ALB18719 S.L.C. Grassley #7

Chuck Grassley

AMENDMENT NO._____ Calendar No._____

Purpose: To modify the definition of the term "hemp" and to require the Attorney General to make a determination as to whether cannabidiol should be a controlled substance and listed in a schedule under the Controlled Substances Act and to expand research on the cannabidiol and marihuana.

IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

S._____

To provide for the reform and continuation of agricultural and other programs of the Department of Agriculture through fiscal year 2023, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENTS intended to be proposed by _____

Viz:

Beginning on page 803, strike line 23 and all that follows through page 804, line 4, and insert the following:

"(1) HEMP.—The term 'hemp'—

"(A) means the plant Cannabis sativa L. and any part of that plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis; and

"(B) does not include the derivatives, extracts, cannabinoids, isomers, acids, salts, and or salts of isomers, whether growing or not, of the Cannabis sativa L.

At the end, add the following:

TITLE XIII—CANNABIDIOL AND MARIJUANA RESEARCH EXPANSION ACT

SEC. 13001. SHORT TITLE.

This title may be cited as the "Cannabidiol and Marijuana Research Expansion Act".

Subtitle A—Registrations for Marihuana Research

SEC. 13101. 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) Registration applications";

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

"(4) Article 7"; and

(5) by inserting before paragraph (4), as so designated, the following:

"(3)(A) The Attorney General shall register a practitioner to conduct research with marihuana if—

"(i) the applicant's research protocol—

"(I) has been reviewed and allowed—

"(aa) by the Secretary 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 section 1301.18 of title 21, Code of Federal Regulations, or any successor thereto;

"(ii) the applicant has demonstrated 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 13104 of the

Cannabidiol and Marijuana Research Expansion Act.

"(B) The Attorney General shall approve an application for registration under this paragraph unless the Attorney General determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

"(i) The applicant's experience in dispensing, or conducting research with respect to, controlled substances.

"(ii) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

"(iii) Compliance with applicable State, Federal, or local laws relating to controlled substances.

"(iv) Such other conduct by the applicant that may threaten the public health and safety.

"(C)(i) Not later than 60 days after the date on which the Attorney General receives a complete application for registration under this paragraph, the Attorney General shall—

"(I) approve the application; or

"(II) request supplemental information.

"(ii) For purposes of clause (i), an application shall be deemed complete when the applicant has submitted documentation showing that the requirements under subparagraph (A) are satisfied.

"(D) Not later than 30 days after the date on which the Attorney General receives supplemental information as described in subparagraph (C)(i)(II) in connection with an application described in this paragraph, the Attorney General shall approve or deny the application.

"(E) If an application described in this paragraph is denied, the Attorney General shall provide a written explanation of the basis of denial to the applicant..".

SEC. 13102. RESEARCH PROTOCOLS.

(a) IN GENERAL.—The Attorney General shall amend section 1301.18 of title 21, Code of Federal Regulations (as in effect on the date of enactment of this Act) by striking subsections (c) and (d) and inserting the following:

"(c) In the event that the registrant desires to increase the quantity of a controlled substance used for an approved research project, he/she shall submit a request to the Registration Unit, Drug Enforcement Administration, by registered mail, return receipt requested. See the Table of DEA Mailing Addresses in 1321.01 of this chap-

ter for the current mailing address. The request shall contain the following information: DEA registration number; name of the controlled substance or substances and the quantity of each authorized in the approved protocol; and the additional quantity of each desired. Upon return of the receipt, the registrant shall be authorized to purchase and use the additional quantity of the controlled substance or substances specified in the request.

"(d) In the event the registrant desires to conduct research beyond the variations provided in the registrant's approved protocol (excluding any increase in the quantity of the controlled substance requested for his/her research project as outlined in subsection (c) of this section), he/she shall submit 3 copies by registered mail, with a return receipt requested, and a copy through the online process established by the Registration Unit, Drug Enforcement Administration of a supplemental protocol in accordance with subsection (a) of this section describing the new research and omitting information in the supplemental protocol which has been stated in the original protocol. Unless explicitly denied, supplemental protocols shall be considered approved 30 days after the date on which the return receipt is returned.".

(b) LIMITATION ON MODIFICATION OF PROTOCOLS.—The Attorney General may not amend section

1301.18 of title 21, Code of Federal Regulations, as amended by the Attorney General pursuant to subsection (a) of this section, or promulgate any other regulation, in a manner that further restricts the ability of a registrant to increase the quantity of a controlled substance used for an approved research project or conduct research beyond the variations provided in the registrant's approved protocol.

SEC. 13103. 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 (e) 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, if the Attorney General places a notice in the Federal Register to increase the number of entities registered under this Act to manufacture marihuana to supply legitimate 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 that the requirements designated in the notice in the Federal Register are satisfied.

"(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) In determining whether to approve an application described in paragraph (1), the Attorney General shall consider the demand from researchers for an adequate and uninterrupted supply of specific strains of marijuana and for marijuana grown to specific manufacturing processes.

"(3) 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 304 (21 U.S.C. 824), by striking "303(g)(1)" each place it appears and inserting "303(h)(1)";

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

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

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

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

(G) 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)".

SEC. 13104. 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. 13105. 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.

Subtitle B—Proceedings for Control, Transfer, or Removal of Cannabidiol

SEC. 13201. SCIENTIFIC AND MEDICAL EVALUATIONS.

Not later than 1 year after the date of enactment of this Act, the Attorney General and the Secretary of Health and Human Services shall each complete the scientific and medical evaluation described in section 201(b) of the Controlled Substances Act (21 U.S.C. 811(b)) as to cannabidiol, which shall take into consideration the factors described in paragraphs (1) through (8) of subsection (c) of section 201 of that Act (21 U.S.C. 811(c)).

SEC. 13202. PROCEEDINGS TO CONTROL, TRANSFER, OR REMOVE CANNABIDIOL.

After taking into consideration the evaluation described in subsection (a) of section 13201, if the Attorney General determines that the evaluations, recommendations, and all other relevant data warrant control, transfer, or removal of cannabidiol, the Attorney General shall initiate proceedings for control, transfer, or removal under section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)).

Subtitle C—Development of FDA-approved Drugs Using Cannabidiol and Marihuana

SEC. 13301. DEFINITIONS.

In this title—

(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 activity that is carried out by the individual or entity with respect to with a controlled substance on the schedule that is applicable to cannabidiol or marihuana, as applicable;

(2) the term "cannabidiol" means the nonpsychoactive substance, cannabidiol, as derived from marihuana or the synthetic formulation;

(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);

(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 Cosmetics 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.);

(7) the term "registered manufacturer" means an individual or entity who is appropriately registered to manufacture controlled substances under the Controlled Substances Act (21 U.S.C. 801 et seq.), including an individual or entity appropriately registered to manufacture controlled substances as part of research; and

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

SEC. 13302. MEDICAL RESEARCH ON CANNABIDIOL.

(a) IN GENERAL.—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, 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.

(b) REGISTRATION FOR RESEARCH INVOLVING CANNABIDIOL.—

(1) INITIAL PERIOD.—During the period beginning on the date of enactment of this Act and ending on the date on which the Attorney General makes a determination regarding control of cannabidiol, an individual or entity engaged in medical research for drug development may distribute, dispense, or possess cannabidiol for purposes of the medical research for drug development if the individual or entity is registered under the Controlled Substances Act (21 U.S.C. 801 et seq.) to engage in such activity with a controlled substance in schedule II in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)).

(2) COMPLETION OF ONGOING RESEARCH.—If, as a result of the determination and proceedings described in title II, cannabidiol is a controlled substance in schedule I in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)), an individual or entity engaged in medical research for drug development may continue to distribute, dispense, or possess cannabidiol for purposes of completing the medical research for drug development if the individual or entity—

(A) was engaged in the medical research for drug development in accordance with para-

graph (1) on or before the date on which the proceedings are completed; and

(B) is registered under the Controlled Substances Act (21 U.S.C. 801 et seq.) to engage in such activity with a controlled substance in schedule II in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)).

SEC. 13303. 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. 13304. GOOD MANUFACTURING PRACTICES.

Not later than 180 days after the date of enactment of this Act, the Commissioner of Food and Drugs shall develop and publish recommendations for good manufacturing practices for growing and producing marihuana for medical research for drug development.

SEC. 13305. 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 are—

"(A) approved for medical research for drug development (as such terms are defined in section 13301 of the Cannabidiol and Marijuana 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 that has been approved for—

"(A) medical research for drug development authorized under section 13302 of the Cannabidiol and Marijuana 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.).".

Subtitle D—Relation to the Single Convention on Narcotic Drugs

SEC. 13401. RELATION TO THE SINGLE CONVENTION ON NARCOTIC DRUGS.

(a) CONSTRUCTIVE POSSESSION AND CONTROL.—The registration of manufacturers and distributors of marihuana pursuant to this title shall constitute constructive possession and control by the Federal Government for the purposes of the obligations under the Single Convention on Narcotic Drugs.

(b) ARTICLE 28.—Article 28 of the Single Convention on Narcotic Drugs shall not be construed to prohibit, or impose additional restrictions upon, the manufacturing of marihuana that is conducted in accordance with this title.

(c) SINGLE CONVENTION ON NARCOTIC DRUGS DEFINED.—In this section, the term "Single Convention on Narcotic Drugs" means the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961.

Subtitle E—Safe Harbor

SEC. 13501. DEFINITIONS.

In this subtitle—

(1) the term "adult" means an individual who is not less than 18 years of age;

(2) the term "child" means an individual who is not more than 17 years of age;

(3) the term "intractable epilepsy" means an epileptic seizure disorder for which standard medical treatment—

(A) does not prevent or significantly ameliorate recurring, uncontrollable seizures; or

(B) results in harmful side effects; and

(4) the term "neurologist" means an allopathic or osteopathic physician board-certified in neurology in good standing and licensed in the State in which the physician practices neurology.

SEC. 13502. SAFE HARBOR.

Notwithstanding the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), or any other Federal law, it shall not be unlawful for—

(1) a legal guardian to possess or transport cannabidiol or any other nonpsychoactive component of marihuana for purposes of dispensing the cannabidiol or other nonpsychoactive component to a child of the legal guardian if—

(A) the child has been treated by a neurologist for intractable epilepsy for not less than 6 months;

(B) the child's neurologist attests that other treatment options have not resulted in significant clinical improvement;

(C) the child's neurologist attests that he or she has discussed the currently known potential harms and benefits of using cannabidiol or other nonpsychoactive components of marihuana as a treatment with the child's legal guardian;

(D) the child's neurologist attests that he or she will monitor the child for potential adverse reactions; and

(E) the legal guardian provides documentation for the requirements under subparagraphs (A), (B), (C), and (D);

(2) an adult to possess or transport cannabidiol or any other nonpsychoactive component of marihuana if—

(A) the adult has been treated by a neurologist for intractable epilepsy for not less than 6 months;

(B) the adult's neurologist attests that other treatment options have not resulted in significant clinical improvement;

(C) the adult's neurologist attests that he or she has discussed the currently known potential harms and benefits of using cannabidiol or other nonpsychoactive components of marihuana as a treatment with the adult;

(D) the adult's neurologist attests that he or she will monitor the adult for potential adverse reactions; and

(E) the adult provides documentation for the requirements under subparagraphs (A), (B), (C), and (D); or

(3) a State-licensed physician to discuss the currently known potential harms and benefits of cannabidiol or any other nonpsychoactive component of marihuana as a treatment with a patient of the physician, or the legal guardian of the patient if the patient is a child.

SEC. 13503. SUNSET.

This subtitle shall cease to have force or effect on the date that is 4 years after the date of enactment of this Act.

Subtitle F—Federal Research

SEC. 13601. FEDERAL RESEARCH.

The Secretary of Health and Human Services, either directly or through awarding grants, contracts, or cooperative agreements shall expand, intensify, and coordinate the activities of the National Institutes of Health and other relevant Federal agencies to better determine—

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

(2) the potential impacts of marihuana, including—

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

(B) the effect of various delta-9-tetrahydrocannabinol levels on cognitive abilities that are required to operate motor vehicles or other heavy equipment.