

# Calendar No. 18

119<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 331

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

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## IN THE SENATE OF THE UNITED STATES

JANUARY 30, 2025

Mr. CASSIDY (for himself, Mr. HEINRICH, Mr. GRASSLEY, Mr. MARSHALL, Mr. YOUNG, Mr. DAINES, Mr. ROUNDS, Mrs. CAPITO, Mr. SCHMITT, Mr. KENNEDY, Mr. GALLEG0, Ms. HASSAN, Ms. CORTEZ MASTO, Mrs. SHAHEEN, Mr. KING, Mr. KELLY, Mr. CORNYN, Mr. HAWLEY, Mr. TILLIS, Mr. GRAHAM, Mr. CRUZ, Mrs. BRITT, Mrs. BLACKBURN, Mr. LEE, and Mrs. MOODY) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

MARCH 3, 2025

Reported by Mr. GRASSLEY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italie*]

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## 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,*

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 “(c)(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, hydroxy, halo,  
25 haloalkyl, amino, or nitro groups.

1           “(C) By substitution in or on the piperidine  
2 ring with alkyl, alkenyl, alkoxy, 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 (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 HIS 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(e).

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(e) of the Con-  
2           trolled Substances Act (21 U.S.C. 822(e)) 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(e)(3) of the Controlled Substances Act (21  
 13 U.S.C. 822(e)(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(e);

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 (2), 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)”; and

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)”; and

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

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)”; and

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(e).”.

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).

22 **SECTION 1. SHORT TITLE.**

23 *This Act may be cited as the “Halt All Lethal Traf-*  
 24 *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 schedule*  
5 *I the following:*

6 *“(e)(1) Unless specifically exempted or unless listed in*  
7 *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 the*  
11 *existence of such salts, isomers, and salts of isomers is pos-*  
12 *sible within the specific chemical designation.*

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

17 *“(A) By replacement of the phenyl portion of the*  
18 *phenethyl group by any monocycle, whether or not*  
19 *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 Gen-  
11           eral 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 the  
16           definition of the term ‘fentanyl-related substance’ in para-  
17           graph (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 satisfies  
21           the definition of the term ‘fentanyl-related substance’ in  
22           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) (re-*  
 7 *lating 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 CON-*  
 11 *DUCTING CERTAIN RESEARCH WITH SCHEDULE I CON-*  
 12 *TROLLED 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 subsection.

18 “(2) *RESEARCH SUBJECT TO EXPEDITED PROCE-*  
 19 *DURES.*—Research described in this paragraph is re-  
 20 search that—

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

25 “(B) *is—*

1           “(i) conducted by the Department of  
2           Health and Human Services, the Depart-  
3           ment of Defense, or the Department of Vet-  
4           erans 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 Vet-  
10          erans 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 is  
19          30 days after the date on which the practi-  
20          tioner sends a notice to the Attorney Gen-  
21          eral containing the following information,  
22          with respect to each substance with which  
23          the practitioner will conduct the research:

24           “(I) The chemical name of the  
25          substance.

1           “(II) *The quantity of the sub-*  
2           *stance to be used in the research.*

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

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

16                   “(bb) *in the case of an appli-*  
17                   *cation under section 505(i) of the*  
18                   *Federal Food, Drug, and Cosmetic*  
19                   *Act (21 U.S.C. 355(i)), by sup-*  
20                   *plying the application number*  
21                   *and the sponsor of record on the*  
22                   *application.*

23           “(IV) *Demonstration that the re-*  
24           *searcher is authorized to conduct re-*  
25           *search with respect to the substance*

1                   *under the laws of the State in which*  
2                   *the research will take place.*

3                   “(ii) *VERIFICATION OF INFORMATION*  
4                   *BY HHS OR VA.—Upon request from the At-*  
5                   *torney General, the Secretary of Health and*  
6                   *Human Services, the Department of De-*  
7                   *fense, or the Secretary of Veterans Affairs,*  
8                   *as appropriate, shall verify information*  
9                   *submitted by an applicant under clause*  
10                  *(i)(III).*

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

13                  “(i) *IN GENERAL.—If a practitioner is*  
14                  *not registered to conduct research with a*  
15                  *controlled substance in schedule I or II, the*  
16                  *practitioner may send a notice to the Attor-*  
17                  *ney General containing the information*  
18                  *listed in subparagraph (A)(i), with respect*  
19                  *to each substance with which the practi-*  
20                  *tioner will conduct the research.*

21                  “(ii) *ATTORNEY GENERAL ACTION.—*  
22                  *The Attorney General shall—*

23                         “(I) *treat notice received under*  
24                         *clause (i) as a sufficient application*  
25                         *for a research registration; and*

1                   “(II) not later than 45 days of re-  
2                   ceiving such a notice that contains all  
3                   information required under subpara-  
4                   graph (A)(i)—

5                   “(aa) register the applicant;

6                   or

7                   “(bb) serve an order to show  
8                   cause upon the applicant in ac-  
9                   cordance with section 304(c).

10                  “(4) *ELECTRONIC SUBMISSIONS.*—The Attorney  
11                  General shall provide a means to permit a practi-  
12                  tioner to submit a notification under paragraph (3)  
13                  electronically.

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

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

20                  “(B) a supplemental notification that the  
21                  practitioner may send if the practitioner needs  
22                  additional amounts for the research, which sup-  
23                  plemental notification shall include—

24                  “(i) the name of the practitioner;

1                   “(ii) the additional quantity needed of  
2                   the substance; and

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

8                   “(6) *IMPORTATION AND EXPORTATION REQUIRE-*  
9                   *MENTS NOT AFFECTED.*—Nothing in this subsection  
10                  alters the requirements of part A of title III, regard-  
11                  ing the importation and exportation of controlled sub-  
12                  stances.

13                  “(7) *INSPECTOR GENERAL REPORT.*—Not later  
14                  than 1 year after the date of enactment of the *Halt*  
15                  *All Lethal Trafficking of Fentanyl Act*, the Inspector  
16                  General of the Department of Justice shall complete  
17                  a study, and submit to Congress a report thereon,  
18                  about research described in paragraph (2) of this sub-  
19                  section with fentanyl.”.

20                  (b) *SEPARATE REGISTRATIONS NOT REQUIRED FOR*  
21                  *ADDITIONAL RESEARCHER IN SAME INSTITUTION.*—

22                  (1) *IN GENERAL.*—Section 302(c) of the *Con-*  
23                  *trolled Substances Act* (21 U.S.C. 822(c)) is amended  
24                  by adding at the end the following:

1           “(4) *An agent or employee of a research institu-*  
2           *tion that is conducting research with a controlled sub-*  
3           *stance if—*

4                   “(A) *the agent or employee is acting within*  
5                   *the scope of the professional practice of the agent*  
6                   *or employee;*

7                   “(B) *another agent or employee of the insti-*  
8                   *tution is registered to conduct research with a*  
9                   *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 employee*  
16                           *to perform research under the registration of*  
17                           *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 the*  
21                           *registered researcher, as if the researcher*  
22                           *had directly committed the act, for purposes*  
23                           *of any proceeding under section 304(a) to*  
24                           *suspend or revoke the registration of the reg-*  
25                           *istered 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 304(a),  
5           to allow the agent or employee to possess the sub-  
6           stance without a separate registration.”.

7           (2) *TECHNICAL CORRECTION.*—Section 302(c)(3)  
8           of the Controlled Substances Act (21 U.S.C. 822(c)(3))  
9           is amended by striking “(25)” and inserting “(27)”.

10          (c) *SINGLE REGISTRATION FOR RELATED RESEARCH*  
11 *SITES.*—Section 302(e) of the Controlled Substances Act (21  
12 U.S.C. 822(e)) is amended by adding at the end the fol-  
13 *lowing:*

14          “(4)(A) Notwithstanding paragraph (1), a person reg-  
15 *istered to conduct research with a controlled substance*  
16 *under section 303(g) may conduct the research under a sin-*  
17 *gle registration if—*

18           “(i) the research occurs exclusively on sites all of  
19           which are—

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

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

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

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

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

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

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

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

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

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

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

19                   “(iii) the maintenance of records for the research  
20           sites; and

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

23           (d) *NEW INSPECTION NOT REQUIRED IN CERTAIN SIT-*  
24           *UATIONS.—Section 302(f) of the Controlled Substances Act*  
25           *(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 sched-*  
8           *ule as the first controlled substance, or is in a schedule with*  
9           *a higher numerical designation than the schedule of the first*  
10           *controlled substance, a new inspection by the Attorney Gen-*  
11           *eral 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 reg-*  
15           *istrant maintains effective controls against diversion.”.*

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

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

1           “(1) not later than 90 days after the scheduling  
2           of the newly scheduled substance, the person shall sub-  
3           mit a completed application for registration or modi-  
4           fication of existing registration, to conduct research  
5           on the substance, in accordance with regulations  
6           issued by the Attorney General for purposes of this  
7           paragraph;

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

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

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

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

22          “(4) if the person sends a copy of the application  
23          described in paragraph (1) to a manufacturer or dis-  
24          tributor of the substance, receipt of the copy by the  
25          manufacturer or distributor shall constitute sufficient

1        *evidence that the person is authorized to receive the*  
2        *substance.”.*

3        *(f) TREATMENT OF CERTAIN MANUFACTURING ACTIVI-*  
4        *TIES AS COINCIDENT TO RESEARCH.—Section 302 of the*  
5        *Controlled Substances Act (21 U.S.C. 822), as amended by*  
6        *subsection (e), is amended by adding at the end the fol-*  
7        *lowing:*

8            *“(i) TREATMENT OF CERTAIN MANUFACTURING AC-*  
9        *TIVITIES AS COINCIDENT TO RESEARCH.—*

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

17            *“(A) the activities are performed for the*  
18        *purpose of the research; and*

19            *“(B) the activities and the quantities of the*  
20        *substance involved in the activities are stated*  
21        *in—*

22            *“(i) a notification submitted to the At-*  
23        *torney General under section 303(n);*

1           “(ii) a research protocol filed with an  
2 application for registration approval under  
3 section 303(g); 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 registra-  
13 tion.

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(n); or

22                   “(ii) a research protocol filed with an  
23 application for registration approval under  
24 section 303(g); 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 Cosmetic  
5           Act (21 U.S.C. 355(i)).

6           “(3) EXCEPTION REGARDING MARIHUANA.—The  
7           authority under paragraph (1) to manufacture sub-  
8           stances does not include the authority to grow mari-  
9           huana.”.

10          (g) TRANSPARENCY REGARDING SPECIAL PROCE-  
11 DURES.—Section 303 of the Controlled Substances Act (21  
12 U.S.C. 823), as amended by subsection (a), is amended by  
13 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 proc-  
20                 ess, or subject to criteria, different from the process or  
21                 criteria applicable to applications to conduct research  
22                 with other controlled substances in the same schedule,  
23                 the Attorney General shall make public, including by  
24                 posting on the website of the Drug Enforcement Ad-  
25                 ministration—

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 and  
8           criteria applicable to applications to conduct re-  
9           search with other controlled substances in the  
10          same schedule.

11          “(2) *TIMING OF POSTING.*—*The Attorney General*  
12          *shall make information described in paragraph (1)*  
13          *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. TECHNICAL CORRECTION ON CONTROLLED SUB-**  
17 **STANCES DISPENSING.**

18          *Effective as if included in the enactment of Public Law*  
19 *117–328—*

20                 *(1) section 1252(a) of division FF of Public Law*  
21                 *117–328 (136 Stat. 5681) is amended, in the matter*  
22                 *being inserted into section 302(e) of the Controlled*  
23                 *Substances Act, by striking “303(g)” and inserting*  
24                 *“303(h)”;*



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

3           (A) in subsection (a)—

4                 (i) in the matter preceding paragraph  
5                 (1), by striking “303(g)” and inserting  
6                 “303(h)”;

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

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

14           (B) in subsection (b)—

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

18                 (ii) in the matter being inserted by  
19                 paragraph (1), by striking “303(g)” and in-  
20                 serting “303(h)”;

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

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

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

7                   (vi) in the matter being stricken by  
8                   paragraph (6), by striking “303(g)” and in-  
9                   serting “303(h)”;

10                   (3) section 1263(b) of division FF of Public Law  
11                   117–328 (136 Stat. 5685) is amended—

12                   (A) by striking “303(g)(2)” and inserting  
13                   “303(h)(2)”;

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

16 **SEC. 5. RULEMAKING.**

17                   (a) *INTERIM FINAL RULES.*—The Attorney General—

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

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

23                   (b) *PROCEDURE FOR FINAL RULE.*—

24                   (1) *EFFECTIVENESS OF INTERIM FINAL RULES.*—

25                   A rule issued by the Attorney General as an interim

1 *final rule under subsection (a) shall become imme-*  
2 *diately effective as an interim final rule without re-*  
3 *quiring the Attorney General to demonstrate good*  
4 *cause therefor, notwithstanding subparagraph (B) of*  
5 *the undesignated matter following paragraph (4) of*  
6 *section 553(b) of title 5, United States Code.*

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

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

16 **SEC. 6. PENALTIES.**

17 (a) *IN GENERAL.—Section 401(b)(1) of the Controlled*  
18 *Substances Act (21 U.S.C. 841(b)(1)) is amended—*

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

23 (2) *in subparagraph (B)(vi), by inserting “or a*  
24 *fentanyl-related substance” after “any analogue of N-*

1       *phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]*  
2       *propanamide”.*

3       **(b) IMPORTATION AND EXPORTATION.**—*Section*  
4 *1010(b) of the Controlled Substances Import and Export*  
5 *Act (21 U.S.C. 960(b)) is amended—*

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

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

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

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

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

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

1           **(b) RULE OF CONSTRUCTION.**—*Nothing in the amend-*  
2 *ments made by this Act may be construed as evidence that,*  
3 *in applying sections 401(b)(1) of the Controlled Substances*  
4 *Act (21 U.S.C. 841(b)(1)) and 1010(b) of the Controlled*  
5 *Substances Import and Export Act (21 U.S.C. 960(b)) with*  
6 *respect to conduct occurring before the date of the enactment*  
7 *of this Act, a fentanyl-related substance (as defined by such*  
8 *amendments) is not an analogue of N-phenyl-N-[1-(2-*  
9 *phenylethyl)-4-piperidinyl] propanamide.*

10           **(c) SENSE OF CONGRESS.**—*Congress agrees with the*  
11 *interpretation of the Controlled Substances Act (21 U.S.C.*  
12 *801 et seq.) in United States v. McCray, 346 F. Supp. 3d*  
13 *363 (W.D.N.Y. 2018).*

**Calendar No. 18**

119<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**S. 331**

**A BILL**

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

MARCH 3, 2025

Reported with an amendment