II

117TH CONGRESS
2D SESSION

S. 5123

To amend the Controlled Substances Act to modify the registration requirements relating to research, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 17, 2022

Mr. BOOKER (for himself and Mr. PAUL) 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 to modify the registration requirements relating to research, 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 ''Breakthrough Therapies Act''.

SEC. 2. 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 new subsection:

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

''(1) IN GENERAL.—Notwithstanding subsection (f), a practitioner may conduct research that is described by paragraph (2) and that is with 1 or more schedule I substances if one of the following conditions is satisfied:

''(A) RESEARCHER WITH A CURRENT SCHEDULE I OR II RESEARCH REGISTRATION.—If the practitioner is registered to conduct research with a controlled substance in schedule I or II, the practitioner may conduct research under this paragraph 30 days after the practitioner has sent a notice to the Attorney General containing the following information, with respect to each substance with which the research will be conducted:

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

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

''(iii) Demonstration that the research is in the category described by paragraph (2), which demonstration can be satisfied—

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

''(II) 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 such 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.

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

"(i) RESEARCH REGISTRATION.—If the practitioner is not currently 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), with respect to each substance with which the research will be conducted, and the Attorney General will treat such notice as a sufficient application for a research registration. Not later than 45 days of receiving such a notice that contains all information required by subparagraph (A), the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title.

"(C) VERIFICATION OF INFORMATION.—On 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 subparagraph (A)(iii).

''(2) RESEARCH SUBJECT TO EXPEDITED PROCEDURE.—Research is described by this paragraph if—

''(A) the research is the subject of an application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for the investigation of a drug which is in effect in accordance with section 312.40 of title 21, Code of Federal Regulations; or

''(B) the research is conducted by the Department of Health and Human Services or the Department of Veterans Affairs or is funded partly or entirely by a grant, contract, cooperative agreement, or other transaction from the Department of Health and Human Services, Department of Veterans Affairs, or a State health department.

''(3) ELECTRONIC SUBMISSIONS.—The Attorney General shall provide a means to permit practitioners to submit notifications under paragraph (1) electronically.

''(4) LIMITATION ON AMOUNTS.—A practitioner conducting research with a schedule I substance pursuant to this subsection shall only be permitted to

possess the amounts of schedule I substance identified in—

''(A) the notification to the Attorney General under paragraph (1); or

''(B) a supplemental notification that the practitioner may send if the practitioner needs additional amounts for the research, which supplemental notification shall include the registrant's name, the additional quantity needed of the substance, and 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 (1).

''(5) IMPORTATION AND EXPORTATION REQUIREMENTS NOT AFFECTED.—Nothing in this section 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 of the Controlled Substances Act (21 U.S.C. 822) is amended in subsection (c), by adding the following paragraph:

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

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

''(B) another agent or employee of such 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 such agent or employee to perform research under the registered researcher's registration; and

''(iii) affirms that all acts taken by such agent or employee involving controlled substances shall be attributable to the registered researcher, as if the researcher had directly committed such acts, for purposes of any proceeding under section 304(a) (21 U.S.C. 824(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) (21 U.S.C. 824(a)), to allow such agent or employee to possess such substance without a separate registration.''.

(c) SINGLE REGISTRATION FOR RELATED RESEARCH SITES.—Such section 302 is further amended in subsection (e) by adding at the end the following new paragraph:

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

''(i) such research occurs exclusively on sites all of which are within the same city or county and are under the control of the same institution, organization, or agency; and

''(ii) the researcher notifies the Attorney General of all sites where the research will be conducted or where the controlled substance

will be stored or administered prior to commencing such research.

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

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

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

''(C) The Attorney General may, in consultation with the Secretary of Health and Human Services, issue regulations addressing—

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

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

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

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

(d) NEW INSPECTION NOT REQUIRED IN CERTAIN SITUATIONS.—Such section 302 is further amended in subsection (f)—

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

(2) by adding a new paragraph, as follows:

''(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 this paragraph shall prohibit the Attorney General from conducting any inspection if the Attorney General deems it necessary to ensure that the registrant maintains effective controls against diversion.''.

(e) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I.—Such section 302 is further amended by adding at the end the following new subsection:

''(h) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I.—If a person is conducting research on a substance at the time the substance is added to schedule I, and such person is already registered to conduct research with a controlled substance in schedule I, then—

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

''(2) the person may, notwithstanding subsections (a) and (b), continue to conduct the research on such substance until the person withdraws such application or until the Attorney General serves on the person an order to show cause proposing the denial of the application pursuant to section 304(c);

''(3) if the Attorney General serves such an order to show cause and the person requests a hearing, such 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 referred to in that paragraph to a manufacturer or distributor of such substance, receipt of such copy by such manufacturer or distributor shall constitute sufficient evidence that the person is authorized to receive such substance.''.

(f) TREATMENT OF CERTAIN MANUFACTURING ACTIVITIES AS COINCIDENT TO RESEARCH.—Such section 302 (21 U.S.C. 822) is further amended by adding at the end the following new subsection:

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

''(1) IN GENERAL.—Except as specified 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 listed in paragraph (2), without being required to obtain a manufacturing registration, if such activities are performed for the purpose of the research and if the activities and the quantities of the substance involved in those activities are stated in—

''(A) a notification submitted to the Attorney General under section 303(l);

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

''(C) a notification to the Attorney General that includes the registrant's name and 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 the information provided as part of a notification submitted to the Attorney General under section 303(l) (21 U.S.C. 823(l)) or a research protocol filed with the application for registration approval; and

''(B) dosage form development studies performed for the purpose of satisfying FDA regulatory requirements for submitting an investigational new drug application.

''(3) EXCEPTION REGARDING MARIHUANA.—The authority under paragraph (1) to manufacture

substances does not include authority to grow marihuana.''.

(g) TRANSPARENCY REGARDING SPECIAL PROCEDURES.—Section 303 of such Act (21 U.S.C. 823) is further amended by adding at the end the following new subsection:

''(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 such 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 such substances; and

''(C) how such process and criteria differ from those applicable to applications to conduct

research with other controlled substances in the same schedule.

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

SEC. 3. CURRENTLY ACCEPTED MEDICAL USE WITH SEVERE RESTRICTIONS.

(a) DEFINITIONS.—Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended by inserting after paragraph (7) the following:

''(7)(A) Subject to subparagraph (B), the term 'currently accepted medical use with severe restrictions', with respect to a drug or other substance, includes a drug or other substance that is an active moiety or active ingredient (whether in natural or synthetic form) of an investigational new drug for which a waiver is in effect under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)) and that the Secretary—

''(i) designates as a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)); or

''(ii) authorizes for expanded access under subsection (b) or (c) of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb), either alone or as part of a therapeutic protocol, to treat patients with serious or life-threatening diseases for which no comparable or satisfactory therapies are available.

''(B) A drug or other substance shall not meet the criteria under subparagraph (A) for having a currently accepted medical use with severe restrictions if—

''(i) in the case of a drug or other substance described in subparagraph (A)(ii)—

''(I) the Secretary places the expanded access or protocol for such drug on clinical hold as described in section 312.42 of title 21, Code of Federal Regulations (or any successor regulations);

''(II) there is no other investigational new drug containing the drug or other substance for which expanded access has been authorized under section 561(a) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(a)); and

''(III) the drug or other substance does not meet the requirements of subparagraph (A)(i); or

''(ii) the drug or other substance is an active moiety or active ingredient (whether natural or synthetic) of an application approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).''.

(b) AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES.—Section 201(j) of the Controlled Substances Act (21 U.S.C. 811(j)) is amended—

(1) in paragraph (1), by inserting ''a drug designated as a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)), or a drug authorized for expanded access under subsection (b) or (c) of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb)'' after ''subsection (f),''; and

(2) in paragraph (2)—

(A) in subparagraph (A), by striking ''; or'' and inserting a semicolon;

(B) in subparagraph (B), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following:

''(C) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has designated a drug as a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)) or authorized a drug for expanded access under subsection (b) or (c) of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb); or

''(D) the date on which the Attorney General receives any written notification demonstrating that the Secretary, before the date of enactment of this subparagraph, designated a drug as a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)) or authorized a drug for expanded access under subsection (b) or (c) of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).''.

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