

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 467
OFFERED BY MR. PAPPAS OF NEW HAMPSHIRE**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Save Americans from
3 the Fentanyl Emergency Act” or the “SAFE 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 fentanyl-re-
12 lated substances, or which contains their salts, isomers,
13 and salts of isomers whenever the existence of such salts,
14 isomers, and salts of isomers is possible within the specific
15 chemical designation.

16 “(2) In this subsection, except as provided in para-
17 graph (3), the term ‘fentanyl-related substance’ means

1 any substance that is structurally related to fentanyl by
2 one or more of the following modifications:

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

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

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

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

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

17 “(3) A substance that meets the criteria specified in
18 paragraph (2) to be considered a fentanyl-related sub-
19 stance shall not be so considered as meeting such criteria
20 if such substance—

21 “(A) is controlled by action of the Attorney
22 General pursuant to section 201;

23 “(B) is expressly listed in this schedule or an-
24 other schedule by a statutory provision other than
25 this subsection; or

1 “(C) is removed from this schedule, or resched-
2 uled to another schedule, pursuant to section 201(k).

3 “(4) The Attorney General shall publish in the Fed-
4 eral Register a list of individual substances that meet the
5 definition of fentanyl-related substances in paragraph (2)
6 within 60 days of determining such substances meet such
7 definition. The absence of a substance on any such list
8 does not negate the control status of such substance if
9 the substance meets the criteria specified in paragraph (2)
10 to be considered a fentanyl-related substance.

11 “(5) Notwithstanding any other provision of this title
12 or title III, fentanyl-related substances shall not be subject
13 to quantity-based mandatory minimum penalties pursuant
14 to subparagraph (A)(vi) or (B)(vi) of section 401(b)(1) of
15 this title or paragraph (1)(F) or (2)(F) of section 1010(b)
16 of title III.”.

17 **SEC. 3. PENALTY PROVISIONS WITH RESPECT TO**
18 **FENTANYL-RELATED SUBSTANCES—DOMES-**
19 **TIC OFFENSES.**

20 Section 401(b)(1) of the Controlled Substances Act
21 (21 U.S.C. 841(b)(1)) is amended—

22 (1) in subparagraph (A), by striking clause (vi)
23 and inserting the following:

1 “(vi)(I) 400 grams or more of a mixture or sub-
2 stance containing a detectable amount of fentanyl;
3 or

4 “(II) 100 grams or more of a mixture or sub-
5 stance containing a detectable amount of any ana-
6 logue of fentanyl that is controlled in schedule I or
7 II or that is treated as a schedule I controlled sub-
8 stance pursuant to section 203(a), except for a
9 fentanyl-related substance as defined in schedule
10 I(e) of section 202(c);”;

11 (2) in subparagraph (B), by striking clause (vi)
12 and inserting the following:

13 “(vi)(I) 40 grams or more of a mixture or sub-
14 stance containing a detectable amount of fentanyl;
15 or

16 “(II) 10 grams or more of a mixture or sub-
17 stance containing a detectable amount of any ana-
18 logue of fentanyl that is controlled in schedule I or
19 II or that is treated as a schedule I controlled sub-
20 stance pursuant to section 203(a), except for a
21 fentanyl-related substance as defined in schedule
22 I(e) of section 202(c);” and

23 (3) in subparagraph (C), by inserting “, includ-
24 ing a fentanyl-related substance as defined in sched-

1 ule I(e) of section 202(c),” after “a controlled sub-
2 stance in schedule I or II,”.

3 **SEC. 4. PENALTY PROVISIONS WITH RESPECT TO**
4 **FENTANYL-RELATED SUBSTANCES—IMPORT**
5 **AND EXPORT OFFENSES.**

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

8 (1) in paragraph (1), by striking subparagraph
9 (F) and inserting the following:

10 “(F)(i) 400 grams or more of a mixture or sub-
11 stance containing a detectable amount of fentanyl;
12 or

13 “(ii) 100 grams or more of a mixture or sub-
14 stance containing a detectable amount of any ana-
15 logue of fentanyl that is controlled in schedule I or
16 II or that is treated as a schedule I controlled sub-
17 stance pursuant to section 203(a) of the Controlled
18 Substances Act, except for a fentanyl-related sub-
19 stance as defined in schedule I(e) of section 202(c)
20 of the Controlled Substances Act;”;

21 (2) in paragraph (2), by striking subparagraph
22 (F) and inserting the following:

23 “(F)(i) 40 grams or more of a mixture or sub-
24 stance containing a detectable amount of fentanyl;
25 or

1 “(ii) 10 grams or more of a mixture or sub-
2 stance containing a detectable amount of any ana-
3 logue of fentanyl that is controlled in schedule I or
4 II or that is treated as a schedule I controlled sub-
5 stance pursuant to section 203(a) of the Controlled
6 Substances Act, except for a fentanyl-related sub-
7 stance as defined in schedule I(e) of section 202(c)
8 of the Controlled Substances Act;” and

9 (3) in paragraph (3), by inserting “including a
10 fentanyl-related substance as defined in schedule
11 I(e) of section 202(c) of the Controlled Substances
12 Act,” after “a controlled substance in schedule I or
13 II,”.

14 **SEC. 5. REMOVAL FROM SCHEDULE I OF FENTANYL-RE-**
15 **LATED SUBSTANCES.**

16 Section 201 of the Controlled Substances Act (21
17 U.S.C. 811) is amended by adding at the end the following
18 new subsection:

19 “(k) REMOVAL FROM SCHEDULE I OF FENTANYL-
20 RELATED SUBSTANCES.—

21 “(1) DETERMINATION RESULTING IN RE-
22 MOVAL.—If the Secretary determines, taking into
23 consideration factors as set forth in paragraph (3),
24 that a fentanyl-related substance has a potential for

1 abuse that is less than the drugs or other substances
2 in schedule V—

3 “(A) the Secretary shall submit to the At-
4 torney General a scientific and medical evalua-
5 tion of that fentanyl-related substance sup-
6 porting that determination;

7 “(B) the Secretary shall submit any such
8 evaluation and determination in writing and in-
9 clude the bases therefor;

10 “(C) the scientific and medical determina-
11 tion of the Secretary contained in such evalua-
12 tion shall be binding on the Attorney General;
13 and

14 “(D) not later than 90 days after receiving
15 such evaluation and determination, the Attor-
16 ney General shall issue an order removing such
17 fentanyl-related substance from the schedules
18 under section 202.

19 “(2) DETERMINATION RESULTING IN RESCHED-
20 ULING.—If the Secretary determines, taking into
21 consideration factors as set forth in paragraph (3),
22 that a fentanyl-related substance has a potential for
23 abuse that is less than the drugs or other substances
24 in schedules I and II—

1 “(A) the Secretary shall submit to the At-
2 torney General a scientific and medical evalua-
3 tion of that fentanyl-related substance sup-
4 porting that determination;

5 “(B) the Secretary shall submit any such
6 evaluation and determination in writing and in-
7 clude the bases therefor;

8 “(C) the scientific and medical determina-
9 tion of the Secretary contained in such evalua-
10 tion shall be binding on the Attorney General;
11 and

12 “(D) not later than 90 days after receiving
13 such evaluation, the Attorney General shall
14 issue an order removing such fentanyl-related
15 substance from schedule I and controlling such
16 substance under schedule III.

17 “(3) EVALUATION FACTORS.—

18 “(A) IN GENERAL.—In making a deter-
19 mination under paragraph (1) or (2), the Sec-
20 retary—

21 “(i) shall consider—

22 “(I) the factor listed in para-
23 graph (2) of subsection (c);

24 “(II) the factors listed in para-
25 graphs (1), (3), and (6) of such sub-

1 section to the extent evidence exists
2 with respect to such factors; and

3 “(III) any information submitted
4 to the Secretary by the Attorney Gen-
5 eral for purposes of such determina-
6 tion; and

7 “(ii) may consider the factors listed in
8 paragraphs (4), (5), and (7) of subsection
9 (c) if the Secretary finds that evidence ex-
10 ists with respect to such factors.

11 “(B) CONSIDERATION OF SCIENTIFIC EVI-
12 DENCE OF PHARMACOLOGICAL EFFECT.—

13 “(i) IN GENERAL.—For the purposes
14 of subparagraph (A)(i)(I), consideration by
15 the Secretary of the results of an assess-
16 ment consisting of the studies described in
17 clause (ii) shall suffice to constitute consid-
18 eration of the factor listed in paragraph
19 (2) of subsection (c) if—

20 “(I) each such study is per-
21 formed according to scientific methods
22 and protocols commonly accepted in
23 the scientific community; and

1 “(II) the Secretary determines
2 that such assessment is adequate for
3 such purposes.

4 “(ii) DESCRIBED STUDIES.—The
5 studies described in this clause are any of
6 the following:

7 “(I) A receptor binding study
8 that can demonstrate whether the
9 substance has affinity for the human
10 mu opioid receptor.

11 “(II) An in vitro functional assay
12 that can demonstrate whether the
13 substance has agonist activity at the
14 human mu opioid receptor.

15 “(III) One or more in vivo ani-
16 mal behavioral studies that can dem-
17 onstrate whether the substance has
18 abuse-related drug effects consistent
19 with mu opioid agonist activity, such
20 as demonstrating similarity to the ef-
21 fects of morphine.

22 “(4) ADVANCE NOTICE REGARDING EVALUA-
23 TION AND CONCLUSION.—The Secretary shall give
24 the Attorney General at least 30 days notice before
25 sending the Attorney General an evaluation and de-

1 termination under paragraph (1) or (2) with respect
2 to a fentanyl-related substance.

3 “(5) EXCEPTION FOR TREATY OBLIGATIONS.—

4 If a fentanyl-related substance is a substance that
5 the United States is obligated to control under inter-
6 national treaties, conventions, or protocols in effect
7 on the date of enactment of the Save Americans
8 from the Fentanyl Emergency Act, this subsection
9 shall not require the Attorney General—

10 “(A) to remove such substance from con-
11 trol; or

12 “(B) to place such substance in a schedule
13 less restrictive than that which the Attorney
14 General determines is necessary to carry out
15 such obligations.

16 “(6) IDENTIFICATION OF FENTANYL-RELATED
17 SUBSTANCES.—If the Attorney General or any offi-
18 cial of the Department of Justice determines that a
19 substance is a fentanyl-related substance, the Attor-
20 ney General shall—

21 “(A) within 30 days of such determination,
22 notify the Secretary; and

23 “(B) include in such notification the iden-
24 tity of the substance, its structure, and the
25 basis for the determination.

1 “(7) PETITIONS FOR REMOVING A FENTANYL-
2 RELATED SUBSTANCE.—

3 “(A) IN GENERAL.—If a person petitions
4 the Attorney General to remove a fentanyl-re-
5 lated substance from schedule I(e) or to re-
6 schedule such a substance to another schedule,
7 the Attorney General shall consider such a peti-
8 tion in accordance with the procedures and
9 standards set forth in—

10 “(i) subsections (a) and (b) of this
11 section; and

12 “(ii) section 1308.43 of title 21, Code
13 of Federal Regulations (or any successor
14 regulations).

15 “(B) ATTORNEY GENERAL TO INFORM
16 SECRETARY.—Within 30 days of receiving such
17 a petition, the Attorney General shall forward a
18 copy of the petition to the Secretary.

19 “(C) DETERMINATION PROCEDURE NOT
20 PRECLUDED BY FILING OF PETITION.—The fil-
21 ing of a petition under this paragraph shall not
22 preclude the Secretary from making a deter-
23 mination and sending an evaluation under para-
24 graph (1) or (2).

1 “(8) RULE OF CONSTRUCTION.—Nothing in
2 this subsection shall be construed to preclude the At-
3 torney General from transferring a substance listed
4 in schedule I to another schedule, or removing such
5 substance entirely from the schedules, pursuant to
6 other provisions of this section and section 202.

7 “(9) SUBSEQUENT CONTROLLING OF REMOVED
8 SUBSTANCE.—A substance removed from schedule I
9 pursuant to this subsection may, at any time, be
10 controlled pursuant to the other provisions of this
11 section and section 202 without regard to the re-
12 moval pursuant to this subsection.

13 “(10) EVALUATIONS OR STUDIES.—The Sec-
14 retary may enter into contracts or other agreements
15 to conduct or support evaluations or studies of
16 fentanyl-related substances.

17 “(11) DEFINITION.—In this subsection, the
18 term ‘fentanyl-related substance’ means a fentanyl-
19 related substance as defined in schedule I(e) of sec-
20 tion 202(c).”.

21 **SEC. 6. PAST CASES INVOLVING REMOVED OR RESCHED-**
22 **ULED SUBSTANCES.**

23 (a) DOMESTIC CASES.—Section 401(b) of the Con-
24 trolled Substances Act (21 U.S.C. 841(b)) is amended by
25 adding at the end the following:

1 “(8) PAST CONVICTIONS INVOLVING FENTANYL-RE-
2 LATED SUBSTANCE.—

3 “(A) IN GENERAL.—In the case of a defendant
4 whose offense of conviction under this title involved
5 a fentanyl-related substance (as defined in schedule
6 I(e) of section 202(c) as of the date the offense was
7 committed) that has since been removed from des-
8 ignation as a fentanyl-related substance for purposes
9 of this title and has been placed on any schedule
10 other than schedule I or II or has been removed
11 from the controlled substance schedules, the sen-
12 tencing court may, on motion of the defendant, the
13 Bureau of Prisons, the attorney for the Government,
14 or on its own motion, after considering the factors
15 set forth in section 3553(a) of title 18, United
16 States Code, vacate the previously imposed sentence,
17 or impose a reduced sentence on any count of con-
18 viction as if the removal or placement was in effect
19 at the time that the offense was committed. Nothing
20 in this section may be construed to require a court
21 to vacate or reduce any sentence.

22 “(B) DEFENDANT NOT REQUIRED TO BE
23 PRESENT.—Notwithstanding rule 43 of the Federal
24 Rules of Criminal Procedure, the defendant is not
25 required to be present at any hearing on whether to

1 vacate or reduce a sentence pursuant to this sec-
2 tion.”.

3 (b) IMPORT AND EXPORT CASES.—Section 1010(b)
4 of the Controlled Substances Import and Export Act (21
5 U.S.C. 960(b)) is amended by adding at the end the fol-
6 lowing:

7 “(8) In the case of a defendant whose offense of con-
8 viction under this title involved a fentanyl-related sub-
9 stance (as defined in schedule I(e) of section 202(c) of
10 the Controlled Substances Act as of the date the offense
11 was committed) that has since been removed from des-
12 ignation as a fentanyl-related substance for purposes of
13 this title and has been placed on any schedule other than
14 schedule I or II or has been removed from the controlled
15 substance schedules, the sentencing court may, on motion
16 of the defendant, the Bureau of Prisons, the attorney for
17 the Government, or on its own motion, after considering
18 the factors set forth in section 3553(a) of title 18, United
19 States Code, vacate the previously imposed sentence, or
20 impose a reduced sentence on any count of conviction as
21 if the removal or placement was in effect at the time that
22 the offense was committed. Nothing in this section may
23 be construed to require a court to vacate or reduce any
24 sentence.”.

1 **SEC. 7. 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 by adding at
6 the end the following new subsection:

7 “(m) SPECIAL PROVISIONS FOR THOSE CONDUCTING
8 CERTAIN RESEARCH WITH SCHEDULE I CONTROLLED
9 SUBSTANCES.—

10 “(1) IN GENERAL.—Notwithstanding subsection
11 (f), a practitioner may conduct research that is de-
12 scribed in paragraph (2) and that is with one or
13 more controlled substances in schedule I if one of
14 the following conditions is satisfied:

15 “(A) RESEARCHER WITH A CURRENT
16 SCHEDULE I OR II RESEARCH REGISTRATION.—
17 If the practitioner is registered to conduct re-
18 search with a controlled substance in schedule
19 I or II, the practitioner may conduct research
20 under this paragraph 30 days after the practi-
21 tioner has sent a notice to the Attorney General
22 containing the following information, with re-
23 spect to each substance with which the research
24 will be conducted:

25 “(i) The chemical name of the sub-
26 stance.

1 “(ii) The quantity of the substance to
2 be used in such research.

3 “(iii) Demonstration that the research
4 is described in paragraph (2), which dem-
5 onstration can be satisfied—

6 “(I) in the case of research de-
7 scribed in paragraph (2)(A), by sup-
8 plying the number of the application
9 submitted under section 505(i) of the
10 Federal Food, Drug, and Cosmetic
11 Act or section 351(a)(3) of the Public
12 Health Service Act and the sponsor of
13 record on such application; or

14 “(II) in the case of research de-
15 scribed in paragraph (2)(B), by iden-
16 tifying the sponsoring agency and
17 supplying the number of the grant,
18 contract, cooperative agreement, other
19 transaction, or project.

20 “(iv) Demonstration that the re-
21 searcher is authorized to conduct research
22 with respect to the substance under the
23 laws of the State in which the research will
24 take place.

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

3 If the practitioner is not currently registered to
4 conduct research with a controlled substance in
5 schedule I or II—

6 “(i) the practitioner may send a no-
7 tice to the Attorney General containing the
8 information listed in subparagraph (A),
9 with respect to each substance with which
10 the research will be conducted;

11 “(ii) the Attorney General shall treat
12 such notice as a sufficient application for
13 a research registration; and

14 “(iii) within 45 days after receiving
15 such a notice that contains all information
16 required by subparagraph (A), the Attor-
17 ney General shall register the applicant, or
18 serve an order to show cause upon the ap-
19 plicant in accordance with section 304(c).

20 “(C) VERIFICATION OF INFORMATION.—

21 On request from the Attorney General, the Sec-
22 retary of Health and Human Services or the
23 Secretary of Veterans Affairs, as appropriate,
24 shall verify information submitted by an appli-
25 cant under subparagraph (A)(iii).

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

4 “(A) is the subject of an application under
5 section 505(i) of the Federal Food, Drug, and
6 Cosmetic Act or section 351(a)(3) of the Public
7 Health Service Act for the investigation of a
8 drug which is in effect in accordance with sec-
9 tion 312.40 of title 21, Code of Federal Regula-
10 tions; or

11 “(B) is conducted by the Department of
12 Health and Human Services, the Department of
13 Justice, or the Department of Veterans Affairs
14 or is funded partly or entirely by a grant, con-
15 tract, cooperative agreement, or other trans-
16 action from the Department of Health and
17 Human Services, the Department of Justice, or
18 the Department of Veterans Affairs.

19 “(3) ELECTRONIC SUBMISSIONS.—The Attorney
20 General shall provide a means to allow practitioners
21 to submit notifications under paragraph (1) elec-
22 tronically.

23 “(4) LIMITATION ON AMOUNTS.—A practitioner
24 conducting research with a controlled substance in
25 schedule I pursuant to this subsection shall be al-

1 lowed to possess only the amounts of the controlled
2 substance in schedule I identified in—

3 “(A) the notification to the Attorney Gen-
4 eral under paragraph (1); or

5 “(B) if the practitioner needs additional
6 amounts for the research, a supplemental notifi-
7 cation under this subsection that includes the
8 practitioner’s name, the additional quantity
9 needed of the substance, and an attestation
10 that the research to be conducted with the sub-
11 stance is consistent with the scope of the re-
12 search that was the subject of the notification
13 under paragraph (1).

14 “(5) IMPORTATION AND EXPORTATION RE-
15 QUIREMENTS NOT AFFECTED.—Nothing in this sec-
16 tion alters the requirements of part A of title III re-
17 garding the importation and exportation of con-
18 trolled substances.”.

19 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
20 ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Sub-
21 section (c) of section 302 of the Controlled Substances Act
22 (21 U.S.C. 822) is amended by adding at the end the fol-
23 lowing:

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

4 “(A) such agent or employee is acting
5 within the scope of his or her professional prac-
6 tice;

7 “(B) another agent or employee of such 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 such agent or em-
16 ployee to perform research under the reg-
17 istered researcher’s registration; and

18 “(iii) affirms that all acts taken by
19 such agent or employee involving controlled
20 substances shall be attributable to the reg-
21 istered researcher, as if the researcher had
22 directly committed such acts, for purposes
23 of any proceeding under section 304(a) to
24 suspend or revoke the registration of the
25 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 such agent or employee to pos-
6 sess such substance without a separate registra-
7 tion.”.

8 (c) SINGLE REGISTRATION FOR RELATED RESEARCH
9 SITES.—Such section 302(e) of the Controlled Substances
10 Act (21 U.S.C. 822(e)) is amended by adding at the end
11 the 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 such research at mul-
15 tiple sites under a single registration if—

16 “(i) such research occurs exclusively at sites
17 which are all within the same city or county and are
18 all under the control of the same institution, organi-
19 zation, or agency; and

20 “(ii) the researcher notifies the Attorney Gen-
21 eral, prior to commencing such research, of all sites
22 where—

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

24 “(II) the controlled substance will be
25 stored or administered.

1 “(B) A site described by subparagraph (A) shall be
2 included in such registration only if the researcher has no-
3 tified the Attorney General of such site—

4 “(i) in the application for such registration; or

5 “(ii) before the research is conducted, or before
6 the controlled substance is stored or administered, at
7 such site.

8 “(C) The Attorney General may, in consultation with
9 the Secretary of Health and Human Services, issue regu-
10 lations addressing—

11 “(i) the manner in which controlled substances
12 may be delivered to research sites described in sub-
13 paragraph (A);

14 “(ii) the storage and security of controlled sub-
15 stances at such research sites;

16 “(iii) the maintenance of records for such re-
17 search sites; and

18 “(iv) any other matters necessary to ensure ef-
19 fective controls against diversion at such research
20 sites.”.

21 (d) NEW INSPECTION NOT REQUIRED IN CERTAIN
22 SITUATIONS.—Subsection (f) of section 302 of the Con-
23 trolled Substances Act (21 U.S.C. 822) is amended—

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

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

2 “(2)(A) A new inspection by the Attorney General of
3 a registered location is not required if a person is reg-
4 istered under this title to conduct research with a con-
5 trolled substance and applies for a registration, or for a
6 modification of a registration, to conduct research with a
7 second controlled substance that is—

8 “(i) in the same schedule as the first controlled
9 substance; or

10 “(ii) is in a schedule with a higher numerical
11 designation than the schedule of the first controlled
12 substance.

13 “(B) Nothing in this paragraph shall prohibit the At-
14 torney General from conducting any inspection if the At-
15 torney General deems it necessary to ensure that the reg-
16 istrant maintains effective controls against diversion.”.

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

21 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES
22 NEWLY ADDED TO SCHEDULE I.—If a person is con-
23 ducting research on a substance at the time the substance
24 is added to schedule I, and such person is already reg-

1 istered under this title to conduct research with a con-
2 trolled substance in schedule I, then—

3 “(1) the person shall, within 90 days of the
4 scheduling in schedule I, submit a completed appli-
5 cation for registration under this title or modifica-
6 tion of an existing registration under this title, to
7 conduct research on such substance, in accordance
8 with regulations issued by the Attorney General;

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

12 “(A) the person withdraws such applica-
13 tion; or

14 “(B) the Attorney General serves on the
15 person an order to show cause proposing the
16 denial of the application pursuant to section
17 304(c);

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

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

1 distributor of such substance, receipt of such copy
2 by such manufacturer or distributor shall constitute
3 sufficient evidence that the person is authorized to
4 receive such 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 further amended by adding at the
9 end the following:

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

12 “(1) IN GENERAL.—Except as specified in
13 paragraph (3), a person who is registered to perform
14 research on a controlled substance may perform
15 manufacturing activities with small quantities of
16 that substance, including activities listed in para-
17 graph (2), without being required to obtain a manu-
18 facturing registration, if such activities are per-
19 formed for the purpose of the research and if the ac-
20 tivities and the quantities of the substance involved
21 in those activities are stated in—

22 “(A) a notification submitted to the Attor-
23 ney General under section 303(m);

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

4 “(C) a notification to the Attorney General
5 that includes the registrant’s name and an at-
6 testation that the research to be conducted with
7 the small quantities of manufactured substance
8 is consistent with the scope of the research that
9 is the basis for the registration.

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

12 “(A) processing the substance to create ex-
13 tracts, tinctures, oils, solutions, derivatives, or
14 other forms of the substance consistent with the
15 information provided as part of a notification
16 submitted to the Attorney General under sec-
17 tion 303(m) or a research protocol filed with
18 the application for registration approval; and

19 “(B) dosage form development studies per-
20 formed for the purpose of satisfying regulatory
21 requirements of the Food and Drug Adminis-
22 tration for submitting an investigational new
23 drug application.

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

1 substances does not include authority to grow mari-
2 huana.”.

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

7 “(n) 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 such 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 will be
22 applied to applications to conduct research with
23 such substances; and

24 “(C) how such process and criteria differ
25 from those applicable to applications to conduct

1 research with other controlled substances in the
2 same schedule.

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

8 **SEC. 8. RULEMAKING.**

9 (a) INTERIM FINAL RULES.—The Attorney Gen-
10 eral—

11 (1) not later than 1 year of the date of enact-
12 ment of this Act, shall issue rules to implement this
13 Act and the amendments made by this Act; and

14 (2) may issue such rules as interim final rules.

15 (b) PROCEDURE FOR FINAL RULE.—A rule issued by
16 the Attorney General as an interim final rule under sub-
17 section (a) shall become immediately effective as an in-
18 terim final rule without requiring the Attorney General to
19 demonstrate good cause therefor. The interim final rule
20 shall give interested persons the opportunity to comment
21 and to request a hearing. After the conclusion of such pro-
22 ceedings, the Attorney General shall issue a final rule in
23 accordance with section 553 of title 5, United States Code.

1 **SEC. 9. GAO REPORT.**

2 (a) IN GENERAL.—Not more than 4 years after the
3 date of enactment of this Act, the Comptroller General
4 of the United States shall submit to the Committees on
5 Energy and Commerce and the Judiciary of the House
6 of Representatives and the Committee on the Judiciary
7 of the Senate a report analyzing the implementation and
8 impact, to the extent information is available, of perma-
9 nent class scheduling pursuant to schedule I(e) of section
10 202(c) of the Controlled Substances Act, as added by sec-
11 tion 2 of this Act, of fentanyl-related substances (as de-
12 fined in such schedule I(e)), which report shall include—

13 (1) an analysis of the impact on research of
14 fentanyl-related substances;

15 (2) an analysis of any actions taken to remove
16 or reschedule in a different class any fentanyl-re-
17 lated substance;

18 (3) an analysis of the impact of permanent
19 scheduling on the unlawful importation, manufac-
20 ture, trafficking, and use of fentanyl-related sub-
21 stances, taking into consideration data collected con-
22 cerning the proliferation of fentanyl-related sub-
23 stances since class scheduling was instituted;

24 (4) an analysis of sentences attributable to
25 criminal charges involving fentanyl-related sub-
26 stances, comparing those sentences to sentences at-

1 tributable to criminal charges involving fentanyl and
2 individually scheduled fentanyl analogues; and

3 (5) an analysis of the efficacy of class sched-
4 uling generally, in terms of reducing the prolifera-
5 tion of new controlled substance analogues.

6 (b) CONSULTATIONS.—In developing the report re-
7 quired by subsection (a), the Comptroller General—

8 (1) shall consider the views of the Secretary of
9 Health and Human Services, the Attorney General,
10 the Secretary of Homeland Security, the Secretary
11 of State, the Director of the Office of National Drug
12 Control Policy, the scientific and medical research
13 community, the State and local law enforcement
14 community, and the civil rights and criminal justice
15 reform communities; and

16 (2) to the greatest extent possible, should base
17 such report on reliable data and empirical informa-
18 tion.

