

119TH CONGRESS
1ST SESSION

S. _____

To amend the Controlled Substances Act with respect to the scheduling of fentanyl-related substances, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. CASSIDY (for himself, Mr. HEINRICH, and Mr. GRASSLEY) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To amend the Controlled Substances Act with respect to the scheduling of fentanyl-related 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 “Halt All Lethal Traf-
5 ficking of Fentanyl Act” or the “HALT Fentanyl Act”.

1 **SEC. 2. CLASS SCHEDULING OF FENTANYL-RELATED SUB-**
2 **STANCES.**

3 Section 202(c) of the Controlled Substances Act (21
4 U.S.C. 812(c)) is amended by adding at the end of sched-
5 ule I the following:

6 “(e)(1) Unless specifically exempted or unless listed
7 in another schedule, any material, compound, mixture, or
8 preparation which contains any quantity of a fentanyl-re-
9 lated substance, or which contains the salts, isomers, and
10 salts of isomers of a fentanyl-related substance whenever
11 the existence of such salts, isomers, and salts of isomers
12 is possible within the specific chemical designation.

13 “(2) For purposes of paragraph (1), except as pro-
14 vided in paragraph (3), the term ‘fentanyl-related sub-
15 stance’ means any substance that is structurally related
16 to fentanyl by 1 or more of the following modifications:

17 “(A) By replacement of the phenyl portion of
18 the phenethyl group by any monocycle, whether or
19 not further substituted in or on the monocycle.

20 “(B) By substitution in or on the phenethyl
21 group with alkyl, alkenyl, alkoxy, hydroxyl, halo,
22 haloalkyl, amino, or nitro groups.

23 “(C) By substitution in or on the piperidine
24 ring with alkyl, alkenyl, alkoxy, ester, ether,
25 hydroxyl, halo, haloalkyl, amino, or nitro groups.

1 “(D) By replacement of the aniline ring with
2 any aromatic monocycle whether or not further sub-
3 stituted in or on the aromatic monocycle.

4 “(E) By replacement of the N-propionyl group
5 with another acyl group.

6 “(3) A substance that satisfies the definition of the
7 term ‘fentanyl-related substance’ in paragraph (2) shall
8 nonetheless not be treated as a fentanyl-related substance
9 subject to this schedule if the substance—

10 “(A) is controlled by action of the Attorney
11 General under section 201; or

12 “(B) is otherwise expressly listed in a schedule
13 other than this schedule.

14 “(4)(A) The Attorney General may by order publish
15 in the Federal Register a list of substances that satisfy
16 the definition of the term ‘fentanyl-related substance’ in
17 paragraph (2).

18 “(B) The absence of a substance from a list published
19 under subparagraph (A) does not negate the control status
20 of the substance under this schedule if the substance satis-
21 fies the definition of the term ‘fentanyl-related substance’
22 in paragraph (2).”.

1 **SEC. 3. REGISTRATION REQUIREMENTS RELATED TO RE-**
2 **SEARCH.**

3 (a) ALTERNATIVE REGISTRATION PROCESS FOR
4 SCHEDULE I RESEARCH.—Section 303 of the Controlled
5 Substances Act (21 U.S.C. 823) is amended—

6 (1) by redesignating the second subsection (l)
7 (relating to required training for prescribers) as sub-
8 section (m); and

9 (2) by adding at the end the following:

10 “(n) SPECIAL PROVISIONS FOR PRACTITIONERS
11 CONDUCTING CERTAIN RESEARCH WITH SCHEDULE I
12 CONTROLLED SUBSTANCES.—

13 “(1) IN GENERAL.—Notwithstanding subsection
14 (g), a practitioner may conduct research described in
15 paragraph (2) of this subsection with 1 or more
16 schedule I substances in accordance with subpara-
17 graph (A) or (B) of paragraph (3) of this sub-
18 section.

19 “(2) RESEARCH SUBJECT TO EXPEDITED PRO-
20 CEDURES.—Research described in this paragraph is
21 research that—

22 “(A) is with respect to a drug that is the
23 subject of an investigational use exemption
24 under section 505(i) of the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 355(i)); or

26 “(B) is—

1 “(i) conducted by the Department of
2 Health and Human Services, the Depart-
3 ment of Defense, or the Department of
4 Veterans Affairs; or

5 “(ii) funded partly or entirely by a
6 grant, contract, cooperative agreement, or
7 other transaction from the Department of
8 Health and Human Services, the Depart-
9 ment of Defense, or the Department of
10 Veterans Affairs.

11 “(3) EXPEDITED PROCEDURES.—

12 “(A) RESEARCHER WITH A CURRENT
13 SCHEDULE I OR II RESEARCH REGISTRATION.—

14 “(i) IN GENERAL.—If a practitioner is
15 registered to conduct research with a con-
16 trolled substance in schedule I or II, the
17 practitioner may conduct research under
18 this subsection on and after the date that
19 is 30 days after the date on which the
20 practitioner sends a notice to the Attorney
21 General containing the following informa-
22 tion, with respect to each substance with
23 which the practitioner will conduct the re-
24 search:

1 “(I) The chemical name of the
2 substance.

3 “(II) The quantity of the sub-
4 stance to be used in the research.

5 “(III) Demonstration that the re-
6 search is in the category described in
7 paragraph (2), which demonstration
8 may be satisfied—

9 “(aa) in the case of a grant,
10 contract, cooperative agreement,
11 or other transaction, or intra-
12 mural research project, by identi-
13 fying the sponsoring agency and
14 supplying the number of the
15 grant, contract, cooperative
16 agreement, other transaction, or
17 project; or

18 “(bb) in the case of an ap-
19 plication under section 505(i) of
20 the Federal Food, Drug, and
21 Cosmetic Act (21 U.S.C. 355(i)),
22 by supplying the application
23 number and the sponsor of
24 record on the application.

1 “(IV) Demonstration that the re-
2 searcher is authorized to conduct re-
3 search with respect to the substance
4 under the laws of the State in which
5 the research will take place.

6 “(ii) VERIFICATION OF INFORMATION
7 BY HHS OR VA.—Upon request from the
8 Attorney General, the Secretary of Health
9 and Human Services, the Department of
10 Defense, or the Secretary of Veterans Af-
11 fairs, as appropriate, shall verify informa-
12 tion submitted by an applicant under
13 clause (i)(III).

14 “(B) RESEARCHER WITHOUT A CURRENT
15 SCHEDULE I OR II RESEARCH REGISTRATION.—

16 “(i) IN GENERAL.—If a practitioner is
17 not registered to conduct research with a
18 controlled substance in schedule I or II,
19 the practitioner may send a notice to the
20 Attorney General containing the informa-
21 tion listed in subparagraph (A)(i), with re-
22 spect to each substance with which the
23 practitioner will conduct the research.

24 “(ii) ATTORNEY GENERAL ACTION.—
25 The Attorney General shall—

1 “(I) treat notice received under
2 clause (i) as a sufficient application
3 for a research registration; and

4 “(II) not later than 45 days of
5 receiving such a notice that contains
6 all information required under sub-
7 paragraph (A)(i)—

8 “(aa) register the applicant;
9 or

10 “(bb) serve an order to show
11 cause upon the applicant in ac-
12 cordance with section 304(c).

13 “(4) ELECTRONIC SUBMISSIONS.—The Attorney
14 General shall provide a means to permit a practi-
15 tioner to submit a notification under paragraph (3)
16 electronically.

17 “(5) LIMITATION ON AMOUNTS.—A practitioner
18 conducting research with a schedule I substance
19 under this subsection may only possess the amounts
20 of schedule I substance identified in—

21 “(A) the notification to the Attorney Gen-
22 eral under paragraph (3); or

23 “(B) a supplemental notification that the
24 practitioner may send if the practitioner needs

1 additional amounts for the research, which sup-
2 plemental notification shall include—

3 “(i) the name of the practitioner;

4 “(ii) the additional quantity needed of
5 the substance; and

6 “(iii) an attestation that the research
7 to be conducted with the substance is con-
8 sistent with the scope of the research that
9 was the subject of the notification under
10 paragraph (3).

11 “(6) IMPORTATION AND EXPORTATION RE-
12 QUIREMENTS NOT AFFECTED.—Nothing in this sub-
13 section alters the requirements of part A of title III,
14 regarding the importation and exportation of con-
15 trolled substances.

16 “(7) INSPECTOR GENERAL REPORT.—Not later
17 than 1 year after the date of enactment of the Halt
18 All Lethal Trafficking of Fentanyl Act, the Inspec-
19 tor General of the Department of Justice shall com-
20 plete a study, and submit to Congress a report
21 thereon, about research described in paragraph (2)
22 of this subsection with fentanyl.”.

23 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
24 ADDITIONAL RESEARCHER IN SAME INSTITUTION.—

1 (1) IN GENERAL.—Section 302(c) of the Con-
2 trolled Substances Act (21 U.S.C. 822(c)) is amend-
3 ed by adding at the end the following:

4 “(4) An agent or employee of a research insti-
5 tution that is conducting research with a controlled
6 substance if—

7 “(A) the agent or employee is acting with-
8 in the scope of the professional practice of the
9 agent or employee;

10 “(B) another agent or employee of the in-
11 stitution is registered to conduct research with
12 a controlled substance in the same schedule;

13 “(C) the researcher who is so registered—

14 “(i) informs the Attorney General of
15 the name, position title, and employing in-
16 stitution of the agent or employee who is
17 not separately registered;

18 “(ii) authorizes that agent or em-
19 ployee to perform research under the reg-
20 istration of the registered researcher; and

21 “(iii) affirms that any act taken by
22 that agent or employee involving a con-
23 trolled substance shall be attributable to
24 the registered researcher, as if the re-
25 searcher had directly committed the act,

1 for purposes of any proceeding under sec-
2 tion 304(a) to suspend or revoke the reg-
3 istration of the registered researcher; and
4 “(D) the Attorney General does not, within
5 30 days of receiving the information, authoriza-
6 tion, and affirmation described in subparagraph
7 (C), refuse, for a reason listed in section
8 304(a), to allow the agent or employee to pos-
9 sess the substance without a separate registra-
10 tion.”.

11 (2) TECHNICAL CORRECTION.—Section
12 302(c)(3) of the Controlled Substances Act (21
13 U.S.C. 822(c)(3)) is amended by striking “(25)”
14 and inserting “(27)”.

15 (c) SINGLE REGISTRATION FOR RELATED RESEARCH
16 SITES.—Section 302(e) of the Controlled Substances Act
17 (21 U.S.C. 822(e)) is amended by adding at the end the
18 following:

19 “(4)(A) Notwithstanding paragraph (1), a person
20 registered to conduct research with a controlled substance
21 under section 303(g) may conduct the research under a
22 single registration if—

23 “(i) the research occurs exclusively on sites all
24 of which are—

25 “(I) within the same city or county; and

1 “(II) under the control of the same institu-
2 tion, organization, or agency; and

3 “(ii) before commencing the research, the re-
4 searcher notifies the Attorney General of each site
5 where—

6 “(I) the research will be conducted; or

7 “(II) the controlled substance will be
8 stored or administered.

9 “(B) A site described in subparagraph (A) shall be
10 included in a registration described in that subparagraph
11 only if the researcher has notified the Attorney General
12 of the site—

13 “(i) in the application for the registration; or

14 “(ii) before the research is conducted, or before
15 the controlled substance is stored or administered, at
16 the site.

17 “(C) The Attorney General may, in consultation with
18 the Secretary, issue regulations addressing, with respect
19 to research sites described in subparagraph (A)—

20 “(i) the manner in which controlled substances
21 may be delivered to the research sites;

22 “(ii) the storage and security of controlled sub-
23 stances at the research sites;

24 “(iii) the maintenance of records for the re-
25 search sites; and

1 “(iv) any other matters necessary to ensure ef-
2 fective controls against diversion at the research
3 sites.”.

4 (d) NEW INSPECTION NOT REQUIRED IN CERTAIN
5 SITUATIONS.—Section 302(f) of the Controlled Sub-
6 stances Act (21 U.S.C. 822(f)) is amended—

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

9 (2) by adding at the end the following:

10 “(2)(A) If a person is registered to conduct research
11 with a controlled substance and applies for a registration,
12 or for a modification of a registration, to conduct research
13 with a second controlled substance that is in the same
14 schedule as the first controlled substance, or is in a sched-
15 ule with a higher numerical designation than the schedule
16 of the first controlled substance, a new inspection by the
17 Attorney General of the registered location is not required.

18 “(B) Nothing in subparagraph (A) shall prohibit the
19 Attorney General from conducting an inspection that the
20 Attorney General determines necessary to ensure that a
21 registrant maintains effective controls against diversion.”.

22 (e) CONTINUATION OF RESEARCH ON SUBSTANCES
23 NEWLY ADDED TO SCHEDULE I.—Section 302 of the
24 Controlled Substances Act (21 U.S.C. 822) is amended
25 by adding at the end the following:

1 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES
2 NEWLY ADDED TO SCHEDULE I.—If a person is con-
3 ducting research on a substance when the substance is
4 added to schedule I, and the person is already registered
5 to conduct research with a controlled substance in sched-
6 ule I—

7 “(1) not later than 90 days after the scheduling
8 of the newly scheduled substance, the person shall
9 submit a completed application for registration or
10 modification of existing registration, to conduct re-
11 search on the substance, in accordance with regula-
12 tions issued by the Attorney General for purposes of
13 this paragraph;

14 “(2) the person may, notwithstanding sub-
15 sections (a) and (b), continue to conduct the re-
16 search on the substance until—

17 “(A) the person withdraws the application
18 described in paragraph (1) of this subsection;
19 or

20 “(B) the Attorney General serves on the
21 person an order to show cause proposing the
22 denial of the application under section 304(c);

23 “(3) if the Attorney General serves an order to
24 show cause as described in paragraph (2)(B) and
25 the person requests a hearing, the hearing shall be

1 held on an expedited basis and not later than 45
2 days after the request is made, except that the hear-
3 ing may be held at a later time if so requested by
4 the person; and

5 “(4) if the person sends a copy of the applica-
6 tion described in paragraph (1) to a manufacturer or
7 distributor of the substance, receipt of the copy by
8 the manufacturer or distributor shall constitute suf-
9 ficient evidence that the person is authorized to re-
10 ceive the substance.”.

11 (f) TREATMENT OF CERTAIN MANUFACTURING AC-
12 TIVITIES AS COINCIDENT TO RESEARCH.—Section 302 of
13 the Controlled Substances Act (21 U.S.C. 822), as amend-
14 ed by subsection (e), is amended by adding at the end
15 the following:

16 “(i) TREATMENT OF CERTAIN MANUFACTURING AC-
17 TIVITIES AS COINCIDENT TO RESEARCH.—

18 “(1) IN GENERAL.—Except as provided in para-
19 graph (3), a person who is registered to perform re-
20 search on a controlled substance may perform manu-
21 facturing activities with small quantities of that sub-
22 stance, including activities described in paragraph
23 (2), without being required to obtain a manufac-
24 turing registration, if—

1 “(A) the activities are performed for the
2 purpose of the research; and

3 “(B) the activities and the quantities of
4 the substance involved in the activities are stat-
5 ed in—

6 “(i) a notification submitted to the
7 Attorney General under section 303(n);

8 “(ii) a research protocol filed with an
9 application for registration approval under
10 section 303(g); or

11 “(iii) a notification to the Attorney
12 General that includes—

13 “(I) the name of the registrant;
14 and

15 “(II) an attestation that the re-
16 search to be conducted with the small
17 quantities of manufactured substance
18 is consistent with the scope of the re-
19 search that is the basis for the reg-
20 istration.

21 “(2) ACTIVITIES INCLUDED.—Activities per-
22 mitted under paragraph (1) include—

23 “(A) processing the substance to create ex-
24 tracts, tinctures, oils, solutions, derivatives, or
25 other forms of the substance consistent with—

1 “(i) the information provided as part
2 of a notification submitted to the Attorney
3 General under section 303(n); or

4 “(ii) a research protocol filed with an
5 application for registration approval under
6 section 303(g); and

7 “(B) dosage form development studies per-
8 formed for the purpose of requesting an inves-
9 tigational new drug exemption under section
10 505(i) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355(i)).

12 “(3) EXCEPTION REGARDING MARIHUANA.—
13 The authority under paragraph (1) to manufacture
14 substances does not include the authority to grow
15 marihuana.”.

16 (g) TRANSPARENCY REGARDING SPECIAL PROCE-
17 DURES.—Section 303 of the Controlled Substances Act
18 (21 U.S.C. 823), as amended by subsection (a), is amend-
19 ed by adding at the end the following:

20 “(o) TRANSPARENCY REGARDING SPECIAL PROCE-
21 DURES.—

22 “(1) IN GENERAL.—If the Attorney General de-
23 termines, with respect to a controlled substance, that
24 an application by a practitioner to conduct research
25 with the substance should be considered under a

1 process, or subject to criteria, different from the
2 process or criteria applicable to applications to con-
3 duct research with other controlled substances in the
4 same schedule, the Attorney General shall make
5 public, including by posting on the website of the
6 Drug Enforcement Administration—

7 “(A) the identities of all substances for
8 which such determinations have been made;

9 “(B) the process and criteria that shall be
10 applied to applications to conduct research with
11 those substances; and

12 “(C) how the process and criteria described
13 in subparagraph (B) differ from the process
14 and criteria applicable to applications to con-
15 duct research with other controlled substances
16 in the same schedule.

17 “(2) TIMING OF POSTING.—The Attorney Gen-
18 eral shall make information described in paragraph
19 (1) public upon making a determination described in
20 that paragraph, regardless of whether a practitioner
21 has submitted such an application at that time.”.

22 **SEC. 4. TECHNICAL CORRECTION ON CONTROLLED SUB-**
23 **STANCES DISPENSING.**

24 Effective as if included in the enactment of Public
25 Law 117–328—

1 (1) section 1252(a) of division FF of Public
2 Law 117–328 (136 Stat. 5681) is amended, in the
3 matter being inserted into section 302(e) of the Con-
4 trolled Substances Act, by striking “303(g)” and in-
5 serting “303(h)”;

6 (2) section 1262 of division FF of Public Law
7 117–328 (136 Stat. 5681) is amended—

8 (A) in subsection (a)—

9 (i) in the matter preceding paragraph
10 (1), by striking “303(g)” and inserting
11 “303(h)”;

12 (ii) in the matter being stricken by
13 subsection (a)(2), by striking “(g)(1)” and
14 inserting “(h)(1)”;

15 (iii) in the matter being inserted by
16 subsection (a)(2), by striking “(g) Practi-
17 tioners” and inserting “(h) Practitioners”;
18 and

19 (B) in subsection (b)—

20 (i) in the matter being stricken by
21 paragraph (1), by striking “303(g)(1)”
22 and inserting “303(h)(1)”;

23 (ii) in the matter being inserted by
24 paragraph (1), by striking “303(g)” and
25 inserting “303(h)”;

1 (iii) in the matter being stricken by
2 paragraph (2)(A), by striking “303(g)(2)”
3 and inserting “303(h)(2)”;

4 (iv) in the matter being stricken by
5 paragraph (3), by striking “303(g)(2)(B)”
6 and inserting “303(h)(2)(B)”;

7 (v) in the matter being stricken by
8 paragraph (5), by striking “303(g)” and
9 inserting “303(h)”;

10 (vi) in the matter being stricken by
11 paragraph (6), by striking “303(g)” and
12 inserting “303(h)”;

13 (3) section 1263(b) of division FF of Public
14 Law 117–328 (136 Stat. 5685) is amended—

15 (A) by striking “303(g)(2)” and inserting
16 “303(h)(2)”;

17 (B) by striking “(21 U.S.C. 823(g)(2))”
18 and inserting “(21 U.S.C. 823(h)(2))”.

19 **SEC. 5. RULEMAKING.**

20 (a) INTERIM FINAL RULES.—The Attorney Gen-
21 eral—

22 (1) shall, not later than 6 months after the date
23 of enactment of this Act, issue rules to implement
24 this Act and the amendments made by this Act; and

1 (2) may issue the rules under paragraph (1) as
2 interim final rules.

3 (b) PROCEDURE FOR FINAL RULE.—

4 (1) EFFECTIVENESS OF INTERIM FINAL
5 RULES.—A rule issued by the Attorney General as
6 an interim final rule under subsection (a) shall be-
7 come immediately effective as an interim final rule
8 without requiring the Attorney General to dem-
9 onstrate good cause therefor, notwithstanding sub-
10 paragraph (B) of section 553(b) of title 5, United
11 States Code.

12 (2) OPPORTUNITY FOR COMMENT AND HEAR-
13 ING.—An interim final rule issued under subsection
14 (a) shall give interested persons the opportunity to
15 comment and to request a hearing.

16 (3) FINAL RULE.—After the conclusion of such
17 proceedings, the Attorney General shall issue a final
18 rule to implement this Act and the amendments
19 made by this Act in accordance with section 553 of
20 title 5, United States Code.

21 **SEC. 6. PENALTIES.**

22 (a) IN GENERAL.—Section 401(b)(1) of the Con-
23 trolled Substances Act (21 U.S.C. 841(b)(1)) is amend-
24 ed—

1 (1) in subparagraph (A)(vi), by inserting “or a
2 fentanyl-related substance” after “any analogue of
3 N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]
4 propanamide”; and

5 (2) in subparagraph (B)(vi), by inserting “or a
6 fentanyl-related substance” after “any analogue of
7 N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]
8 propanamide”.

9 (b) IMPORTATION AND EXPORTATION.—Section
10 1010(b) of the Controlled Substances Import and Export
11 Act (21 U.S.C. 960(b)) is amended—

12 (1) in paragraph (1)(F), by inserting “or a
13 fentanyl-related substance” after “any analogue of
14 N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]
15 propanamide”; and

16 (2) in paragraph (2)(F), by inserting “or a
17 fentanyl-related substance” after “any analogue of
18 N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]
19 propanamide”.

20 (c) DEFINITION OF FENTANYL-RELATED SUB-
21 STANCE.—Section 102 of the Controlled Substances Act
22 (21 U.S.C. 802) is amended by adding at the end the fol-
23 lowing:

1 “(60) The term ‘fentanyl-related substance’ has the
2 meaning given the term in subsection (e)(2) of schedule
3 I of section 202(c).”.

4 **SEC. 7. APPLICABILITY; OTHER MATTERS.**

5 (a) IN GENERAL.—Irrespective of the date on which
6 the rules required by section 4 are finalized, the amend-
7 ments made by this Act apply beginning as of the date
8 of enactment of this Act.

9 (b) RULE OF CONSTRUCTION.—Nothing in the
10 amendments made by this Act may be construed as evi-
11 dence that, in applying sections 401(b)(1) and 1010(b) of
12 the Controlled Substances Act (21 U.S.C. 841(b)(1),
13 960(b)) with respect to conduct occurring before the date
14 of the enactment of this Act, a fentanyl-related substance
15 (as defined by such amendments) is not an analogue of
16 N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]
17 propanamide.

18 (c) SENSE OF CONGRESS.—Congress agrees with the
19 interpretation of the Controlled Substances Act (21
20 U.S.C. 801 et seq.) in *United States v. McCray*, 346 F.
21 Supp. 3d 363 (W.D.N.Y. 2018).