

117TH CONGRESS  
2D SESSION

# H. R. 6946

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

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 7, 2022

Mr. PAPPAS (for himself, Mr. NEWHOUSE, and Mr. BUDD) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## 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 of 2022” or the “SAFE Act  
6 of 2022”.

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(e);”;

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 EVIDENCE OF PHARMACOLOGICAL EFFECT.—

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

10                   “(I) each such study is performed  
11 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 of 2022, this sub-  
22 section 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 “(1) 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(e).

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       “(3)(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(l);

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(l) or a research protocol filed with the  
9                   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                   “(m) 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(e) of the Controlled Substances Act, as added by sec-

1 tion 2 of this Act, of fentanyl-related substances (as de-  
2 fined in such schedule I(e)), which report shall include—

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

5 (2) an analysis of any actions taken to remove  
6 or reschedule in a different class any fentanyl-re-  
7 lated substance;

8 (3) an analysis of the impact of permanent  
9 scheduling on the unlawful importation, manufac-  
10 ture, trafficking, and use of fentanyl-related sub-  
11 stances, taking into consideration data collected con-  
12 cerning the proliferation of fentanyl-related sub-  
13 stances since class scheduling was instituted;

14 (4) an analysis of sentences attributable to  
15 criminal charges involving fentanyl-related sub-  
16 stances, comparing those sentences to sentences at-  
17 tributable to criminal charges involving fentanyl and  
18 individually scheduled fentanyl analogues; and

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

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

24 (1) shall consider the views of the Secretary of  
25 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.

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