

117TH CONGRESS  
1ST SESSION

# H. R. 2405

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

APRIL 8, 2021

Mr. GRIFFITH (for himself and Mr. CRENSHAW) 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

---

## 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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Streamlining Research  
5 on Controlled Substances Act of 2021”.

1 **SEC. 2. CLARIFICATION OF CERTAIN REGISTRATION RE-**  
2 **QUIREMENTS RELATED TO RESEARCH.**

3 (a) EXCEPTION FOR AGENTS OR EMPLOYEES OF  
4 REGISTERED RESEARCHERS.—Section 302(c) of the Con-  
5 trolled Substances Act (21 U.S.C. 822(c)) is amended in  
6 paragraph (1) by striking “or dispenser” and inserting  
7 “dispenser, or researcher”.

8 (b) CONFORMING AMENDMENT.—Section 102(3) of  
9 the Controlled Substances Act (21 U.S.C. 802(3)) is  
10 amended by striking “or dispenser” and inserting “dis-  
11 penser, or researcher”.

12 (c) SINGLE REGISTRATION FOR CONTIGUOUS RE-  
13 SEARCH SITES.—Section 302(e) of the Controlled Sub-  
14 stances Act (21 U.S.C. 822(e)) is amended by adding at  
15 the end the following new paragraph:

16 “(3) Notwithstanding paragraph (1), a person reg-  
17 istered to conduct research with a controlled substance  
18 under section 303(f) may conduct such research under a  
19 single registration if such research occurs exclusively on  
20 a single, contiguous campus and the registrant notifies the  
21 Attorney General in writing of all sites on the campus  
22 where the research will be conducted or where the con-  
23 trolled substance will be stored or administered. The reg-  
24 istrant must so notify the Attorney General prior to con-  
25 ducting research at such additional sites.”.

1 (d) NEW INSPECTION NOT REQUIRED IN CERTAIN  
2 SITUATIONS.—Section 303(f) of the Controlled Sub-  
3 stances Act (21 U.S.C. 823(f)) is amended—

4 (1) by redesignating paragraphs (1) through  
5 (5) as subparagraphs (A) through (E), respectively,  
6 and by moving the margins of such subparagraphs  
7 two ems to the right;

8 (2) by striking “(f) The” and inserting “(f)(1)  
9 The”; and

10 (3) by adding at the end, after the matter fol-  
11 lowing subparagraph (E), as so redesignated, the  
12 following new paragraph:

13 “(2)(A) If a person is registered to conduct research  
14 with a controlled substance and applies for a registration,  
15 or a modification of a registration to conduct research  
16 with a second controlled substance that is in the same  
17 schedule or in a schedule with a higher numerical designa-  
18 tion, a new inspection by the Attorney General of the reg-  
19 istered location is not required.

20 “(B) Nothing in this paragraph shall prohibit the At-  
21 torney General from conducting any inspection if the At-  
22 torney General deems it necessary.”.

23 (e) CONTINUATION OF RESEARCH ON SUBSTANCES  
24 NEWLY ADDED TO SCHEDULE I; AUTHORITY TO CON-  
25 DUCT RESEARCH WITH OTHER SUBSTANCES IN SCHED-

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

4 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES  
 5 NEWLY ADDED TO SCHEDULE I; AUTHORITY TO CON-  
 6 DUCT RESEARCH WITH OTHER SUBSTANCES IN SCHED-  
 7 ULE I.—

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

13 “(A) the person shall, within 30 days of  
 14 the scheduling of the newly scheduled sub-  
 15 stance, submit a completed application for reg-  
 16 istration or modification of existing registration,  
 17 to conduct research on such substance, in ac-  
 18 cordance with the regulations issued by the At-  
 19 torney General;

20 “(B) the person may, notwithstanding sub-  
 21 sections (a) and (b), continue to conduct the re-  
 22 search on such substance until the application  
 23 referred to in subparagraph (A) is withdrawn  
 24 by the applicant or until the Attorney General  
 25 serves on the applicant an order to show cause

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

3 “(C) if the Attorney General serves such  
4 an order to show cause and the applicant re-  
5 quests a hearing, such hearing shall be held on  
6 an expedited basis and not later than 45 days  
7 after the request is made, except that the hear-  
8 ing may be held at a later time if so requested  
9 by the applicant.

10 “(2)(A) A person who is registered to conduct  
11 research with a controlled substance in schedule I  
12 may, notwithstanding subsections (a) and (b), con-  
13 duct research with another controlled substance in  
14 schedule I, provided the following conditions are  
15 met:

16 “(i) The person has applied for a modifica-  
17 tion of the person’s registration to authorize re-  
18 search with such other controlled substance in  
19 accordance with the regulations issued by the  
20 Attorney General.

21 “(ii) The Attorney General has obtained  
22 verification from the Secretary that the re-  
23 search protocol submitted with the application  
24 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

1 approved by the Attorney General without being re-  
2 quired to obtain a manufacturing registration:

3 “(A) Processing the substance to create ex-  
4 tracts, tinctures, oils, solutions, derivatives, or  
5 other forms of the substance consistent with the  
6 approved research protocol.

7 “(B) Dosage form development for the  
8 purpose of satisfying regulatory requirements  
9 implemented by the Food and Drug Adminis-  
10 tration for submitting an investigational new  
11 drug application.

12 “(2) EXCEPTION REGARDING MARIHUANA.—  
13 The authority under paragraph (1) does not include  
14 authority to grow marihuana.”.

15 **SEC. 3. REVIEW OF RESEARCH REGISTRATION PROCESS.**

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

22 (1) an evaluation of the impacts of the amend-  
23 ments made by section 2 on the risk of the diversion  
24 of controlled substances used in research and related  
25 public safety considerations; and

1           (2) identification of opportunities to reduce any  
2           unnecessary burden on persons seeking registration,  
3           potential redundancies, and inefficiencies in the  
4           process to obtain or modify Federal authorization to  
5           conduct research with controlled substances, includ-  
6           ing the process for obtaining a registration under  
7           section 303 of the Controlled Substances Act (21  
8           U.S.C. 823) and the process by which the Secretary  
9           of Health and Human Services reviews research pro-  
10          tocols.

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

○