

114TH CONGRESS
2D SESSION

S. 3269

To require the Attorney General to make a determination as to whether cannabidiol should be a controlled substance and listed in a schedule under the Controlled Substances Act and to expand research on the potential medical benefits of cannabidiol and other marijuana components.

IN THE SENATE OF THE UNITED STATES

JULY 14, 2016

Mrs. FEINSTEIN (for herself, Mr. GRASSLEY, Mr. LEAHY, and Mr. TILLIS) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To require the Attorney General to make a determination as to whether cannabidiol should be a controlled substance and listed in a schedule under the Controlled Substances Act and to expand research on the potential medical benefits of cannabidiol and other marijuana components.

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 “Cannabidiol Research
5 Expansion Act”.

1 **SEC. 2. DEFINITIONS.**

2 In this Act—

3 (1) the term “authorized medical research”
4 means medical research that is—

5 (A) investigational use research conducted
6 in accordance with section 505(i) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C.
8 355(i)) or otherwise permitted by the Depart-
9 ment of Health and Human Services to deter-
10 mine the potential medical benefits of mari-
11 huana or cannabidiol as a drug;

12 (B) conducted in a State that allows the
13 manufacturing, distribution, dispensing, or pos-
14 session of, or research with respect to, mari-
15 huana or cannabidiol under the laws of the
16 State; and

17 (C) conducted by a covered institution of
18 higher education or registered manufacturer
19 that is appropriately registered under the Con-
20 trolled Substances Act (21 U.S.C. 801 et seq.);

21 (2) the term “cannabidiol” means the
22 nonpsychoactive substance, cannabidiol, as derived
23 from marihuana or the synthetic formulation;

24 (3) the terms “controlled substance”, “dis-
25 pense”, “distribute”, “marihuana”, and “manufac-
26 ture” have the meanings given such terms in section

1 102 of the Controlled Substances Act (21 U.S.C.
2 802);

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

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

10 (ii) is an accredited medical school or an
11 accredited school of osteopathic medicine; and

12 (B) is appropriately registered under the
13 Controlled Substances Act (21 U.S.C. 801 et
14 seq.);

15 (5) the term “drug” has the meaning given the
16 term in section 201(g)(1) of the Federal Food Drug
17 and Cosmetics Act (21 U.S.C. 321(g)(1));

18 (6) the term “registered manufacturer” means
19 an individual or entity who is appropriately reg-
20 istered to manufacture controlled substances under
21 the Controlled Substances Act (21 U.S.C. 801 et
22 seq.), including an individual or entity appropriately
23 registered to manufacture controlled substances as
24 part of research; and

1 (7) the term “State” means any State of the
2 United States, the District of Columbia, and any
3 territory of the United States.

4 **SEC. 3. PROCEEDINGS FOR CONTROL OF CANNABIDIOL.**

5 (a) SCIENTIFIC AND MEDICAL EVALUATIONS.—Not
6 later than 1 year after the date of enactment of this Act,
7 the Attorney General and the Secretary of Health and
8 Human Services shall each complete the scientific and
9 medical evaluation described in section 201(b) of the Con-
10 trolled Substances Act (21 U.S.C. 811(b)) as to
11 cannabidiol, which shall take into consideration the factors
12 described in paragraphs (1) through (8) of subsection (c)
13 of section 201 of that Act (21 U.S.C. 811(c)).

14 (b) PROCEEDINGS TO CONTROL CANNABIDIOL.—
15 After taking into consideration the evaluation described in
16 subsection (a), if the Attorney General determines that the
17 evaluations, recommendations, and all other relevant data
18 warrant control of cannabidiol, the Attorney General shall
19 initiate proceedings for control under section 201(a) of the
20 Controlled Substances Act (21 U.S.C. 811(a)).

21 **SEC. 4. RESEARCH PROTOCOLS.**

22 The Attorney General shall amend section 1301.18
23 of title 21, Code of Federal Regulations (as in effect on
24 the date of enactment of this Act) by striking subsections
25 (c) and (d) and inserting the following:

1 “(c) In the event that the registrant desires to in-
2 crease the quantity of a controlled substance used for an
3 approved research project, he/she shall submit a request
4 to the Registration Unit, Drug Enforcement Administra-
5 tion, by registered mail, return receipt requested. See the
6 Table of DEA Mailing Addresses in § 1321.01 of this
7 chapter for the current mailing address. The request shall
8 contain the following information: DEA registration num-
9 ber; name of the controlled substance or substances and
10 the quantity of each authorized in the approved protocol;
11 and the additional quantity of each desired. Upon return
12 of the receipt, the registrant shall be authorized to pur-
13 chase and use the additional quantity of the controlled
14 substance or substances specified in the request.

15 “(d) In the event the registrant desires to conduct
16 research beyond the variations provided in the registrant’s
17 approved protocol (excluding any increase in the quantity
18 of the controlled substance requested for his/her research
19 project as outlined in subsection (c) of this section), he/
20 she shall submit three copies by registered mail, with a
21 return receipt requested, of a supplemental protocol in ac-
22 cordance with subsection (a) of this section describing the
23 new research and omitting information in the supple-
24 mental protocol which has been stated in the original pro-
25 tocol. Unless explicitly denied, supplemental protocols

1 shall be considered approved 30 days after the date on
 2 which the return receipt is returned.”.

3 **SEC. 5. MEDICAL RESEARCH ON CANNABIDIOL.**

4 (a) IN GENERAL.—Notwithstanding any provision of
 5 the Controlled Substances Act (21 U.S.C. 801 et seq.),
 6 the Safe and Drug-Free Schools and Communities Act (20
 7 U.S.C. 7101 et seq.), chapter 81 of title 41, United States
 8 Code, or any other Federal law, a covered institution of
 9 higher education or a registered manufacturer may manu-
 10 facture, distribute, dispense, or possess marihuana or
 11 cannabidiol if the marihuana or cannabidiol is manufac-
 12 tured, distributed, dispensed, or possessed, respectively,
 13 for purposes of authorized medical research.

14 (b) REGISTRATION FOR RESEARCH INVOLVING
 15 CANNABIDIOL.—

16 (1) INITIAL PERIOD.—During the period begin-
 17 ning on the date of enactment of this Act and end-
 18 ing on the date on which the Attorney General
 19 makes a determination regarding control of
 20 cannabidiol, an individual or entity engaged in au-
 21 thorized medical research may distribute, dispense,
 22 or possess cannabidiol for purposes of the authorized
 23 medical research if the individual or entity is reg-
 24 istered under the Controlled Substances Act (21
 25 U.S.C. 801 et seq.) to engage in such activity with

1 a controlled substance in schedule II in section
2 202(c) of the Controlled Substances Act (21 U.S.C.
3 812(c)).

4 (2) COMPLETION OF ONGOING RESEARCH.—If,
5 as a result of the determination and proceedings de-
6 scribed in section 3, cannabidiol is a controlled sub-
7 stance in schedule I in section 202(c) of the Con-
8 trolled Substances Act (21 U.S.C. 812(c)), an indi-
9 vidual or entity engaged in authorized medical re-
10 search may continue to distribute, dispense, or pos-
11 sess cannabidiol for purposes of completing the au-
12 thorized medical research if the individual or enti-
13 ty—

14 (A) was engaged in the authorized medical
15 research in accordance with paragraph (1) on
16 or before the date on which the proceedings are
17 completed; and

18 (B) is registered under the Controlled Sub-
19 stances Act (21 U.S.C. 801 et seq.) to engage
20 in such activity with a controlled substance in
21 schedule II in section 202(c) of the Controlled
22 Substances Act (21 U.S.C. 812(c)).

23 (c) TIMELY PROCESSING OF REGISTRATION APPLI-
24 CATIONS.—

1 (1) IN GENERAL.—Not later than 60 days after
 2 the Attorney General receives an application for reg-
 3 istration under the Controlled Substances Act (21
 4 U.S.C. 801 et seq.) to manufacture, distribute, dis-
 5 pense, or possess controlled substances, the Attorney
 6 General shall—

7 (A) grant or deny the application; or

8 (B) request supplemental information.

9 (2) ADDITIONAL INFORMATION.—Not later
 10 than 30 days after the Attorney General receives
 11 supplemental information as described in paragraph
 12 (1)(B) in connection with an application described in
 13 paragraph (1), the Attorney General shall grant or
 14 deny the application.

15 (d) INFORMATION REGARDING DENIALS.—If an ap-
 16 plication described in subsection (c)(1) is denied, the At-
 17 torney General shall provide a written explanation of the
 18 basis of denial to the applicant.

19 **SEC. 6. IMPORTATION OF CANNABIDIOL FOR RESEARCH**
 20 **PURPOSES.**

21 The Controlled Substances Import and Export Act
 22 (21 U.S.C. 951 et seq.) is amended—

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

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

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

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

5 “(3) such amounts of marihuana or cannabidiol
6 as approved for authorized medical research (as such
7 terms are defined in section 2 of the Cannabidiol
8 Research Expansion Act).”; and

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

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

13 “(A) import into the customs territory of the
14 United States from any place outside thereof (but
15 within the United States), or import into the United
16 States from any place outside thereof, any controlled
17 substance or list I chemical, or

18 “(B) export from the United States any con-
19 trolled substance or list I chemical,
20 unless there is in effect with respect to such person
21 a registration issued by the Attorney General under
22 section 1008, or unless such person is exempt from
23 registration under subsection (b).

24 “(2) Paragraph (1) shall not apply to the im-
25 port or export of marihuana or cannabidiol that has

1 been approved for authorized medical research au-
2 thorized under section 5 of the Cannabidiol Research
3 Expansion Act.”.

4 **SEC. 7. SAFE HARBOR.**

5 (a) DEFINITIONS.—In this section—

6 (1) the term “adult” means an individual who
7 is not less than 18 years of age;

8 (2) the term “child” means an individual who
9 is not more than 17 years of age;

10 (3) the term “intractable epilepsy” means an
11 epileptic seizure disorder for which standard medical
12 treatment—

13 (A) does not prevent or significantly ame-
14 liorate recurring, uncontrollable seizures; or

15 (B) results in harmful side effects; and

16 (4) the term “neurologist” means an allopathic
17 or osteopathic physician board-certified in neurology
18 in good standing and licensed in the State in which
19 the physician practices neurology.

20 (b) SAFE HARBOR.—Notwithstanding the Controlled
21 Substances Act (21 U.S.C. 801 et seq.), the Controlled
22 Substances Import and Export Act (21 U.S.C. 951 et
23 seq.), or any other Federal law, it shall not be unlawful
24 for—

1 (1) a legal guardian to possess or transport
2 cannabidiol or any other nonpsychoactive component
3 of marihuana for purposes of dispensing the
4 cannabidiol or other nonpsychoactive component to a
5 child of the legal guardian if—

6 (A) the child has been treated by a neu-
7 rologist for intractable epilepsy for not less than
8 6 months;

9 (B) the child's neurologist certifies that
10 other treatment options have been ineffective;

11 (C) the child's neurologist certifies that the
12 benefits of using the cannabidiol or other
13 nonpsychoactive component of marihuana rea-
14 sonably outweigh the potential risks for the
15 child; and

16 (D) the legal guardian provides docu-
17 mentation for the requirements under subpara-
18 graphs (A), (B), and (C);

19 (2) an adult to possess or transport cannabidiol
20 or any other nonpsychoactive component of mari-
21 huana if—

22 (A) the adult has been treated by a neu-
23 rologist for intractable epilepsy for not less than
24 6 months;

1 (B) the adult's neurologist certifies that
2 other treatment options have been ineffective;

3 (C) the adult's neurologist certifies that
4 the benefits of using the cannabidiol or other
5 nonpsychoactive component of marihuana rea-
6 sonably outweigh the potential risks for the
7 adult; and

8 (D) the adult provides documentation for
9 the requirements under subparagraphs (A),
10 (B), and (C); or

11 (3) a physician who is licensed under State law
12 to discuss the potential harms and benefits of
13 cannabidiol or any other nonpsychoactive component
14 of marihuana as a treatment with a patient of the
15 physician, or the legal guardian of the patient if the
16 patient is a child.

17 (c) SUNSET.—This section shall cease to have force
18 or effect on the date that is 4 years after the date of enact-
19 ment of this Act.

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