



1           “(C) the scientific and medical determina-  
2           tion of the Secretary contained in such evalua-  
3           tion shall be binding on the Attorney General;  
4           and

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

10          “(2) DETERMINATION RESULTING IN RESCHED-  
11          ULING.—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 schedules I and II—

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, the Attorney General shall  
5           issue an order removing such fentanyl-related  
6           substance from schedule I and controlling such  
7           substance under schedule III.

8           “(3) EVALUATION FACTORS.—

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

12                           “(i) shall consider—

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

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

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

23                                   “(ii) may consider the factors listed in  
24                                   paragraphs (4), (5), and (7) of subsection

1 (c) if the Secretary finds that evidence ex-  
2 ists with respect to such factors.

3 “(B) CONSIDERATION OF SCIENTIFIC EVI-  
4 DENCE OF PHARMACOLOGICAL EFFECT.—

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

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

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

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

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

1                   “(II) An in vitro functional assay  
2                   that can demonstrate whether the  
3                   substance has agonist activity at the  
4                   human mu opioid receptor.

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

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

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

1           “(A) to remove such substance from con-  
2           trol; or

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

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

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

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

17          “(7) PETITIONS FOR REMOVING A FENTANYL-  
18          RELATED SUBSTANCE.—

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

1 “(i) subsections (a) and (b) of this  
2 section; and

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

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

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

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

22 “(9) SUBSEQUENT CONTROLLING OF REMOVED  
23 SUBSTANCE.—A substance removed from schedule I  
24 pursuant to this subsection may, at any time, be  
25 controlled pursuant to the other provisions of this

1 section and section 202 without regard to the re-  
2 moval pursuant to this subsection.

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

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

