

Mr. CARTER of Georgia. Mr. Speaker, in closing, I encourage my colleagues to support this bill, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, again, I urge my colleagues on both sides of the aisle to support this very important piece of bipartisan legislation. In the aftermath of COVID, we realize more and more that this type of electronic notarization really is the way to go.

Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 3962, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. CLOUD. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this motion will be postponed.

MEDICAL MARIJUANA AND CANNABIDIOL RESEARCH EXPANSION ACT

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 8454) to expand research on cannabidiol and marijuana, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 8454

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Medical Marijuana and Cannabidiol Research Expansion Act”.

(b) TABLE OF CONTENTS.—The table of contents for 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.

SEC. 2. DEFINITIONS.

(a) IN GENERAL.—In this Act—

(1) the term “appropriately registered” means that an individual or entity is registered under the 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 controlled substance on the schedule that is applicable to cannabidiol or marijuana, as applicable;

(2) the term “cannabidiol” means—

(A) the substance, cannabidiol, as derived from marijuana that has a delta-9-tetrahydrocannabinol level that is greater than 0.3 percent; and

(B) the synthetic equivalent of the substance described in subparagraph (A);

(3) the terms “controlled substance”, “dispense”, “distribute”, “manufacture”, “marijuana”, and “practitioner” have the meanings given such terms in section 102 of the Controlled Substances Act (21 U.S.C. 802), as amended by this Act;

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

(A) it has highest or higher research activity, as defined by the Carnegie Classification of Institutions of Higher Education; or

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

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

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

(6) the term “medical research for drug development” means medical research that is—

(A) a preclinical study or clinical investigation conducted in accordance with section 505(i) of the Federal Food, Drug, and Cosmetic 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 marijuana 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.

(b) UPDATING TERM.—Section 102(16) of the Controlled Substances Act (21 U.S.C. 802(16)) is amended—

(1) in subparagraph (A), by striking “the term ‘marihuana’ means” and inserting “the terms ‘marihuana’ and ‘marijuana’ mean”; and

(2) in subparagraph (B), by striking “The term ‘marihuana’ does not” and inserting “The terms ‘marihuana’ and ‘marijuana’ do not”.

SEC. 3. DETERMINATION OF BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled “Budgetary Effects of PAYGO Legislation” for this Act, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, provided that such statement has been submitted prior to the vote on passage.

TITLE I—REGISTRATIONS FOR MARIJUANA RESEARCH

SEC. 101. MARIJUANA 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”;

(4) by striking “Article 7” and inserting the following:

“(3) Article 7”;

(5) by inserting after paragraph (2)(A), as so designated, the following:

“(B)(i) The Attorney General shall register a practitioner to conduct research with marijuana (including any derivative, extract, preparation, and compound thereof) if—

“(I) the applicant’s research protocol has been reviewed and allowed—

“(aa) by the Secretary of Health and Human Services under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i));

“(bb) by the National Institutes of Health or another Federal agency that funds scientific research; or

“(cc) pursuant to sections 1301.18 and 1301.32 of title 21, Code of Federal Regulations, or any successors thereto; and

“(II) the applicant has demonstrated to the Attorney General that there are effective procedures in place to adequately safeguard against diversion of the controlled substance for legitimate medical or scientific use pursuant to section 105 of the Medical Marijuana and Cannabidiol Research Expansion Act, including demonstrating that the security measures are adequate for storing the quantity of marijuana the applicant would be authorized to possess.

“(ii) The Attorney General may deny an application for registration under this subparagraph only if the Attorney General determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the Attorney General shall consider the factors listed in—

“(I) subparagraphs (B) through (E) of paragraph (1); and

“(II) subparagraph (A) of paragraph (1), if the applicable State requires practitioners conducting research to register with a board or authority described in such subparagraph (A).

“(iii)(I) Not later than 60 days after the date on which the Attorney General receives a complete application for registration under this subparagraph, the Attorney General shall—

“(aa) approve the application; or

“(bb) request supplemental information.

“(II) For purposes of subclause (I), an application shall be deemed complete when the applicant has submitted documentation showing that the requirements under clause (i) are satisfied.

“(iv) Not later than 30 days after the date on which the Attorney General receives supplemental information as described in clause (iii)(I)(bb) in connection with an application described in this subparagraph, the Attorney General shall approve or deny the application.

“(v) If an application described in this subparagraph is denied, the Attorney General shall provide a written explanation of the basis of denial to the applicant.”.

SEC. 102. RESEARCH PROTOCOLS.

(a) IN GENERAL.—Paragraph (2)(B) of section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)), as added by section 101 of this Act, is further amended by adding at the end the following:

“(vi)(I) If the Attorney General grants an application for registration under clause (i),

the registrant may amend or supplement the research protocol without notification to, or review by, the Drug Enforcement Administration if the registrant does not change—

“(aa) the quantity or type of marijuana or cannabidiol (including any derivative, extract, preparation, and compound thereof);

“(bb) the source of such marijuana or cannabidiol; or

“(cc) the conditions under which such marijuana or cannabidiol is stored, tracked, or administered.

“(II)(aa) If a registrant under clause (i) seeks to change the type of marijuana or cannabidiol (including any derivative, extract, preparation, and compound thereof), the source of such marijuana or cannabidiol, or the conditions under which such marijuana or cannabidiol is stored, tracked, or administered, the registrant shall notify the Attorney General via registered mail, or an electronic means permitted by the Attorney General, not later than 30 days before implementing an amended or supplemental research protocol.

“(bb) A registrant may proceed with an amended or supplemental research protocol described in item (aa) if the Attorney General does not explicitly object during the 30-day period beginning on the date on which the Attorney General receives the notice under item (aa).

“(cc) The Attorney General may only object to an amended or supplemental research protocol under this subclause if additional security measures are needed to safeguard against diversion or abuse.

“(dd) If a registrant under clause (i) seeks to address additional security measures identified by the Attorney General under item (cc), the registrant shall notify the Attorney General via registered mail, or an electronic means permitted by the Attorney General, not later than 30 days before implementing an amended or supplemental research protocol.

“(ee) A registrant may proceed with an amended or supplemental research protocol described in item (dd) if the Attorney General does not explicitly object during the 30-day period beginning on the date on which the Attorney General receives the notice under item (dd).

“(III)(aa) If a registrant under clause (i) seeks to change the quantity of marijuana needed for research and the change in quantity does not impact the factors described in item (bb) or (cc) of subclause (I) of this clause, the registrant shall notify the Attorney General via registered mail or using an electronic means permitted by the Attorney General.

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

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

“(BB) the quantity of marijuana or cannabidiol already obtained;

“(CC) the quantity of additional marijuana or cannabidiol needed to complete the research; and

“(DD) an attestation that the change in quantity does not impact the source of the marijuana or cannabidiol or the conditions under which the marijuana or cannabidiol is stored, tracked, or administered.

“(cc) The Attorney General shall ensure that—

“(AA) any registered mail return receipt with respect to a notification under item (aa) is submitted for delivery to the registrant providing the notification not later than 3 days after receipt of the notification by the Attorney General; and

“(BB) notice of receipt of a notification using an electronic means permitted under item (aa) is provided to the registrant providing the notification not later than 3 days

after receipt of the notification by the Attorney General.

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

“(BB) The date described in this subitem is the date on which a registrant submitting a notification under item (aa) receives the registered mail return receipt with respect to the notification or the date on which the registrant receives notice that the notification using an electronic means permitted under item (aa) was received by the Attorney General, as the case may be.

“(ee) A notification submitted under item (aa) shall be deemed to be approved unless the Attorney General, not later than 10 days after receiving the notification, explicitly objects based on a finding that the change in quantity—

“(AA) does impact the source of the marijuana or cannabidiol or the conditions under which the marijuana or cannabidiol is stored, tracked, or administered; or

“(BB) necessitates that the registrant implement additional security measures to safeguard against diversion or abuse.

“(IV) Nothing in this clause shall limit the authority of the Secretary of Health and Human Services over requirements related to research protocols, including changes in—

“(aa) the method of administration of marijuana or cannabidiol;

“(bb) the dosing of marijuana or cannabidiol; and

“(cc) the number of individuals or patients involved in research.”

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

SEC. 103. APPLICATIONS TO MANUFACTURE MARIJUANA FOR RESEARCH.

(a) IN GENERAL.—Section 303 of the Controlled Substances Act (21 U.S.C. 823), as amended by sections 101 and 102 of this Act, is further amended—

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

(2) by inserting after subsection (b) the following:

“(c)(1)(A) As it relates to applications to manufacture marijuana for research purposes, when the Attorney General places a notice in the Federal Register to increase the number of entities registered under this Act to manufacture marijuana to supply appropriately registered researchers in the United States, the Attorney General shall, not later than 60 days after the date on which the Attorney General receives a completed application—

“(i) approve the application; or

“(ii) request supplemental information.

“(B) For purposes of subparagraph (A), an application shall be deemed complete when the applicant has submitted documentation showing each of the following:

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

“(ii) The requirements under this Act are satisfied.

“(iii) The applicant will limit the transfer and sale of any marijuana manufactured under this subsection—

“(I) to researchers who are registered under this Act to conduct research with controlled 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.

“(C) Not later than 30 days after the date on which the Attorney General receives supplemental information requested under subparagraph (A)(ii) with respect to an application, the Attorney General shall approve or deny the application.

“(2) If an application described in this subsection is denied, the Attorney General shall provide a written explanation of the basis of denial to the applicant.”

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

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

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

(b) TECHNICAL AND CONFORMING AMENDMENTS.—

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

(A) in section 102 (21 U.S.C. 802)—

(i) in paragraph (5)(B)—

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

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

(ii) in paragraph (54), by striking “303(f)” each place it appears and inserting “303(g)”;

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

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

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

(E) in section 309A(a)(2) (21 U.S.C. 829a(a)(2)), in the matter preceding subparagraph (A), by striking “303(g)(2)” and inserting “303(h)(2)”;

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

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

(H) in section 403(c)(2)(B) (21 U.S.C. 843(c)(2)(B)), by striking “303(f)” and inserting “303(g)”;

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

(2) Section 1008(c) of the Controlled Substances Import and Export Act (21 U.S.C. 958(c)) is amended—

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

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

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

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

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

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

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

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

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

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

SEC. 104. ADEQUATE AND UNINTERRUPTED SUPPLY.

(a) IN GENERAL.—On an annual basis, the Attorney General, in consultation with the Secretary of Health and Human Services, shall assess whether there is an adequate and uninterrupted supply of marijuana, including of specific strains, for research purposes.

(b) REPORT TO CONGRESS.—If the Attorney General, in consultation with the Secretary of Health and Human Services, determines there is an inadequate or interrupted supply of marijuana, including of specific strains for research purposes, the Attorney General shall report to Congress within 60 days of the determination on at least—

(1) the factors contributing to the inadequate or interrupted supply of marijuana;

(2) expected impacts of the inadequate or interrupted supply on ongoing research protocols; and

(3) specific steps the Attorney General will take to restore an adequate and uninterrupted supply of marijuana, including of specific strains, for research purposes.

SEC. 105. SECURITY REQUIREMENTS.

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

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

SEC. 106. PROHIBITION AGAINST REINSTATING INTERDISCIPLINARY REVIEW PROCESS FOR NON-NIH-FUNDED RESEARCHERS.

The Secretary of Health and Human Services may not—

(1) reinstate the Public Health Service interdisciplinary review process described in the guidance 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.

TITLE II—DEVELOPMENT OF 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 institution of higher education, practitioner, or manufacturer may manufacture, distribute, dispense, or possess marijuana or cannabidiol if the marijuana or cannabidiol is manufactured, distributed, dispensed, or

possessed, respectively, for purposes of medical research for drug development or subsequent commercial production in accordance with section 202.

SEC. 202. REGISTRATION FOR THE COMMERCIAL PRODUCTION AND DISTRIBUTION OF FOOD AND DRUG ADMINISTRATION-APPROVED DRUGS.

The Attorney General shall register an applicant to manufacture or distribute cannabidiol or marijuana for the purpose of commercial production of a drug containing or derived from marijuana that is approved by the Secretary of Health and Human Services under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), in accordance with the applicable requirements under subsection (a) or (b) of section 303 of the Controlled Substances Act (21 U.S.C. 823).

TITLE III—DOCTOR-PATIENT RELATIONSHIP

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

(2) the currently known potential harms and benefits of marijuana and marijuana derivatives, including cannabidiol, as a treatment with the patient or the legal guardian of the patient of the physician if the patient is a legal adult.

TITLE IV—FEDERAL RESEARCH

SEC. 401. FEDERAL RESEARCH.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in coordination with the Director of the National Institutes of Health and the heads of other relevant Federal agencies, shall submit to the Caucus on International Narcotics Control, the Committee on the Judiciary, and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce and the Committee on the Judiciary of the House of Representatives a report on—

(1) the potential therapeutic effects of cannabidiol or marijuana on serious medical conditions, including intractable epilepsy;

(2) the potential effects of marijuana, including—

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

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

(3) the barriers associated with researching marijuana or cannabidiol in States that have legalized the use of such substances, which shall include—

(A) recommendations as to how such barriers might be overcome, including whether public-private partnerships or Federal-State research partnerships may or should be implemented to provide researchers with access to additional strains of marijuana and cannabidiol; and

(B) recommendations as to what safeguards must be in place to verify—

(i) the levels of tetrahydrocannabinol, cannabidiol, or other cannabinoids contained in products obtained from such States is accurate; and

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

(b) ACTIVITIES.—To the extent practicable, the Secretary of Health and Human Services, either directly or through awarding grants,

contacts, or cooperative agreements, shall expand and coordinate the activities of the National Institutes of Health and other relevant Federal agencies to better determine the effects of cannabidiol and marijuana, as outlined in the report submitted under paragraphs (1) and (2) of subsection (a).

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Georgia (Mr. CARTER) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H.R. 8454.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of H.R. 8454, the Medical Marijuana and Cannabidiol Research Expansion Act, legislation that would expand comprehensive cannabis research.

In March, the Senate passed S. 253, the Cannabidiol and Marijuana Research Expansion Act. In April, the House considered and passed H.R. 5657, the Medical Marijuana Research Act, which also passed with strong bipartisan support last Congress.

The bill before us today, H.R. 8454, represents a bipartisan, bicameral agreement that resolves the differences between both bills and brings us to a historic, overdue moment for Congress.

The consumption of marijuana and marijuana-derived CBD for medical use is approved and regulated in 37 States, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands. This translates to tens of millions of Americans consuming marijuana every year. Yet, we still do not have a comprehensive body of research on the safety or therapeutic effects or benefits of marijuana products.

Because of its status as a schedule I substance, research on marijuana has been regulated in a restrictive, time-consuming way, and the existing research is not representative of the products that are currently available to many Americans.

H.R. 8454 streamlines the registration process for conducting research on marijuana and manufacturing marijuana products for research purposes and drug development. The bill maintains the appropriate oversight and control by the Department of Health and Human Services and the Drug Enforcement Administration and requires both applicants and regulators to adhere to clear protocols and timelines.

The bill requires HHS and DEA to respond to registration applicants in a timely manner and requires a regular assessment to confirm an adequate supply of marijuana, including specific

strains, for medical research. This ensures that the marijuana being provided for medical research appropriately reflects the strains and THC content in millions of products across the country.

Mr. Speaker, this bill also clarifies that doctors can discuss with patients the potential harms and benefits of marijuana as a medical treatment.

Finally, H.R. 8454 requires HHS to submit a report to Congress on the potential therapeutic effects of marijuana and CBD for serious medical conditions, effects on the developing human brain and body, and existing barriers to research.

Mr. Speaker, I thank Representatives BLUMENAUER, HARRIS, HOLMES NORTON, DINGELL, COHEN, GRIFFITH, LEE, and CASE for their leadership on this issue. I urge my colleagues to support the bill and look forward to the Senate acting expeditiously on our agreement to expand comprehensive cannabis research while protecting public health and safety.

Mr. Speaker, I reserve the balance of my time.

Mr. CARTER of Georgia. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today to speak in favor of H.R. 8454, the Medical Marijuana and Cannabidiol Research Expansion Act. This bill is a revised version of H.R. 5657, Medical Marijuana Research Act, which was led by Representatives HARRIS and BLUMENAUER, and overwhelmingly passed the House in April.

The text of H.R. 8454 that we are considering today is largely similar to H.R. 5657, but it is consensus language that was agreed to through bipartisan negotiations with the Senate. I am pleased we were able to get the language to a good place.

Marijuana is a schedule I controlled substance under the Controlled Substances Act. Research on these substances must be conducted in accordance with the Controlled Substances Act and requires the Drug Enforcement Administration approve research protocol.

If a researcher desires to make changes to an approved project, the researcher must submit a request to do so, which is then reviewed and must be approved by both the DEA and the FDA.

In addition to the extensive regulatory hurdles that researchers face, the actual supply of research-grade marijuana is relatively limited. The supply is subject to the single convention on narcotic drugs, which imposes certain obligations related to governmental oversight of its cultivation.

While the DEA and the National Institute on Drug Abuse have taken some steps to increase the number of domestic manufacturers of research-grade marijuana, more could be done in this space. The Medical Marijuana Research Expansion Act improves the Federal research landscape by streamlining

both the research and manufacturing registration processes.

This is critical to better understand the potential benefits and possible risks associated with marijuana use, as researchers must be able to study actual products that are currently used by consumers for both medical and recreational use. These data are long overdue, as policy decisions have far outpaced the science.

States that have fully legalized marijuana have done so in a relative information vacuum with less understanding of what it is and what it does than virtually any nutritional supplement currently on the market, and with far less information than they have on legal substances that are easily abused, such as alcohol or tobacco.

Until we make it easier to conduct the research, making fully informed policy decisions will remain challenging. Even rescheduling the substance administratively will necessitate robust data on potential medical use.

Recent evaluations conducted separately by the FDA and the National Academies of Sciences, Engineering, and Medicine have both illustrated the challenges of meeting the required standard of evidence for demonstrating effective medical use. Both studies concluded that lack of research was a significant factor in denying rescheduling petitions in the past.

If Congress does not act, we will continue to have limited ability to study these products in clinical trial settings. This commonsense solution will better our understanding of marijuana through legal, Federally sanctioned and scientifically valid research on this substance.

Mr. Speaker, I thank Representatives BLUMENAUER and HARRIS, along with Chairman PALLONE, for working together on this legislation, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I have no additional speakers, and I reserve the balance of my time.

Mr. CARTER of Georgia. Mr. Speaker, I yield such time as he may consume to the gentleman from Maryland (Mr. HARRIS), one of the leaders on this important subject.

Mr. HARRIS. Mr. Speaker, the chairman of the committee got it right, this is historic. This bill is overdue, bipartisan, and bicameral, as it should be.

Today, I rise in support of H.R. 8454, the Medical Marijuana and Cannabidiol Research Expansion Act.

Representative BLUMENAUER and I have jointly cosponsored this bill for four Congresses. Talk about overdue. Although we disagree about recreational marijuana—he supports it; I oppose it—we both concur that in regard to medical marijuana, we need to do the rigorous research to answer the questions.

As a physician, I realize that if we are going to have marijuana legal in over three dozen States for medical uses, we really ought to be able to do

the research on it to see what it can and can't be used for. Many claims are made about it—some are legitimate, some will be found to be illegitimate—but the American public deserves to know whether medical marijuana and cannabidiol work for those claims that are being made.

This bill makes it easier to do the necessary, rigorous medical research just like is done for any other drug that has a claim of efficacy in this country. The American public deserves to know what medical marijuana is useful for, because for anyone with those conditions where it is found to be useful, it could be a godsend. But for other conditions where the claims won't be found to be valid with rigorous research, it would be found to be ineffective, and that would help protect American patients as well.

This would modernize our research methods, bringing medical marijuana up to the scientific standards we use for every other type of medication that is sold as a drug in this country.

Mr. Speaker, I urge support of this bill.

Mr. PALLONE. Mr. Speaker, I reserve the balance of my time.

Mr. CARTER of Georgia. Mr. Speaker, I yield such time as he may consume to the gentleman from Virginia (Mr. GRIFFITH).

Mr. GRIFFITH. Mr. Speaker, I thank my friend, and leader of the committee, FRANK PALLONE.

H.R. 8454 is an important bill, and it is interesting to hear the conversation here on the floor. Mr. CARTER was talking about the history that you couldn't get marijuana rescheduled because they didn't have enough research, and you can't get the research because it is scheduled as a schedule I drug, so we have been trapped in this vortex where we can't get the information.

I, too, am against recreational marijuana. But for medical marijuana, I think it has a great benefit. For years, we have been in this trap where you couldn't do sufficient research, therefore you couldn't reschedule it. It is crazy. We are going to fix it here today.

My belief is that medical marijuana can be beneficial when used in a proper setting. Despite the increasing use of cannabis products around the country, there have been very few legitimate peer-reviewed studies to determine the effect of cannabis on the body.

We know it does some good anecdotally for patients with juvenile seizures. What we don't know is how much THC has to be in the cannabidiol to make it effective. This is what we need research for.

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This bill allows us to obtain approval to conduct cannabis research and obtain quality product, not just one strain out of Mississippi, but multiple products, quality products, monitored by the Government, to make sure it is not being misused, to be used in this research.

It encourages research by improving and streamlining the registration process for marijuana. It also ensures the availability of verified cannabis products necessary for legitimate research by allowing approved institutions of higher education, practitioners, and manufacturers to manufacture and distribute marijuana for the purpose of conducting research.

As someone who has advocated for this legislation for years, I appreciate the work that has been done to get us here today.

Whatever position you may have on marijuana use, you need to know that this bill will allow us to come together and support more scientific research so that we can make informed decisions as we move forward as legislators.

I have to tell you, being here live as a legislator is also important, because the genesis of this bill was several conversations that took place on the floor of this House when people who disagree on the underlying issue would argue about what research showed. It finally became clear to Representative BLUMENAUER, to Representative HARRIS, to myself, and to others, that we had to have more research in order to get the right answers for the American people.

Mr. Speaker, I urge everyone to support H.R. 8454.

Mr. CARTER of Georgia. Mr. Speaker, I would encourage my colleagues to support this legislation, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, again, I think this is a great way of dealing with this issue overall and getting the Senate on board.

Mr. Speaker, I urge my colleagues to support this important legislation, and I yield back the balance of my time.

Ms. ESHOO. Mr. Speaker, I rise in support of H.R. 8454, the Medical Marijuana and Cannabidiol Research Expansion Act. I advanced a precursor to this bipartisan bill through my Health Subcommittee and I'm proud to support it on the Floor today.

According to the Department of Health and Human Services National Survey on Drug Use, over 48 million Americans reported using cannabis in the past year. Thirty-seven states now allow the medicinal use of cannabis and 19 states and the District of Columbia have legalized cannabis for adult use.

But state laws and federal policy are a thousand miles apart. As more states allow cannabis, the federal government still strictly controls and prohibits it, even restricting legitimate medical research.

The Medical Marijuana Research Act addresses these restrictions on research and alleviates a burdensome, out-of-date process for scientific researchers. First, it creates a new, less cumbersome registration process specifically for marijuana, reducing approval wait times and costly security measures. Second, this bill makes it easier for researchers to obtain the cannabis they need for their studies through reforms in production and distribution regulations.

Under this bill scientists will no longer be forced to wait more than a year to become federally-approved to conduct cannabis research. They will also not be forced to use the

cannabis grown by a government-authorized farm at the University of Mississippi. This cannabis lacks the properties and potency of commercially-available cannabis and leads to inadequate research.

This is a commonsense bill that will update federal policy to advance research on cannabis and its compounds. I urge my colleagues to support this bill.

Mr. BLUMENAUER. Mr. Speaker, today I will vote to pass the Medical Marijuana and Cannabidiol Research Expansion Act. This legislation would remove barriers for research into cannabis and facilitate access to an increased supply of cannabis for research purposes.

The cannabis laws in this country are broken, including our laws that govern cannabis research. Because cannabis is a Schedule I substance, researchers must jump through hoops and comply with onerous requirements just to do basic research on the medical potential of the plant.

The Medical Marijuana and Cannabidiol Research Expansion Act amends the Controlled Substances Act to streamline the registration process and expands opportunity for our researchers to investigate the potential and impacts of cannabis.

My partners in the House and Senate and I worked closely with experts in Congress and the Department of Health and Human Services (HHS) to ensure this legislation will expand cannabis research, not restrict it. Specifically, the use of "practitioners" includes "NIH-funded researchers," according to feedback from HHS. This ensures that this legislation will not restrict researchers already considered entities eligible to conduct research under the Controlled Substances Act. H.R. 8454 is designed to streamline and broaden access to researching marijuana.

Enacting this legislation will be an important step forward in making the federal government a real partner in the path forward on cannabis. In addition to this legislation, we must continue to advance banking access for cannabis businesses; prioritize expungements, clemencies, and resentencing for cannabis convictions; make robust investments in cannabis research; develop accurate tests for impairment; ensure our veterans can access medical cannabis; and invest in communities targeted in the failed war on drugs.

The Medical Marijuana and Cannabidiol Research Expansion Act demonstrates the power of good faith bipartisan engagement on cannabis policy and the opportunity of this moment to enact laws our communities need.

I look forward to working with Senators DIANNE FEINSTEIN, BRIAN SCHATZ, and CHUCK GRASSLEY and my co-lead Representative ANDY HARRIS to enact this legislation and expand our Nation's cannabis research capabilities.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 8454, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. CLOUD. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this motion will be postponed.

GABRIELLA MILLER KIDS FIRST RESEARCH ACT 2.0

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 623) to require certain civil penalties to be transferred to a fund through which amounts are made available for the Gabriella Miller Kids First Pediatric Research Program at the National Institutes of Health, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 623

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Gabriella Miller Kids First Research Act 2.0".

SEC. 2. FUNDING FOR THE PEDIATRIC RESEARCH INITIATIVE.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(1) in section 402A(a)(2) (42 U.S.C. 282a(a)(2))—

(A) in the heading—

(i) by striking "10-YEAR"; and

(ii) by striking "THROUGH COMMON FUND";

(B) by striking "to the Common Fund" and inserting "to the Division of Program Coordination, Planning, and Strategic Initiatives";

(C) by striking "10-Year";

(D) by striking "and reserved under subsection (c)(1)(B)(i) of this section"; and

(E) by inserting before the period the following: ", and \$25,000,000 for each of fiscal years 2023 through 2027";

(2) in each of paragraphs (1)(A) and (2)(C) of section 402A(c) (42 U.S.C. 282a(c)), by striking "section 402(b)(7)(B)" and inserting "section 402(b)(7)(B)(i)"; and

(3) in section 402(b)(7)(B)(ii) (42 U.S.C. 282(b)(7)(B)(ii)), by striking "the Common Fund" and inserting "the Division of Program Coordination, Planning, and Strategic Initiatives".

SEC. 3. COORDINATION OF NIH FUNDING FOR PEDIATRIC RESEARCH.

(a) SENSE OF CONGRESS.—It is the sense of the Congress that the Director of the National Institutes of Health should continue to oversee and coordinate research that is conducted or supported by the National Institutes of Health for research on pediatric cancer and other pediatric diseases and conditions, including through the Pediatric Research Initiative Fund.

(b) AVOIDING DUPLICATION.—Section 402(b)(7)(B)(ii) of the Public Health Service Act (42 U.S.C. 282(b)(7)(B)(ii)) is amended by inserting "and shall prioritize, as appropriate, such pediatric research that does not duplicate existing research activities of the National Institutes of Health" before "and".

SEC. 4. REPORT ON PROGRESS AND INVESTMENTS IN PEDIATRIC RESEARCH.

Not later than 5 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report that—

(1) details pediatric research projects and initiatives receiving funds allocated pursuant to section 402(b)(7)(B)(ii) of the Public Health Service Act (42 U.S.C. 282(b)(7)(B)(ii)); and