AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 253

To expand research on the cannabidiol and marihuana.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Cannabidiol and Marihuana Research Expansion Act''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. DEFINITIONS.

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 marihuana, as applicable;

(2) the term ''cannabidiol'' means—

(A) the substance, cannabidiol, as derived from marihuana 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'', ''marihuana'', 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)(i) 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 marihuana or cannabidiol as a drug; and

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

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

TITLE I—REGISTRATIONS FOR MARIHUANA RESEARCH

SEC. 101. MARIHUANA RESEARCH APPLICATIONS.

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

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

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

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

''(2)(A) Registration applications'';

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

''(3) Article 7''; and

(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 marihuana if—

''(I) the applicant's research protocol—

''(aa) 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 Cannabidiol and Marihuana Research Expansion Act, including demonstrating that the security measures are adequate for storing the quantity of marihuana 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 appli-

cation 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 amended 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 reapplying if the registrant does not change—

''(aa) the quantity or type of drug;

''(bb) the source of the drug; or

''(cc) the conditions under which the drug is stored, tracked, or administered.

''(II)(aa) If a registrant under clause (i) seeks to change the type of drug, the source of the drug, or conditions under which the drug 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 marihuana 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 marihuana already obtained;

''(CC) the quantity of additional marihuana needed to complete the research; and

''(DD) an attestation that the change in quantity does not impact the source of the drug or the conditions under which the drug 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 drug or the conditions under which the drug 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 marihuana;

''(bb) the dosing of marihuana; 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 MARIHUANA FOR RESEARCH.

(a) IN GENERAL.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is 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 marihuana for research purposes, if the Attorney General places a notice in the Federal Register to increase the number of entities registered under this Act to manu-

facture marihuana 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 marihuana 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 marihuana 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 Cannabidiol and Marihuana Research Expansion Act.

''(vii) The applicant is licensed by each State in which the applicant will conduct operations under this subsection, to manufacture marihuana, 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)''; and

(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 (52)(B)—

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

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

(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)''; and

(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)''; and

(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)''; and

(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)''; and

(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.

On an annual basis, the Attorney General shall assess whether there is an adequate and uninterrupted supply of marihuana, including of specific strains, for research purposes.

SEC. 105. SECURITY REQUIREMENTS.

(a) IN GENERAL.—An individual or entity engaged in researching marihuana 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 marihuana or its components.

TITLE II—DEVELOPMENT OF FDA-APPROVED DRUGS USING CANNABIDIOL AND MARIHUANA

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-

stitution of higher education, a practitioner, or a manufacturer may manufacture, distribute, dispense, or possess marihuana or cannabidiol if the marihuana 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 marihuana for the purpose of commercial production of a drug containing or derived from marihuana 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).

SEC. 203. IMPORTATION OF CANNABIDIOL FOR RESEARCH PURPOSES.

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

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

(A) in paragraph (1), by striking ''and'' at the end;

(B) in paragraph (2)(C), by inserting ''and'' after ''uses,''; and

(C) inserting before the undesignated matter following paragraph (2)(C) the following:

''(3) such amounts of marihuana or cannabidiol (as defined in section 2 of the Cannabidiol and Marihuana Research Expansion Act) as are—

''(A) approved for medical research for drug development (as such terms are defined in section 2 of the Cannabidiol and Marihuana Research Expansion Act), or

''(B) necessary for registered manufacturers to manufacture drugs containing marihuana or cannabidiol that have been approved for use by the Commissioner of Food and Drugs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),''; and

(2) in section 1007 (21 U.S.C. 957), by amending subsection (a) to read as follows:

''(a)(1) Except as provided in paragraph (2), no person may—

''(A) import into the customs territory of the United States from any place outside thereof (but

within the United States), or import into the United States from any place outside thereof, any controlled substance or list I chemical, or

''(B) export from the United States any controlled substance or list I chemical,

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

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

''(A) medical research for drug development authorized under section 201 of the Cannabidiol and Marihuana Research Expansion Act; or

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

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 marihuana 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 marihuana and marihuana 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 marihuana on serious medical conditions, including intractable epilepsy;

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