

117TH CONGRESS
1ST SESSION

S. 253

To expand research on the cannabidiol and marihuana.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 4, 2021

Mrs. FEINSTEIN (for herself, Mr. GRASSLEY, Mr. SCHATZ, Mr. DURBIN, Ms. KLOBUCHAR, Mr. TILLIS, Mr. KAINE, Ms. ERNST, Mr. TESTER, and Ms. MURKOWSKI) 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 delta-9-
 13 tetrahydrocannabinol level that is greater than
 14 0.3 percent; 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-

metec Act (21 U.S.C. 355(i)) or otherwise permitted by the Department of Health and Human Services to determine the potential medical benefits of marihuana or cannabidiol as a drug; and

(B) conducted by a covered institution of higher education, practitioner, or manufacturer that is appropriately registered under the Controlled Substances Act (21 U.S.C. 801 et seq.); and

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

TITLE I—REGISTRATIONS FOR MARIHUANA RESEARCH

SEC. 101. MARIHUANA RESEARCH APPLICATIONS.

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

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

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

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

“(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
 11 303(f) of the Controlled Substances Act (21 U.S.C.
 12 823(f)), as amended by section 101 of this Act, is further
 13 amended 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)(aa) If a registrant under clause (i) seeks to
 2 change the quantity of marihuana needed for research and
 3 the change in quantity does not impact the factors de-
 4 scribed in item (bb) or (cc) of subclause (I) of this clause,
 5 the registrant shall notify the Attorney General via reg-
 6 istered mail or using an electronic means permitted by the
 7 Attorney General.

8 “(bb) A notification under item (aa) shall include—

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

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

13 “(CC) the quantity of additional marihuana
 14 needed to complete the research; and

15 “(DD) an attestation that the change in quan-
 16 tity does not impact the source of the drug or the
 17 conditions under which the drug is stored, tracked,
 18 or administered.

19 “(cc) The Attorney General shall ensure that—

20 “(AA) any registered mail return receipt with
 21 respect to a notification under item (aa) is sub-
 22 mitted for delivery to the registrant providing the
 23 notification not later than 3 days after receipt of the
 24 notification by the Attorney General; and

1 “(BB) notice of receipt of a notification using
2 an electronic means permitted under item (aa) is
3 provided to the registrant providing the notification
4 not later than 3 days after receipt of the notification
5 by the Attorney General.

6 “(dd)(AA) On and after the date described in subitem
7 (BB), a registrant that submits a notification in accord-
8 ance with item (aa) may proceed with the research as if
9 the change in quantity has been approved on such date,
10 unless the Attorney General notifies the registrant of an
11 objection described in item (ee).

12 “(BB) The date described in this subitem is the date
13 on which a registrant submitting a notification under item
14 (aa) receives the registered mail return receipt with re-
15 spect to the notification or the date on which the reg-
16 istrant receives notice that the notification using an elec-
17 tronic means permitted under item (aa) was received by
18 the Attorney General, as the case may be.

19 “(ee) A notification submitted under item (aa) shall
20 be deemed to be approved unless the Attorney General,
21 not later than 10 days after receiving the notification, ex-
22 plicitly objects based on a finding that the change in quan-
23 tity—

1 “(AA) does impact the source of the drug or
 2 the conditions under which the drug is stored,
 3 tracked, or administered; or

4 “(BB) necessitates that the registrant imple-
 5 ment additional security measures to safeguard
 6 against diversion or abuse.

7 “(IV) Nothing in this clause shall limit the authority
 8 of the Secretary of Health and Human Services over re-
 9 quirements related to research protocols, including
 10 changes in—

11 “(aa) the method of administration of mari-
 12 huana;

13 “(bb) the dosing of marihuana; and

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

16 (b) REGULATIONS.—Not later than 1 year after the
 17 date of enactment of this Act, the Attorney General shall
 18 promulgate regulations to carry out the amendment made
 19 by this section.

20 **SEC. 103. APPLICATIONS TO MANUFACTURE MARIHUANA**
 21 **FOR RESEARCH.**

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

24 (1) by redesignating subsections (c) through (k)
 25 as subsections (d) through (l), respectively;

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

3 “(c)(1)(A) As it relates to applications to manufac-
4 ture marihuana for research purposes, if the Attorney
5 General places a notice in the Federal Register to increase
6 the number of entities registered under this Act to manu-
7 facture marihuana to supply appropriately registered re-
8 searchers in the United States, the Attorney General shall,
9 not later than 60 days after the date on which the Attor-
10 ney General receives a completed application—

11 “(i) approve the application; or

12 “(ii) request supplemental information.

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

16 “(i) The requirements designated in the notice
17 in the Federal Register are satisfied.

18 “(ii) The requirements under this Act are satis-
19 fied.

20 “(iii) The applicant will limit the transfer and
21 sale of any marihuana manufactured under this sub-
22 section—

23 “(I) to researchers who are registered
24 under this Act to conduct research with con-
25 trolled substances in schedule I; and

1 “(II) for purposes of use in preclinical re-
2 search or in a clinical investigation pursuant to
3 an investigational new drug exemption under
4 505(i) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355(i)).

6 “(iv) The applicant will transfer or sell any
7 marihuana manufactured under this subsection only
8 with prior, written consent for the transfer or sale
9 by the Attorney General.

10 “(v) The applicant has completed the applica-
11 tion and review process under subsection (a) for the
12 bulk manufacture of controlled substances in sched-
13 ule I.

14 “(vi) The applicant has established and begun
15 operation of a process for storage and handling of
16 controlled substances in schedule I, including for in-
17 ventory control and monitoring security in accord-
18 ance with section 105 of the Cannabidiol and Mari-
19 huana Research Expansion Act.

20 “(vii) The applicant is licensed by each State in
21 which the applicant will conduct operations under
22 this subsection, to manufacture marihuana, if that
23 State requires such a license.

24 “(C) Not later than 30 days after the date on which
25 the Attorney General receives supplemental information

1 requested under subparagraph (A)(ii) with respect to an
 2 application, the Attorney General shall approve or deny
 3 the application.

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

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

10 (4) in subsection (j)(1), as so redesignated, by
 11 striking “subsection (d)” and inserting “subsection
 12 (e)”; and

13 (5) in subsection (k), as so redesignated, by
 14 striking “subsection (f)” each place it appears and
 15 inserting “subsection (g)”.

16 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

17 (1) The Controlled Substances Act (21 U.S.C.
 18 801 et seq.) is amended—

19 (A) in section 102 (21 U.S.C. 802)—

20 (i) in paragraph (16)(B)—

21 (I) in clause (i), by striking “or”

22 at the end;

23 (II) by redesignating clause (ii)

24 as (iii); and

1 (III) by inserting after clause (i)
 2 the following:

3 “(ii) the synthetic equivalent of hemp-de-
 4 rived cannabidiol that contains less than 0.3
 5 percent tetrahydrocannabinol; or”;

6 (ii) in paragraph (52)(B)—

7 (I) by striking “303(f)” each
 8 place it appears and inserting
 9 “303(g)”; and

10 (II) in clause (i), by striking
 11 “(d), or (e)” and inserting “(e), or
 12 (f)”; and

13 (iii) in paragraph (54), by striking
 14 “303(f)” each place it appears and insert-
 15 ing “303(g)”;

16 (B) in section 302(g)(5)(A)(iii)(I)(bb) (21
 17 U.S.C. 822(g)(5)(A)(iii)(I)(bb)), by striking
 18 “303(f)” and inserting “303(g)”;

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

22 (D) in section 307(d)(2) (21 U.S.C.
 23 827(d)(2)), by striking “303(f)” and inserting
 24 “303(g)”;

1 (E) in section 309A(a)(2) (21 U.S.C.
 2 829a(a)(2)), in the matter preceding subpara-
 3 graph (A), by striking “303(g)(2)” and insert-
 4 ing “303(h)(2)”;

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

8 (G) in section 401(h)(2) (21 U.S.C.
 9 841(h)(2)), by striking “303(f)” each place it
 10 appears and inserting “303(g)”;

11 (H) in section 403(c)(2)(B) (21 U.S.C.
 12 843(c)(2)(B)), by striking “303(f)” and insert-
 13 ing “303(g)”;

14 (I) in section 512(c)(1) (21 U.S.C.
 15 882(c)(1)) by striking “303(f)” and inserting
 16 “303(g)”.

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

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

22 (B) in paragraph (2)(B), by striking
 23 “303(h)” and inserting “303(i)”.

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

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

4 (B) in section 544(a)(3) (42 U.S.C.
5 290dd-3(a)(3)), by striking “303(g)” and in-
6 serting “303(h)”.

7 (4) Title XVIII of the Social Security Act (42
8 U.S.C. 1395 et seq.) is amended—

9 (A) in section 1833(bb)(3)(B) (42 U.S.C.
10 1395l(bb)(3)(B)), by striking “303(g)” and in-
11 serting “303(h)”;

12 (B) in section 1834(o)(3)(C)(ii) (42 U.S.C.
13 1395m(o)(3)(C)(ii)), by striking “303(g)” and
14 inserting “303(h)”;

15 (C) in section 1866F(c)(3)(C) (42 U.S.C.
16 1395cc-6(c)(3)(C)), by striking “303(g)” and
17 inserting “303(h)”.

18 (5) Section 1903(aa)(2)(C)(ii) of the Social Se-
19 curity Act (42 U.S.C. 1396b(aa)(2)(C)(ii)) is
20 amended by striking “303(g)” each place it appears
21 and inserting “303(h)”.

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

23 On an annual basis, the Attorney General shall assess
24 whether there is an adequate and uninterrupted supply of

1 marihuana, including of specific strains, for research pur-
 2 poses.

3 **SEC. 105. SECURITY REQUIREMENTS.**

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

7 (b) REQUIREMENTS FOR OTHER MEASURES.—Any
 8 other security measures required by the Attorney General
 9 to safeguard against diversion shall be consistent with
 10 those required for practitioners conducting research on
 11 other controlled substances in schedules I and II in section
 12 202(c) of the Controlled Substances Act (21 U.S.C.
 13 812(c)) that have a similar risk of diversion and abuse.

14 **SEC. 106. PROHIBITION AGAINST REINSTATING INTER-**
 15 **DISCIPLINARY REVIEW PROCESS FOR NON-**
 16 **NIH-FUNDED RESEARCHERS.**

17 The Secretary of Health and Human Services may
 18 not—

19 (1) reinstate the Public Health Service inter-
 20 disciplinary review process described in the guidance
 21 entitled “Guidance on Procedures for the Provision
 22 of Marijuana for Medical Research” (issued on May
 23 21, 1999); or

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

4 **TITLE II—DEVELOPMENT OF**
 5 **FDA-APPROVED DRUGS**
 6 **USING CANNABIDIOL AND**
 7 **MARIHUANA**

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

9 Notwithstanding any provision of the Controlled Sub-
 10 stances Act (21 U.S.C. 801 et seq.), the Safe and Drug-
 11 Free Schools and Communities Act (20 U.S.C. 7101 et
 12 seq.), chapter 81 of title 41, United States Code, or any
 13 other Federal law, an appropriately registered covered in-
 14 stitution of higher education, a practitioner, or a manufac-
 15 turer may manufacture, distribute, dispense, or possess
 16 marihuana or cannabidiol if the marihuana or cannabidiol
 17 is manufactured, distributed, dispensed, or possessed, re-
 18 spectively, for purposes of medical research for drug devel-
 19 opment or subsequent commercial production in accord-
 20 ance with section 202.

21 **SEC. 202. REGISTRATION FOR THE COMMERCIAL PRODUC-**
 22 **TION AND DISTRIBUTION OF FOOD AND**
 23 **DRUG ADMINISTRATION-APPROVED DRUGS.**

24 The Attorney General shall register an applicant to
 25 manufacture or distribute cannabidiol or marihuana for

1 the purpose of commercial production of a drug containing
 2 or derived from marihuana that is approved by the Sec-
 3 retary of Health and Human Services under section 505
 4 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 5 355), in accordance with the applicable requirements
 6 under subsection (a) or (b) of section 303 of the Con-
 7 trolled Substances Act (21 U.S.C. 823).

8 **SEC. 203. IMPORTATION OF CANNABIDIOL FOR RESEARCH**
 9 **PURPOSES.**

10 The Controlled Substances Import and Export Act
 11 (21 U.S.C. 951 et seq.) is amended—

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

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

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

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

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

22 “(A) approved for medical research for
 23 drug development (as such terms are defined in
 24 section 2 of the Cannabidiol and Marihuana Re-
 25 search Expansion Act), or

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

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

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

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

16 “(B) export from the United States any con-
17 trolled substance or list I chemical,

18 unless there is in effect with respect to such person a reg-
19 istration issued by the Attorney General under section
20 1008, or unless such person is exempt from registration
21 under subsection (b).

22 “(2) Paragraph (1) shall not apply to the import or
23 export of marihuana or cannabidiol (as defined in section
24 2 of the Cannabidiol and Marihuana Research Expansion
25 Act) that has been approved for—

1 “(A) medical research for drug development au-
 2 thorized under section 201 of the Cannabidiol and
 3 Marihuana Research Expansion Act; or

4 “(B) use by registered manufacturers to manu-
 5 facture drugs containing marihuana or cannabidiol
 6 that have been approved for use by the Commis-
 7 sioner of Food and Drugs under the Federal Food,
 8 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).”.

9 **TITLE III—DOCTOR-PATIENT** 10 **RELATIONSHIP**

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

12 It shall not be a violation of the Controlled Sub-
 13 stances Act (21 U.S.C. 801 et seq.) for a State-licensed
 14 physician to discuss—

15 (1) the currently known potential harms and
 16 benefits of marihuana derivatives, including
 17 cannabidiol, as a treatment with the legal guardian
 18 of the patient of the physician if the patient is a
 19 child; or

20 (2) the currently known potential harms and
 21 benefits of marihuana and marihuana derivatives,
 22 including cannabidiol, as a treatment with the pa-
 23 tient or the legal guardian of the patient of the phy-
 24 sician if the patient is a legal adult.

1 **TITLE IV—FEDERAL RESEARCH**

2 **SEC. 401. FEDERAL RESEARCH.**

3 (a) IN GENERAL.—Not later than 1 year after the
 4 date of enactment of this Act, the Secretary of Health and
 5 Human Services, in coordination with the Director of the
 6 National Institutes of Health and the heads of other rel-
 7 evant Federal agencies, shall submit to the Caucus on
 8 International Narcotics Control, the Committee on the Ju-
 9 diciary, and the Committee on Health, Education, Labor,
 10 and Pensions of the Senate and the Committee on Energy
 11 and Commerce and the Committee on the Judiciary of the
 12 House of Representatives a report on—

13 (1) the potential therapeutic effects of
 14 cannabidiol or marihuana on serious medical condi-
 15 tions, including intractable epilepsy;

16 (2) the potential effects of marihuana, includ-
 17 ing—

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

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

1 (3) the barriers associated with researching
 2 marihuana or cannabidiol in States that have legal-
 3 ized the use of such substances, which shall in-
 4 clude—

5 (A) recommendations as to how such bar-
 6 riers might be overcome, including whether pub-
 7 lic-private partnerships or Federal-State re-
 8 search partnerships may or should be imple-
 9 mented to provide researchers with access to
 10 additional strains of marihuana and
 11 cannabidiol; and

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

14 (i) the levels of tetrahydrocannabinol,
 15 cannabidiol, or other cannabinoids con-
 16 tained in products obtained from such
 17 States is accurate; and

18 (ii) that such products do not contain
 19 harmful or toxic components.

20 (b) ACTIVITIES.—To the extent practicable, the Sec-
 21 retary of Health and Human Services, either directly or
 22 through awarding grants, contracts, or cooperative agree-
 23 ments, shall expand and coordinate the activities of the
 24 National Institutes of Health and other relevant Federal
 25 agencies to better determine the effects of cannabidiol and

- 1 marihuana, as outlined in the report submitted under
- 2 paragraphs (1) and (2) of subsection (a).

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