

115TH CONGRESS
1ST SESSION

S. _____

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

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

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) a preclinical study or clinical investiga-
6 tion conducted in accordance with section
7 505(i) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 355(i)) or otherwise per-
9 mitted by the Department of Health and
10 Human Services to determine the potential
11 medical benefits of marihuana or cannabidiol as
12 a drug; and

13 (B) conducted by a covered institution of
14 higher education, practitioner, or manufacturer
15 that is appropriately registered under the Con-
16 trolled Substances Act (21 U.S.C. 801 et seq.);

17 (2) the term “cannabidiol” means the
18 nonpsychoactive substance, cannabidiol, as derived
19 from marihuana or the synthetic formulation;

20 (3) the terms “controlled substance”, “dis-
21 pense”, “distribute”, “manufacture”, “marihuana”,
22 and “practitioner” have the meanings given such
23 terms in section 102 of the Controlled Substances
24 Act (21 U.S.C. 802);

25 (4) the term “covered institution of higher edu-
26 cation” means an institution of higher education (as

1 defined in section 101 of the Higher Education Act
2 of 1965 (20 U.S.C. 1001)) that—

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

6 (ii) is an accredited medical school or an
7 accredited school of osteopathic medicine; and

8 (B) is appropriately registered under the
9 Controlled Substances Act (21 U.S.C. 801 et
10 seq.);

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

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

21 (7) the term “State” means any State of the
22 United States, the District of Columbia, and any
23 territory of the United States.

1 **SEC. 3. PROCEEDINGS FOR CONTROL, TRANSFER, OR RE-**
2 **MOVAL OF CANNABIDIOL.**

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

12 (b) **PROCEEDINGS TO CONTROL, TRANSFER, OR RE-**
13 **MOVE CANNABIDIOL.**—After taking into consideration the
14 evaluation described in subsection (a), if the Attorney
15 General determines that the evaluations, recommenda-
16 tions, and all other relevant data warrant control, trans-
17 fer, or removal of cannabidiol, the Attorney General shall
18 initiate proceedings for control, transfer, or removal under
19 section 201(a) of the Controlled Substances Act (21
20 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 paragraph (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 paragraph (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, an appropriately reg-
9 istered covered institution of higher education, a practi-
10 tioner, or a manufacturer may manufacture, distribute,
11 dispense, or possess marihuana or cannabidiol if the mari-
12 huana or cannabidiol is manufactured, distributed, dis-
13 pensed, or possessed, respectively, for purposes of author-
14 ized medical research.

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

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

1 U.S.C. 801 et seq.) to engage in such activity with
2 a controlled substance in schedule II in section
3 202(c) of the Controlled Substances Act (21 U.S.C.
4 812(c)).

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

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

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

24 (c) REGISTRATION FOR THE COMMERCIAL PRODUC-
25 TION AND DISTRIBUTION OF FOOD AND DRUG ADMINIS-

1 TRATION APPROVED DRUGS.—The Attorney General shall
2 register an applicant to manufacture or distribute
3 cannabidiol or marihuana for the purpose of commercial
4 production of a drug containing or derived from mari-
5 huana that is approved by the Secretary of Health and
6 Human Services under section 505 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355), in accordance
8 with the applicable requirements under subsection (a) or
9 (b) of section 303 of the Controlled Substances Act (21
10 U.S.C. 823).

11 (d) TIMELY PROCESSING OF REGISTRATION APPLI-
12 CATIONS.—

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

19 (A) grant or deny the application; or

20 (B) request supplemental information.

21 (2) ADDITIONAL INFORMATION.—Not later
22 than 30 days after the Attorney General receives
23 supplemental information as described in paragraph
24 (1)(B) in connection with an application described in

1 paragraph (1), the Attorney General shall grant or
2 deny the application.

3 (e) INFORMATION REGARDING DENIALS.—If an ap-
4 plication described in subsection (d)(1) is denied, the At-
5 torney General shall provide a written explanation of the
6 basis of denial to the applicant.

7 **SEC. 6. IMPORTATION OF CANNABIDIOL FOR RESEARCH**
8 **PURPOSES.**

9 The Controlled Substances Import and Export Act
10 (21 U.S.C. 951 et seq.) is amended—

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

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

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

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

18 “(3) such amounts of marihuana or cannabidiol
19 as are—

20 “(A) approved for authorized medical re-
21 search (as such terms are defined in section 2
22 of the Cannabidiol Research Expansion Act), or

23 “(B) necessary for registered manufactur-
24 ers to manufacture drugs containing marihuana
25 or cannabidiol that have been approved for use

1 by the Commissioner of Food and Drugs under
2 the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 301 et seq.),”; and
4 (2) in section 1007 (21 U.S.C. 957), by amend-
5 ing subsection (a) to read as follows:

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

8 “(A) import into the customs territory of the
9 United States from any place outside thereof (but
10 within the United States), or import into the United
11 States from any place outside thereof, any controlled
12 substance or list I chemical, or

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

19 “(2) Paragraph (1) shall not apply to the im-
20 port or export of marihuana or cannabidiol that has
21 been approved for—

22 “(A) authorized medical research author-
23 ized under section 5 of the Cannabidiol Re-
24 search Expansion Act; or

1 “(B) use by registered manufacturers to
2 manufacture drugs containing marihuana or
3 cannabidiol that have been approved for use by
4 the Commissioner of Food and Drugs under the
5 Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 301 et seq.).”.

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

8 (a) DEFINITIONS.—In this section—

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

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

13 (3) the term “intractable epilepsy” means an
14 epileptic seizure disorder for which standard medical
15 treatment—

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

18 (B) results in harmful side effects; and

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

23 (b) SAFE HARBOR.—Notwithstanding the Controlled
24 Substances Act (21 U.S.C. 801 et seq.), the Controlled
25 Substances Import and Export Act (21 U.S.C. 951 et

1 seq.), or any other Federal law, it shall not be unlawful
2 for—

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

8 (A) the child has been treated by a neu-
9 rologist for intractable epilepsy for not less than
10 6 months;

11 (B) the child's neurologist attests that
12 other treatment options have not resulted in
13 significant clinical improvement;

14 (C) the child's neurologist attests that he
15 or she has discussed the currently known poten-
16 tial harms and benefits of using cannabidiol or
17 other nonpsychoactive components of mari-
18 huana as a treatment with the child's legal
19 guardian;

20 (D) the child's neurologist attests that he
21 or she will monitor the child for potential ad-
22 verse reactions; and

23 (E) the legal guardian provides docu-
24 mentation for the requirements under subpara-
25 graphs (A), (B), (C), and (D);

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

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

7 (B) the adult’s neurologist attests that
8 other treatment options have not resulted in
9 significant clinical improvement;

10 (C) the adult’s neurologist attests that he
11 or she has discussed the currently known poten-
12 tial harms and benefits of using cannabidiol or
13 other nonpsychoactive components of mari-
14 huana as a treatment with the adult;

15 (D) the adult’s neurologist attests that he
16 or she will monitor the adult for potential ad-
17 verse reactions; and

18 (E) the adult provides documentation for
19 the requirements under subparagraphs (A),
20 (B), (C), and (D); or

21 (3) a State-licensed physician to discuss the
22 currently known potential harms and benefits of
23 cannabidiol or any other nonpsychoactive component
24 of marihuana as a treatment with a patient of the

1 physician, or the legal guardian of the patient if the
2 patient is a child.

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

6 **SEC. 8. FEDERAL RESEARCH.**

7 The Secretary of Health and Human Services, either
8 directly or through awarding grants, contracts, or coopera-
9 tive agreements to covered institutions of higher edu-
10 cation, medical or osteopathic schools, or practitioners, or
11 a consortia of covered institutions of higher education,
12 medical or osteopathic schools, or practitioners, shall ex-
13 pand, intensify, and coordinate the activities of the Na-
14 tional Institutes of Health with respect to research on
15 cannabidiol and other nonpsychoactive components of
16 marihuana to better determine their potential therapeutic
17 effects on serious medical conditions, including intractable
18 epilepsy.