

117TH CONGRESS  
1ST SESSION

# H. R. 2041

To amend the Controlled Substances Act to list fentanyl-related substances as schedule I controlled substances.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 18, 2021

Mr. LUETKEMEYER (for himself, Mr. LONG, Mr. SMITH of Missouri, Mrs. HARTZLER, Mr. GRAVES of Missouri, Mr. SESSIONS, Mr. JACKSON, Mr. BABIN, Mr. CRAWFORD, Mr. ALLEN, Mr. RODNEY DAVIS of Illinois, Mr. BAIRD, Mr. RESCHENTHALER, and Mr. TIFFANY) 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 amend the Controlled Substances Act to list fentanyl-related substances as schedule I controlled substances.

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 “Stopping Illicit Traf-  
5 ficking Act of 2021” or the “SIFT Act of 2021”.

1 **SEC. 2. FENTANYL-RELATED SUBSTANCES.**

2 Section 202(c) of the Controlled Substances Act (21  
3 U.S.C. 812) is amended—

4 (1) by adding at the end of subsection (b) of  
5 Schedule I the following:

6 “(23) Isobutyryl fentanyl.

7 “(24) Para-Methoxybutyrylfentanyl.

8 “(25) Valeryl fentanyl.

9 “(26) Cyclopentyl fentanyl.

10 “(27) Para-Chloroisobutyryl fentanyl.”; and

11 (2) by adding at the end of Schedule I the fol-  
12 lowing:

13 “(e)(1) Unless specifically exempted or unless listed  
14 in another schedule, any material, compound, mixture, or  
15 preparation which contains any quantity of fentanyl-re-  
16 lated substances, or which contains their salts, isomers,  
17 and salts of isomers whenever the existence of such salts,  
18 isomers, and salts of isomers is possible within the specific  
19 chemical designation.

20 “(2) In paragraph (1), the term ‘fentanyl-related sub-  
21 stances’ includes the following:

22 “(A) Any substance that is structurally related  
23 to fentanyl by one or more of the following modifica-  
24 tions:

25 “(i) By replacement of the phenyl portion  
26 of the phenethyl group by any monocycle,

1           whether or not further substituted in or on the  
2           monocycle.

3           “(ii) By substitution in or on the phenethyl  
4           group with alkyl, alkenyl, alkoxy, hydroxy, halo,  
5           haloalkyl, amino or nitro groups.

6           “(iii) By substitution in or on the piper-  
7           idine ring with alkyl, alkenyl, alkoxy, ester,  
8           ether, hydroxy, halo, haloalkyl, amino or nitro  
9           groups.

10          “(iv) By replacement of the aniline ring  
11          with any aromatic monocycle whether or not  
12          further substituted in or on the aromatic mono-  
13          cycle.

14          “(v) By replacement of the N-propionyl  
15          group by another acyl group.

16          “(B) 4'-Methyl acetyl fentanyl.

17          “(C) Crotonyl fentanyl.

18          “(D) 2'-Fluoro ortho-fluorofentanyl.

19          “(E) Ortho-Methyl acetylfentanyl.

20          “(F) Thiofuranyl fentanyl.

21          “(G) Ortho-Fluorobutyryl fentanyl.

22          “(H) Ortho-Fluoroacryl fentanyl.

23          “(I) Beta-Methyl fentanyl.

24          “(J) Phenyl fentanyl.

25          “(K) Para-Methylfentanyl.

1 “(L) Beta’-Phenyl fentanyl.

2 “(M) Benzodioxole fentanyl.”.

3 **SEC. 3. REMOVAL FROM SCHEDULE I(e) OF FENTANYL-RE-**  
4 **LATED SUBSTANCES.**

5 Section 201 of the Controlled Substances Act (21  
6 U.S.C. 811) is amended by adding at the end the following  
7 new subsection:

8 “(k)(1) If the Secretary finds, based on the factors  
9 specified in paragraph (4), that a substance listed in  
10 schedule I(e) has no potential for abuse, the Secretary  
11 shall—

12 “(A) notify the Attorney General at least 90  
13 days prior to submitting an evaluation scientific and  
14 medical evaluation of that substance supporting that  
15 conclusion; and

16 “(B) submit to the Attorney General such eval-  
17 uation and conclusion that—

18 “(i) is in writing; and

19 “(ii) includes the bases for such conclu-  
20 sion.

21 “(2) Not later than 90 days after the receipt of such  
22 evaluation and conclusion, the Attorney General shall  
23 issue an order removing such substance from the schedule.

24 “(3)(A) If the Secretary finds, based on the factors  
25 specified in paragraph (4), that a substance listed in

1 schedule I(e) does not meet the requirements for inclusion  
2 in that schedule, and that the substance has a low poten-  
3 tial for abuse, the Secretary shall submit to the Attorney  
4 General a scientific and medical evaluation of that sub-  
5 stance supporting those conclusions that is in writing and  
6 that includes the bases for that conclusion.

7 “(B) Within 180 days of receipt of such evaluation  
8 and conclusion, the Attorney General shall—

9 “(i) issue an order removing such substance  
10 from scheduling for research purposes only, or

11 “(ii) notify the Secretary in writing that the At-  
12 torney General declines to issue such an order.

13 “(4) In making the evaluation and conclusion de-  
14 scribed in paragraph (1) or (3), the Secretary—

15 “(A) shall consider the factors specified in  
16 paragraphs (1), (2), (3), and (6) of subsection (c)  
17 and any information submitted to the Attorney Gen-  
18 eral under paragraph (1) of this subsection; and

19 “(B) may also consider factors specified in  
20 paragraphs (4), (5), and (7) of subsection (c) if the  
21 Secretary finds that reliable evidence exists with re-  
22 spect to such factors.

23 “(5) Nothing in this subsection shall preclude the At-  
24 torney General from transferring a substance listed in  
25 schedule I to another schedule, or removing such sub-

1 stance entirely from the schedules, pursuant to other pro-  
 2 visions of this section or section 202.

3 “(6) A substance removed from schedule I(e) pursu-  
 4 ant to paragraph (1) or (3) may, at any time, be controlled  
 5 pursuant to the other provisions of this section or section  
 6 202 without regard to that removal.”.

7 **SEC. 4. CLARIFICATION OF CERTAIN REGISTRATION RE-**  
 8 **QUIREMENTS RELATED TO RESEARCH.**

9 (a) EXCEPTION FOR AGENTS OR EMPLOYEES OF  
 10 REGISTERED RESEARCHERS.—Section 302(c)(1) of the  
 11 Controlled Substances Act (21 U.S.C. 822(c)(1)) is  
 12 amended by striking “or dispenser” and inserting “dis-  
 13 penser, or researcher”.

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

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

22 “(3) Notwithstanding paragraph (1), a person  
 23 registered to conduct research with a controlled sub-  
 24 stance under section 303(f) may conduct such re-  
 25 search under a single registration if such research

1 occurs exclusively on a single, contiguous campus  
2 and the registrant notifies the Attorney General in  
3 writing of all sites on the campus where the research  
4 will be conducted or where the controlled substance  
5 will be stored or administered. If the registrant  
6 seeks to conduct such research at additional sites,  
7 the registrant shall submit a new notification before  
8 conducting such research at any such additional  
9 sites.”.

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

13 (1) by redesignating paragraphs (1) through  
14 (5) as subparagraphs (A) through (E), respectively,  
15 and by moving the margins of such subparagraphs  
16 (as so redesignated) two ems to the right;

17 (2) by striking “(f) The” and inserting “(f)(1)  
18 The”; and

19 (3) by adding at the end the following new  
20 paragraph:

21 “(2)(A) If a person is registered to conduct research  
22 with a controlled substance and applies to be registered,  
23 or to modify a registration to conduct research with a sec-  
24 ond controlled substance that is in the same schedule or  
25 in a schedule with a higher numerical designation, a new

1 inspection by the Attorney General of the registered loca-  
2 tion is not required.

3 “(B) Nothing in this paragraph shall prohibit the At-  
4 torney General from conducting any inspection if the At-  
5 torney General determines such an inspection is nec-  
6 essary.”.

7 (e) CONTINUATION OF RESEARCH ON NEWLY ADDED  
8 SUBSTANCES; AUTHORITY TO CONDUCT RESEARCH WITH  
9 OTHER SUBSTANCES.—Section 302 of the Controlled  
10 Substances Act (21 U.S.C. 822), as amended by sub-  
11 sections (a) and (c), is further amended by adding at the  
12 end the following new subsection:

13 “(h)(1) In the case of a person who is conducting  
14 research on a substance at the time the substance is added  
15 to schedule I and who is already registered to conduct re-  
16 search with another controlled substance in schedule I or  
17 II, the person—

18 “(A) within 30 days of the scheduling of such  
19 substance, shall submit a completed application for  
20 registration or modification of the existing registra-  
21 tion of such person, to conduct research on such  
22 substance, in accordance with the regulations issued  
23 by the Attorney General; and



1           “(B) notwithstanding subsections (a) and (b),  
2           may continue to conduct the research on such sub-  
3           stance until the date on which—

4                   “(i) the application referred to in subpara-  
5                   graph (A) is withdrawn by the applicant; or

6                   “(ii) the Attorney General serves on the  
7                   applicant an order to show cause proposing the  
8                   denial of the application pursuant to section  
9                   304(c).

10          “(2) If the Attorney General serves an order to show  
11          cause under paragraph (1)(B) and the applicant requests  
12          a hearing, such hearing shall be held—

13                   “(A) on an expedited basis; and

14                   “(B) not later than 45 days after the request  
15          is made, or such a later time as requested by the ap-  
16          plicant.

17          “(3)(A) A person who is registered to conduct re-  
18          search with a controlled substance in schedule I may, not-  
19          withstanding subsections (a) and (b), conduct research  
20          with another controlled substance in schedule I, if each  
21          of following conditions are met:

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

1           “(ii) The Attorney General has obtained  
2           verification from the Secretary that the research  
3           protocol submitted with the application is meri-  
4           torious.

5           “(iii) The Attorney General has determined  
6           under subparagraph (B) that the conduct of such re-  
7           search is consistent with United States obligations  
8           under the Single Convention on Narcotic Drugs,  
9           1961.

10          “(B) Not later than 30 days after receiving an appli-  
11          cation under clause (i), the Attorney General shall deter-  
12          mine whether the conduct of research that is the subject  
13          of the application is consistent with United States obliga-  
14          tions under the Single Convention on Narcotic Drugs,  
15          1961.

16          “(C) Nothing in this section shall be construed to  
17          alter the authority of the Attorney General to initiate pro-  
18          ceedings to deny, suspend, or revoke any registration in  
19          accordance with sections 303 and 304.”.

20          (f) TREATMENT OF CERTAIN ACTIVITIES AS COINCI-  
21          DENT TO RESEARCH.—Section 302 of the Controlled Sub-  
22          stances Act (21 U.S.C. 822), as amended by subsections  
23          (a), (c), and (e), is further amended by adding at the end  
24          the following new subsection:

1 “(i) A person who is registered to perform research  
2 with a controlled substance (other than marihuana) under  
3 this title may, without being required to registered to man-  
4 ufacture such substance, using small quantities of such  
5 substance, perform the following activities:

6 “(1) Processing the substance to create ex-  
7 tracts, tinctures, oils, solutions, derivatives, or other  
8 forms of the substance consistent with the approved  
9 research protocol.

10 “(2) Dosage form development for the purpose  
11 of satisfying requirements with respect to the sub-  
12 mission of an investigational new drug application  
13 under section 505(i) of the Federal Food, Drug, and  
14 Cosmetic Act.”.

15 **SEC. 5. 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 jointly  
19 conduct a review of the processes used to register or mod-  
20 ify a registration to conduct research with controlled sub-  
21 stances under the Controlled Substances Act (21 U.S.C.  
22 801 et seq.), including—

23 (1) an evaluation of the impacts of the amend-  
24 ments made by this Act on the risk of the diversion

1 of controlled substances used in research and related  
2 public safety considerations; and

3 (2) an identification of opportunities to reduce  
4 any unnecessary burden on persons seeking registra-  
5 tion, potential redundancies, and inefficiencies in  
6 such processes, including—

7 (A) the process for obtaining a registration  
8 under section 303 of the Controlled Substances  
9 Act (21 U.S.C. 823); and

10 (B) the process by which the Secretary re-  
11 views research protocols submitted with respect  
12 to such registration.

13 (b) GUIDANCE.—Not later than 60 days after con-  
14 cluding the review described in subsection (a), the Attor-  
15 ney General and the Secretary shall, as appropriate, joint-  
16 ly issue guidance to registrants and potential registrants  
17 clarifying the process for registration.

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