Act, the Attorney General shall

1 promulgate regulations to carry out the amendment made
2 by this section.

3 **SEC. 103. APPLICATIONS TO MANUFACTURE MARIHUANA**
4 **FOR RESEARCH.**

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

7 (1) by redesignating subsections (c) through (k)
8 as subsections (d) through (l), respectively;

9 (2) by inserting after subsection (b) the fol-
10 lowing:

11 “(c)(1)(A) As it relates to applications to manufac-
12 ture marihuana for research purposes, if the Attorney
13 General places a notice in the Federal Register to increase
14 the number of entities registered under this Act to manu-
15 facture marihuana to supply appropriately registered re-
16 searchers in the United States, the Attorney General shall,
17 not later than 60 days after the date on which the Attor-
18 ney General receives a completed application—

19 (i) approve the application; or

20 (ii) request supplemental information.

21 “(B) For purposes of subparagraph (A), an applica-
22 tion shall be deemed complete when the applicant has sub-
23 mitted documentation showing each of the following:

24 (i) The requirements designated in the notice
25 in the Federal Register are satisfied.

1 “(ii) The requirements under this Act are satis-
2 fied.

3 “(iii) The applicant will limit the transfer and
4 sale of any marihuana manufactured under this sub-
5 section—

6 “(I) to researchers who are registered
7 under this Act to conduct research with con-
8 trolled substances in schedule I; and

9 “(II) for purposes of use in preclinical re-
10 search or in a clinical investigation pursuant to
11 an investigational new drug exemption under
12 505(i) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 355(i)).

14 “(iv) The applicant will transfer or sell any
15 marihuana manufactured under this subsection only
16 with prior, written consent for the transfer or sale
17 by the Attorney General.

18 “(v) The applicant has completed the applica-
19 tion and review process under subsection (a) for the
20 bulk manufacture of controlled substances in sched-
21 ule I.

22 “(vi) The applicant has established and begun
23 operation of a process for storage and handling of
24 controlled substances in schedule I, including for in-
25 ventory control and monitoring security in accord-

1 ance with section 105 of the Cannabidiol and Mari-
2 huana Research Expansion Act.

3 “(vii) The applicant is licensed by each State in
4 which the applicant will conduct operations under
5 this subsection, to manufacture marihuana, if that
6 State requires such a license.

7 “(C) Not later than 30 days after the date on which
8 the Attorney General receives supplemental information
9 requested under subparagraph (A)(ii) with respect to an
10 application, the Attorney General shall approve or deny
11 the application.

12 “(2) If an application described in this subsection is
13 denied, the Attorney General shall provide a written expla-
14 nation of the basis of denial to the applicant.”;

15 (3) in subsection (h)(2), as so redesignated, by
16 striking “subsection (f)” each place it appears and
17 inserting “subsection (g)”;

18 (4) in subsection (j)(1), as so redesignated, by
19 striking “subsection (d)” and inserting “subsection
20 (e)”;

21 (5) in subsection (k), as so redesignated, by
22 striking “subsection (f)” each place it appears and
23 inserting “subsection (g)”.

24 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

1 (1) The Controlled Substances Act (21 U.S.C.
2 801 et seq.) is amended—

3 (A) in section 102 (21 U.S.C. 802)—

4 (i) in paragraph (16)(B)—

5 (I) in clause (i), by striking “or”
6 at the end;

7 (II) by redesignating clause (ii)
8 as (iii); and

9 (III) by inserting after clause (i)
10 the following:

11 “(ii) the synthetic equivalent of hemp-de-
12 rived cannabidiol that contains less than 0.3
13 percent tetrahydrocannabinol; or”;

14 (ii) in paragraph (52)(B)—

15 (I) by striking “303(f)” each
16 place it appears and inserting
17 “303(g)”; and

18 (II) in clause (i), by striking
19 “(d), or (e)” and inserting “(e), or
20 (f)”; and

21 (iii) in paragraph (54), by striking
22 “303(f)” each place it appears and insert-
23 ing “303(g)”;

1 (B) in section 304 (21 U.S.C. 824), by
2 striking “303(g)(1)” each place it appears and
3 inserting “303(h)(1)”;

4 (C) in section 307(d)(2) (21 U.S.C.
5 827(d)(2)), by striking “303(f)” and inserting
6 “303(g)”;

7 (D) in section 311(h) (21 U.S.C. 831(h)),
8 by striking “303(f)” each place it appears and
9 inserting “303(g)”;

10 (E) in section 401(h)(2) (21 U.S.C.
11 841(h)(2)), by striking “303(f)” each place it
12 appears and inserting “303(g)”;

13 (F) in section 403(c)(2)(B) (21 U.S.C.
14 843(c)(2)(B)), by striking “303(f)” and insert-
15 ing “303(g)”;

16 (G) in section 512(c)(1) (21 U.S.C.
17 882(c)(1)) by striking “303(f)” and inserting
18 “303(g)”.

19 (2) Section 1008(e) of the Controlled Sub-
20 stances Import and Export Act (21 U.S.C. 958(e))
21 is amended—

22 (A) in paragraph (1), by striking “303(d)”
23 and inserting “303(e)”;

24 (B) in paragraph (2)(B), by striking
25 “303(h)” and inserting “303(i)”.

1 (3) Title V of the Public Health Service Act (42
2 U.S.C. 290aa et seq.) is amended—

3 (A) in section 520E–4(c) (42 U.S.C.
4 290bb–36d(c)), by striking “303(g)(2)(B)” and
5 inserting “303(h)(2)(B)”; and

6 (B) in section 544(a)(3) (42 U.S.C.
7 290dd–3(a)(3)), by striking “303(g)” and in-
8 serting “303(h)”.

9 **SEC. 104. ADEQUATE AND UNINTERRUPTED SUPPLY.**

10 On an annual basis, the Attorney General shall assess
11 whether there is an adequate and uninterrupted supply of
12 marihuana, including of specific strains, for research pur-
13 poses.

14 **SEC. 105. SECURITY REQUIREMENTS.**

15 (a) IN GENERAL.—An individual or entity engaged
16 in researching marihuana or its components shall store it
17 in a securely locked, substantially constructed cabinet.

18 (b) REQUIREMENTS FOR OTHER MEASURES.—Any
19 other security measures required by the Attorney General
20 to safeguard against diversion shall be consistent with
21 those required for practitioners conducting research on
22 other controlled substances in schedules I and II in section
23 202(c) of the Controlled Substances Act (21 U.S.C.
24 812(c)) that have a similar risk of diversion and abuse.

1 **SEC. 106. PROHIBITION AGAINST REINSTATING INTER-**
 2 **DISCIPLINARY REVIEW PROCESS FOR NON-**
 3 **NIH FUNDED RESEARCHERS.**

4 The Secretary of Health and Human Services may
 5 not—

6 (1) reinstate the Public Health Service inter-
 7 disciplinary review process described in the guidance
 8 entitled “Guidance on Procedures for the Provision
 9 of Marijuana for Medical Research” (issued on May
 10 21, 1999); or

11 (2) require another review of scientific protocols
 12 that is applicable only to research on marihuana or
 13 its components.

14 **TITLE II—DEVELOPMENT OF**
 15 **FDA-APPROVED DRUGS**
 16 **USING CANNABIDIOL AND**
 17 **MARIHUANA**

18 **SEC. 201. MEDICAL RESEARCH ON CANNABIDIOL.**

19 Notwithstanding any provision of the Controlled Sub-
 20 stances Act (21 U.S.C. 801 et seq.), the Safe and Drug-
 21 Free Schools and Communities Act (20 U.S.C. 7101 et
 22 seq.), chapter 81 of title 41, United States Code, or any
 23 other Federal law, an appropriately registered covered in-
 24 stitution of higher education, a practitioner, or a manufac-
 25 turer may manufacture, distribute, dispense, or possess
 26 marihuana or cannabidiol if the marihuana or cannabidiol

1 is manufactured, distributed, dispensed, or possessed, re-
 2 spectively, for purposes of medical research for drug devel-
 3 opment or subsequent commercial production in accord-
 4 ance with section 202.

5 **SEC. 202. REGISTRATION FOR THE COMMERCIAL PRODUC-**
 6 **TION AND DISTRIBUTION OF FOOD AND**
 7 **DRUG ADMINISTRATION APPROVED DRUGS.**

8 The Attorney General shall register an applicant to
 9 manufacture or distribute cannabidiol or marihuana for
 10 the purpose of commercial production of a drug containing
 11 or derived from marihuana that is approved by the Sec-
 12 retary of Health and Human Services under section 505
 13 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 14 355), in accordance with the applicable requirements
 15 under subsection (a) or (b) of section 303 of the Con-
 16 trolled Substances Act (21 U.S.C. 823).

17 **SEC. 203. IMPORTATION OF CANNABIDIOL FOR RESEARCH**
 18 **PURPOSES.**

19 The Controlled Substances Import and Export Act
 20 (21 U.S.C. 951 et seq.) is amended—

21 (1) in section 1002(a) (21 U.S.C. 952(a))—

22 (A) in paragraph (1), by striking “and” at
 23 the end;

24 (B) in paragraph (2)(C), by inserting
 25 “and” after “uses,”; and

1 (C) inserting before the undesignated mat-
2 ter following paragraph (2)(C) the following:

3 “(3) such amounts of marihuana or cannabidiol
4 (as defined in section 2 of the Cannabidiol and Mar-
5 ihuana Research Expansion Act) as are—

6 “(A) approved for medical research for
7 drug development (as such terms are defined in
8 section 2 of the Cannabidiol and Marihuana Re-
9 search Expansion Act), or

10 “(B) necessary for registered manufactur-
11 ers to manufacture drugs containing marihuana
12 or cannabidiol that have been approved for use
13 by the Commissioner of Food and Drugs under
14 the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 301 et seq.),”; and

16 (2) in section 1007 (21 U.S.C. 957), by amend-
17 ing subsection (a) to read as follows:

18 “(a)(1) Except as provided in paragraph (2), no per-
19 son may—

20 “(A) import into the customs territory of the
21 United States from any place outside thereof (but
22 within the United States), or import into the United
23 States from any place outside thereof, any controlled
24 substance or list I chemical, or

1 “(B) export from the United States any con-
2 trolled substance or list I chemical,
3 unless there is in effect with respect to such person
4 a registration issued by the Attorney General under
5 section 1008, or unless such person is exempt from
6 registration under subsection (b).

7 “(2) Paragraph (1) shall not apply to the im-
8 port or export of marihuana or cannabidiol (as de-
9 fined in section 2 of the Cannabidiol and Marihuana
10 Research Expansion Act) that has been approved
11 for—

12 “(A) medical research for drug develop-
13 ment authorized under section 201 of the
14 Cannabidiol and Marihuana Research Expan-
15 sion Act; or

16 “(B) use by registered manufacturers to
17 manufacture drugs containing marihuana or
18 cannabidiol that have been approved for use by
19 the Commissioner of Food and Drugs under the
20 Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 301 et seq.).”.

1 **TITLE III—DOCTOR-PATIENT**
2 **RELATIONSHIP**

3 **SEC. 301. DOCTOR-PATIENT RELATIONSHIP.**

4 It shall not be unlawful for a State-licensed physician
5 to discuss—

6 (1) the currently known potential harms and
7 benefits of marihuana derivatives, including
8 cannabidiol, as a treatment with the legal guardian
9 of the patient of the physician if the patient is a
10 child; or

11 (2) the currently known potential harms and
12 benefits of marihuana and marihuana derivatives,
13 including cannabidiol, as a treatment with the pa-
14 tient or the legal guardian of the patient of the phy-
15 sician if the patient is a legal adult.

16 **TITLE IV—FEDERAL RESEARCH**

17 **SEC. 401. FEDERAL RESEARCH.**

18 (a) IN GENERAL.—Not later than 1 year after the
19 date of enactment of this Act, the Secretary of Health and
20 Human Services, in coordination with the Director of the
21 National Institutes of Health and the heads of other rel-
22 evant Federal agencies, shall submit to the Caucus on
23 International Narcotics Control, the Committee on the Ju-
24 diciary, and the Committee on Health, Education, Labor,
25 and Pensions of the Senate and the Committee on Energy

1 and Commerce and the Committee on the Judiciary of the
2 House of Representatives a report on—

3 (1) the potential therapeutic effects of
4 cannabidiol or marihuana on serious medical condi-
5 tions, including intractable epilepsy;

6 (2) the potential effects of marihuana, includ-
7 ing—

8 (A) the effect of increasing delta-9-
9 tetrahydrocannabinol levels on the human body
10 and developing adolescent brains; and

11 (B) the effect of various delta-9-
12 tetrahydrocannabinol levels on cognitive abili-
13 ties, such as those that are required to operate
14 motor vehicles or other heavy equipment; and

15 (3) the barriers associated with researching
16 marihuana or cannabidiol in States that have legal-
17 ized the use of such substances, which shall in-
18 clude—

19 (A) recommendations as to how such bar-
20 riers might be overcome, including whether pub-
21 lic-private partnerships or Federal-State re-
22 search partnerships may or should be imple-
23 mented to provide researchers with access to
24 additional strains of marihuana and
25 cannabidiol; and

1 (B) recommendations as to what safe-
2 guards must be in place to verify—

3 (i) the levels of tetrahydrocannabinol,
4 cannabidiol, or other cannabinoids con-
5 tained in products obtained from such
6 States is accurate; and

7 (ii) that such products do not contain
8 harmful or toxic components.

9 (b) ACTIVITIES.—To the extent practicable, the Sec-
10 retary of Health and Human Services, either directly or
11 through awarding grants, contracts, or cooperative agree-
12 ments, shall expand and coordinate the activities of the
13 National Institutes of Health and other relevant Federal
14 agencies to better determine the effects of cannabidiol and
15 marihuana, as outlined in the report submitted under
16 paragraphs (1) and (2) of subsection (a).

○