115TH CONGRESS
1ST SESSION

S. 1276

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 potential medical benefits of cannabidiol and other marihuana components.

IN THE SENATE OF THE UNITED STATES

MAY 25, 2017

Mrs. FEINSTEIN (for herself, Mr. GRASSLEY, Mr. DURBIN, Mr. TILLIS, and Mrs. ERNST) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

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 potential medical benefits of cannabidiol and other marihuana components.

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 ''Cannabidiol Research Expansion Act''.

SEC. 2. DEFINITIONS.

In this Act—

(1) the term ''authorized medical research'' 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.);

(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 ''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

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

SEC. 3. PROCEEDINGS FOR CONTROL, TRANSFER, OR REMOVAL OF CANNABIDIOL.

(a) 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)).

(b) PROCEEDINGS TO CONTROL, TRANSFER, OR REMOVE CANNABIDIOL.—After taking into consideration the evaluation described in subsection (a), 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)).

SEC. 4. RESEARCH PROTOCOLS.

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 chapter 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 paragraph (c) of this section), he/she shall submit three copies by registered mail, with a return receipt requested, of a supplemental protocol in accordance with paragraph (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.''.

SEC. 5. 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 authorized medical research.

(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 authorized medical research may distribute, dispense, or possess cannabidiol for purposes of the authorized medical research 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 section 3, 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 authorized medical research may continue to distribute, dispense, or possess cannabidiol for purposes of completing the authorized medical research if the individual or entity—

(A) was engaged in the authorized medical research in accordance with paragraph (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)).

(c) REGISTRATION FOR THE COMMERCIAL PRODUCTION AND DISTRIBUTION OF FOOD AND DRUG ADMINIS-

TRATION 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).

(d) TIMELY PROCESSING OF REGISTRATION APPLICATIONS.—

(1) IN GENERAL.—Not later than 60 days after the Attorney General receives an application for registration under the Controlled Substances Act (21 U.S.C. 801 et seq.) to manufacture, distribute, dispense, or possess controlled substances, the Attorney General shall—

(A) grant or deny the application; or

(B) request supplemental information.

(2) ADDITIONAL INFORMATION.—Not later than 30 days after the Attorney General receives supplemental information as described in paragraph (1)(B) in connection with an application described in

paragraph (1), the Attorney General shall grant or deny the application.

(e) INFORMATION REGARDING DENIALS.—If an application described in subsection (d)(1) is denied, the Attorney General shall provide a written explanation of the basis of denial to the applicant.

SEC. 6. 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 authorized medical research (as such terms are defined in section 2 of the Cannabidiol 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) authorized medical research authorized under section 5 of the Cannabidiol 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.).''.

SEC. 7. SAFE HARBOR.

(a) DEFINITIONS.—In this section—

(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.

(b) 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.

(c) SUNSET.—This section shall cease to have force or effect on the date that is 4 years after the date of enactment of this Act.

SEC. 8. FEDERAL RESEARCH.

The Secretary of Health and Human Services, either directly or through awarding grants, contracts, or cooperative agreements to covered institutions of higher education, medical or osteopathic schools, or practitioners, or a consortia of covered institutions of higher education, medical or osteopathic schools, or practitioners, shall expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on cannabidiol and other nonpsychoactive components of marihuana to better determine their potential therapeutic effects on serious medical conditions, including intractable epilepsy.

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