

119TH CONGRESS
1ST SESSION

H. R. 27

IN THE SENATE OF THE UNITED STATES

FEBRUARY 10, 2025

Received; read twice and referred to the Committee on the Judiciary

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Halt All Lethal Traf-
3 ficking of Fentanyl Act” or the “HALT Fentanyl Act”.

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

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

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

16 “(2) For purposes of paragraph (1), except as
17 provided in paragraph (3), the term ‘fentanyl-related
18 substance’ means any substance that is structurally
19 related to fentanyl by 1 or more of the following
20 modifications:

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

25 “(B) By substitution in or on the
26 phenethyl group with alkyl, alkenyl, alkoxy,

1 hydroxyl, halo, haloalkyl, amino, or nitro
2 groups.

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

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

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

13 “(3) A substance that satisfies the definition of
14 the term ‘fentanyl-related substance’ in paragraph
15 (2) shall nonetheless not be treated as a fentanyl-re-
16 lated substance subject to this schedule if the sub-
17 stance—

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

20 “(B) is otherwise expressly listed in a
21 schedule other than this schedule.

22 “(4)(A) The Attorney General may by order
23 publish in the Federal Register a list of substances
24 that satisfy the definition of the term ‘fentanyl-re-
25 lated substance’ in paragraph (2).

1 “(B) The absence of a substance from a
2 list published under subparagraph (A) does not
3 negate the control status of the substance
4 under this schedule if the substance satisfies
5 the definition of the term ‘fentanyl-related sub-
6 stance’ in paragraph (2).”.

7 **SEC. 3. REGISTRATION REQUIREMENTS RELATED TO RE-**
8 **SEARCH.**

9 (a) **ALTERNATIVE REGISTRATION PROCESS FOR**
10 **SCHEDULE I RESEARCH.**—Section 303 of the Controlled
11 Substances Act (21 U.S.C. 823) is amended—

12 (1) by redesignating the second subsection (l)
13 (relating to required training for prescribers) as sub-
14 section (m); and

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

16 “(n) **SPECIAL PROVISIONS FOR PRACTITIONERS**
17 **CONDUCTING CERTAIN RESEARCH WITH SCHEDULE I**
18 **CONTROLLED SUBSTANCES.**—

19 “(1) **IN GENERAL.**—Notwithstanding subsection
20 (g), a practitioner may conduct research described in
21 paragraph (2) of this subsection with 1 or more
22 schedule I substances in accordance with subpara-
23 graph (A) or (B) of paragraph (3) of this sub-
24 section.

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

4 “(A) is with respect to a drug that is the
5 subject of an investigational use exemption
6 under section 505(i) of the Federal Food, Drug,
7 and Cosmetic Act; or

8 “(B) is—

9 “(i) conducted by the Department of
10 Health and Human Services, the Depart-
11 ment of Defense, or the Department of
12 Veterans Affairs; or

13 “(ii) funded partly or entirely by a
14 grant, contract, cooperative agreement, or
15 other transaction from the Department of
16 Health and Human Services, the Depart-
17 ment of Defense, or the Department of
18 Veterans Affairs.

19 “(3) EXPEDITED PROCEDURES.—

20 “(A) RESEARCHER WITH A CURRENT
21 SCHEDULE I OR II RESEARCH REGISTRATION.—

22 “(i) IN GENERAL.—If a practitioner is
23 registered to conduct research with a con-
24 trolled substance in schedule I or II, the
25 practitioner may conduct research under

1 this subsection on and after the date that
2 is 30 days after the date on which the
3 practitioner sends a notice to the Attorney
4 General containing the following informa-
5 tion, with respect to each substance with
6 which the practitioner will conduct the re-
7 search:

8 “(I) The chemical name of the
9 substance.

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

12 “(III) Demonstration that the re-
13 search is in the category described in
14 paragraph (2), which demonstration
15 may be satisfied—

16 “(aa) in the case of a grant,
17 contract, cooperative agreement,
18 or other transaction, or intra-
19 mural research project, by identi-
20 fying the sponsoring agency and
21 supplying the number of the
22 grant, contract, cooperative
23 agreement, other transaction, or
24 project; or

1 “(bb) in the case of an ap-
2 plication under section 505(i) of
3 the Federal Food, Drug, and
4 Cosmetic Act, by supplying the
5 application number and the spon-
6 sor of record on the application.

7 “(IV) Demonstration that the re-
8 searcher is authorized to conduct re-
9 search with respect to the substance
10 under the laws of the State in which
11 the research will take place.

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

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

22 “(i) IN GENERAL.—If a practitioner is
23 not registered to conduct research with a
24 controlled substance in schedule I or II,
25 the practitioner may send a notice to the

1 Attorney General containing the informa-
2 tion listed in subparagraph (A)(i), with re-
3 spect to each substance with which the
4 practitioner will conduct the research.

5 “(ii) ATTORNEY GENERAL ACTION.—

6 The Attorney General shall—

7 “(I) treat notice received under
8 clause (i) as a sufficient application
9 for a research registration; and

10 “(II) not later than 45 days of
11 receiving such a notice that contains
12 all information required under sub-
13 paragraph (A)(i)—

14 “(aa) register the applicant;

15 or

16 “(bb) serve an order to show
17 cause upon the applicant in ac-
18 cordance with section 304(c).

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

23 “(5) LIMITATION ON AMOUNTS.—A practitioner
24 conducting research with a schedule I substance

1 under this subsection may only possess the amounts
2 of schedule I substance identified in—

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

5 “(B) a supplemental notification that the
6 practitioner may send if the practitioner needs
7 additional amounts for the research, which sup-
8 plemental notification shall include—

9 “(i) the name of the practitioner;

10 “(ii) the additional quantity needed of
11 the substance; and

12 “(iii) an attestation that the research
13 to be conducted with the substance is con-
14 sistent with the scope of the research that
15 was the subject of the notification under
16 paragraph (3).

17 “(6) IMPORTATION AND EXPORTATION RE-
18 QUIREMENTS NOT AFFECTED.—Nothing in this sub-
19 section alters the requirements of part A of title III,
20 regarding the importation and exportation of con-
21 trolled substances.

22 “(7) INSPECTOR GENERAL REPORT.—Not later
23 than 1 year after the date of enactment of this Act,
24 the Inspector General of the Department of Justice
25 shall complete a study, and submit a report thereon,

1 about research described in paragraph (2) of this
2 subsection with fentanyl.”.

3 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
4 ADDITIONAL RESEARCHER IN SAME INSTITUTION.—

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

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

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

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

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

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

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

1 “(iii) affirms that any act taken by
2 that agent or employee involving a con-
3 trolled substance shall be attributable to
4 the registered researcher, as if the re-
5 searcher had directly committed the act,
6 for purposes of any proceeding under sec-
7 tion 304(a) to suspend or revoke the reg-
8 istration of the registered researcher; and

9 “(D) the Attorney General does not, within
10 30 days of receiving the information, authoriza-
11 tion, and affirmation described in subparagraph
12 (C), refuse, for a reason listed in section
13 304(a), to allow the agent or employee to pos-
14 sess the substance without a separate registra-
15 tion.”.

16 (2) TECHNICAL CORRECTION.—Section
17 302(c)(3) of the Controlled Substances Act (21
18 U.S.C. 822(c)(3)) is amended by striking “(25)”
19 and inserting “(27)”.

20 (c) SINGLE REGISTRATION FOR RELATED RESEARCH
21 SITES.—Section 302(e) of the Controlled Substances Act
22 (21 U.S.C. 822(e)) is amended by adding at the end the
23 following:

24 “(4)(A) Notwithstanding paragraph (1), a per-
25 son registered to conduct research with a controlled

1 substance under section 303(g) may conduct the re-
2 search under a single registration if—

3 “(i) the research occurs exclusively on
4 sites all of which are—

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

7 “(II) under the control of the
8 same institution, organization, or
9 agency; and

10 “(ii) before commencing the research,
11 the researcher notifies the Attorney Gen-
12 eral of each site where—

13 “(I) the research will be con-
14 ducted; or

15 “(II) the controlled substance
16 will be stored or administered.

17 “(B) A site described in subparagraph (A)
18 shall be included in a registration described in
19 that subparagraph only if the researcher has
20 notified the Attorney General of the site—

21 “(i) in the application for the registra-
22 tion; or

23 “(ii) before the research is conducted,
24 or before the controlled substance is stored
25 or administered, at the site.

1 “(C) The Attorney General may, in con-
2 sultation with the Secretary, issue regulations
3 addressing, with respect to research sites de-
4 scribed in subparagraph (A)—

5 “(i) the manner in which controlled
6 substances may be delivered to the re-
7 search sites;

8 “(ii) the storage and security of con-
9 trolled substances at the research sites;

10 “(iii) the maintenance of records for
11 the research sites; and

12 “(iv) any other matters necessary to
13 ensure effective controls against diversion
14 at the research sites.”.

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

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

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

21 “(2)(A) If a person is registered to conduct re-
22 search with a controlled substance and applies for a
23 registration, or for a modification of a registration,
24 to conduct research with a second controlled sub-
25 stance that is in the same schedule as the first con-

1 trolled substance, or is in a schedule with a higher
2 numerical designation than the schedule of the first
3 controlled substance, a new inspection by the Attor-
4 ney General of the registered location is not re-
5 quired.

6 “(B) Nothing in subparagraph (A) shall pro-
7 hibit the Attorney General from conducting an in-
8 spection that the Attorney General determines nec-
9 essary to ensure that a registrant maintains effective
10 controls against diversion.”.

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

15 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES
16 NEWLY ADDED TO SCHEDULE I.—If a person is con-
17 ducting research on a substance when the substance is
18 added to schedule I, and the person is already registered
19 to conduct research with a controlled substance in sched-
20 ule I—

21 “(1) not later than 90 days after the scheduling
22 of the newly scheduled substance, the person shall
23 submit a completed application for registration or
24 modification of existing registration, to conduct re-
25 search on the substance, in accordance with regula-

1 tions issued by the Attorney General for purposes of
2 this paragraph;

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

6 “(A) the person withdraws the application
7 described in paragraph (1) of this subsection;

8 or

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

12 “(3) if the Attorney General serves an order to
13 show cause as described in paragraph (2)(B) and
14 the person requests a hearing, the hearing shall be
15 held on an expedited basis and not later than 45
16 days after the request is made, except that the hear-
17 ing may be held at a later time if so requested by
18 the person; and

19 “(4) if the person sends a copy of the applica-
20 tion described in paragraph (1) to a manufacturer or
21 distributor of the substance, receipt of the copy by
22 the manufacturer or distributor shall constitute suf-
23 ficient evidence that the person is authorized to re-
24 ceive the substance.”.

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

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

8 “(1) IN GENERAL.—Except as provided in para-
9 graph (3), a person who is registered to perform re-
10 search on a controlled substance may perform manu-
11 facturing activities with small quantities of that sub-
12 stance, including activities described in paragraph
13 (2), without being required to obtain a manufac-
14 turing registration, if—

15 “(A) the activities are performed for the
16 purpose of the research; and

17 “(B) the activities and the quantities of
18 the substance involved in the activities are stat-
19 ed in—

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

22 “(ii) a research protocol filed with an
23 application for registration approval under
24 section 303(g); or

1 “(iii) a notification to the Attorney
2 General that includes—

3 “(I) the name of the registrant;
4 and

5 “(II) an attestation that the re-
6 search to be conducted with the small
7 quantities of manufactured substance
8 is consistent with the scope of the re-
9 search that is the basis for the reg-
10 istration.

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

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

16 “(i) the information provided as part
17 of a notification submitted to the Attorney
18 General under section 303(n); or

19 “(ii) a research protocol filed with an
20 application for registration approval under
21 section 303(g); and

22 “(B) dosage form development studies per-
23 formed for the purpose of requesting an inves-
24 tigational new drug exemption under section

1 505(i) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 355(i)).

3 “(3) EXCEPTION REGARDING MARIHUANA.—
4 The authority under paragraph (1) to manufacture
5 substances does not include the authority to grow
6 marihuana.”.

7 (g) TRANSPARENCY REGARDING SPECIAL PROCE-
8 DURES.—Section 303 of the Controlled Substances Act
9 (21 U.S.C. 823), as amended by subsection (a), is amend-
10 ed by adding at the end the following:

11 “(o) TRANSPARENCY REGARDING SPECIAL PROCE-
12 DURES.—

13 “(1) IN GENERAL.—If the Attorney General de-
14 termines, with respect to a controlled substance, that
15 an application by a practitioner to conduct research
16 with the substance should be considered under a
17 process, or subject to criteria, different from the
18 process or criteria applicable to applications to con-
19 duct research with other controlled substances in the
20 same schedule, the Attorney General shall make
21 public, including by posting on the website of the
22 Drug Enforcement Administration—

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

1 “(B) the process and criteria that shall be
2 applied to applications to conduct research with
3 those substances; and

4 “(C) how the process and criteria described
5 in subparagraph (B) differ from the process
6 and criteria applicable to applications to con-
7 duct research with other controlled substances
8 in the same schedule.

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

14 **SEC. 4. TECHNICAL CORRECTION ON CONTROLLED SUB-**
15 **STANCES DISPENSING.**

16 Effective as if included in the enactment of Public
17 Law 117–328—

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

23 (2) section 1262 of division FF of Public Law
24 117–328 (136 Stat. 5681) is amended—

25 (A) in subsection (a)—

1 (i) in the matter preceding paragraph
2 (1), by striking “303(g)” and inserting
3 “303(h)”;

4 (ii) in the matter being stricken by
5 subsection (a)(2), by striking “(g)(1)” and
6 inserting “(h)(1)”; and

7 (iii) in the matter being inserted by
8 subsection (a)(2), by striking “(g) Practi-
9 tioners” and inserting “(h) Practitioners”;
10 and

11 (B) in subsection (b)—

12 (i) in the matter being stricken by
13 paragraph (1), by striking “303(g)(1)”
14 and inserting “303(h)(1)”;

15 (ii) in the matter being inserted by
16 paragraph (1), by striking “303(g)” and
17 inserting “303(h)”;

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

21 (iv) in the matter being stricken by
22 paragraph (3), by striking “303(g)(2)(B)”
23 and inserting “303(h)(2)(B)”;

1 (v) in the matter being stricken by
2 paragraph (5), by striking “303(g)” and
3 inserting “303(h)”; and

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

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

9 (A) by striking “303(g)(2)” and inserting
10 “303(h)(2)”; and

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

13 **SEC. 5. RULEMAKING.**

14 (a) INTERIM FINAL RULES.—The Attorney Gen-
15 eral—

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

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

21 (b) PROCEDURE FOR FINAL RULE.—

22 (1) EFFECTIVENESS OF INTERIM FINAL
23 RULES.—A rule issued by the Attorney General as
24 an interim final rule under subsection (a) shall be-
25 come immediately effective as an interim final rule

1 without requiring the Attorney General to dem-
2 onstrate good cause therefor, notwithstanding sub-
3 paragraph (B) of section 553(b) of title 5, United
4 States Code.

5 (2) OPPORTUNITY FOR COMMENT AND HEAR-
6 ING.—An interim final rule issued under subsection
7 (a) shall give interested persons the opportunity to
8 comment and to request a hearing.

9 (3) FINAL RULE.—After the conclusion of such
10 proceedings, the Attorney General shall issue a final
11 rule to implement this Act and the amendments
12 made by this Act in accordance with section 553 of
13 title 5, United States Code.

14 **SEC. 6. PENALTIES.**

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

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

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

1 (b) IMPORTATION AND EXPORTATION.—Section
2 1010(b) of the Controlled Substances Import and Export
3 Act (21 U.S.C. 960(b)) is amended—

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

8 (2) in paragraph (2)(F), by inserting “or a
9 fentanyl-related substance” after “any analogue of
10 N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]
11 propanamide”.

12 (c) DEFINITION OF FENTANYL-RELATED SUB-
13 STANCE.—Section 102 of the Controlled Substances Act
14 (21 U.S.C. 802) is amended by adding at the end the fol-
15 lowing:

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

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

20 (a) IN GENERAL.—Irrespective of the date on which
21 the rules required by section 5 are finalized, the amend-
22 ments made by this Act apply beginning as of the enact-
23 ment of this Act.

24 (b) RULE OF CONSTRUCTION.—Nothing in the
25 amendments made by this Act may be construed as evi-

1 dence that, in applying sections 401(b)(1) and 1010(b) of
2 the Controlled Substances Act (21 U.S.C. 841(b)(1) and
3 960(b)) with respect to conduct occurring before the date
4 of the enactment of this Act, a fentanyl-related substance
5 (as defined by such amendments) is not an analogue of
6 N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]
7 propanamide.

8 (c) SENSE OF CONGRESS.—The Congress agrees with
9 the interpretation of the Controlled Substances Act (21
10 U.S.C. 801 et seq.) in *United States v. McCray*, 346 F.
11 Supp. 3d 363 (2018).

Passed the House of Representatives February 6,
2025.

Attest:

KEVIN F. MCCUMBER,

Clerk.