

118TH CONGRESS
1ST SESSION

H. R. 467

IN THE SENATE OF THE UNITED STATES

MAY 30, 2023

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 pro-
17 vided in paragraph (3), the term ‘fentanyl-related sub-
18 stance’ means any substance that is structurally related
19 to fentanyl by 1 or more of the following modifications:

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

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

1 “(C) By substitution in or on the piperidine
2 ring with alkyl, alkenyl, alkoxyl, ester, ether,
3 hydroxyl, halo, haloalkyl, amino, or nitro groups.

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

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

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

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

15 “(B) is otherwise expressly listed in a schedule
16 other than this schedule.

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

21 “(B) The absence of a substance from a list published
22 under subparagraph (A) does not negate the control status
23 of the substance under this schedule if the substance satis-
24 fies the definition of the term ‘fentanyl-related substance’
25 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 (f), 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; 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, by supplying the
22 application number and the spon-
23 sor of record on the application.

24 “(IV) Demonstration that the re-
25 searcher is authorized to conduct re-

1 search with respect to the substance
2 under the laws of the State in which
3 the research will take place.

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

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

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

22 “(ii) ATTORNEY GENERAL ACTION.—
23 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 this Act,
18 the Inspector General of the Department of Justice
19 shall complete a study, and submit a report thereon,
20 about research described in paragraph (2) of this
21 subsection with fentanyl.”.

22 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
23 ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Sec-
24 tion 302(c) of the Controlled Substances Act (21 U.S.C.
25 822(c)) is amended by adding at the end the following:

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

4 “(A) the agent or employee is acting with-
5 in the scope of the professional practice of the
6 agent or employee;

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

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

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

15 “(ii) authorizes that agent or em-
16 ployee to perform research under the reg-
17 istration of the registered researcher; and

18 “(iii) affirms that any act taken by
19 that agent or employee involving a con-
20 trolled substance shall be attributable to
21 the registered researcher, as if the re-
22 searcher had directly committed the act,
23 for purposes of any proceeding under sec-
24 tion 304(a) to suspend or revoke the reg-
25 istration of the registered researcher; and

1 “(D) the Attorney General does not, within
2 30 days of receiving the information, authoriza-
3 tion, and affirmation described in subparagraph
4 (C), refuse, for a reason listed in section
5 304(a), to allow the agent or employee to pos-
6 sess the substance without a separate registra-
7 tion.”.

8 (c) SINGLE REGISTRATION FOR RELATED RESEARCH
9 SITES.—Section 302(e) of the Controlled Substances Act
10 (21 U.S.C. 822(e)) is amended by adding at the end the
11 following:

12 “(4)(A) Notwithstanding paragraph (1), a person
13 registered to conduct research with a controlled substance
14 under section 303(f) may conduct the research under a
15 single registration if—

16 “(i) the research occurs exclusively on sites all
17 of which are—

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

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

21 “(ii) before commencing the research, the re-
22 searcher notifies the Attorney General of each site
23 where—

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

1 “(II) the controlled substance will be
2 stored or administered.

3 “(B) A site described in subparagraph (A) shall be
4 included in a registration described in that subparagraph
5 only if the researcher has notified the Attorney General
6 of the site—

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

8 “(ii) before the research is conducted, or before
9 the controlled substance is stored or administered, at
10 the site.

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

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

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

18 “(iii) the maintenance of records for the re-
19 search sites; and

20 “(iv) any other matters necessary to ensure ef-
21 fective controls against diversion at the research
22 sites.”.

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

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

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

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

12 “(B) Nothing in subparagraph (A) shall prohibit the
13 Attorney General from conducting an inspection that the
14 Attorney General determines necessary to ensure that a
15 registrant maintains effective controls against diversion.”.

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

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

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

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

11 “(A) the person withdraws the application
12 described in paragraph (1) of this subsection;
13 or

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

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

24 “(4) if the person sends a copy of the applica-
25 tion described in paragraph (1) to a manufacturer or

1 distributor of the substance, receipt of the copy by
2 the manufacturer or distributor shall constitute suf-
3 ficient evidence that the person is authorized to re-
4 ceive the substance.”.

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

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

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

19 “(A) the activities are performed for the
20 purpose of the research; and

21 “(B) the activities and the quantities of
22 the substance involved in the activities are stat-
23 ed in—

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

1 “(ii) a research protocol filed with an
2 application for registration approval under
3 section 303(f); or

4 “(iii) a notification to the Attorney
5 General that includes—

6 “(I) the name of the registrant;

7 and

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

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

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

19 “(i) the information provided as part
20 of a notification submitted to the Attorney
21 General under section 303(l); or

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

1 “(B) dosage form development studies per-
2 formed for the purpose of requesting an inves-
3 tigational new drug exemption under section
4 505(i) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355(i)).

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

10 (g) TRANSPARENCY REGARDING SPECIAL PROCE-
11 DURES.—Section 303 of the Controlled Substances Act
12 (21 U.S.C. 823), as amended by subsection (a), is amend-
13 ed by adding at the end the following:

14 “(o) TRANSPARENCY REGARDING SPECIAL PROCE-
15 DURES.—

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

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

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

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

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

16 **SEC. 4. RULEMAKING.**

17 (a) INTERIM FINAL RULES.—The Attorney Gen-
18 eral—

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

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

24 (b) PROCEDURE FOR FINAL RULE.—

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

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

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

18 **SEC. 5. PENALTIES.**

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

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

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

5 (b) IMPORTATION AND EXPORTATION.—Section
6 1010(b) of the Controlled Substances Import and Export
7 Act (21 U.S.C. 960(b)) is amended—

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

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

16 **SEC. 6. APPLICABILITY; OTHER MATTERS.**

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

21 (b) RULE OF CONSTRUCTION.—Nothing in the
22 amendments made by this Act may be construed as evi-
23 dence that, in applying sections 401(b)(1) and 1010(b) of
24 the Controlled Substances Act (21 U.S.C. 841(b)(1) and
25 960(b)) with respect to conduct occurring before the date

1 of the enactment of this Act, a fentanyl-related substance
2 (as defined by such amendments) is not an analogue of
3 N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]
4 propanamide.

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

Passed the House of Representatives May 25, 2023.

Attest: CHERYL L. JOHNSON,
Clerk.

By LISA P. GRANT

Deputy Clerk.