117TH CONGRESS 2D SESSION

H. R. 8454

To expand research on cannabidiol and marijuana, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

July 21, 2022

Mr. Blumenauer (for himself, Mr. Harris, Mr. Griffith, Mr. Joyce of Ohio, Ms. Norton, Ms. Mace, and Mr. Perlmutter) 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 expand research on cannabidiol and marijuana, 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; TABLE OF CONTENTS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Medical Marijuana and Cannabidiol Research Expansion
- 6 Act".
- 7 (b) Table of Contents for
- 8 this Act is as follows:

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

TITLE I—REGISTRATIONS FOR MARIJUANA RESEARCH

- Sec. 101. Marijuana research applications.
- Sec. 102. Research protocols.
- Sec. 103. Applications to manufacture marijuana 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 MARIJUANA

- Sec. 201. Medical research on cannabidiol.
- Sec. 202. Registration for the commercial production and distribution of Food and Drug Administration-approved drugs.

TITLE III—DOCTOR-PATIENT RELATIONSHIP

Sec. 301. Doctor-patient relationship.

TITLE IV—FEDERAL RESEARCH

Sec. 401. Federal research.

1 SEC. 2. DEFINITIONS.

- 2 (a) IN GENERAL.—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 marijuana, as applicable;
- 10 (2) the term "cannabidiol" means—
- 11 (A) the substance, cannabidiol, as derived
- from marijuana that has a delta-9-
- tetrahydrocannabinol level that is greater than
- 14 0.3 percent; and

1	(B) the synthetic equivalent of the sub-
2	stance described in subparagraph (A);
3	(3) the terms "controlled substance", "dis-
4	pense", "distribute", "manufacture", "marijuana",
5	and "practitioner" have the meanings given such
6	terms in section 102 of the Controlled Substances
7	Act (21 U.S.C. 802), as amended by this Act;
8	(4) the term "covered institution of higher edu-
9	cation" means an institution of higher education (as
10	defined in section 101 of the Higher Education Act
11	of 1965 (20 U.S.C. 1001)) that—
12	(A)(i) has highest or higher research activ-
13	ity, as defined by the Carnegie Classification of
14	Institutions of Higher Education; or
15	(ii) is an accredited medical school or an
16	accredited school of osteopathic medicine; and
17	(B) is appropriately registered under the
18	Controlled Substances Act (21 U.S.C. 801 et
19	seq.);
20	(5) the term "drug" has the meaning given the
21	term in section 201(g)(1) of the Federal Food,
22	Drug, and Cosmetic Act (21 U.S.C. 321(g)(1));
23	(6) the term "medical research for drug devel-
24	opment" means medical research that is—

1	(A) a preclinical study or clinical investiga-
2	tion conducted in accordance with section
3	505(i) of the Federal Food, Drug, and Cos-
4	metic Act (21 U.S.C. 355(i)) or otherwise per-
5	mitted by the Department of Health and
6	Human Services to determine the potential
7	medical benefits of marijuana or cannabidiol as
8	a drug; and
9	(B) conducted by a covered institution of
10	higher education, practitioner, or manufacturer
11	that is appropriately registered under the Con-
12	trolled Substances Act (21 U.S.C. 801 et seq.);
13	and
14	(7) the term "State" means any State of the
15	United States, the District of Columbia, and any
16	territory of the United States.
17	(b) Updating Term.—Section 102(16) of the Con-
18	trolled Substances Act (21 U.S.C. 802(16)) is amended—
19	(1) in subparagraph (A), by striking "the term
20	'marihuana' means' and inserting "the terms 'mari-
21	huana' and 'marijuana' mean''; and
22	(2) in subparagraph (B), by striking "The term
23	'marihuana' does not" and inserting "The terms
24	'marihuana' and 'marijuana' do not''.

TITLE I—REGISTRATIONS FOR MARIJUANA RESEARCH

3	SEC. 101. MARIJUANA RESEARCH APPLICATIONS.
4	Section 303(f) of the Controlled Substances Act (21
5	U.S.C. 823(f)) is amended—
6	(1) by redesignating paragraphs (1) through
7	(5) as subparagraphs (A) through (E), respectively;
8	(2) by striking "(f) The Attorney General" and
9	inserting "(f)(1) The Attorney General";
10	(3) by striking "Registration applications" and
11	inserting the following:
12	"(2)(A) Registration applications";
13	(4) by striking "Article 7" and inserting the
14	following:
15	"(3) Article 7"; and
16	(5) by inserting after paragraph (2)(A), as so
17	designated, the following:
18	"(B)(i) The Attorney General shall register a practi-
19	tioner to conduct research with marijuana (including any
20	derivative, extract, preparation, and compound thereof)
21	if—
22	"(I) the applicant's research protocol—
23	"(aa) has been reviewed and allowed—
24	"(AA) by the Secretary of Health and
25	Human Services under section 505(i) of

1	the Federal Food, Drug, and Cosmetic Act
2	(21 U.S.C. 355(i));
3	"(BB) by the National Institutes of
4	Health or another Federal agency that
5	funds scientific research; or
6	"(CC) pursuant to sections 1301.18
7	and 1301.32 of title 21, Code of Federal
8	Regulations, or any successors thereto; and
9	"(II) the applicant has demonstrated to the At-
10	torney General that there are effective procedures in
11	place to adequately safeguard against diversion of
12	the controlled substance for legitimate medical or
13	scientific use pursuant to section 105 of the Medical
14	Marijuana and Cannabidiol Research Expansion Act,
15	including demonstrating that the security measures
16	are adequate for storing the quantity of marijuana
17	the applicant would be authorized to possess.
18	"(ii) The Attorney General may deny an application
19	for registration under this subparagraph only if the Attor-
20	ney General determines that the issuance of the registra-
21	tion would be inconsistent with the public interest. In de-
22	termining the public interest, the Attorney General shall
23	consider the factors listed in—
24	"(I) subparagraphs (B) through (E) of para-
25	graph (1); and

- 1 "(II) subparagraph (A) of paragraph (1), if the
- applicable State requires practitioners conducting re-
- 3 search to register with a board or authority de-
- 4 scribed in such subparagraph (A).
- 5 "(iii)(I) Not later than 60 days after the date on
- 6 which the Attorney General receives a complete applica-
- 7 tion for registration under this subparagraph, the Attor-
- 8 ney General shall—
- 9 "(aa) approve the application; or
- "(bb) request supplemental information.
- 11 "(II) For purposes of subclause (I), an application
- 12 shall be deemed complete when the applicant has sub-
- 13 mitted documentation showing that the requirements
- 14 under clause (i) are satisfied.
- 15 "(iv) Not later than 30 days after the date on which
- 16 the Attorney General receives supplemental information as
- 17 described in clause (iii)(I)(bb) in connection with an appli-
- 18 cation described in this subparagraph, the Attorney Gen-
- 19 eral shall approve or deny the application.
- 20 "(v) If an application described in this subparagraph
- 21 is denied, the Attorney General shall provide a written ex-
- 22 planation of the basis of denial to the applicant.".
- 23 SEC. 102. RESEARCH PROTOCOLS.
- 24 (a) IN GENERAL.—Paragraph (2)(B) of section
- 25 303(f) of the Controlled Substances Act (21 U.S.C.

- 1 823(f)), as added by section 101 of this Act, is further
- 2 amended by adding at the end the following:
- 3 "(vi)(I) If the Attorney General grants an application
- 4 for registration under clause (i), the registrant may amend
- 5 or supplement the research protocol without notification
- 6 to, or review by, the Drug Enforcement Administration
- 7 if the registrant does not change—
- 8 "(aa) the quantity or type of marijuana or
- 9 cannabidiol (including any derivative, extract, prepa-
- 10 ration, and compound thereof);
- 11 "(bb) the source of such marijuana or
- cannabidiol; or
- "(cc) the conditions under which such mari-
- juana or cannabidiol is stored, tracked, or adminis-
- tered.
- 16 "(II)(aa) If a registrant under clause (i) seeks to
- 17 change the type of marijuana or cannabidiol (including
- 18 any derivative, extract, preparation, and compound there-
- 19 of), the source of such marijuana or cannabidiol, or the
- 20 conditions under which such marijuana or cannabidiol is
- 21 stored, tracked, or administered, the registrant shall notify
- 22 the Attorney General via registered mail, or an electronic
- 23 means permitted by the Attorney General, not later than
- 24 30 days before implementing an amended or supplemental
- 25 research protocol.

- 1 "(bb) A registrant may proceed with an amended or
- 2 supplemental research protocol described in item (aa) if
- 3 the Attorney General does not explicitly object during the
- 4 30-day period beginning on the date on which the Attorney
- 5 General receives the notice under item (aa).
- 6 "(cc) The Attorney General may only object to an
- 7 amended or supplemental research protocol under this
- 8 subclause if additional security measures are needed to
- 9 safeguard against diversion or abuse.
- 10 "(dd) If a registrant under clause (i) seeks to address
- 11 additional security measures identified by the Attorney
- 12 General under item (cc), the registrant shall notify the At-
- 13 torney General via registered mail, or an electronic means
- 14 permitted by the Attorney General, not later than 30 days
- 15 before implementing an amended or supplemental research
- 16 protocol.
- 17 "(ee) A registrant may proceed with an amended or
- 18 supplemental research protocol described in item (dd) if
- 19 the Attorney General does not explicitly object during the
- 20 30-day period beginning on the date on which the Attorney
- 21 General receives the notice under item (dd).
- 22 "(III)(aa) If a registrant under clause (i) seeks to
- 23 change the quantity of marijuana needed for research and
- 24 the change in quantity does not impact the factors de-
- 25 scribed in item (bb) or (cc) of subclause (I) of this clause,

1	the registrant shall notify the Attorney General via reg-
2	istered mail or using an electronic means permitted by the
3	Attorney General.
4	"(bb) A notification under item (aa) shall include—
5	"(AA) the Drug Enforcement Administration
6	registration number of the registrant;
7	"(BB) the quantity of marijuana or cannabidiol
8	already obtained;
9	"(CC) the quantity of additional marijuana or
10	cannabidiol needed to complete the research; and
11	"(DD) an attestation that the change in quan-
12	tity does not impact the source of the marijuana or
13	cannabidiol or the conditions under which the mari-
14	juana or cannabidiol is stored, tracked, or adminis-
15	tered.
16	"(cc) The Attorney General shall ensure that—
17	"(AA) any registered mail return receipt with
18	respect to a notification under item (aa) is sub-
19	mitted for delivery to the registrant providing the
20	notification not later than 3 days after receipt of the
21	notification by the Attorney General; and
22	"(BB) notice of receipt of a notification using
23	an electronic means permitted under item (aa) is
24	provided to the registrant providing the notification

- 1 not later than 3 days after receipt of the notification
- 2 by the Attorney General.
- 3 "(dd)(AA) On and after the date described in subitem
- 4 (BB), a registrant that submits a notification in accord-
- 5 ance with item (aa) may proceed with the research as if
- 6 the change in quantity has been approved on such date,
- 7 unless the Attorney General notifies the registrant of an
- 8 objection described in item (ee).
- 9 "(BB) The date described in this subitem is the date
- 10 on which a registrant submitting a notification under item
- 11 (aa) receives the registered mail return receipt with re-
- 12 spect to the notification or the date on which the reg-
- 13 istrant receives notice that the notification using an elec-
- 14 tronic means permitted under item (aa) was received by
- 15 the Attorney General, as the case may be.
- 16 "(ee) A notification submitted under item (aa) shall
- 17 be deemed to be approved unless the Attorney General,
- 18 not later than 10 days after receiving the notification, ex-
- 19 plicitly objects based on a finding that the change in quan-
- 20 tity—
- 21 "(AA) does impact the source of the marijuana
- or cannabidiol or the conditions under which the
- 23 marijuana or cannabidiol is stored, tracked, or ad-
- 24 ministered; or

- "(BB) necessitates that the registrant imple-1 2 ment additional security measures to safeguard 3 against diversion or abuse. "(IV) Nothing in this clause shall limit the authority 4 5 of the Secretary of Health and Human Services over requirements related to research protocols, including 6 7 changes in— "(aa) the method of administration of mari-8 9 juana or cannabidiol; 10 "(bb) the dosing of marijuana or cannabidiol;
- 12 "(cc) the number of individuals or patients in-
- volved in research.".

and

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

11

- 18 SEC. 103. APPLICATIONS TO MANUFACTURE MARIJUANA
- 19 FOR RESEARCH.
- 20 (a) In General.—Section 303 of the Controlled
- 21 Substances Act (21 U.S.C. 823), as amended by sections
- 22 101 and 102 of this Act, is further amended—
- (1) by redesignating subsections (c) through (k)
- 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 marijuana for research purposes, when 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 marijuana 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 marijuana 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

- "(II) for purposes of use in preclinical research or in a clinical investigation pursuant to an investigational new drug exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).
 - "(iv) The applicant will transfer or sell any marijuana manufactured under this subsection only with prior, written consent for the transfer or sale by the Attorney General.
 - "(v) The applicant has completed the application and review process under subsection (a) for the bulk manufacture of controlled substances in schedule I.
 - "(vi) The applicant has established and begun operation of a process for storage and handling of controlled substances in schedule I, including for inventory control and monitoring security in accordance with section 105 of the Medical Marijuana and Cannabidiol Research Expansion Act.
 - "(vii) The applicant is licensed by each State in which the applicant will conduct operations under this subsection, to manufacture marijuana, if that 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 (52)(B)—
21	(I) by striking "303(f)" each
22	place it appears and inserting
23	"303(\varphi)": and

1	(II) in clause (i), by striking
2	"(d), or (e)" and inserting "(e), or
3	(f)"; and
4	(ii) in paragraph (54), by striking
5	"303(f)" each place it appears and insert-
6	ing "303(g)";
7	(B) in section $302(g)(5)(A)(iii)(I)(bb)$ (21)
8	U.S.C. $822(g)(5)(A)(iii)(I)(bb))$, by striking
9	"303(f)" and inserting "303(g)";
10	(C) in section 304 (21 U.S.C. 824), by
11	striking "303(g)(1)" each place it appears and
12	inserting "303(h)(1)";
13	(D) in section $307(d)(2)$ (21 U.S.C.
14	827(d)(2)), by striking "303(f)" and inserting
15	"303(g)";
16	(E) in section 309A(a)(2) (21 U.S.C.
17	829a(a)(2)), in the matter preceding subpara-
18	graph (A), by striking "303(g)(2)" and insert-
19	ing "303(h)(2)";
20	(F) in section 311(h) (21 U.S.C. 831(h)),
21	by striking "303(f)" each place it appears and
22	inserting "303(g)";
23	(G) in section $401(h)(2)$ (21 U.S.C.
24	841(h)(2)), by striking "303(f)" each place it
25	appears and inserting "303(g)";

1	(H) in section $403(c)(2)(B)$ (21 U.S.C.
2	843(c)(2)(B)), by striking "303(f)" and insert-
3	ing "303(g)"; and
4	(I) in section $512(c)(1)$ (21 U.S.C.
5	882(c)(1)) by striking " $303(f)$ " and inserting
6	"303(g)".
7	(2) Section 1008(c) of the Controlled Sub-
8	stances Import and Export Act (21 U.S.C. 958(c))
9	is amended—
10	(A) in paragraph (1), by striking "303(d)"
11	and inserting "303(e)"; and
12	(B) in paragraph (2)(B), by striking
13	"303(h)" and inserting "303(i)".
14	(3) Title V of the Public Health Service Act (42
15	U.S.C. 290aa et seq.) is amended—
16	(A) in section 520E-4(c) (42 U.S.C.
17	290bb -36 d(c)), by striking " 303 (g)(2)(B)" and
18	inserting " $303(h)(2)(B)$ "; and
19	(B) in section $544(a)(3)$ (42 U.S.C.
20	290dd-3(a)(3)), by striking "303(g)" and in-
21	serting "303(h)".
22	(4) Title XVIII of the Social Security Act (42
23	U.S.C. 1395 et seq.) is amended—

1 (A) in section 1833(bb)(3)(B) (42 U.S.C. 2 1395l(bb)(3)(B)), by striking "303(g)" and inserting "303(h)"; 3 4 (B) in section 1834(o)(3)(C)(ii) (42 U.S.C. 5 1395m(0)(3)(C)(ii), by striking "303(g)" and inserting "303(h)"; and 6 7 (C) in section 1866F(c)(3)(C) (42 U.S.C. 1395cc-6(c)(3)(C)), by striking "303(g)" and 8 9 inserting "303(h)". 10 (5) Section 1903(aa)(2)(C)(ii) of the Social Se-11 curity Act (42 U.S.C. 1396b(aa)(2)(C)(ii) is 12 amended by striking "303(g)" each place it appears 13 and inserting "303(h)". 14 SEC. 104. ADEQUATE AND UNINTERRUPTED SUPPLY. 15 (a) IN GENERAL.—On an annual basis, the Attorney General, in consultation with the Secretary of Health and 16 17 Human Services, shall assess whether there is an adequate 18 and uninterrupted supply of marijuana, including of spe-19 cific strains, for research purposes. 20 (b) Report to Congress.—If the Attorney Gen-21 eral, in consultation with the Secretary of Health and Human Services, determines there is an inadequate or in-23 terrupted supply of marijuana, including of specific strains for research purposes, the Attorney General shall report

- 1 to Congress within 60 days of the determination on at
- 2 least—
- 3 (1) the factors contributing to the inadequate
- 4 or interrupted supply of marijuana;
- 5 (2) expected impacts of the inadequate or inter-
- 6 rupted supply on ongoing research protocols; and
- 7 (3) specific steps the Attorney General will take
- 8 to restore an adequate and uninterrupted supply of
- 9 marijuana, including of specific strains, for research
- purposes.

11 SEC. 105. SECURITY REQUIREMENTS.

- 12 (a) IN GENERAL.—An individual or entity engaged
- 13 in researching marijuana or its components shall store it
- 14 in a securely locked, substantially constructed cabinet.
- 15 (b) REQUIREMENTS FOR OTHER MEASURES.—Any
- 16 other security measures required by the Attorney General
- 17 to safeguard against diversion shall be consistent with
- 18 those required for practitioners conducting research on
- 19 other controlled substances in schedules I and II in section
- 20 202(c) of the Controlled Substances Act (21 U.S.C.
- 21 812(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 marijuana or
13	its components.
14	TITLE II—DEVELOPMENT OF
14 15	TITLE II—DEVELOPMENT OF FDA-APPROVED DRUGS
15	FDA-APPROVED DRUGS
15 16 17	FDA-APPROVED DRUGS USING CANNABIDIOL AND
15 16 17	FDA-APPROVED DRUGS USING CANNABIDIOL AND MARIJUANA
15 16 17 18	FDA-APPROVED DRUGS USING CANNABIDIOL AND MARIJUANA SEC. 201. MEDICAL RESEARCH ON CANNABIDIOL.
15 16 17 18	FDA-APPROVED DRUGS USING CANNABIDIOL AND MARIJUANA SEC. 201. MEDICAL RESEARCH ON CANNABIDIOL. Notwithstanding any provision of the Controlled Sub-
115 116 117 118 119 220	FDA-APPROVED DRUGS USING CANNABIDIOL AND MARIJUANA SEC. 201. MEDICAL RESEARCH ON CANNABIDIOL. Notwithstanding any provision of the Controlled Substances Act (21 U.S.C. 801 et seq.), the Safe and Drug-
115 116 117 118 119 220 221	FDA-APPROVED DRUGS USING CANNABIDIOL AND MARIJUANA SEC. 201. MEDICAL RESEARCH ON CANNABIDIOL. Notwithstanding any provision of the Controlled Substances Act (21 U.S.C. 801 et seq.), the Safe and Drug- Free Schools and Communities Act (20 U.S.C. 7101 et
115 116 117 118 119 220 221 222	FDA-APPROVED DRUGS USING CANNABIDIOL AND MARIJUANA SEC. 201. MEDICAL RESEARCH ON CANNABIDIOL. Notwithstanding any provision of the Controlled Substances Act (21 U.S.C. 801 et seq.), the Safe and Drug- Free Schools and Communities Act (20 U.S.C. 7101 et seq.), chapter 81 of title 41, United States Code, or any
15 16 17 18 19 20 21 22 23	FDA-APPROVED DRUGS USING CANNABIDIOL AND MARIJUANA SEC. 201. MEDICAL RESEARCH ON CANNABIDIOL. Notwithstanding any provision of the Controlled Substances Act (21 U.S.C. 801 et seq.), the Safe and Drug- Free Schools and Communities Act (20 U.S.C. 7101 et seq.), chapter 81 of title 41, United States Code, or any other Federal law, an appropriately registered covered in-

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 marijuana for
10	the purpose of commercial production of a drug containing
11	or derived from marijuana 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	TITLE III—DOCTOR-PATIENT
18	RELATIONSHIP
19	SEC. 301. DOCTOR-PATIENT RELATIONSHIP.
20	It shall not be a violation of the Controlled Sub-
21	stances Act (21 U.S.C. 801 et seq.) for a State-licensed
22	physician to discuss—
23	(1) the currently known potential harms and
24	benefits of marijuana derivatives, including
25	cannabidiol, as a treatment with the legal guardian

1	of the patient of the physician if the patient is a
2	child; or
3	(2) the currently known potential harms and
4	benefits of marijuana and marijuana derivatives, in-
5	cluding cannabidiol, as a treatment with the patient
6	or the legal guardian of the patient of the physician
7	if the patient is a legal adult.
8	TITLE IV—FEDERAL RESEARCH
9	SEC. 401. FEDERAL RESEARCH.
10	(a) In General.—Not later than 1 year after the
11	date of enactment of this Act, the Secretary of Health and
12	Human Services, in coordination with the Director of the
13	National Institutes of Health and the heads of other rel-
14	evant Federal agencies, shall submit to the Caucus on
15	International Narcotics Control, the Committee on the Ju-
16	diciary, and the Committee on Health, Education, Labor,
17	and Pensions of the Senate and the Committee on Energy
18	and Commerce and the Committee on the Judiciary of the
19	House of Representatives a report on—
20	(1) the potential therapeutic effects of
21	cannabidiol or marijuana on serious medical condi-
22	tions, including intractable epilepsy;
23	(2) the potential effects of marijuana, includ-

ing—

24

1	(A) the effect of increasing delta-9-
2	tetrahydrocannabinol levels on the human body
3	and developing adolescent brains; and
4	(B) the effect of various delta-9-
5	tetrahydrocannabinol levels on cognitive abili-
6	ties, such as those that are required to operate
7	motor vehicles or other heavy equipment; and
8	(3) the barriers associated with researching
9	marijuana or cannabidiol in States that have legal-
10	ized the use of such substances, which shall in-
11	clude—
12	(A) recommendations as to how such bar-
13	riers might be overcome, including whether pub-
14	lic-private partnerships or Federal-State re-
15	search partnerships may or should be imple-
16	mented to provide researchers with access to
17	additional strains of marijuana and cannabidiol;
18	and
19	(B) recommendations as to what safe-
20	guards must be in place to verify—
21	(i) the levels of tetrahydrocannabinol,
22	cannabidiol, or other cannabinoids con-
23	tained in products obtained from such
24	States is accurate; and

1	(ii) that such products do not contain
2	harmful or toxic components.
3	(b) Activities.—To the extent practicable, the Sec-
4	retary of Health and Human Services, either directly or
5	through awarding grants, contacts, or cooperative agree-
6	ments, shall expand and coordinate the activities of the
7	National Institutes of Health and other relevant Federal
8	agencies to better determine the effects of cannabidiol and
9	marijuana, as outlined in the report submitted under para-
10	graphs (1) and (2) of subsection (a).

 \bigcirc