

[118H568]

.....
(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Mr. PAPPAS introduced the following bill; which was referred to the Committee
on _____

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Save Americans from
5 the Fentanyl Emergency Act” or the “SAFE Act”.

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

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

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

13 “(2) In this subsection, except as provided in para-
14 graph (3), the term ‘fentanyl-related substance’ means
15 any substance that is structurally related to fentanyl by
16 one or more of the following modifications:

17 “(A) By replacement of the phenyl portion of
18 the phenethyl group by any monocycle, whether or
19 not 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 meets the criteria specified in
7 paragraph (2) to be considered a fentanyl-related sub-
8 stance shall not be so considered as meeting such criteria
9 if such substance—

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

12 “(B) is expressly listed in this schedule or an-
13 other schedule by a statutory provision other than
14 this subsection; or

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

17 “(4) The Attorney General shall publish in the Fed-
18 eral Register a list of individual substances that meet the
19 definition of fentanyl-related substances in paragraph (2)
20 within 60 days of determining such substances meet such
21 definition. The absence of a substance on any such list
22 does not negate the control status of such substance if
23 the substance meets the criteria specified in paragraph (2)
24 to be considered a fentanyl-related substance.

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

7 **SEC. 3. PENALTY PROVISIONS WITH RESPECT TO**
8 **FENTANYL-RELATED SUBSTANCES—DOMES-**
9 **TIC OFFENSES.**

10 Section 401(b)(1) of the Controlled Substances Act
11 (21 U.S.C. 841(b)(1)) is amended—

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

14 “(vi)(I) 400 grams or more of a mixture or sub-
15 stance containing a detectable amount of fentanyl;
16 or

17 “(II) 100 grams or more of a mixture or sub-
18 stance containing a detectable amount of any ana-
19 logue of fentanyl that is controlled in schedule I or
20 II or that is treated as a schedule I controlled sub-
21 stance pursuant to section 203(a), except for a
22 fentanyl-related substance as defined in schedule
23 I(e) of section 202(c);”;

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

1 “(vi)(I) 40 grams or more of a mixture or sub-
2 stance containing a detectable amount of fentanyl;
3 or

4 “(II) 10 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);” and

11 (3) in subparagraph (C), by inserting “, includ-
12 ing a fentanyl-related substance as defined in sched-
13 ule I(e) of section 202(c),” after “a controlled sub-
14 stance in schedule I or II,”.

15 **SEC. 4. PENALTY PROVISIONS WITH RESPECT TO**
16 **FENTANYL-RELATED SUBSTANCES—IMPORT**
17 **AND EXPORT OFFENSES.**

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

20 (1) in paragraph (1), by striking subparagraph
21 (F) and inserting the following:

22 “(F)(i) 400 grams or more of a mixture or sub-
23 stance containing a detectable amount of fentanyl;
24 or

1 “(ii) 100 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;”;

9 (2) in paragraph (2), by striking subparagraph
10 (F) and inserting the following:

11 “(F)(i) 40 grams or more of a mixture or sub-
12 stance containing a detectable amount of fentanyl;
13 or

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

22 (3) in paragraph (3), by inserting “including a
23 fentanyl-related substance as defined in schedule
24 I(e) of section 202(c) of the Controlled Substances

1 Act,” after “a controlled substance in schedule I or
2 II,”.

3 **SEC. 5. REMOVAL FROM SCHEDULE I OF FENTANYL-RE-**
4 **LATED SUBSTANCES.**

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

8 “(k) REMOVAL FROM SCHEDULE I OF FENTANYL-
9 RELATED SUBSTANCES.—

10 “(1) DETERMINATION RESULTING IN RE-
11 MOVAL.—If the Secretary determines, taking into
12 consideration factors as set forth in paragraph (3),
13 that a fentanyl-related substance has a potential for
14 abuse that is less than the drugs or other substances
15 in schedule V—

16 “(A) the Secretary shall submit to the At-
17 torney General a scientific and medical evalua-
18 tion of that fentanyl-related substance sup-
19 porting that determination;

20 “(B) the Secretary shall submit any such
21 evaluation and determination in writing and in-
22 clude the bases therefor;

23 “(C) the scientific and medical determina-
24 tion of the Secretary contained in such evalua-

1 tion shall be binding on the Attorney General;
2 and

3 “(D) not later than 90 days after receiving
4 such evaluation and determination, the Attor-
5 ney General shall issue an order removing such
6 fentanyl-related substance from the schedules
7 under section 202.

8 “(2) DETERMINATION RESULTING IN RESCHED-
9 ULING.—If the Secretary determines, taking into
10 consideration factors as set forth in paragraph (3),
11 that a fentanyl-related substance has a potential for
12 abuse that is less than the drugs or other substances
13 in schedules I and II—

14 “(A) the Secretary shall submit to the At-
15 torney General a scientific and medical evalua-
16 tion of that fentanyl-related substance sup-
17 porting that determination;

18 “(B) the Secretary shall submit any such
19 evaluation and determination in writing and in-
20 clude the bases therefor;

21 “(C) the scientific and medical determina-
22 tion of the Secretary contained in such evalua-
23 tion shall be binding on the Attorney General;
24 and

1 “(D) not later than 90 days after receiving
2 such evaluation, the Attorney General shall
3 issue an order removing such fentanyl-related
4 substance from schedule I and controlling such
5 substance under schedule III.

6 “(3) EVALUATION FACTORS.—

7 “(A) IN GENERAL.—In making a deter-
8 mination under paragraph (1) or (2), the Sec-
9 retary—

10 “(i) shall consider—

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

13 “(II) the factors listed in para-
14 graphs (1), (3), and (6) of such sub-
15 section to the extent evidence exists
16 with respect to such factors; and

17 “(III) any information submitted
18 to the Secretary by the Attorney Gen-
19 eral for purposes of such determina-
20 tion; and

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

1 “(B) CONSIDERATION OF SCIENTIFIC EVI-
2 DENCE OF PHARMACOLOGICAL EFFECT.—

3 “(i) IN GENERAL.—For the purposes
4 of subparagraph (A)(i)(I), consideration by
5 the Secretary of the results of an assess-
6 ment consisting of the studies described in
7 clause (ii) shall suffice to constitute consid-
8 eration of the factor listed in paragraph
9 (2) of subsection (c) if—

10 “(I) each such study is per-
11 formed according to scientific methods
12 and protocols commonly accepted in
13 the scientific community; and

14 “(II) the Secretary determines
15 that such assessment is adequate for
16 such purposes.

17 “(ii) DESCRIBED STUDIES.—The
18 studies described in this clause are any of
19 the following:

20 “(I) A receptor binding study
21 that can demonstrate whether the
22 substance has affinity for the human
23 mu opioid receptor.

24 “(II) An in vitro functional assay
25 that can demonstrate whether the

1 substance has agonist activity at the
2 human mu opioid receptor.

3 “(III) One or more in vivo ani-
4 mal behavioral studies that can dem-
5 onstrate whether the substance has
6 abuse-related drug effects consistent
7 with mu opioid agonist activity, such
8 as demonstrating similarity to the ef-
9 fects of morphine.

10 “(4) ADVANCE NOTICE REGARDING EVALUA-
11 TION AND CONCLUSION.—The Secretary shall give
12 the Attorney General at least 30 days notice before
13 sending the Attorney General an evaluation and de-
14 termination under paragraph (1) or (2) with respect
15 to a fentanyl-related substance.

16 “(5) EXCEPTION FOR TREATY OBLIGATIONS.—
17 If a fentanyl-related substance is a substance that
18 the United States is obligated to control under inter-
19 national treaties, conventions, or protocols in effect
20 on the date of enactment of the Save Americans
21 from the Fentanyl Emergency Act, this subsection
22 shall not require the Attorney General—

23 “(A) to remove such substance from con-
24 trol; or

1 “(B) to place such substance in a schedule
2 less restrictive than that which the Attorney
3 General determines is necessary to carry out
4 such obligations.

5 “(6) IDENTIFICATION OF FENTANYL-RELATED
6 SUBSTANCES.—If the Attorney General or any offi-
7 cial of the Department of Justice determines that a
8 substance is a fentanyl-related substance, the Attor-
9 ney General shall—

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

12 “(B) include in such notification the iden-
13 tity of the substance, its structure, and the
14 basis for the determination.

15 “(7) PETITIONS FOR REMOVING A FENTANYL-
16 RELATED SUBSTANCE.—

17 “(A) IN GENERAL.—If a person petitions
18 the Attorney General to remove a fentanyl-re-
19 lated substance from schedule I(e) or to re-
20 schedule such a substance to another schedule,
21 the Attorney General shall consider such a peti-
22 tion in accordance with the procedures and
23 standards set forth in—

24 “(i) subsections (a) and (b) of this
25 section; and

1 “(ii) section 1308.43 of title 21, Code
2 of Federal Regulations (or any successor
3 regulations).

4 “(B) ATTORNEY GENERAL TO INFORM
5 SECRETARY.—Within 30 days of receiving such
6 a petition, the Attorney General shall forward a
7 copy of the petition to the Secretary.

8 “(C) DETERMINATION PROCEDURE NOT
9 PRECLUDED BY FILING OF PETITION.—The fil-
10 ing of a petition under this paragraph shall not
11 preclude the Secretary from making a deter-
12 mination and sending an evaluation under para-
13 graph (1) or (2).

14 “(8) RULE OF CONSTRUCTION.—Nothing in
15 this subsection shall be construed to preclude the At-
16 torney General from transferring a substance listed
17 in schedule I to another schedule, or removing such
18 substance entirely from the schedules, pursuant to
19 other provisions of this section and section 202.

20 “(9) SUBSEQUENT CONTROLLING OF REMOVED
21 SUBSTANCE.—A substance removed from schedule I
22 pursuant to this subsection may, at any time, be
23 controlled pursuant to the other provisions of this
24 section and section 202 without regard to the re-
25 moval pursuant to this subsection.

1 “(10) EVALUATIONS OR STUDIES.—The Sec-
2 retary may enter into contracts or other agreements
3 to conduct or support evaluations or studies of
4 fentanyl-related substances.

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

9 **SEC. 6. PAST CASES INVOLVING REMOVED OR RESCHED-**
10 **ULED SUBSTANCES.**

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

14 “(8) PAST CONVICTIONS INVOLVING FENTANYL-RE-
15 LATED SUBSTANCE.—

16 “(A) IN GENERAL.—In the case of a defendant
17 whose offense of conviction under this title involved
18 a fentanyl-related substance (as defined in schedule
19 I(e) of section 202(c) as of the date the offense was
20 committed) that has since been removed from des-
21 ignation as a fentanyl-related substance for purposes
22 of this title and has been placed on any schedule
23 other than schedule I or II or has been removed
24 from the controlled substance schedules, the sen-
25 tencing court may, on motion of the defendant, the

1 Bureau of Prisons, the attorney for the Government,
2 or on its own motion, after considering the factors
3 set forth in section 3553(a) of title 18, United
4 States Code, vacate the previously imposed sentence,
5 or impose a reduced sentence on any count of con-
6 viction as if the removal or placement was in effect
7 at the time that the offense was committed. Nothing
8 in this section may be construed to require a court
9 to vacate or reduce any sentence.

10 “(B) DEFENDANT NOT REQUIRED TO BE
11 PRESENT.—Notwithstanding rule 43 of the Federal
12 Rules of Criminal Procedure, the defendant is not
13 required to be present at any hearing on whether to
14 vacate or reduce a sentence pursuant to this sec-
15 tion.”.

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

20 “(8) In the case of a defendant whose offense of con-
21 viction under this title involved a fentanyl-related sub-
22 stance (as defined in schedule I(e) of section 202(c) of
23 the Controlled Substances Act as of the date the offense
24 was committed) that has since been removed from des-
25 ignation as a fentanyl-related substance for purposes of

1 this title and has been placed on any schedule other than
2 schedule I or II or has been removed from the controlled
3 substance schedules, the sentencing court may, on motion
4 of the defendant, the Bureau of Prisons, the attorney for
5 the Government, or on its own motion, after considering
6 the factors set forth in section 3553(a) of title 18, United
7 States Code, vacate the previously imposed sentence, or
8 impose a reduced sentence on any count of conviction as
9 if the removal or placement was in effect at the time that
10 the offense was committed. Nothing in this section may
11 be construed to require a court to vacate or reduce any
12 sentence.”.

13 **SEC. 7. REGISTRATION REQUIREMENTS RELATED TO RE-**
14 **SEARCH.**

15 (a) **ALTERNATIVE REGISTRATION PROCESS FOR**
16 **SCHEDULE I RESEARCH.**—Section 303 of the Controlled
17 Substances Act (21 U.S.C. 823) is amended by adding at
18 the end the following new subsection:

19 “(m) **SPECIAL PROVISIONS FOR THOSE CONDUCTING**
20 **CERTAIN RESEARCH WITH SCHEDULE I CONTROLLED**
21 **SUBSTANCES.**—

22 “(1) **IN GENERAL.**—Notwithstanding subsection
23 (f), a practitioner may conduct research that is de-
24 scribed in paragraph (2) and that is with one or

1 more controlled substances in schedule I if one of
2 the following conditions is satisfied:

3 “(A) RESEARCHER WITH A CURRENT
4 SCHEDULE I OR II RESEARCH REGISTRATION.—

5 If the practitioner is registered to conduct re-
6 search with a controlled substance in schedule
7 I or II, the practitioner may conduct research
8 under this paragraph 30 days after the practi-
9 tioner has sent a notice to the Attorney General
10 containing the following information, with re-
11 spect to each substance with which the research
12 will be conducted:

13 “(i) The chemical name of the sub-
14 stance.

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

17 “(iii) Demonstration that the research
18 is described in paragraph (2), which dem-
19 onstration can be satisfied—

20 “(I) in the case of research de-
21 scribed in paragraph (2)(A), by sup-
22 plying the number of the application
23 submitted under section 505(i) of the
24 Federal Food, Drug, and Cosmetic
25 Act or section 351(a)(3) of the Public

1 Health Service Act and the sponsor of
2 record on such application; or

3 “(II) in the case of research de-
4 scribed in paragraph (2)(B), by iden-
5 tifying the sponsoring agency and
6 supplying the number of the grant,
7 contract, cooperative agreement, other
8 transaction, or project.

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

14 “(B) RESEARCHER WITHOUT A CURRENT
15 SCHEDULE I OR II RESEARCH REGISTRATION.—
16 If the practitioner is not currently registered to
17 conduct research with a controlled substance in
18 schedule I or II—

19 “(i) the practitioner may send a no-
20 tice to the Attorney General containing the
21 information listed in subparagraph (A),
22 with respect to each substance with which
23 the research will be conducted;

1 “(ii) the Attorney General shall treat
2 such notice as a sufficient application for
3 a research registration; and

4 “(iii) within 45 days after receiving
5 such a notice that contains all information
6 required by subparagraph (A), the Attor-
7 ney General shall register the applicant, or
8 serve an order to show cause upon the ap-
9 plicant in accordance with section 304(c).

10 “(C) VERIFICATION OF INFORMATION.—

11 On request from the Attorney General, the Sec-
12 retary of Health and Human Services or the
13 Secretary of Veterans Affairs, as appropriate,
14 shall verify information submitted by an appli-
15 cant under subparagraph (A)(iii).

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

19 “(A) is the subject of an application under
20 section 505(i) of the Federal Food, Drug, and
21 Cosmetic Act or section 351(a)(3) of the Public
22 Health Service Act for the investigation of a
23 drug which is in effect in accordance with sec-
24 tion 312.40 of title 21, Code of Federal Regula-
25 tions; or

1 “(B) is conducted by the Department of
2 Health and Human Services, the Department of
3 Justice, or the Department of Veterans Affairs
4 or is funded partly or entirely by a grant, con-
5 tract, cooperative agreement, or other trans-
6 action from the Department of Health and
7 Human Services, the Department of Justice, or
8 the Department of Veterans Affairs.

9 “(3) ELECTRONIC SUBMISSIONS.—The Attorney
10 General shall provide a means to allow practitioners
11 to submit notifications under paragraph (1) elec-
12 tronically.

13 “(4) LIMITATION ON AMOUNTS.—A practitioner
14 conducting research with a controlled substance in
15 schedule I pursuant to this subsection shall be al-
16 lowed to possess only the amounts of the controlled
17 substance in schedule I identified in—

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

20 “(B) if the practitioner needs additional
21 amounts for the research, a supplemental notifi-
22 cation under this subsection that includes the
23 practitioner’s name, the additional quantity
24 needed of the substance, and an attestation
25 that the research to be conducted with the sub-

1 stance is consistent with the scope of the re-
2 search that was the subject of the notification
3 under paragraph (1).

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

9 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
10 ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Sub-
11 section (c) of section 302 of the Controlled Substances Act
12 (21 U.S.C. 822) is amended by adding at the end the fol-
13 lowing:

14 “(4) An agent or employee of a research insti-
15 tution that is conducting research with a controlled
16 substance if—

17 “(A) such agent or employee is acting
18 within the scope of his or her professional prac-
19 tice;

20 “(B) another agent or employee of such in-
21 stitution is registered to conduct research with
22 a controlled substance in the same schedule;

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

24 “(i) informs the Attorney General of
25 the name, position title, and employing in-

1 stitution of the agent or employee who is
2 not separately registered;

3 “(ii) authorizes such agent or em-
4 ployee to perform research under the reg-
5 istered researcher’s registration; and

6 “(iii) affirms that all acts taken by
7 such agent or employee involving controlled
8 substances shall be attributable to the reg-
9 istered researcher, as if the researcher had
10 directly committed such acts, for purposes
11 of any proceeding under section 304(a) to
12 suspend or revoke the registration of the
13 registered researcher; and

14 “(D) the Attorney General does not, within
15 30 days of receiving the information, authoriza-
16 tion, and affirmation described in subparagraph
17 (C), refuse, for a reason listed in section
18 304(a), to allow such agent or employee to pos-
19 sess such substance without a separate registra-
20 tion.”.

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

1 “(4)(A) Notwithstanding paragraph (1), a person
2 registered to conduct research with a controlled substance
3 under section 303(f) may conduct such research at mul-
4 tiple sites under a single registration if—

5 “(i) such research occurs exclusively at sites
6 which are all within the same city or county and are
7 all under the control of the same institution, organi-
8 zation, or agency; and

9 “(ii) the researcher notifies the Attorney Gen-
10 eral, prior to commencing such research, of all sites
11 where—

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

13 “(II) the controlled substance will be
14 stored or administered.

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

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

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

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

1 “(i) the manner in which controlled substances
2 may be delivered to research sites described in sub-
3 paragraph (A);

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

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

8 “(iv) any other matters necessary to ensure ef-
9 fective controls against diversion at such research
10 sites.”.

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

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

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

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

23 “(i) in the same schedule as the first controlled
24 substance; or

1 “(ii) is in a schedule with a higher numerical
2 designation than the schedule of the first controlled
3 substance.

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

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

12 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES
13 NEWLY ADDED TO SCHEDULE I.—If a person is con-
14 ducting research on a substance at the time the substance
15 is added to schedule I, and such person is already reg-
16 istered under this title to conduct research with a con-
17 trolled substance in schedule I, then—

18 “(1) the person shall, within 90 days of the
19 scheduling in schedule I, submit a completed appli-
20 cation for registration under this title or modifica-
21 tion of an existing registration under this title, to
22 conduct research on such substance, in accordance
23 with regulations issued by the Attorney General;

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

4 “(A) the person withdraws such applica-
5 tion; or

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

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

16 “(4) if the person sends a copy of the applica-
17 tion required by paragraph (1) to a manufacturer or
18 distributor of such substance, receipt of such copy
19 by such manufacturer or distributor shall constitute
20 sufficient evidence that the person is authorized to
21 receive such substance.”.

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

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

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

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

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

17 “(B) a protocol filed with an application
18 for registration approval under section 303(f);
19 or

20 “(C) a notification to the Attorney General
21 that includes the registrant’s name and an at-
22 testation that the research to be conducted with
23 the small quantities of manufactured substance
24 is consistent with the scope of the research that
25 is the basis for the registration.

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

3 “(A) processing the substance to create ex-
4 tracts, tinctures, oils, solutions, derivatives, or
5 other forms of the substance consistent with the
6 information provided as part of a notification
7 submitted to the Attorney General under sec-
8 tion 303(m) or a research protocol filed with
9 the application for registration approval; and

10 “(B) dosage form development studies per-
11 formed for the purpose of satisfying regulatory
12 requirements of the Food and Drug Adminis-
13 tration for submitting an investigational new
14 drug application.

15 “(3) EXCEPTION REGARDING MARIHUANA.—
16 The authority under paragraph (1) to manufacture
17 substances does not include authority to grow mari-
18 huana.”.

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

23 “(n) TRANSPARENCY REGARDING SPECIAL PROCE-
24 DURES.—

1 “(1) IN GENERAL.—If the Attorney General de-
2 termines, with respect to a controlled substance, that
3 an application by a practitioner to conduct research
4 with such substance should be considered under a
5 process, or subject to criteria, different from the
6 process or criteria applicable to applications to con-
7 duct research with other controlled substances in the
8 same schedule, the Attorney General shall make
9 public, including by posting on the website of the
10 Drug Enforcement Administration—

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

13 “(B) the process and criteria that will be
14 applied to applications to conduct research with
15 such substances; and

16 “(C) how such process and criteria differ
17 from those applicable to applications to conduct
18 research with other controlled substances in the
19 same schedule.

20 “(2) TIMING OF POSTING.—The Attorney Gen-
21 eral shall make such information public upon mak-
22 ing such determination, regardless of whether a
23 practitioner has submitted such an application at
24 that time.”.

1 **SEC. 8. RULEMAKING.**

2 (a) INTERIM FINAL RULES.—The Attorney Gen-
3 eral—

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

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

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

17 **SEC. 9. GAO REPORT.**

18 (a) IN GENERAL.—Not more than 4 years after the
19 date of enactment of this Act, the Comptroller General
20 of the United States shall submit to the Committees on
21 Energy and Commerce and the Judiciary of the House
22 of Representatives and the Committee on the Judiciary
23 of the Senate a report analyzing the implementation and
24 impact, to the extent information is available, of perma-
25 nent class scheduling pursuant to schedule I(e) of section
26 202(c) of the Controlled Substances Act, as added by sec-

tion of this Act, of fentanyl-related substances (as defined in such schedule I(e)), which report shall include—

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

(2) an analysis of any actions taken to remove or reschedule in a different class any fentanyl-related substance;

(3) an analysis of the impact of permanent scheduling on the unlawful importation, manufacture, trafficking, and use of fentanyl-related substances, taking into consideration data collected concerning the proliferation of fentanyl-related substances since class scheduling was instituted;

(4) an analysis of sentences attributable to criminal charges involving fentanyl-related substances, comparing those sentences to sentences attributable to criminal charges involving fentanyl and individually scheduled fentanyl analogues; and

(5) an analysis of the efficacy of class scheduling generally, in terms of reducing the proliferation of new controlled substance analogues.

(b) CONSULTATIONS.—In developing the report required by subsection (a), the Comptroller General—

(1) shall consider the views of the Secretary of Health and Human Services, the Attorney General,

1 the Secretary of Homeland Security, the Secretary
2 of State, the Director of the Office of National Drug
3 Control Policy, the scientific and medical research
4 community, the State and local law enforcement
5 community, and the civil rights and criminal justice
6 reform communities; and

7 (2) to the greatest extent possible, should base
8 such report on reliable data and empirical informa-
9 tion.