II

117TH CONGRESS
1ST SESSION

S. 3336

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

IN THE SENATE OF THE UNITED STATES

DECEMBER 8, 2021

Mr. CASSIDY (for himself and Mr. BURR) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

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

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 ''Halt All Lethal Trafficking of Fentanyl Act'' or the ''HALT Fentanyl Act''.

SEC. 2. CLASS SCHEDULING OF FENTANYL-RELATED SUBSTANCES.

Section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end of schedule I the following:

''(e)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of a fentanyl-related substance, or which contains the salts, isomers, and salts of isomers of a fentanyl-related substance whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

''(2) For purposes of paragraph (1), except as provided in paragraph (3), the term 'fentanyl-related substance' means any substance that is structurally related to fentanyl by 1 or more of the following modifications:

''(A) By replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle.

''(B) By substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino, or nitro groups.

''(C) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino, or nitro groups.

''(D) By replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle.

''(E) By replacement of the N–propionyl group with another acyl group.

''(3) A substance that satisfies the definition of the term 'fentanyl-related substance' in paragraph (2) shall nonetheless not be treated as a fentanyl-related substance subject to this schedule if the substance—

''(A) is controlled by action of the Attorney General under section 201; or

''(B) is otherwise expressly listed in a schedule other than this schedule.

''(4)(A) The Attorney General may by order publish in the Federal Register a list of substances that satisfy the definition of the term 'fentanyl-related substance' in paragraph (2).

''(B) The absence of a substance from a list published under subparagraph (A) does not negate the control status of the substance under this schedule if the substance satisfies the definition of the term 'fentanyl-related substance' in paragraph (2).''.

SEC. 3. 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 by adding at the end the following:

''(l) 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; or

''(B) is—

''(i) conducted by the Department of Health and Human Services 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 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 intra-

mural 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, 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 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.''.

(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 con-

trolled 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:

''(3)(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 hearing 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(l);

''(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(l); 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 MARIHUANA.—The authority under paragraph (1) to manufacture substances does not include the authority to grow marihuana.".

(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:

"(m) 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.''.

SEC. 4. RULEMAKING.

(a) INTERIM FINAL RULES.—The Attorney General—

(1) shall, not later than 1 year of the date of enactment of this Act, issue rules to implement this Act and the amendments made by this Act; and

(2) may issue the rules under paragraph (1) as interim final rules.

(b) PROCEDURE FOR FINAL RULE.—

(1) EFFECTIVENESS OF INTERIM FINAL RULES.—A rule issued by the Attorney General as an interim final rule under subsection (a) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor, notwithstanding subparagraph (B) of section 553(b) of title 5, United States Code.

(2) OPPORTUNITY FOR COMMENT AND HEARING.—An interim final rule issued under subsection (a) shall give interested persons the opportunity to comment and to request a hearing.

(3) FINAL RULE.—After the conclusion of such proceedings, the Attorney General shall issue a final rule to implement this Act and the amendments made by this Act in accordance with section 553 of title 5, United States Code.

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