118TH CONGRESS
1ST SESSION

# S. _____

To extend the temporary order for fentanyl-related substances.

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IN THE SENATE OF THE UNITED STATES

_____

_____ introduced the following bill; which was read twice and referred to the Committee on _____

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# A BILL

To extend the temporary order for fentanyl-related substances.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Temporary Emergency Scheduling and Testing of Fentanyl Analogues Act of 2023'' or the ''TEST Act''.

**SEC. 2. FINDINGS.**

Congress finds the following:

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

Drug Enforcement Administration must make a finding of the potential for abuse and currently accepted medical use of the substance.

(2) Under section 201(b) of the Controlled Substances Act (21 U.S.C. 811(b)), the Attorney General must request a scheduling recommendation from the Secretary of Health and Human Services based on an 8-factor medical and scientific analysis.

(3) The Secretary is required to return a recommendation to the Attorney General within a reasonable amount of time and the recommendation shall be binding on the Attorney General as to scientific and medical matters.

(4) The scientific and medical evaluation conducted by the Secretary is necessary to understand the characteristics of any substance, including whether the substance may be harmful, harmless, or have potential medical uses.

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

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

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

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

**SEC. 3. DEFINITIONS.**

In this Act:

(1) EVALUATION.—The term ''evaluation'' means a scientific and medical evaluation, as conducted by the Secretary of Health and Human Services at the request of the Attorney General, and the recommendations as to whether such drug or other substance should be so controlled or removed as a controlled substance from the schedules pursuant to section 201(b) of the Controlled Substances Act (21 U.S.C. 811(b)).

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

**SEC. 4. EVALUATION OF ENCOUNTERED FENTANYL-RELATED SUBSTANCES.**

(a) IDENTIFIED SUBSTANCES.—

(1) IN GENERAL.—The Attorney General shall complete the proceedings to schedule or transfer between schedules, or remove any fentanyl-related substances from the schedules pursuant to subsection (k) of section 201 of the Controlled Substances Act (21 U.S.C. 811), as added by section 5 of this Act—

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

(i) the Drug Enforcement Administration has identified, as of the date of enactment of this Act; and

(ii) is not permanently scheduled; and

(B) not later than 3 years after the date on which a fentanyl-related substance is identified if the fentanyl-related substance—

(i) is identified after the date of enactment of this Act; and

(ii) is not permanently scheduled.

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

(A) notify the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives of the delay and publish the notification on a public website; and

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

**SEC. 5. REMOVAL FROM SCHEDULE I OF FENTANYL-RELATED SUBSTANCES.**

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

''(k) DETERMINATION RESULTING IN REMOVAL.—

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

''(A) the Secretary shall submit to the Attorney General a scientific and medical evaluation of that fentanyl-related substance supporting that determination;

''(B) the Secretary shall submit any such evaluation and determination in writing and include the bases therefor;

''(C) the scientific and medical determination of the Secretary contained in such evaluation shall be binding on the Attorney General; and

''(D) not later than 90 days after receiving such evaluation and determination, the Attorney General shall issue an order removing such

fentanyl-related substance from the schedules under section 202.

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

''(A) the Secretary shall submit to the Attorney General a scientific and medical evaluation of that fentanyl-related substance supporting that determination;

''(B) the Secretary shall submit any such evaluation and determination in writing and include the bases therefor;

''(C) the scientific and medical determination of the Secretary contained in such evaluation shall be binding on the Attorney General; and

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

''(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

the factor listed in paragraph (2) of subsection (c) if—

"(I) each such study is performed according to scientific methods and protocols commonly accepted in the scientific community; and

"(II) the Secretary determines that such assessment is adequate for such purposes.

"(ii) DESCRIBED STUDIES.—The studies described in this clause include the following:

"(I) A receptor binding study that can demonstrate whether the substance has affinity for the human mu opioid receptor.

"(II) An in vitro functional assay that can demonstrate whether the substance has agonist activity at the human mu opioid receptor.

"(III) One or more in vivo animal behavioral studies that can demonstrate whether the substance has abuse-related drug effects consistent with mu opioid agonist activity, such

as demonstrating similarity to the effects of morphine.

''(l) PUBLICATION.—

''(1) IN GENERAL.—The Secretary shall publish on a public website—

''(A) information related to each evaluation conducted pursuant to subsection (k)(3) within 60 days of the completion of the scientific and medical evaluation, even if such evaluation did not result in a descheduling or rescheduling determination; and

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

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

''(m) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Secretary $50,000,000 for fiscal years 2023 and 2024, to remain available until expended, for the evaluation fentanyl-related substances pursuant to this section.''.

**SEC. 6. REGISTRATION REQUIREMENTS RELATED TO RESEARCH.**

(a) ALTERNATIVE REGISTRATION PROCESS FOR SCHEDULE I RESEARCH.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended—

(1) by redesignating the second subsection (l) (relating to required training for prescribers) as subsection (m); and

(2) by adding at the end the following:

''(n) SPECIAL PROVISIONS FOR PRACTITIONERS CONDUCTING CERTAIN RESEARCH WITH SCHEDULE I CONTROLLED SUBSTANCES.—

''(1) IN GENERAL.—Notwithstanding subsection (f), a practitioner may conduct research described in paragraph (2) of this subsection with 1 or more schedule I substances in accordance with subparagraph (A) or (B) of paragraph (3) of this subsection.

''(2) RESEARCH SUBJECT TO EXPEDITED PROCEDURES.—Research described in this paragraph is research that—

''(A) is with respect to a drug that is the subject of an investigational use exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)); or

''(B) is—

''(i) conducted by the Department of Health and Human Services, the Department of Defense, or the Department of Veterans Affairs; or

''(ii) funded partly or entirely by a grant, contract, cooperative agreement, or other transaction from the Department of Health and Human Services, the Department of Defense, or the Department of Veterans Affairs.

''(3) EXPEDITED PROCEDURES.—

''(A) RESEARCHER WITH A CURRENT SCHEDULE I OR II RESEARCH REGISTRATION.—

''(i) IN GENERAL.—If a practitioner is registered to conduct research with a controlled substance in schedule I or II, the practitioner may conduct research under this subsection on and after the date that is 30 days after the date on which the practitioner sends a notice to the Attorney General containing the following information, with respect to each substance with which the practitioner will conduct the research:

''(I) The chemical name of the substance.

''(II) The quantity of the substance to be used in the research.

''(III) Demonstration that the research is in the category described in paragraph (2), which demonstration may be satisfied—

''(aa) in the case of a grant, contract, cooperative agreement, or other transaction, or intramural research project, by identifying the sponsoring agency and supplying the number of the grant, contract, cooperative agreement, other transaction, or project; or

''(bb) in the case of an application under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)), by supplying the application number and the sponsor of record on the application.

''(IV) Demonstration that the researcher is authorized to conduct research with respect to the substance under the laws of the State in which the research will take place.

''(ii) VERIFICATION OF INFORMATION BY HHS OR VA.—Upon request from the Attorney General, the Secretary of Health and Human Services, the Secretary of Defense, or the Secretary of Veterans Affairs, as appropriate, shall verify information submitted by an applicant under clause (i)(III).

''(B) RESEARCHER WITHOUT A CURRENT SCHEDULE I OR II RESEARCH REGISTRATION.—

''(i) IN GENERAL.—If a practitioner is not registered to conduct research with a controlled substance in schedule I or II, the practitioner may send a notice to the Attorney General containing the information listed in subparagraph (A)(i), with respect to each substance with which the practitioner will conduct the research.

''(ii) ATTORNEY GENERAL ACTION.—The Attorney General shall—

''(I) treat notice received under clause (i) as a sufficient application for a research registration; and

''(II) not later than 45 days of receiving such a notice that contains all information required under subparagraph (A)(i)—

''(aa) register the applicant; or

''(bb) serve an order to show cause upon the applicant in accordance with section 304(c).

''(4) ELECTRONIC SUBMISSIONS.—The Attorney General shall provide a means to permit a practitioner to submit a notification under paragraph (3) electronically.

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

''(A) the notification to the Attorney General under paragraph (3); or

''(B) a supplemental notification that the practitioner may send if the practitioner needs

additional amounts for the research, which supplemental notification shall include—

''(i) the name of the practitioner;

''(ii) the additional quantity needed of the substance; and

''(iii) an attestation that the research to be conducted with the substance is consistent with the scope of the research that was the subject of the notification under paragraph (3).

''(6) IMPORTATION AND EXPORTATION REQUIREMENTS NOT AFFECTED.—Nothing in this subsection alters the requirements of part A of title III, regarding the importation and exportation of controlled substances.

''(7) INSPECTOR GENERAL REPORT.—Not later than 1 year after the date of enactment of this Act, the Inspector General of the Department of Justice shall complete a study, and submit to Congress a report thereon, about research described in paragraph (2) of this subsection with fentanyl.''.

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

''(4) An agent or employee of a research institution that is conducting research with a controlled substance if—

''(A) the agent or employee is acting within the scope of the professional practice of the agent or employee;

''(B) another agent or employee of the institution is registered to conduct research with a controlled substance in the same schedule;

''(C) the researcher who is so registered—

''(i) informs the Attorney General of the name, position title, and employing institution of the agent or employee who is not separately registered;

''(ii) authorizes that agent or employee to perform research under the registration of the registered researcher; and

''(iii) affirms that any act taken by that agent or employee involving a controlled substance shall be attributable to the registered researcher, as if the researcher had directly committed the act, for purposes of any proceeding under section 304(a) to suspend or revoke the registration of the registered researcher; and

''(D) the Attorney General does not, within 30 days of receiving the information, authorization, and affirmation described in subparagraph (C), refuse, for a reason listed in section 304(a), to allow the agent or employee to possess the substance without a separate registration.''.

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

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

''(i) the research occurs exclusively on sites all of which are—

''(I) within the same city or county; and

''(II) under the control of the same institution, organization, or agency; and

''(ii) before commencing the research, the researcher notifies the Attorney General of each site where—

''(I) the research will be conducted; or

''(II) the controlled substance will be stored or administered.

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

''(i) in the application for the registration; or

''(ii) before the research is conducted, or before the controlled substance is stored or administered, at the site.

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

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

''(ii) the storage and security of controlled substances at the research sites;

''(iii) the maintenance of records for the research sites; and

''(iv) any other matters necessary to ensure effective controls against diversion at the research sites.''.

(d) NEW INSPECTION NOT REQUIRED IN CERTAIN SITUATIONS.—Section 302(f) of the Controlled Substances Act (21 U.S.C. 822(f)) is amended—

(1) by striking ''(f) The'' and inserting ''(f)(1) The''; and

(2) by adding at the end the following:

''(2)(A) If a person is registered to conduct research with a controlled substance and applies for a registration, or for a modification of a registration, to conduct research with a second controlled substance that is in the same schedule as the first controlled substance, or is in a schedule with a higher numerical designation than the schedule of the first controlled substance, a new inspection by the Attorney General of the registered location is not required.

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

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

''(h) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I.—If a person is conducting research on a substance when the substance is

added to schedule I, and the person is already registered to conduct research with a controlled substance in schedule I—

''(1) not later than 90 days after the scheduling of the newly scheduled substance, the person shall submit a completed application for registration or modification of existing registration, to conduct research on the substance, in accordance with regulations issued by the Attorney General for purposes of this paragraph;

''(2) the person may, notwithstanding subsections (a) and (b), continue to conduct the research on the substance until—

''(A) the person withdraws the application described in paragraph (1) of this subsection; or

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

''(3) if the Attorney General serves an order to show cause as described in paragraph (2)(B) and the person requests a hearing, the hearing shall be held on an expedited basis and not later than 45 days after the request is made, except that the hear-

ing may be held at a later time if so requested by the person; and

''(4) if the person sends a copy of the application described in paragraph (1) to a manufacturer or distributor of the substance, receipt of the copy by the manufacturer or distributor shall constitute sufficient evidence that the person is authorized to receive the substance.''.

(f) TREATMENT OF CERTAIN MANUFACTURING ACTIVITIES AS COINCIDENT TO RESEARCH.—Section 302 of the Controlled Substances Act (21 U.S.C. 822), as amended by subsection (e), is amended by adding at the end the following:

''(i) TREATMENT OF CERTAIN MANUFACTURING ACTIVITIES AS COINCIDENT TO RESEARCH.—

''(1) IN GENERAL.—Except as provided in paragraph (3), a person who is registered to perform research on a controlled substance may perform manufacturing activities with small quantities of that substance, including activities described in paragraph (2), without being required to obtain a manufacturing registration, if—

''(A) the activities are performed for the purpose of the research; and

''(B) the activities and the quantities of the substance involved in the activities are stated in—

''(i) a notification submitted to the Attorney General under section 303(n);

''(ii) a research protocol filed with an application for registration approval under section 303(f); or

''(iii) a notification to the Attorney General that includes—

''(I) the name of the registrant; and

''(II) an attestation that the research to be conducted with the small quantities of manufactured substance is consistent with the scope of the research that is the basis for the registration.

''(2) ACTIVITIES INCLUDED.—Activities permitted under paragraph (1) include—

''(A) processing the substance to create extracts, tinctures, oils, solutions, derivatives, or other forms of the substance consistent with—

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

"(ii) a research protocol filed with an application for registration approval under section 303(f); and

"(B) dosage form development studies performed for the purpose of requesting an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).

"(3) EXCEPTION REGARDING MARIJUANA.—The authority under paragraph (1) to manufacture substances does not include the authority to grow marijuana.".

(g) TRANSPARENCY REGARDING SPECIAL PROCEDURES.—Section 303 of the Controlled Substances Act (21 U.S.C. 823), as amended by subsection (a), is amended by adding at the end the following:

"(o) TRANSPARENCY REGARDING SPECIAL PROCEDURES.—

"(1) IN GENERAL.—If the Attorney General determines, with respect to a controlled substance, that an application by a practitioner to conduct research with the substance should be considered under a

process, or subject to criteria, different from the process or criteria applicable to applications to conduct research with other controlled substances in the same schedule, the Attorney General shall make public, including by posting on the website of the Drug Enforcement Administration—

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

''(B) the process and criteria that shall be applied to applications to conduct research with those substances; and

''(C) how the process and criteria described in subparagraph (B) differ from the process and criteria applicable to applications to conduct research with other controlled substances in the same schedule.

''(2) TIMING OF POSTING.—The Attorney General shall make information described in paragraph (1) public upon making a determination described in that paragraph, regardless of whether a practitioner has submitted such an application at that time.''.