

118TH CONGRESS
1ST SESSION

S. 1950

To extend the temporary order for fentanyl-related substances.

IN THE SENATE OF THE UNITED STATES

JUNE 13, 2023

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 2023” or the “TEST Act”.

7 SEC. 2. FINDINGS.

8 Congress finds the following:

9 (1) Passed in 1970, the Controlled Substances
10 Act (21 U.S.C. 801 et seq.) created 5 schedules for
11 controlled substances. To schedule a substance, the

1 Drug Enforcement Administration must make a
2 finding of the potential for abuse and currently ac-
3 cepted medical use of the substance.

4 (2) Under section 201(b) of the Controlled Sub-
5 stances Act (21 U.S.C. 811(b)), the Attorney Gen-
6 eral must request a scheduling recommendation
7 from the Secretary of Health and Human Services
8 based on an 8-factor medical and scientific analysis.

9 (3) The Secretary is required to return a rec-
10 ommendation to the Attorney General within a rea-
11 sonable amount of time and the recommendation
12 shall be binding on the Attorney General as to sci-
13 entific and medical matters.

14 (4) The scientific and medical evaluation con-
15 ducted by the Secretary is necessary to understand
16 the characteristics of any substance, including
17 whether the substance may be harmful, harmless, or
18 have potential medical uses.

19 (5) Since October 2016, the Drug Enforcement
20 Administration has identified 36 fentanyl-related
21 substances to be scheduled pursuant to section
22 201(b) of the Controlled Substances Act (21 U.S.C.
23 811(b)).

24 (6) As of April 2023, of the 36 fentanyl-related
25 substances described in paragraph (5), 24 have been

1 subjected to scientific and medical analysis. There
2 remain 12 fentanyl-related substances for which the
3 Drug Enforcement Administration has yet to begin
4 or complete a scientific medical evaluation.

5 (7) In the midst of the fentanyl crisis that is
6 ravaging communities across the United States, it is
7 imperative that the Federal Government analyze and
8 study fentanyl-related substances expeditiously and
9 that the scientific community be able to research
10 these substances in order to develop life-saving anti-
11 dotes and treatments. The most promising life-sav-
12 ing antidotes and treatments for fentanyl addiction
13 and overdose are likely to share molecular properties
14 with fentanyl and its related substances.

15 **SEC. 3. DEFINITIONS.**

16 In this Act:

17 (1) **EVALUATION.**—The term “evaluation”
18 means a scientific and medical evaluation, as con-
19 ducted by the Secretary of Health and Human Serv-
20 ices at the request of the Attorney General, and the
21 recommendations as to whether such drug or other
22 substance should be so controlled or removed as a
23 controlled substance from the schedules pursuant to
24 section 201(b) of the Controlled Substances Act (21
25 U.S.C. 811(b)).

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

5 **SEC. 4. EVALUATION OF ENCOUNTERED FENTANYL-RE-**
6 **LATED SUBSTANCES.**

7 (a) IDENTIFIED SUBSTANCES.—

8 (1) IN GENERAL.—The Attorney General shall
9 complete the proceedings to schedule or transfer be-
10 tween schedules, or remove any fentanyl-related sub-
11 stances from the schedules pursuant to subsection
12 (k) of section 201 of the Controlled Substances Act
13 (21 U.S.C. 811), as added by section 5 of this Act—

14 (A) not later than 1 year after the date of
15 enactment of this Act for each fentanyl-related
16 substance that—

17 (i) the Drug Enforcement Administra-
18 tion has identified, as of the date of enact-
19 ment of this Act; and

20 (ii) is not permanently scheduled; and

21 (B) not later than 3 years after the date
22 on which a fentanyl-related substance is identi-
23 fied if the fentanyl-related substance—

24 (i) is identified after the date of en-
25 actment of this Act; and

(ii) is not permanently scheduled.

2 (2) EXTENSION.—If the Attorney General is
3 unable to complete the proceedings described in
4 paragraph (1) within the required time period the
5 Attorney General shall—

11 (B) complete the proceedings described in
12 paragraph (1) not later than 1 year after the
13 notification required under subparagraph (A) of
14 this paragraph.

(b) TEMPORARY SCHEDULING.—Notwithstanding any other provision of law, the Attorney General may schedule a fentanyl-related substance identified after the date of enactment of this Act in schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) in accordance with section 201(h) of that Act (21 U.S.C. 811(h)) for not longer than 3 years after the date on which the order scheduling the fentanyl-related substance is issued.

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.—

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

4 “(i) shall consider—

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

7 “(II) the factors listed in para-
8 graphs (1), (3), and (6) of such sub-
9 section to the extent evidence exists
10 with respect to such factors; and

11 “(III) any information submitted
12 to the Secretary by the Attorney Gen-
13 eral for purposes of such determina-
14 tion; and

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

19 “(B) CONSIDERATION OF SCIENTIFIC EVI-
20 DENCE OF PHARMACOLOGICAL EFFECT.—

21 “(i) IN GENERAL.—For the purposes
22 of subparagraph (A)(i)(I), consideration by
23 the Secretary of the results of an assess-
24 ment consisting of the studies described in
25 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 include the
12 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) PUBLICATION.—

4 “(1) IN GENERAL.—The Secretary shall publish
5 on a public website—

6 “(A) information related to each evaluation
7 conducted pursuant to subsection (k)(3) within
8 60 days of the completion of the scientific and
9 medical evaluation, even if such evaluation did
10 not result in a descheduling or rescheduling de-
11 termination; and

12 “(B) the results and any other information
13 related to previously evaluated fentanyl-related
14 services pursuant to subsection (l).

15 “(2) APPLICABILITY.—Paragraph (1) shall not
16 apply to an evaluation conducted for an application
17 for a new drug under section 505 of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 355).

19 “(m) AUTHORIZATION OF APPROPRIATIONS.—There
20 is authorized to be appropriated to the Secretary
21 \$50,000,000 for fiscal years 2023 and 2024, to remain
22 available until expended, for the evaluation fentanyl-re-
23 lated substances pursuant to this section.”.

1 SEC. 6. REGISTRATION REQUIREMENTS RELATED TO RE-

2 SEARCH.

3 (a) ALTERNATIVE REGISTRATION PROCESS FOR
4 SCHEDULE I RESEARCH.—Section 303 of the Controlled
5 Substances Act (21 U.S.C. 823) is amended—6 (1) by redesignating the second subsection (l)
7 (relating to required training for prescribers) as sub-
8 section (m); and

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

10 “(n) SPECIAL PROVISIONS FOR PRACTITIONERS
11 CONDUCTING CERTAIN RESEARCH WITH SCHEDULE I
12 CONTROLLED SUBSTANCES.—13 “(1) IN GENERAL.—Notwithstanding subsection
14 (f), a practitioner may conduct research described in
15 paragraph (2) of this subsection with 1 or more
16 schedule I substances in accordance with subparagraph
17 (A) or (B) of paragraph (3) of this sub-
18 section.19 “(2) RESEARCH SUBJECT TO EXPEDITED PRO-
20 CEDURES.—Research described in this paragraph is
21 research that—22 “(A) is with respect to a drug that is the
23 subject of an investigational use exemption
24 under section 505(i) of the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 355(i)); or

26 “(B) is—

1 “(i) conducted by the Department of
2 Health and Human Services, the Depart-
3 ment of Defense, or the Department of
4 Veterans Affairs; or

5 “(ii) funded partly or entirely by a
6 grant, contract, cooperative agreement, or
7 other transaction from the Department of
8 Health and Human Services, the Depart-
9 ment of Defense, or the Department of
10 Veterans Affairs.

11 “(3) EXPEDITED PROCEDURES.—

12 “(A) RESEARCHER WITH A CURRENT
13 SCHEDULE I OR II RESEARCH REGISTRATION.—

14 “(i) IN GENERAL.—If a practitioner is
15 registered to conduct research with a con-
16 trolled substance in schedule I or II, the
17 practitioner may conduct research under
18 this subsection on and after the date that
19 is 30 days after the date on which the
20 practitioner sends a notice to the Attorney
21 General containing the following informa-
22 tion, with respect to each substance with
23 which the practitioner will conduct the re-
24 search:

1 “(I) The chemical name of the
2 substance.

3 “(II) The quantity of the sub-
4 stance to be used in the research.

5 “(III) Demonstration that the re-
6 search is in the category described in
7 paragraph (2), which demonstration
8 may be satisfied—

9 “(aa) in the case of a grant,
10 contract, cooperative agreement,
11 or other transaction, or intra-
12 mural research project, by identi-
13 fying the sponsoring agency and
14 supplying the number of the
15 grant, contract, cooperative
16 agreement, other transaction, or
17 project; or

18 “(bb) in the case of an ap-
19 plication under section 505(i) of
20 the Federal Food, Drug, and
21 Cosmetic Act (21 U.S.C. 355(i)),
22 by supplying the application
23 number and the sponsor of
24 record on the application.

1 “(IV) Demonstration that the re-
2 searcher is authorized to conduct re-
3 search with respect to the substance
4 under the laws of the State in which
5 the research will take place.

6 “(ii) VERIFICATION OF INFORMATION
7 BY HHS OR VA.—Upon request from the
8 Attorney General, the Secretary of Health
9 and Human Services, the Secretary of De-
10 fense, or the Secretary of Veterans Affairs,
11 as appropriate, shall verify information
12 submitted by an applicant under clause
13 (i)(III).

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

16 “(i) IN GENERAL.—If a practitioner is
17 not registered to conduct research with a
18 controlled substance in schedule I or II,
19 the practitioner may send a notice to the
20 Attorney General containing the informa-
21 tion listed in subparagraph (A)(i), with re-
22 spect to each substance with which the
23 practitioner will conduct the research.

24 “(ii) ATTORNEY GENERAL ACTION.—
25 The Attorney General shall—

1 “(I) treat notice received under
2 clause (i) as a sufficient application
3 for a research registration; and

4 “(II) not later than 45 days of
5 receiving such a notice that contains
6 all information required under sub-
7 paragraph (A)(i)—

8 “(aa) register the applicant;

9 or

10 “(bb) serve an order to show
11 cause upon the applicant in ac-
12 cordance with section 304(c).

13 “(4) ELECTRONIC SUBMISSIONS.—The Attorney
14 General shall provide a means to permit a practi-
15 tioner to submit a notification under paragraph (3)
16 electronically.

17 “(5) LIMITATION ON AMOUNTS.—A practitioner
18 conducting research with a schedule I substance
19 under this subsection may only possess the amounts
20 of schedule I substance identified in—

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

23 “(B) a supplemental notification that the
24 practitioner may send if the practitioner needs

1 additional amounts for the research, which sup-
2 plemental notification shall include—

3 “(i) the name of the practitioner;
4 “(ii) the additional quantity needed of
5 the substance; and
6 “(iii) an attestation that the research
7 to be conducted with the substance is con-
8 sistent with the scope of the research that
9 was the subject of the notification under
10 paragraph (3).

11 “(6) IMPORTATION AND EXPORTATION RE-
12 QUIREMENTS NOT AFFECTED.—Nothing in this sub-
13 section alters the requirements of part A of title III,
14 regarding the importation and exportation of con-
15 trolled substances.

16 “(7) INSPECTOR GENERAL REPORT.—Not later
17 than 1 year after the date of enactment of this Act,
18 the Inspector General of the Department of Justice
19 shall complete a study, and submit to Congress a re-
20 port thereon, about research described in paragraph
21 (2) of this subsection with fentanyl.”.

22 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
23 ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Sec-
24 tion 302(c) of the Controlled Substances Act (21 U.S.C.
25 822(c)) is amended by adding at the end the following:

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

4 “(A) the agent or employee is acting with-
5 in the scope of the professional practice of the
6 agent or employee;

7 “(B) another agent or employee of the in-
8 stitution is registered to conduct research with
9 a controlled substance in the same schedule;

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

11 “(i) informs the Attorney General of
12 the name, position title, and employing in-
13 stitution of the agent or employee who is
14 not separately registered;

15 “(ii) authorizes that agent or em-
16 ployee to perform research under the reg-
17 istration of the registered researcher; and

18 “(iii) affirms that any act taken by
19 that agent or employee involving a con-
20 trolled substance shall be attributable to
21 the registered researcher, as if the re-
22 searcher had directly committed the act,
23 for purposes of any proceeding under sec-
24 tion 304(a) to suspend or revoke the reg-
25 istration of the registered researcher; and

1 “(D) the Attorney General does not, within
2 30 days of receiving the information, authoriza-
3 tion, and affirmation described in subparagraph
4 (C), refuse, for a reason listed in section
5 304(a), to allow the agent or employee to pos-
6 sess the substance without a separate regis-
7 tration.”.

8 (c) SINGLE REGISTRATION FOR RELATED RESEARCH
9 SITES.—Section 302(e) of the Controlled Substances Act
10 (21 U.S.C. 822(e)) is amended by adding at the end the
11 following:

12 “(4)(A) Notwithstanding paragraph (1), a person
13 registered to conduct research with a controlled substance
14 under section 303(f) may conduct the research under a
15 single registration if—

16 “(i) the research occurs exclusively on sites all
17 of which are—

18 “(I) within the same city or county; and
19 “(II) under the control of the same institu-
20 tion, organization, or agency; and

21 “(ii) before commencing the research, the re-
22 searcher notifies the Attorney General of each site
23 where—

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

1 “(II) the controlled substance will be
2 stored or administered.

3 “(B) A site described in subparagraph (A) shall be
4 included in a registration described in that subparagraph
5 only if the researcher has notified the Attorney General
6 of the site—

7 “(i) in the application for the registration; or
8 “(ii) before the research is conducted, or before
9 the controlled substance is stored or administered, at
10 the site.

11 “(C) The Attorney General may, in consultation with
12 the Secretary, issue regulations addressing, with respect
13 to research sites described in subparagraph (A)—

14 “(i) the manner in which controlled substances
15 may be delivered to the research sites;

16 “(ii) the storage and security of controlled sub-
17 stances at the research sites;

18 “(iii) the maintenance of records for the re-
19 search sites; and

20 “(iv) any other matters necessary to ensure ef-
21 fective controls against diversion at the research
22 sites.”.

23 (d) NEW INSPECTION NOT REQUIRED IN CERTAIN
24 SITUATIONS.—Section 302(f) of the Controlled Sub-
25 stances Act (21 U.S.C. 822(f)) is amended—

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

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

4 “(2)(A) If a person is registered to conduct research
5 with a controlled substance and applies for a registration,
6 or for a modification of a registration, to conduct research
7 with a second controlled substance that is in the same
8 schedule as the first controlled substance, or is in a sched-
9 ule with a higher numerical designation than the schedule
10 of the first controlled substance, a new inspection by the
11 Attorney General of the registered location is not required.

12 “(B) Nothing in subparagraph (A) shall prohibit the
13 Attorney General from conducting an inspection that the
14 Attorney General determines necessary to ensure that a
15 registrant maintains effective controls against diversion.”.

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

20 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES
21 NEWLY ADDED TO SCHEDULE I.—If a person is con-
22 ducting research on a substance when the substance is
23 added to schedule I, and the person is already registered
24 to conduct research with a controlled substance in sched-
25 ule I—

1 “(1) not later than 90 days after the scheduling
2 of the newly scheduled substance, the person shall
3 submit a completed application for registration or
4 modification of existing registration, to conduct re-
5 search on the substance, in accordance with regula-
6 tions issued by the Attorney General for purposes of
7 this paragraph;

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

11 “(A) the person withdraws the application
12 described in paragraph (1) of this subsection;
13 or

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

17 “(3) if the Attorney General serves an order to
18 show cause as described in paragraph (2)(B) and
19 the person requests a hearing, the hearing shall be
20 held on an expedited basis and not later than 45
21 days after the request is made, except that the hear-
22 ing may be held at a later time if so requested by
23 the person; and

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

1 distributor of the substance, receipt of the copy by
2 the manufacturer or distributor shall constitute suf-
3 ficient evidence that the person is authorized to re-
4 ceive the substance.”.

5 (f) TREATMENT OF CERTAIN MANUFACTURING AC-
6 TIVITIES AS COINCIDENT TO RESEARCH.—Section 302 of
7 the Controlled Substances Act (21 U.S.C. 822), as amend-
8 ed by subsection (e), is amended by adding at the end
9 the following:

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

12 “(1) IN GENERAL.—Except as provided in para-
13 graph (3), a person who is registered to perform re-
14 search on a controlled substance may perform manu-
15 facturing activities with small quantities of that sub-
16 stance, including activities described in paragraph
17 (2), without being required to obtain a manufac-
18 turing registration, if—

19 “(A) the activities are performed for the
20 purpose of the research; and

21 “(B) the activities and the quantities of
22 the substance involved in the activities are stat-
23 ed in—

24 “(i) a notification submitted to the
25 Attorney General under section 303(n);

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

4 “(iii) a notification to the Attorney
5 General that includes—

6 “(I) the name of the registrant;
7 and

8 “(II) an attestation that the re-
9 search to be conducted with the small
10 quantities of manufactured substance
11 is consistent with the scope of the re-
12 search that is the basis for the reg-
13 istration.

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

16 “(A) processing the substance to create ex-
17 tracts, tinctures, oils, solutions, derivatives, or
18 other forms of the substance consistent with—

19 “(i) the information provided as part
20 of a notification submitted to the Attorney
21 General under section 303(n); or

22 “(ii) a research protocol filed with an
23 application for registration approval under
24 section 303(f); and

1 “(B) dosage form development studies per-
2 formed for the purpose of requesting an inves-
3 tigational new drug exemption under section
4 505(i) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355(i)).

6 “(3) EXCEPTION REGARDING MARIJUANA.—The
7 authority under paragraph (1) to manufacture sub-
8 stances does not include the authority to grow mari-
9 juana.”.

10 (g) TRANSPARENCY REGARDING SPECIAL PROCE-
11 DURES.—Section 303 of the Controlled Substances Act
12 (21 U.S.C. 823), as amended by subsection (a), is amend-
13 ed by adding at the end the following:

14 “(o) TRANSPARENCY REGARDING SPECIAL PROCE-
15 DURES.—

16 “(1) IN GENERAL.—If the Attorney General de-
17 termines, with respect to a controlled substance, that
18 an application by a practitioner to conduct research
19 with the substance should be considered under a
20 process, or subject to criteria, different from the
21 process or criteria applicable to applications to con-
22 duct research with other controlled substances in the
23 same schedule, the Attorney General shall make
24 public, including by posting on the website of the
25 Drug Enforcement Administration—

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

3 “(B) the process and criteria that shall be
4 applied to applications to conduct research with
5 those substances; and

6 “(C) how the process and criteria described
7 in subparagraph (B) differ from the process
8 and criteria applicable to applications to con-
9 duct research with other controlled substances
10 in the same schedule.

11 “(2) TIMING OF POSTING.—The Attorney Gen-
12 eral shall make information described in paragraph
13 (1) public upon making a determination described in
14 that paragraph, regardless of whether a practitioner
15 has submitted such an application at that time.”.

○