

117TH CONGRESS
1ST SESSION

S. 3336

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

DECEMBER 8, 2021

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

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”.

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

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

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

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

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

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

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

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

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

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

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

7 “(B) is otherwise expressly listed in a schedule
8 other than this schedule.

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

13 “(B) The absence of a substance from a list published
14 under subparagraph (A) does not negate the control status
15 of the substance under this schedule if the substance satis-
16 fies the definition of the term ‘fentanyl-related substance’
17 in paragraph (2).”.

18 **SEC. 3. REGISTRATION REQUIREMENTS RELATED TO RE-**
19 **SEARCH.**

20 (a) **ALTERNATIVE REGISTRATION PROCESS FOR**
21 **SCHEDULE I RESEARCH.**—Section 303 of the Controlled
22 Substances Act (21 U.S.C. 823) is amended by adding at
23 the end the following:

1 “(1) SPECIAL PROVISIONS FOR PRACTITIONERS CON-
 2 DUCTING CERTAIN RESEARCH WITH SCHEDULE I CON-
 3 TROLLED SUBSTANCES.—

4 “(1) IN GENERAL.—Notwithstanding subsection
 5 (f), a practitioner may conduct research described in
 6 paragraph (2) of this subsection with 1 or more
 7 schedule I substances in accordance with subpara-
 8 graph (A) or (B) of paragraph (3) of this sub-
 9 section.

10 “(2) RESEARCH SUBJECT TO EXPEDITED PRO-
 11 CEDURES.—Research described in this paragraph is
 12 research that—

13 “(A) is with respect to a drug that is the
 14 subject of an investigational use exemption
 15 under section 505(i) of the Federal Food, Drug,
 16 and Cosmetic Act; or

17 “(B) is—

18 “(i) conducted by the Department of
 19 Health and Human Services or the De-
 20 partment of Veterans Affairs; or

21 “(ii) funded partly or entirely by a
 22 grant, contract, cooperative agreement, or
 23 other transaction from the Department of
 24 Health and Human Services or the De-
 25 partment of Veterans Affairs.

1 “(3) EXPEDITED PROCEDURES.—

2 “(A) RESEARCHER WITH A CURRENT
3 SCHEDULE I OR II RESEARCH REGISTRATION.—

4 “(i) IN GENERAL.—If a practitioner is
5 registered to conduct research with a con-
6 trolled substance in schedule I or II, the
7 practitioner may conduct research under
8 this subsection on and after the date that
9 is 30 days after the date on which the
10 practitioner sends a notice to the Attorney
11 General containing the following informa-
12 tion, with respect to each substance with
13 which the practitioner will conduct the re-
14 search:

15 “(I) The chemical name of the
16 substance.

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

19 “(III) Demonstration that the re-
20 search is in the category described in
21 paragraph (2), which demonstration
22 may be satisfied—

23 “(aa) in the case of a grant,
24 contract, cooperative agreement,
25 or other transaction, or intra-

1 mural research project, by identi-
2 fying the sponsoring agency and
3 supplying the number of the
4 grant, contract, cooperative
5 agreement, other transaction, or
6 project; or

7 “(bb) in the case of an ap-
8 plication under section 505(i) of
9 the Federal Food, Drug, and
10 Cosmetic Act, by supplying the
11 application number and the spon-
12 sor of record on the application.

13 “(IV) Demonstration that the re-
14 searcher is authorized to conduct re-
15 search with respect to the substance
16 under the laws of the State in which
17 the research will take place.

18 “(ii) VERIFICATION OF INFORMATION
19 BY HHS OR VA.—Upon request from the
20 Attorney General, the Secretary of Health
21 and Human Services or the Secretary of
22 Veterans Affairs, as appropriate, shall
23 verify information submitted by an appli-
24 cant under clause (i)(III).

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

3 “(i) IN GENERAL.—If a practitioner is
4 not registered to conduct research with a
5 controlled substance in schedule I or II,
6 the practitioner may send a notice to the
7 Attorney General containing the informa-
8 tion listed in subparagraph (A)(i), with re-
9 spect to each substance with which the
10 practitioner will conduct the research.

11 “(ii) ATTORNEY GENERAL ACTION.—
12 The Attorney General shall—

13 “(I) treat notice received under
14 clause (i) as a sufficient application
15 for a research registration; and

16 “(II) not later than 45 days of
17 receiving such a notice that contains
18 all information required under sub-
19 paragraph (A)(i)—

20 “(aa) register the applicant;
21 or

22 “(bb) serve an order to show
23 cause upon the applicant in ac-
24 cordance with section 304(c).

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

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

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

11 “(B) a supplemental notification that the
12 practitioner may send if the practitioner needs
13 additional amounts for the research, which sup-
14 plemental notification shall include—

15 “(i) the name of the practitioner;

16 “(ii) the additional quantity needed of
17 the substance; and

18 “(iii) an attestation that the research
19 to be conducted with the substance is con-
20 sistent with the scope of the research that
21 was the subject of the notification under
22 paragraph (3).

23 “(6) IMPORTATION AND EXPORTATION RE-
24 QUIREMENTS NOT AFFECTED.—Nothing in this sub-
25 section alters the requirements of part A of title III,

1 regarding the importation and exportation of con-
2 trolled substances.”.

3 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
4 ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Sec-
5 tion 302(c) of the Controlled Substances Act (21 U.S.C.
6 822(c)) is amended by adding at the end the following:

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

10 “(A) the agent or employee is acting with-
11 in the scope of the professional practice of the
12 agent or employee;

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

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

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

21 “(ii) authorizes that agent or em-
22 ployee to perform research under the reg-
23 istration of the registered researcher; and

24 “(iii) affirms that any act taken by
25 that agent or employee involving a con-

1 trolled substance shall be attributable to
 2 the registered researcher, as if the re-
 3 searcher had directly committed the act,
 4 for purposes of any proceeding under sec-
 5 tion 304(a) to suspend or revoke the reg-
 6 istration of the registered researcher; and
 7 “(D) the Attorney General does not, within
 8 30 days of receiving the information, authoriza-
 9 tion, and affirmation described in subparagraph
 10 (C), refuse, for a reason listed in section
 11 304(a), to allow the agent or employee to pos-
 12 sess the substance without a separate registra-
 13 tion.”.

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

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

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

24 “(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”; and

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(l);

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

4 “(ii) a research protocol filed with an
 5 application for registration approval under
 6 section 303(f); 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 “(m) 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. RULEMAKING.**

23 (a) INTERIM FINAL RULES.—The Attorney Gen-
 24 eral—

1 (1) shall, not later than 1 year of the date of
2 enactment of this Act, issue rules to implement this
3 Act and the amendments made by this Act; and

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

6 (b) PROCEDURE FOR FINAL RULE.—

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

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

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

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