

116TH CONGRESS
1ST SESSION

H. R. 5421

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

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 12, 2019

Mr. LUETKEMEYER (for himself, Mrs. WAGNER, Mr. CLAY, Mr. SMITH of Missouri, Mr. LONG, Mr. GRAVES of Missouri, and Mr. CLEAVER) 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 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 2019” or the “SIFT Act of 2019”.

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

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

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

3 “(23) Isobutyryl fentanyl.

4 “(24) Para-Methoxybutyrylfentanyl.

5 “(25) Valeryl fentanyl.

6 “(26) Cyclopentyl fentanyl.

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

8 (2) by adding at the end of Schedule I the fol-
9 lowing:

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

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

19 “(A) Any substance that is structurally related
20 to fentanyl by one or more of the following modifica-
21 tions:

22 “(i) By replacement of the phenyl portion
23 of the phenethyl group by any monocycle,
24 whether or not further substituted in or on the
25 monocycle.

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

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

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

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

14 “(B) 4'-Methyl acetyl fentanyl.

15 “(C) Crotonyl fentanyl.

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

17 “(E) Ortho-Methyl acetylfentanyl.

18 “(F) Thiofuranyl fentanyl.

19 “(G) Ortho-Fluorobutyryl fentanyl.

20 “(H) Ortho-Fluoroacryl fentanyl.

21 “(I) Beta-Methyl fentanyl.

22 “(J) Phenyl fentanyl.

23 “(K) Para-Methylfentanyl.

24 “(L) Beta'-Phenyl fentanyl.

25 “(M) Benzodioxole fentanyl.”.

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

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

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

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

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

16 “(i) is in writing; and

17 “(ii) includes the bases for such conclu-
18 sion.

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

22 “(3)(A) If the Secretary finds, based on the factors
23 specified in paragraph (4), that a substance listed in
24 schedule I(e) does not meet the requirements for inclusion
25 in that schedule, and that the substance has a low poten-
26 tial for abuse, the Secretary shall submit to the Attorney

1 General a scientific and medical evaluation of that sub-
2 stance supporting those conclusions that is in writing and
3 that includes the bases for that conclusion.

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

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

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

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

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

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

20 “(5) Nothing in this subsection shall preclude the At-
21 torney General from transferring a substance listed in
22 schedule I to another schedule, or removing such sub-
23 stance entirely from the schedules, pursuant to other pro-
24 visions of this section or section 202.

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

5 **SEC. 4. CLARIFICATION OF CERTAIN REGISTRATION RE-**
 6 **QUIREMENTS RELATED TO RESEARCH.**

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

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

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

20 “(3) Notwithstanding paragraph (1), a person
 21 registered to conduct research with a controlled sub-
 22 stance under section 303(f) may conduct such re-
 23 search under a single registration if such research
 24 occurs exclusively on a single, contiguous campus
 25 and the registrant notifies the Attorney General in

1 writing of all sites on the campus where the research
2 will be conducted or where the controlled substance
3 will be stored or administered. If the registrant
4 seeks to conduct such research at additional sites,
5 the registrant shall submit a new notification before
6 conducting such research at any such additional
7 sites.”.

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

11 (1) by striking “(f) The” and inserting “(f)(1)
12 The”; and

13 (2) by adding a new paragraph, as follows:

14 “(2)(A) If a person is registered to conduct research
15 with a controlled substance and applies to be registered,
16 or to modify a registration to conduct research with a sec-
17 ond controlled substance that is in the same schedule or
18 in a schedule with a higher numerical designation, a new
19 inspection by the Attorney General of the registered loca-
20 tion is not required.

21 “(B) Nothing in this paragraph shall prohibit the At-
22 torney General from conducting any inspection if the At-
23 torney General determines such an inspection is nec-
24 essary.”.

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

7 “(h)(1) In the case of a person who is conducting
8 research on a substance at the time the substance is added
9 to schedule I and who is already registered to conduct re-
10 search with another controlled substance in schedule I or
11 II, the person—

12 “(A) within 30 days of the scheduling of such
13 substance, shall submit a completed application for
14 registration or modification of the existing registra-
15 tion of such person, to conduct research on such
16 substance, in accordance with the regulations issued
17 by the Attorney General; and

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

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

23 “(ii) the Attorney General serves on the
24 applicant an order to show cause proposing the

1 denial of the application pursuant to section
2 304(c).

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

6 “(A) on an expedited basis; and

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

10 “(3)(A) A person who is registered to conduct re-
11 search with a controlled substance in schedule I may, not-
12 withstanding subsections (a) and (b), conduct research
13 with another controlled substance in schedule I, if each
14 of following conditions are met:

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

19 “(ii) The Attorney General has obtained
20 verification from the Secretary that the research
21 protocol submitted with the application is meri-
22 torious.

23 “(iii) The Attorney General has determined
24 under subparagraph (B) that the conduct of such re-
25 search is consistent with United States obligations

1 under the Single Convention on Narcotic Drugs,
2 1961.

3 “(B) Not later than 30 days after receiving an appli-
4 cation under clause (i), the Attorney General shall deter-
5 mine whether the conduct of research that is the subject
6 of the application is consistent with United States obliga-
7 tions under the Single Convention on Narcotic Drugs,
8 1961.

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

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

18 “(i) A person who is registered to perform research
19 with a controlled substance (other than marihuana) under
20 this title may, without being required to registered to man-
21 ufacture such substance, using small quantities of such
22 substance, perform the following activities:

23 “(1) Processing the substance to create ex-
24 tracts, tinctures, oils, solutions, derivatives, or other

1 forms of the substance consistent with the approved
2 research protocol.

3 “(2) Dosage form development for the purpose
4 of satisfying requirements with respect to the sub-
5 mission of an investigational new drug application
6 under section 505(i) of the Federal Food, Drug, and
7 Cosmetic Act.”.

8 **SEC. 5. REVIEW OF RESEARCH REGISTRATION PROCESS.**

9 (a) REVIEW.—Not later than one year after the date
10 of the enactment of this section, the Attorney General and
11 the Secretary of Health and Human Services shall jointly
12 conduct a review of the processes used to register or mod-
13 ify a registration to conduct research with controlled sub-
14 stances under the Controlled Substances Act (21 U.S.C.
15 801 et seq.), including—

16 (1) an evaluation of the impacts of the amend-
17 ments made by this Act on the risk of the diversion
18 of controlled substances used in research and related
19 public safety considerations; and

20 (2) an identification of opportunities to reduce
21 any unnecessary burden on persons seeking registra-
22 tion, potential redundancies, and inefficiencies in
23 such processes, including—

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

4 (B) the process by which the Secretary re-
5 views research protocols submitted with respect
6 to such registration.

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

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