

117TH CONGRESS
2D SESSION

S. 5167

To extend the temporary order for fentanyl-related substances.

IN THE SENATE OF THE UNITED STATES

DECEMBER 1, 2022

Mr. BOOKER introduced the following bill; which was read twice and referred
to the Committee on the Judiciary

A BILL

To extend the temporary order for fentanyl-related
substances.

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 “Temporary Emergency
5 Scheduling and Testing of Fentanyl Analogues Act of
6 2022” or the “TEST Act of 2022”.

7 **SEC. 2. DEFINITIONS.**

8 In this Act:

9 (1) **EVALUATION.**—The term “evaluation”
10 means a scientific and medical evaluation, as con-
11 ducted by the Secretary of Health and Human Serv-

1 ices at the request of the Attorney General, and the
 2 recommendations as to whether such drug or other
 3 substance should be so controlled or removed as a
 4 controlled substance from the schedules pursuant to
 5 section 201(b) of the Controlled Substances Act (21
 6 U.S.C. 811(b)).

7 (2) FENTANYL-RELATED SUBSTANCE.—The
 8 term “fentanyl-related substance” has the meaning
 9 given the term in section 1308.11 of title 21, Code
 10 of Federal Regulations.

11 **SEC. 3. EXTENSION OF TEMPORARY ORDER FOR**
 12 **FENTANYL-RELATED SUBSTANCES.**

13 Section 2 of the Temporary Reauthorization and
 14 Study of the Emergency Scheduling of Fentanyl Ana-
 15 logues Act (Public Law 116–114; 134 Stat. 103) is
 16 amended by striking “December 31, 2022” and inserting
 17 “2 years after the date of enactment of the Temporary
 18 Emergency Scheduling and Testing of Fentanyl Analogues
 19 Act of 2022”.

20 **SEC. 4. EVALUATION OF ENCOUNTERED FENTANYL-RE-**
 21 **LATED SUBSTANCES.**

22 (a) SYNTHETIC COMPOUND.—Not later than 1 year
 23 after the date of enactment of this Act, for each fentanyl-
 24 related substance that the Attorney General has encoun-
 25 tered before the date of enactment of this Act, but not

1 yet conducted an evaluation, the Attorney General shall
2 create a synthetic compound of that substance and submit
3 the compound to the Secretary of Health and Human
4 Services in order to solicit a scientific and medical evalua-
5 tion of that compound from the Secretary.

6 (b) DEADLINE.—

7 (1) IN GENERAL.—Except as provided in para-
8 graph (2), the Secretary of Health and Human
9 Services shall complete the requested scientific and
10 medical evaluation under subsection (a) not later
11 than 1 year after receiving the solicitation from the
12 Attorney General.

13 (2) EXTENSION.—If the Attorney General is
14 unable to create a synthetic compound before the ex-
15 piration of the 1-year period described in paragraph
16 (1)—

17 (A) the Attorney General shall—

18 (i) notify the Committee on the Judi-
19 ciary of the Senate and the Committee on
20 the Judiciary of the House of Representa-
21 tives of the delay and publish the notifica-
22 tion on a public website; and

23 (ii) complete the requirements under
24 subsection (a) not later than 180 days
25 after the expiration of the 1-year period.

1 **SEC. 5. REMOVAL FROM SCHEDULE I OF FENTANYL-RE-**
2 **LATED SUBSTANCES.**

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

6 “(k) DETERMINATION RESULTING IN REMOVAL.—

7 “(1) IN GENERAL.—If the Secretary deter-
8 mines, taking into consideration factors as set forth
9 in paragraph (3), that a fentanyl-related substance
10 has a potential for abuse that is less than the drugs
11 or other substances in schedule V—

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

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

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

23 “(D) not later than 90 days after receiving
24 such evaluation and determination, the Attor-
25 ney General shall issue an order removing such

1 fentanyl-related substance from the schedules
2 under section 202.

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

9 “(A) the Secretary shall submit to the At-
10 torney General a scientific and medical evalua-
11 tion of that fentanyl-related substance sup-
12 porting that determination;

13 “(B) the Secretary shall submit any such
14 evaluation and determination in writing and in-
15 clude the bases therefor;

16 “(C) the scientific and medical determina-
17 tion of the Secretary contained in such evalua-
18 tion shall be binding on the Attorney General;
19 and

20 “(D) not later than 90 days after receiving
21 such evaluation, the Attorney General shall
22 issue an order removing such fentanyl-related
23 substance from schedule I and controlling such
24 substance under schedule III, IV or V.

25 “(3) EVALUATION FACTORS.—

“(A) IN GENERAL.—In making a determination under paragraph (1) or (2), the Secretary—

“(i) shall consider—

“(I) the factor listed in paragraph (2) of subsection (c);

“(II) the factors listed in paragraphs (1), (3), and (6) of such subsection to the extent evidence exists with respect to such factors; and

“(III) any information submitted to the Secretary by the Attorney General for purposes of such determination; and

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

“(B) CONSIDERATION OF SCIENTIFIC EVIDENCE OF PHARMACOLOGICAL EFFECT.—

“(i) IN GENERAL.—For the purposes of subparagraph (A)(i)(I), consideration by the Secretary of the results of an assessment consisting of the studies described in clause (ii) shall constitute consideration of

1 the factor listed in paragraph (2) of sub-
2 section (c) if—

3 “(I) each such study is per-
4 formed according to scientific methods
5 and protocols commonly accepted in
6 the scientific community; and

7 “(II) the Secretary determines
8 that such assessment is adequate for
9 such purposes.

10 “(ii) DESCRIBED STUDIES.—The
11 studies described in this clause are any of
12 the following:

13 “(I) A receptor binding study
14 that can demonstrate whether the
15 substance has affinity for the human
16 mu opioid receptor.

17 “(II) An in vitro functional assay
18 that can demonstrate whether the
19 substance has agonist activity at the
20 human mu opioid receptor.

21 “(III) One or more in vivo ani-
22 mal behavioral studies that can dem-
23 onstrate whether the substance has
24 abuse-related drug effects consistent
25 with mu opioid agonist activity, such

1 as demonstrating similarity to the ef-
2 fects of morphine.

3 “(l) PREVIOUSLY ANALYZED FENTANYL-RELATED
4 SUBSTANCES.—To the extent that the Drug Enforcement
5 Administration or the Department of Health and Human
6 Services has conducted any evaluation or analysis (even
7 if such analysis is not an evaluation under this section)
8 of any fentanyl-related substance before the date of the
9 enactment of this subsection, the Attorney General shall
10 publish the results and any other information related to
11 the evaluation or analysis on a public website not later
12 than 90 days after the date of enactment of this sub-
13 section.

14 “(m) FENTANYL-RELATED SUBSTANCES RESEARCH
15 CAPACITY.—The Drug Enforcement Administration and
16 Department of Health and Human Services shall hire, em-
17 ploy, or retain the staff, researchers, and other qualified
18 individuals necessary to carry out the requirements of
19 paragraphs (1) and (2) of subsection (k), including, if ap-
20 propriate to fulfill those requirements, establishing a con-
21 sortium of chemists and researchers who may be readily
22 hired, employed, or retrained without a request for pro-
23 posals.

24 “(n) EVALUATIONS OR STUDIES.—The Secretary
25 may enter into contracts or other agreements to conduct

1 or support evaluations or studies of fentanyl-related sub-
2 stances.

3 “(o) REGISTRATION REQUIREMENTS FOR RESEARCH
4 APPLICATIONS.—Registration requirements for the re-
5 search of fentanyl-related substances shall be those appli-
6 cable to schedule II substances pursuant to section
7 1301.13 of title 21, Code of Federal Regulations.

8 “(p) PUBLICATION.—The Secretary shall publish on
9 a public website—

10 “(1) each evaluation conducted pursuant to an
11 Attorney General solicitation within 60 days of the
12 completion of the scientific and medical evaluation,
13 even if such evaluation did not result in a
14 descheduling or rescheduling determination; and

15 “(2) the results and any other information re-
16 lated to previously evaluated fentanyl-related serv-
17 ices pursuant to subsection (l).

18 “(q) AUTHORIZATION OF APPROPRIATIONS.—There
19 is authorized to be appropriated to the Secretary
20 \$50,000,000 for fiscal years 2023 and 2024, to remain
21 available until expended, for the evaluation fentanyl-re-
22 lated substances pursuant to section 3 of the Temporary
23 Emergency Scheduling and Testing of Fentanyl Analogues
24 Act of 2022.”.

1 **SEC. 6. NOTIFICATION.**

2 The Attorney General shall notify each individual
3 who is the subject of a pending prosecution for, or has
4 been convicted or sentenced for, an offense involving a
5 fentanyl-related substance that is subsequently removed or
6 rescheduled under paragraphs (1) and (2) of section
7 201(k) of the Controlled Substances Act, as added by sec-
8 tion 5 of this Act, about the change in schedule designa-
9 tion not later than 90 days after the change, and provide
10 information about the effect of the change on their pros-
11 ecution, conviction, or sentence.

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