117TH CONGRESS 2D SESSION

H. R. 8454

AN ACT

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,

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

- 2 (a) SHORT TITLE.—This Act may be cited as the
- 3 "Medical Marijuana and Cannabidiol Research Expansion
- 4 Act".
- 5 (b) Table of Contents for
- 6 this Act is as follows:
 - Sec. 1. Short title; table of contents.
 - Sec. 2. Definitions.
 - Sec. 3. Determination of budgetary effects.

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.

7 SEC. 2. DEFINITIONS.

- 8 (a) IN GENERAL.—In this Act—
- 9 (1) the term "appropriately registered" means
- that an individual or entity is registered under the
- 11 Controlled Substances Act (21 U.S.C. 801 et seq.)
- to engage in the type of activity that is carried out
- by the individual or entity with respect to a con-

1	trolled substance on the schedule that is applicable
2	to cannabidiol or marijuana, as applicable;
3	(2) the term "cannabidiol" means—
4	(A) the substance, cannabidiol, as derived
5	from marijuana that has a delta-9-
6	tetrahydrocannabinol level that is greater than
7	0.3 percent; and
8	(B) the synthetic equivalent of the sub-
9	stance described in subparagraph (A);
10	(3) the terms "controlled substance", "dis-
11	pense", "distribute", "manufacture", "marijuana",
12	and "practitioner" have the meanings given such
13	terms in section 102 of the Controlled Substances
14	Act (21 U.S.C. 802), as amended by this Act;
15	(4) the term "covered institution of higher edu-
16	cation" means an institution of higher education (as
17	defined in section 101 of the Higher Education Act
18	of 1965 (20 U.S.C. 1001)) that—
19	(A)(i) has highest or higher research activ-
20	ity, as defined by the Carnegie Classification of
21	Institutions of Higher Education; or
22	(ii) is an accredited medical school or an
23	accredited school of osteopathic medicine; and

1	(B) is appropriately registered under the
2	Controlled Substances Act (21 U.S.C. 801 et
3	seq.);
4	(5) the term "drug" has the meaning given the
5	term in section 201(g)(1) of the Federal Food,
6	Drug, and Cosmetic Act (21 U.S.C. 321(g)(1));
7	(6) the term "medical research for drug devel-
8	opment" means medical research that is—
9	(A) a preclinical study or clinical investiga-
10	tion conducted in accordance with section
11	505(i) of the Federal Food, Drug, and Cos-
12	metic Act (21 U.S.C. 355(i)) or otherwise per-
13	mitted by the Department of Health and
14	Human Services to determine the potential
15	medical benefits of marijuana or cannabidiol as
16	a drug; and
17	(B) conducted by a covered institution of
18	higher education, practitioner, or manufacturer
19	that is appropriately registered under the Con-
20	trolled Substances Act (21 U.S.C. 801 et seq.);
21	and
22	(7) the term "State" means any State of the
23	United States, the District of Columbia, and any
24	territory of the United States.

1	(b) UPDATING TERM.—Section 102(16) of the Con-
2	trolled Substances Act (21 U.S.C. 802(16)) is amended—
3	(1) in subparagraph (A), by striking "the term
4	'marihuana' means'' and inserting "the terms 'mari-
5	huana' and 'marijuana' mean''; and
6	(2) in subparagraph (B), by striking "The term
7	'marihuana' does not' and inserting "The terms
8	'marihuana' and 'marijuana' do not''.
9	SEC. 3. DETERMINATION OF BUDGETARY EFFECTS.
10	The budgetary effects of this Act, for the purpose of
11	complying with the Statutory Pay-As-You-Go Act of 2010,
12	shall be determined by reference to the latest statement
13	titled "Budgetary Effects of PAYGO Legislation" for this
14	Act, submitted for printing in the Congressional Record
15	by the Chairman of the House Budget Committee, pro-
16	vided that such statement has been submitted prior to the
17	vote on passage.
18	TITLE I—REGISTRATIONS FOR
19	MARIJUANA RESEARCH
20	SEC. 101. MARIJUANA RESEARCH APPLICATIONS.
21	Section 303(f) of the Controlled Substances Act (21
22	U.S.C. 823(f)) is amended—
23	(1) by redesignating paragraphs (1) through
24	(5) as subparagraphs (A) through (E), respectively;

1	(2) by striking "(f) The Attorney General" and
2	inserting "(f)(1) The Attorney General";
3	(3) by striking "Registration applications" and
4	inserting the following:
5	"(2)(A) Registration applications";
6	(4) by striking "Article 7" and inserting the
7	following:
8	"(3) Article 7"; and
9	(5) by inserting after paragraph (2)(A), as so
10	designated, the following:
11	"(B)(i) The Attorney General shall register a practi-
12	tioner to conduct research with marijuana (including any
13	derivative, extract, preparation, and compound thereof)
14	if—
15	"(I) the applicant's research protocol has been
16	reviewed and allowed—
17	"(aa) by the Secretary of Health and
18	Human Services under section 505(i) of the
19	Federal Food, Drug, and Cosmetic Act (21
20	U.S.C. 355(i));
21	"(bb) by the National Institutes of Health
22	or another Federal agency that funds scientific
23	research; or

1	"(cc) pursuant to sections 1301.18 and
2	1301.32 of title 21, Code of Federal Regula-
3	tions, or any successors thereto; and
4	"(II) the applicant has demonstrated to the At-
5	torney General that there are effective procedures in
6	place to adequately safeguard against diversion of
7	the controlled substance for legitimate medical or
8	scientific use pursuant to section 105 of the Medical
9	Marijuana and Cannabidiol Research Expansion Act,
10	including demonstrating that the security measures
11	are adequate for storing the quantity of marijuana
12	the applicant would be authorized to possess.
13	"(ii) The Attorney General may deny an application
14	for registration under this subparagraph only if the Attor-
15	ney General determines that the issuance of the registra-
16	tion would be inconsistent with the public interest. In de-
17	termining the public interest, the Attorney General shall
18	consider the factors listed in—
19	"(I) subparagraphs (B) through (E) of para-
20	graph (1); and
21	"(II) subparagraph (A) of paragraph (1), if the
22	applicable State requires practitioners conducting re-
23	search to register with a board or authority de-
24	scribed in such subparagraph (A).

- 1 "(iii)(I) Not later than 60 days after the date on
- 2 which the Attorney General receives a complete applica-
- 3 tion for registration under this subparagraph, the Attor-
- 4 ney General shall—
- 5 "(aa) approve the application; or
- 6 "(bb) request supplemental information.
- 7 "(II) For purposes of subclause (I), an application
- 8 shall be deemed complete when the applicant has sub-
- 9 mitted documentation showing that the requirements
- 10 under clause (i) are satisfied.
- 11 "(iv) Not later than 30 days after the date on which
- 12 the Attorney General receives supplemental information as
- 13 described in clause (iii)(I)(bb) in connection with an appli-
- 14 cation described in this subparagraph, the Attorney Gen-
- 15 eral shall approve or deny the application.
- 16 "(v) If an application described in this subparagraph
- 17 is denied, the Attorney General shall provide a written ex-
- 18 planation of the basis of denial to the applicant.".
- 19 SEC. 102. RESEARCH PROTOCOLS.
- 20 (a) In General.—Paragraph (2)(B) of section
- 21 303(f) of the Controlled Substances Act (21 U.S.C.
- 22 823(f)), as added by section 101 of this Act, is further
- 23 amended by adding at the end the following:
- 24 "(vi)(I) If the Attorney General grants an application
- 25 for registration under clause (i), the registrant may amend

- 1 or supplement the research protocol without notification
- 2 to, or review by, the Drug Enforcement Administration
- 3 if the registrant does not change—
- 4 "(aa) the quantity or type of marijuana or
- 5 cannabidiol (including any derivative, extract, prepa-
- 6 ration, and compound thereof);
- 7 "(bb) the source of such marijuana or
- 8 cannabidiol; or
- 9 "(cc) the conditions under which such mari-
- juana or cannabidiol is stored, tracked, or adminis-
- 11 tered.
- 12 "(II)(aa) If a registrant under clause (i) seeks to
- 13 change the type of marijuana or cannabidiol (including
- 14 any derivative, extract, preparation, and compound there-
- 15 of), the source of such marijuana or cannabidiol, or the
- 16 conditions under which such marijuana or cannabidiol is
- 17 stored, tracked, or administered, the registrant shall notify
- 18 the Attorney General via registered mail, or an electronic
- 19 means permitted by the Attorney General, not later than
- 20 30 days before implementing an amended or supplemental
- 21 research protocol.
- 22 "(bb) A registrant may proceed with an amended or
- 23 supplemental research protocol described in item (aa) if
- 24 the Attorney General does not explicitly object during the

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

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

- 1 ance with item (aa) may proceed with the research as if
- 2 the change in quantity has been approved on such date,
- 3 unless the Attorney General notifies the registrant of an
- 4 objection described in item (ee).
- 5 "(BB) The date described in this subitem is the date
- 6 on which a registrant submitting a notification under item
- 7 (aa) receives the registered mail return receipt with re-
- 8 spect to the notification or the date on which the reg-
- 9 istrant receives notice that the notification using an elec-
- 10 tronic means permitted under item (aa) was received by
- 11 the Attorney General, as the case may be.
- 12 "(ee) A notification submitted under item (aa) shall
- 13 be deemed to be approved unless the Attorney General,
- 14 not later than 10 days after receiving the notification, ex-
- 15 plicitly objects based on a finding that the change in quan-
- 16 tity—
- 17 "(AA) does impact the source of the marijuana
- or cannabidiol or the conditions under which the
- marijuana or cannabidiol is stored, tracked, or ad-
- 20 ministered; or
- 21 "(BB) necessitates that the registrant imple-
- 22 ment additional security measures to safeguard
- against diversion or abuse.
- 24 "(IV) Nothing in this clause shall limit the authority
- 25 of the Secretary of Health and Human Services over re-

- 1 quirements related to research protocols, including
- 2 changes in—
- 3 "(aa) the method of administration of mari-
- 4 juana or cannabidiol;
- 5 "(bb) the dosing of marijuana or cannabidiol;
- 6 and
- 7 "(cc) the number of individuals or patients in-
- 8 volved in research.".
- 9 (b) REGULATIONS.—Not later than 1 year after the
- 10 date of enactment of this Act, the Attorney General shall
- 11 promulgate regulations to carry out the amendment made
- 12 by this section.
- 13 SEC. 103. APPLICATIONS TO MANUFACTURE MARIJUANA
- 14 FOR RESEARCH.
- 15 (a) In General.—Section 303 of the Controlled
- 16 Substances Act (21 U.S.C. 823), as amended by sections
- 17 101 and 102 of this Act, is further amended—
- 18 (1) by redesignating subsections (c) through (k)
- as subsections (d) through (l), respectively;
- 20 (2) by inserting after subsection (b) the fol-
- 21 lowing:
- (c)(1)(A) As it relates to applications to manufac-
- 23 ture marijuana for research purposes, when the Attorney
- 24 General places a notice in the Federal Register to increase
- 25 the number of entities registered under this Act to manu-

1	facture marijuana to supply appropriately registered re-
2	searchers in the United States, the Attorney General shall,
3	not later than 60 days after the date on which the Attor-
4	ney General receives a completed application—
5	"(i) approve the application; or
6	"(ii) request supplemental information.
7	"(B) For purposes of subparagraph (A), an applica-
8	tion shall be deemed complete when the applicant has sub-
9	mitted documentation showing each of the following:
10	"(i) The requirements designated in the notice
11	in the Federal Register are satisfied.
12	"(ii) The requirements under this Act are satis-
13	fied.
14	"(iii) The applicant will limit the transfer and
15	sale of any marijuana manufactured under this sub-
16	section—
17	"(I) to researchers who are registered
18	under this Act to conduct research with con-
19	trolled substances in schedule I; and
20	"(II) for purposes of use in preclinical re-
21	search or in a clinical investigation pursuant to
22	an investigational new drug exemption under
23	505(i) of the Federal Food, Drug, and Cos-
24	metic Act (21 U.S.C. 355(i)).

- 1 "(iv) The applicant will transfer or sell any 2 marijuana manufactured under this subsection only 3 with prior, written consent for the transfer or sale 4 by the Attorney General.
- "(v) The applicant has completed the applica-6 tion and review process under subsection (a) for the 7 bulk manufacture of controlled substances in sched-8 ule I.
- 9 "(vi) The applicant has established and begun 10 operation of a process for storage and handling of controlled substances in schedule I, including for in-12 ventory control and monitoring security in accord-13 ance with section 105 of the Medical Marijuana and 14 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.
- 19 "(C) Not later than 30 days after the date on which 20 the Attorney General receives supplemental information 21 requested under subparagraph (A)(ii) with respect to an 22 application, the Attorney General shall approve or deny 23 the application.

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1	"(2) If an application described in this subsection is
2	denied, the Attorney General shall provide a written expla-
3	nation of the basis of denial to the applicant.";
4	(3) in subsection (h)(2), as so redesignated, by
5	striking "subsection (f)" each place it appears and
6	inserting "subsection (g)";
7	(4) in subsection $(j)(1)$, as so redesignated, by
8	striking "subsection (d)" and inserting "subsection
9	(e)"; and
10	(5) in subsection (k), as so redesignated, by
11	striking "subsection (f)" each place it appears and
12	inserting "subsection (g)".
13	(b) Technical and Conforming Amendments.—
14	(1) The Controlled Substances Act (21 U.S.C.
15	801 et seq.) is amended—
16	(A) in section 102 (21 U.S.C. 802)—
17	(i) in paragraph (52)(B)—
18	(I) by striking "303(f)" each
19	place it appears and inserting
20	"303(g)"; and
21	(II) in clause (i), by striking
22	"(d), or (e)" and inserting "(e), or
23	(f)"; and

1	(ii) in paragraph (54), by striking
2	"303(f)" each place it appears and insert-
3	ing "303(g)";
4	(B) in section $302(g)(5)(A)(iii)(I)(bb)$ (21
5	U.S.C. $822(g)(5)(A)(iii)(I)(bb))$, by striking
6	"303(f)" and inserting "303(g)";
7	(C) in section 304 (21 U.S.C. 824), by
8	striking "303(g)(1)" each place it appears and
9	inserting "303(h)(1)";
10	(D) in section 307(d)(2) (21 U.S.C.
11	827(d)(2)), by striking "303(f)" and inserting
12	"303(g)";
13	(E) in section 309A(a)(2) (21 U.S.C.
14	829a(a)(2)), in the matter preceding subpara-
15	graph (A), by striking "303(g)(2)" and insert-
16	ing "303(h)(2)";
17	(F) in section 311(h) (21 U.S.C. 831(h)),
18	by striking "303(f)" each place it appears and
19	inserting "303(g)";
20	(G) in section $401(h)(2)$ (21 U.S.C.
21	841(h)(2)), by striking "303(f)" each place it
22	appears and inserting "303(g)";
23	(H) in section $403(c)(2)(B)$ (21 U.S.C.
24	843(c)(2)(B)), by striking " $303(f)$ " and insert-
25	ing "303(g)"; and

1	(I) in section $512(c)(1)$ (21 U.S.C.
2	882(c)(1)) by striking " $303(f)$ " and inserting
3	"303(g)".
4	(2) Section 1008(c) of the Controlled Sub-
5	stances Import and Export Act (21 U.S.C. 958(c))
6	is amended—
7	(A) in paragraph (1), by striking "303(d)"
8	and inserting "303(e)"; and
9	(B) in paragraph (2)(B), by striking
10	"303(h)" and inserting "303(i)".
11	(3) Title V of the Public Health Service Act (42
12	U.S.C. 290aa et seq.) is amended—
13	(A) in section 520E-4(c) (42 U.S.C.
14	290bb-36d(c)), by striking "303(g)(2)(B)" and
15	inserting " $303(h)(2)(B)$ "; and
16	(B) in section 544(a)(3) (42 U.S.C.
17	290dd-3(a)(3)), by striking "303(g)" and in-
18	serting "303(h)".
19	(4) Title XVIII of the Social Security Act (42
20	U.S.C. 1395 et seq.) is amended—
21	(A) in section 1833(bb)(3)(B) (42 U.S.C.
22	1395l(bb)(3)(B)), by striking "303(g)" and in-
23	serting "303(h)":

1 (B) in section 1834(o)(3)(C)(ii) (42 U.S.C. 2 1395m(o)(3)(C)(ii), by striking "303(g)" and inserting "303(h)"; and 3 4 (C) in section 1866F(c)(3)(C) (42 U.S.C. 5 1395ce-6(e)(3)(C), by striking "303(g)" and inserting "303(h)". 6 7 (5) Section 1903(aa)(2)(C)(ii) of the Social Se-U.S.C. 1396b(aa)(2)(C)(ii) is 8 curity Act (42 9 amended by striking "303(g)" each place it appears and inserting "303(h)". 10 SEC. 104. ADEQUATE AND UNINTERRUPTED SUPPLY. 12 (a) IN GENERAL.—On an annual basis, the Attorney 13 General, in consultation with the Secretary of Health and Human Services, shall assess whether there is an adequate 14 15 and uninterrupted supply of marijuana, including of specific strains, for research purposes. 16 17 (b) Report to Congress.—If the Attorney Gen-18 eral, in consultation with the Secretary of Health and 19 Human Services, determines there is an inadequate or interrupted supply of marijuana, including of specific strains 20 21 for research purposes, the Attorney General shall report 22 to Congress within 60 days of the determination on at 23 least— 24 (1) the factors contributing to the inadequate 25 or interrupted supply of marijuana;

1	(2) expected impacts of the inadequate or inter-
2	rupted supply on ongoing research protocols; and
3	(3) specific steps the Attorney General will take
4	to restore an adequate and uninterrupted supply of
5	marijuana, including of specific strains, for research
6	purposes.
7	SEC. 105. SECURITY REQUIREMENTS.
8	(a) In General.—An individual or entity engaged
9	in researching marijuana or its components shall store it
10	in a securely locked, substantially constructed cabinet.
11	(b) Requirements for Other Measures.—Any
12	other security measures required by the Attorney General
13	to safeguard against diversion shall be consistent with
14	those required for practitioners conducting research on
15	other controlled substances in schedules I and II in section
16	202(e) of the Controlled Substances Act (21 U.S.C.
17	812(e)) that have a similar risk of diversion and abuse.
18	SEC. 106. PROHIBITION AGAINST REINSTATING INTER-
19	DISCIPLINARY REVIEW PROCESS FOR NON-
20	NIH-FUNDED RESEARCHERS.
21	The Secretary of Health and Human Services may
22	not—
23	(1) reinstate the Public Health Service inter-
24	disciplinary review process described in the guidance
25	entitled "Guidance on Procedures for the Provision

- of Marijuana for Medical Research" (issued on May 21, 1999); or (2) require another review of scientific protocols that is applicable only to research on marijuana or its components.
- 6 TITLE II—DEVELOPMENT OF
- 7 FDA-APPROVED DRUGS
- 8 USING CANNABIDIOL AND
- 9 **MARIJUANA**
- 10 SEC. 201. MEDICAL RESEARCH ON CANNABIDIOL.
- Notwithstanding any provision of the Controlled Sub-
- 12 stances Act (21 U.S.C. 801 et seq.), the Safe and Drug-
- 13 Free Schools and Communities Act (20 U.S.C. 7101 et
- 14 seq.), chapter 81 of title 41, United States Code, or any
- 15 other Federal law, an appropriately registered covered in-
- 16 stitution of higher education, practitioner, or manufac-
- 17 turer may manufacture, distribute, dispense, or possess
- 18 marijuana or cannabidiol if the marijuana or cannabidiol
- 19 is manufactured, distributed, dispensed, or possessed, re-
- 20 spectively, for purposes of medical research for drug devel-
- 21 opment or subsequent commercial production in accord-
- 22 ance with section 202.

1	SEC. 202. REGISTRATION FOR THE COMMERCIAL PRODUC-
2	TION AND DISTRIBUTION OF FOOD AND
3	DRUG ADMINISTRATION-APPROVED DRUGS.
4	The Attorney General shall register an applicant to
5	manufacture or distribute cannabidiol or marijuana for
6	the purpose of commercial production of a drug containing
7	or derived from marijuana that is approved by the Sec-
8	retary of Health and Human Services under section 505
9	of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10	355), in accordance with the applicable requirements
11	under subsection (a) or (b) of section 303 of the Con-
12	trolled Substances Act (21 U.S.C. 823).
13	TITLE III—DOCTOR-PATIENT
14	RELATIONSHIP
14 15	RELATIONSHIP SEC. 301. DOCTOR-PATIENT RELATIONSHIP.
15	SEC. 301. DOCTOR-PATIENT RELATIONSHIP.
15 16	SEC. 301. DOCTOR-PATIENT RELATIONSHIP. It shall not be a violation of the Controlled Sub-
15 16 17	SEC. 301. DOCTOR-PATIENT RELATIONSHIP. It shall not be a violation of the Controlled Substances Act (21 U.S.C. 801 et seq.) for a State-licensed
15 16 17 18	SEC. 301. DOCTOR-PATIENT RELATIONSHIP. It shall not be a violation of the Controlled Substances Act (21 U.S.C. 801 et seq.) for a State-licensed physician to discuss—
15 16 17 18 19	SEC. 301. DOCTOR-PATIENT RELATIONSHIP. It shall not be a violation of the Controlled Substances Act (21 U.S.C. 801 et seq.) for a State-licensed physician to discuss— (1) the currently known potential harms and
15 16 17 18 19 20	SEC. 301. DOCTOR-PATIENT RELATIONSHIP. It shall not be a violation of the Controlled Substances Act (21 U.S.C. 801 et seq.) for a State-licensed physician to discuss— (1) the currently known potential harms and benefits of marijuana derivatives, including
15 16 17 18 19 20 21	SEC. 301. DOCTOR-PATIENT RELATIONSHIP. It shall not be a violation of the Controlled Substances Act (21 U.S.C. 801 et seq.) for a State-licensed physician to discuss— (1) the currently known potential harms and benefits of marijuana derivatives, including cannabidiol, as a treatment with the legal guardian
15 16 17 18 19 20 21 22	SEC. 301. DOCTOR-PATIENT RELATIONSHIP. It shall not be a violation of the Controlled Substances Act (21 U.S.C. 801 et seq.) for a State-licensed physician to discuss— (1) the currently known potential harms and benefits of marijuana derivatives, including cannabidiol, as a treatment with the legal guardian of the patient of the physician if the patient is a
15 16 17 18 19 20 21 22 23	SEC. 301. DOCTOR-PATIENT RELATIONSHIP. It shall not be a violation of the Controlled Substances Act (21 U.S.C. 801 et seq.) for a State-licensed physician to discuss— (1) the currently known potential harms and benefits of marijuana derivatives, including cannabidiol, as a treatment with the legal guardian of the patient of the physician if the patient is a child; or

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

1	ties, such as those that are required to operate
2	motor vehicles or other heavy equipment; and
3	(3) the barriers associated with researching
4	marijuana or cannabidiol in States that have legal-
5	ized the use of such substances, which shall in-
6	clude—
7	(A) recommendations as to how such bar-
8	riers might be overcome, including whether pub-
9	lic-private partnerships or Federal-State re-
10	search partnerships may or should be imple-
11	mented to provide researchers with access to
12	additional strains of marijuana and cannabidiol;
13	and
14	(B) recommendations as to what safe-
15	guards must be in place to verify—
16	(i) the levels of tetrahydrocannabinol,
17	cannabidiol, or other cannabinoids con-
18	tained in products obtained from such
19	States is accurate; and
20	(ii) that such products do not contain
21	harmful or toxic components.
22	(b) Activities.—To the extent practicable, the Sec-
23	retary of Health and Human Services, either directly or
24	through awarding grants, contacts, or cooperative agree-
25	ments, shall expand and coordinate the activities of the

- 1 National Institutes of Health and other relevant Federal
- 2 agencies to better determine the effects of cannabidiol and
- 3 marijuana, as outlined in the report submitted under para-
- 4 graphs (1) and (2) of subsection (a).

Passed the House of Representatives July 26, 2022. Attest:

Clerk.

117TH CONGRESS H. R. 8454

AN ACT

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