

119TH CONGRESS
1ST SESSION

H. R. 27

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

IN THE HOUSE OF REPRESENTATIVES

JANUARY 3, 2025

Mr. GRIFFITH (for himself, Mr. LATTA, Mr. GUTHRIE, Mr. BILIRAKIS, Mr. HUDSON, Mr. CARTER of Georgia, Mr. PALMER, Mr. DUNN of Florida, Mr. CRENSHAW, Mr. JOYCE of Pennsylvania, Mr. PFLUGER, Mrs. HARSHBARGER, Mrs. CAMMACK, Mrs. MILLER-MEEKS, Mr. WOMACK, Mr. BUCHANAN, Mrs. MILLER of West Virginia, Mr. MOOLENAAR, Mr. BOST, Mr. EVANS of Colorado, Mr. FITZGERALD, Mr. LANGWORTHY, Mr. CLINE, Mr. MEUSER, Mr. VAN DREW, Mr. FEENSTRA, and Mr. NUNN of Iowa) 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 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
14 provided in paragraph (3), the term ‘fentanyl-related
15 substance’ means any substance that is structurally
16 related to fentanyl by 1 or more of the following
17 modifications:

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

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

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

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

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

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

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

18 “(B) is otherwise expressly listed in a
19 schedule other than this schedule.

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

24 “(B) The absence of a substance from a
25 list published under subparagraph (A) does not

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

5 “(B) is—

6 “(i) conducted by the Department of
7 Health and Human Services, the Depart-
8 ment of Defense, or the Department of
9 Veterans Affairs; or

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

16 “(3) EXPEDITED PROCEDURES.—

17 “(A) RESEARCHER WITH A CURRENT
18 SCHEDULE I OR II RESEARCH REGISTRATION.—

19 “(i) IN GENERAL.—If a practitioner is
20 registered to conduct research with a con-
21 trolled substance in schedule I or II, the
22 practitioner may conduct research under
23 this subsection on and after the date that
24 is 30 days after the date on which the
25 practitioner sends a notice to the Attorney

1 General containing the following informa-
2 tion, with respect to each substance with
3 which the practitioner will conduct the re-
4 search:

5 “(I) The chemical name of the
6 substance.

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

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

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

22 “(bb) in the case of an ap-
23 plication under section 505(i) of
24 the Federal Food, Drug, and
25 Cosmetic Act, by supplying the

1 application number and the spon-
2 sor of record on the application.

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

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

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

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

1 “(ii) ATTORNEY GENERAL ACTION.—

2 The Attorney General shall—

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

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

10 “(aa) register the applicant;

11 or

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

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

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

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

1 “(B) a supplemental notification that the
2 practitioner may send if the practitioner needs
3 additional amounts for the research, which sup-
4 plemental notification shall include—

5 “(i) the name of the practitioner;

6 “(ii) the additional quantity needed of
7 the substance; and

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

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

18 “(7) INSPECTOR GENERAL REPORT.—Not later
19 than 1 year after the date of enactment of this Act,
20 the Inspector General of the Department of Justice
21 shall complete a study, and submit a report thereon,
22 about research described in paragraph (2) of this
23 subsection with fentanyl.”.

24 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
25 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 per-
20 son registered to conduct research with a controlled
21 substance under section 303(f) may conduct the re-
22 search under a single registration if—

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

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

3 “(II) under the control of the
4 same institution, organization, or
5 agency; and

6 “(ii) before commencing the research,
7 the researcher notifies the Attorney Gen-
8 eral of each site where—

9 “(I) the research will be con-
10 ducted; or

11 “(II) the controlled substance
12 will be stored or administered.

13 “(B) A site described in subparagraph (A)
14 shall be included in a registration described in
15 that subparagraph only if the researcher has
16 notified the Attorney General of the site—

17 “(i) in the application for the registra-
18 tion; or

19 “(ii) before the research is conducted,
20 or before the controlled substance is stored
21 or administered, at the site.

22 “(C) The Attorney General may, in con-
23 sultation with the Secretary, issue regulations
24 addressing, with respect to research sites de-
25 scribed in subparagraph (A)—

1 “(i) the manner in which controlled
2 substances may be delivered to the re-
3 search sites;

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

6 “(iii) the maintenance of records for
7 the research sites; and

8 “(iv) any other matters necessary to
9 ensure effective controls against diversion
10 at the research sites.”.

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

14 (1) by striking “(f) The” and inserting “(f)(1)
15 The”; and

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

17 “(2)(A) If a person is registered to conduct re-
18 search with a controlled substance and applies for a
19 registration, or for a modification of a registration,
20 to conduct research with a second controlled sub-
21 stance that is in the same schedule as the first con-
22 trolled substance, or is in a schedule with a higher
23 numerical designation than the schedule of the first
24 controlled substance, a new inspection by the Attor-

1 ney General of the registered location is not re-
2 quired.

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

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

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

18 “(1) not later than 90 days after the scheduling
19 of the newly scheduled substance, the person shall
20 submit a completed application for registration or
21 modification of existing registration, to conduct re-
22 search on the substance, in accordance with regula-
23 tions issued by the Attorney General for purposes of
24 this paragraph;

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

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

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

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

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

23 (f) TREATMENT OF CERTAIN MANUFACTURING AC-
24 TIVITIES AS COINCIDENT TO RESEARCH.—Section 302 of
25 the Controlled Substances Act (21 U.S.C. 822), as amend-

1 ed by subsection (e), is amended by adding at the end
2 the following:

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

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

12 “(A) the activities are performed for the
13 purpose of the research; and

14 “(B) the activities and the quantities of
15 the substance involved in the activities are stat-
16 ed in—

17 “(i) a notification submitted to the
18 Attorney General under section 303(l);

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

22 “(iii) a notification to the Attorney
23 General that includes—

24 “(I) the name of the registrant;
25 and

1 “(II) an attestation that the re-
2 search to be conducted with the small
3 quantities of manufactured substance
4 is consistent with the scope of the re-
5 search that is the basis for the reg-
6 istration.

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

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

12 “(i) the information provided as part
13 of a notification submitted to the Attorney
14 General under section 303(l); or

15 “(ii) a research protocol filed with an
16 application for registration approval under
17 section 303(f); and

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

23 “(3) EXCEPTION REGARDING MARIHUANA.—
24 The authority under paragraph (1) to manufacture

1 substances does not include the authority to grow
2 marihuana.”.

3 (g) TRANSPARENCY REGARDING SPECIAL PROCE-
4 DURES.—Section 303 of the Controlled Substances Act
5 (21 U.S.C. 823), as amended by subsection (a), is amend-
6 ed by adding at the end the following:

7 “(o) TRANSPARENCY REGARDING SPECIAL PROCE-
8 DURES.—

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

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

21 “(B) the process and criteria that shall be
22 applied to applications to conduct research with
23 those substances; and

24 “(C) how the process and criteria described
25 in subparagraph (B) differ from the process

1 and criteria applicable to applications to con-
2 duct research with other controlled substances
3 in the same schedule.

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

9 **SEC. 4. TECHNICAL CORRECTION ON CONTROLLED SUB-**
10 **STANCES DISPENSING.**

11 Effective as if included in the enactment of Public
12 Law 117–328—

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

18 (2) section 1262 of division FF of Public Law
19 117–328 (136 Stat. 5681) is amended—

20 (A) in subsection (a)—

21 (i) in the matter preceding paragraph
22 (1), by striking “303(g)” and inserting
23 “303(h)”;

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

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

8 (B) in subsection (b)—

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

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

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

18 (iv) in the matter being stricken by
19 paragraph (3), by striking “303(g)(2)(B)”
20 and inserting “303(h)(2)(B)”;

21 (v) in the matter being stricken by
22 paragraph (5), by striking “303(g)” and
23 inserting “303(h)”;

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

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

6 (A) by striking “303(g)(2)” and inserting
7 “303(h)(2)”; and

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

10 **SEC. 5. RULEMAKING.**

11 (a) INTERIM FINAL RULES.—The Attorney Gen-
12 eral—

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

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

18 (b) PROCEDURE FOR FINAL RULE.—

19 (1) EFFECTIVENESS OF INTERIM FINAL
20 RULES.—A rule issued by the Attorney General as
21 an interim final rule under subsection (a) shall be-
22 come immediately effective as an interim final rule
23 without requiring the Attorney General to dem-
24 onstrate good cause therefor, notwithstanding sub-

1 paragraph (B) of section 553(b) of title 5, United
2 States Code.

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

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

12 **SEC. 6. PENALTIES.**

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

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

20 (2) in subparagraph (B)(vi), by inserting “or a
21 fentanyl-related substance” after “any analogue of
22 N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]
23 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 **SEC. 7. APPLICABILITY; OTHER MATTERS.**

13 (a) IN GENERAL.—Irrespective of the date on which
14 the rules required by section 4 are finalized, the amend-
15 ments made by this Act apply beginning as of the enact-
16 ment of this Act.

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

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

○