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(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. _____

To amend the Controlled Substances Act to improve the process for conducting scientific research on schedule I controlled substances, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. GRIFFITH introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Controlled Substances Act to improve the process for conducting scientific research on schedule I controlled substances, 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 ''Streamlining Research on Controlled Substances Act of 2021''.

SEC. 2. CLARIFICATION OF CERTAIN REGISTRATION REQUIREMENTS RELATED TO RESEARCH.

(a) EXCEPTION FOR AGENTS OR EMPLOYEES OF REGISTERED RESEARCHERS.—Section 302(c) of the Controlled Substances Act (21 U.S.C. 822(c)) is amended in paragraph (1) by striking ''or dispenser'' and inserting ''dispenser, or researcher''.

(b) CONFORMING AMENDMENT.—Section 102(3) of the Controlled Substances Act (21 U.S.C. 802(3)) is amended by striking ''or dispenser'' and inserting ''dispenser, or researcher''.

(c) SINGLE REGISTRATION FOR CONTIGUOUS RESEARCH SITES.—Section 302(e) of the Controlled Substances Act (21 U.S.C. 822(e)) is amended by adding at the end the following new paragraph:

''(3) Notwithstanding paragraph (1), a person registered to conduct research with a controlled substance under section 303(f) may conduct such research under a single registration if such research occurs exclusively on a single, contiguous campus and the registrant notifies the Attorney General in writing of all sites on the campus where the research will be conducted or where the controlled substance will be stored or administered. The registrant must so notify the Attorney General prior to conducting research at such additional sites.''.

(d) NEW INSPECTION NOT REQUIRED IN CERTAIN SITUATIONS.—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, and by moving the margins of such subparagraphs two ems to the right;

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

(3) by adding at the end, after the matter following subparagraph (E), as so redesignated, the following new paragraph:

''(2)(A) If a person is registered to conduct research with a controlled substance and applies for a registration, or a modification of a registration to conduct research with a second controlled substance that is in the same schedule or in a schedule with a higher numerical designation, a new inspection by the Attorney General of the registered location is not required.

''(B) Nothing in this paragraph shall prohibit the Attorney General from conducting any inspection if the Attorney General deems it necessary.''.

(e) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I; AUTHORITY TO CONDUCT RESEARCH WITH OTHER SUBSTANCES IN SCHED-

ULE I.—Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end the following new subsection:

"(h) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I; AUTHORITY TO CONDUCT RESEARCH WITH OTHER SUBSTANCES IN SCHEDULE I.—

"(1) If a person is conducting research on a substance at the time the substance is added to schedule I, and such person is already registered to conduct research with a controlled substance in schedule I or II then—

"(A) the person shall, within 30 days of the scheduling of the newly scheduled substance, submit a completed application for registration or modification of existing registration, to conduct research on such substance, in accordance with the regulations issued by the Attorney General;

"(B) the person may, notwithstanding subsections (a) and (b), continue to conduct the research on such substance until the application referred to in subparagraph (A) is withdrawn by the applicant or until the Attorney General serves on the applicant an order to show cause

proposing the denial of the application pursuant to section 304(c); and

''(C) if the Attorney General serves such an order to show cause and the applicant requests a hearing, such hearing shall be held on an expedited basis and not later than 45 days after the request is made, except that the hearing may be held at a later time if so requested by the applicant.

''(2)(A) A person who is registered to conduct research with a controlled substance in schedule I may, notwithstanding subsections (a) and (b), conduct research with another controlled substance in schedule I, provided the following conditions are met:

''(i) The person has applied for a modification of the person's registration to authorize research with such other controlled substance in accordance with the regulations issued by the Attorney General.

''(ii) The Attorney General has obtained verification from the Secretary that the research protocol submitted with the application is meritorious.

''(iii) The Attorney General has determined that such activity is consistent with United States obligations under the Single Convention on Narcotic Drugs, 1961. The Attorney General shall make such determination not later than 30 days after receiving the application referred to in clause (i).

''(B) Nothing in this section shall be construed to alter the authority of the Attorney General to initiate proceedings to deny, suspend, or revoke any registration in accordance with sections 303 and 304.''.

(f) TREATMENT OF CERTAIN ACTIVITIES AS COINCIDENT TO RESEARCH.—Section 302 of the Controlled Substances Act (21 U.S.C. 822), as amended by subsection (d), is further amended by adding at the end the following new subsection:

''(i) TREATMENT OF CERTAIN ACTIVITIES AS COINCIDENT TO RESEARCH.—

''(1) IN GENERAL.—Except as specified in paragraph (2), a person who is registered to perform research with a controlled substance may perform the following activities with small quantities of that substance, as set forth in the relevant statement or protocol filed with the application for registration

approved by the Attorney General without being required to obtain a manufacturing registration:

"(A) Processing the substance to create extracts, tinctures, oils, solutions, derivatives, or other forms of the substance consistent with the approved research protocol.

"(B) Dosage form development for the purpose of satisfying regulatory requirements implemented by the Food and Drug Administration for submitting an investigational new drug application.

"(2) EXCEPTION REGARDING MARIHUANA.—The authority under paragraph (1) does not include authority to grow marihuana.".

SEC. 3. REVIEW OF RESEARCH REGISTRATION PROCESS.

(a) REVIEW.—Not later than one year after the date of the enactment of this section, the Attorney General and the Secretary of Health and Human Services shall conduct a review of the processes used to obtain or modify Federal authorization to conduct research with controlled substances, including—

(1) an evaluation of the impacts of the amendments made by section 2 on the risk of the diversion of controlled substances used in research and related public safety considerations; and

(2) identification of opportunities to reduce any unnecessary burden on persons seeking registration, potential redundancies, and inefficiencies in the process to obtain or modify Federal authorization to conduct research with controlled substances, including the process for obtaining a registration under section 303 of the Controlled Substances Act (21 U.S.C. 823) and the process by which the Secretary of Health and Human Services reviews research protocols.

(b) GUIDANCE.—Following the review described in subsection (a), the Attorney General and the Secretary of Health and Human Services shall, as appropriate, jointly issue guidance to registrants and potential registrants clarifying the process for registration under section 303 of the Controlled Substances Act (21 U.S.C. 823).