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116TH CONGRESS
1ST SESSION

H. R. 4322

To promote cannabis research, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 12, 2019

Ms. SHALALA (for herself, Mr. GAETZ, and Ms. LEE of California) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To promote cannabis research, and for other purposes.

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 ''Expanding Cannabis Research and Information Act''.

SEC. 2. CANNABIS RESEARCH AT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(a) NATIONAL CANNABIS RESEARCH AGENDA.—Part B of title IV of the Public Health Service Act (42 U.S.C.

284 et seq.) is amended by adding at the end the following:

"SEC. 409K. NATIONAL CANNABIS RESEARCH AGENDA.

"Not later than 1 year after the date of enactment of the Expanding Cannabis Research and Information Act, the Director of NIH, in collaboration with the Director of the Centers for Disease Control and Prevention and the Assistant Secretary for Mental Health and Substance Use, shall develop a national cannabis research agenda that addresses key questions and gaps in evidence, including with respect to each of the following:

"(1) The efficacy of cannabis in providing therapeutic benefits for certain priority diseases or conditions, which may include epilepsy, multiple sclerosis-related spasticity, chemotherapy-induced pain and discomfort, using cannabis as an alternative to opioid analgesics for acute or chronic pain, sleep apnea, Tourette syndrome, anxiety, post-traumatic stress disorder, and any other disease or condition determined to be appropriate and of importance by the Director.

"(2) The effect of cannabis on at-risk populations, including children, older individuals, and pregnant or breast-feeding women.

''(3) The long-term effects of cannabis use, including dose-response relationship and the connection between cannabis use and behavioral health.

''(4) The clinically appropriate modes of delivery of cannabis.

''(5) Public safety considerations related to cannabis, including—

''(A) variation in the potency of cannabis products;

''(B) youth access to and use of cannabis, including marketing, packaging, edible formulations, and flavor options that target youth;

''(C) risk factors for cannabis misuse;

''(D) impaired driving related to cannabis use; and

''(E) accidental ingestion of cannabis.''.

(b) SURVEILLANCE ACTIVITIES.—Part A of title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

''SEC. 310B. SURVEILLANCE ACTIVITIES ON CANNABIS USE.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, in collaboration with the Assistant Secretary for Mental Health and Substance Use, the Administrator of the Centers for Medicare & Medicaid Services, and the Di-

rector of the Agency for Healthcare Research and Quality, shall carry out surveillance activities to collect population-wide data on cannabis use.

''(b) PERMISSIBLE ACTIVITIES.—

''(1) IN GENERAL.—In carrying out activities under this section, the Secretary may collect, as appropriate, with respect to cannabis use—

''(A) data on—

''(i) health outcomes, including biological data;

''(ii) health care utilization, which shall include hospitalizations and utilization of emergency departments related to consumption of cannabis, including among youth;

''(iii) demographic factors associated with cannabis use;

''(iv) the variety of products and delivery modes used; and

''(v) other relevant health information to improve the understanding of cannabis use in all age groups and sub-populations; and

''(B) data through public health surveillance systems, surveys, questionnaires, and

databases of health care records, including, as appropriate, the Behavioral Risk Factor Surveillance System, the Youth Risk Behavioral Surveillance System, the Monitoring the Future health survey, the National Survey on Drug Use and Health, or the Healthcare Cost and Utilization Project (or any successor surveys).

''(2) PRIVACY.—Any data collected under paragraph (1) shall be collected in manner that protects personal privacy to the extent, at a minimum, that is required under applicable Federal and State law.''.

SEC. 3. RESCHEDULING OF MARIHUANA.

(a) IN GENERAL.—Subsection (c) of schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by striking paragraph (10).

(b) SCHEDULE III.—Schedule III of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end the following:

''(f) Marihuana.''.

SEC. 4. CENTERS OF EXCELLENCE IN CANNABIS RESEARCH.

(a) IN GENERAL.—Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.), as amended

by section 2(a), is further amended by adding at the end the following:

"SEC. 409L. CENTERS OF EXCELLENCE IN CANNABIS RESEARCH.

"(a) DESIGNATION.—

"(1) IN GENERAL.—The Director of NIH shall designate institutions of higher education as Centers of Excellence in Cannabis Research for the purpose of interdisciplinary research related to cannabis and other biomedical, behavioral, and social issues related to cannabis. No institution of higher education may be designated as a Center unless an application therefor has been submitted to, and approved by, the Director of NIH. Such an application shall be submitted in such manner and contain such information as the Director of NIH may reasonably require. The Director of NIH may not approve such an application unless—

"(A) the application contains or is supported by reasonable assurances that—

"(i) at least 1 individual employed by the applicant—

"(I) is registered under section 303(f) of the Controlled Substances Act to conduct research with con-

trolled substances in schedule III of section 202(c) of that Act; and

''(II) is an active participant in the cannabis research activities of the applicant;

''(ii) the applicant has not had a registration to conduct research with controlled substances under section 303 of the Controlled Substances Act denied, revoked, or suspended under section 304 of that Act;

''(iii) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on cannabis and to provide coordination of such research among such disciplines;

''(iv) the applicant has available to it sufficient personnel and facilities (including laboratory, reference, storage, security, and data analysis facilities) to carry out the research plan required under subparagraph (B); and

''(v) the applicant has the capacity to conduct academic courses and train stu-

dents and professionals on appropriate research and knowledge of cannabis; and

''(B) the application contains a detailed 5-year plan for research relating to cannabis.

''(2) GEOGRAPHIC REPRESENTATION.—The Director of NIH shall ensure geographic representation across the United States in designating institutions of higher education as Centers of Excellence in Cannabis Research.

''(3) TERM OF DESIGNATION.—A designation under this section shall be for a period of 5 years. An institution of higher education may reapply in accordance with the requirements under paragraph (1) for a subsequent designation under this section.

''(b) CANNABIS RESEARCH.—

''(1) GRANTS OR COOPERATIVE AGREEMENTS.—

''(A) IN GENERAL.—The Director of NIH may make grants to, or enter into cooperative agreements with, Centers that have been designated under this section to expand the current and ongoing interdisciplinary research and clinical trials relating to cannabis research.

''(B) USE OF FUNDS.—Amounts made available under a grant or cooperative agree-

ment under subparagraph (A) may be used to address key questions and gaps in evidence addressed by the national cannabis research agenda described in paragraphs (1) through (5) of section 409K.

''(2) RESEARCH RESULTS.—The Director of NIH shall promptly disseminate research results under this subsection to relevant governmental, academic, and research entities.

''(c) DEFINITIONS.—In this section:

''(1) CANNABIS.—The term 'cannabis' has the meaning given the term 'marihuana' in section 102 of the Controlled Substances Act.

''(2) INSTITUTION OF HIGHER EDUCATION.—The term 'institution of higher education' has the meaning given the term in section 101(a) of the Higher Education Act of 1965.''.

(b) REGISTRATION REQUIREMENTS.—Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) is amended by adding after the period at the end the following: ''The Attorney General shall register under this part practitioners at Centers of Excellence in Cannabis Research designated under section 409L of the Public Health Service Act to conduct research with marihuana. No separate registration shall be required for each indi-

vidual employed by a Center of Excellence in Cannabis Research who is conducting research described in subsection (a)(1) of that section and in accordance with applicable State and local laws, nor shall separate registrations be required for distinct research activities, including research activities related to distinct constituent compounds of marihuana or amended protocols. The registration shall expire on the date on which the entity is no longer designated as such a Center of Excellence in Cannabis Research under that section. A Center of Excellence in Cannabis Research registered under this part may cultivate marihuana, including any constituent component of marihuana, to conduct research under this part if the Attorney General has determined that the research to be conducted is for legitimate scientific research and is consistent with effective controls against diversion. A Center of Excellence in Cannabis Research may contract with such additional manufacturers of marihuana registered under this section to meet the needs of the Center of Excellence in Cannabis Research to the maximum extent permissible under international treaties to which the United States is a signatory and which govern marihuana. Before entering into such contract, the Center of Excellence in Cannabis Research shall submit to the Attorney General a request to enter into the contract that includes information to demonstrate

the experience or capability of the contractor to conduct such cultivation and assurances that the contractor will comply with the provisions of this Act. Not later than 60 days after the date on which the request is submitted, the request shall be deemed to be approved by the Attorney General, unless the Attorney General determines that the granting of such request is inconsistent with the public interest. A Center of Excellence in Cannabis Research registered under this section may purchase or acquire commercially available marihuana for the purpose of research described in section 409L(a)(1) of the Public Health Service Act in accordance with the law of the State in which the transaction occurs. No Federal funds may be used by the Center of Excellence in Cannabis Research for such purchase or acquisition.''.

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