

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

A BILL

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

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 “Breakthrough Thera-
5 pies Act”.

6 **SEC. 2. REGISTRATION REQUIREMENTS RELATED TO RE-**
7 **SEARCH.**

8 (a) ALTERNATIVE REGISTRATION PROCESS FOR
9 SCHEDULE I RESEARCH.—Section 303 of the Controlled

1 Substances Act (21 U.S.C. 823) is amended by adding at
2 the end the following new subsection:

3 “(l) SPECIAL PROVISIONS FOR THOSE CONDUCTING
4 CERTAIN RESEARCH WITH SCHEDULE I CONTROLLED
5 SUBSTANCES.—

6 “(1) IN GENERAL.—Notwithstanding subsection
7 (f), a practitioner may conduct research that is de-
8 scribed by paragraph (2) and that is with 1 or more
9 schedule I substances if one of the following condi-
10 tions is satisfied:

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

13 If the practitioner is registered to conduct re-
14 search with a controlled substance in schedule
15 I or II, the practitioner may conduct research
16 under this paragraph 30 days after the practi-
17 tioner has sent a notice to the Attorney General
18 containing the following information, with re-
19 spect to each substance with which the research
20 will be conducted:

21 “(i) The chemical name of the sub-
22 stance.

23 “(ii) The quantity of the substance to
24 be used in such research.

1 “(iii) Demonstration that the research
2 is in the category described by paragraph
3 (2), which demonstration can be satis-
4 fied—

5 “(I) in the case of a grant, con-
6 tract, cooperative agreement, or other
7 transaction, or intramural research
8 project, by identifying the sponsoring
9 agency and supplying information re-
10 lated to the grant, contract, coopera-
11 tive agreement, other transaction, or
12 project; or

13 “(II) in the case of an applica-
14 tion under section 505(i) of the Fed-
15 eral Food, Drug, and Cosmetic Act,
16 by supplying the application number
17 and the sponsor of record on such ap-
18 plication.

19 “(iv) Demonstration that the re-
20 searcher is authorized to conduct research
21 with respect to the substance under the
22 laws of the State in which the research will
23 take place.

24 “(B) RESEARCHER WITHOUT A CURRENT
25 SCHEDULE I OR II.—

1 “(i) RESEARCH REGISTRATION.—If
2 the practitioner is not currently registered
3 to conduct research with a controlled sub-
4 stance in schedule I or II, the practitioner
5 may send a notice to the Attorney General
6 containing the information listed in sub-
7 paragraph (A), with respect to each sub-
8 stance with which the research will be con-
9 ducted, and the Attorney General will treat
10 such notice as a sufficient application for
11 a research registration. Not later than 45
12 days of receiving such a notice that con-
13 tains all information required by subpara-
14 graph (A), the Attorney General shall reg-
15 ister the applicant, or serve an order to
16 show cause upon the applicant in accord-
17 ance with section 824(c) of this title.

18 “(C) VERIFICATION OF INFORMATION.—
19 On request from the Attorney General, the Sec-
20 retary of Health and Human Services or the
21 Secretary of Veterans Affairs, as appropriate,
22 shall verify information submitted by an appli-
23 cant under subparagraph (A)(iii).

1 “(2) RESEARCH SUBJECT TO EXPEDITED PRO-
2 CEDURE.—Research is described by this paragraph
3 if—

4 “(A) the research is the subject of an ap-
5 plication under section 505(i) of the Federal
6 Food, Drug, and Cosmetic Act for the inves-
7 tigation of a drug which is in effect in accord-
8 ance with section 312.40 of title 21, Code of
9 Federal Regulations; or

10 “(B) the research is conducted by the De-
11 partment of Health and Human Services or the
12 Department of Veterans Affairs or is funded
13 partly or entirely by a grant, contract, coopera-
14 tive agreement, or other transaction from the
15 Department of Health and Human Services,
16 Department of Veterans Affairs, or a State
17 health department.

18 “(3) ELECTRONIC SUBMISSIONS.—The Attorney
19 General shall provide a means to permit practi-
20 tioners to submit notifications under paragraph (1)
21 electronically.

22 “(4) LIMITATION ON AMOUNTS.—A practitioner
23 conducting research with a schedule I substance pur-
24 suant to this subsection shall only be permitted to

1 possess the amounts of schedule I substance identi-
2 fied in—

3 “(A) the notification to the Attorney Gen-
4 eral under paragraph (1); or

5 “(B) a supplemental notification that the
6 practitioner may send if the practitioner needs
7 additional amounts for the research, which sup-
8 plemental notification shall include the reg-
9 istrant’s name, the additional quantity needed
10 of the substance, and an attestation that the re-
11 search to be conducted with the substance is
12 consistent with the scope of the research that
13 was the subject of the notification under para-
14 graph (1).

15 “(5) IMPORTATION AND EXPORTATION RE-
16 QUIREMENTS NOT AFFECTED.—Nothing in this sec-
17 tion alters the requirements of part A of title III, re-
18 garding the importation and exportation of con-
19 trolled substances.”.

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

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

4 “(A) such agent or employee is acting
5 within the scope of his or her professional prac-
6 tice;

7 “(B) another agent or employee of such 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 such agent or em-
16 ployee to perform research under the reg-
17 istered researcher’s registration; and

18 “(iii) affirms that all acts taken by
19 such agent or employee involving controlled
20 substances shall be attributable to the reg-
21 istered researcher, as if the researcher had
22 directly committed such acts, for purposes
23 of any proceeding under section 304(a) (21
24 U.S.C. 824(a)) to suspend or revoke the

1 registration of the registered researcher;
 2 and

3 “(D) the Attorney General does not, within
 4 30 days of receiving the information, authoriza-
 5 tion, and affirmation described in subparagraph
 6 (C), refuse, for a reason listed in section 304(a)
 7 (21 U.S.C. 824(a)), to allow such agent or em-
 8 ployee to possess such substance without a sep-
 9 arate registration.”.

10 (c) SINGLE REGISTRATION FOR RELATED RESEARCH
 11 SITES.—Such section 302 is further amended in sub-
 12 section (e) by adding at the end the following new para-
 13 graph:

14 “(3)(A) Notwithstanding paragraph (1), a per-
 15 son registered to conduct research with a controlled
 16 substance under section 303(f) may conduct such re-
 17 search under a single registration if—

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

22 “(ii) the researcher notifies the Attorney
 23 General of all sites where the research will be
 24 conducted or where the controlled substance

1 will be stored or administered prior to com-
2 mencing such research.

3 “(B) A site described by subparagraph (A) shall
4 be included in such registration only if the re-
5 searcher has notified the Attorney General of such
6 site—

7 “(i) in the application for such registra-
8 tion; or

9 “(ii) before the research is conducted, or
10 before the controlled substance is stored or ad-
11 ministered, at such site.

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

15 “(i) the manner in which controlled sub-
16 stances may be delivered to the research sites
17 described in subparagraph (A);

18 “(ii) the storage and security of controlled
19 substances at such research sites;

20 “(iii) the maintenance of records for such
21 research sites; and

22 “(iv) any other matters necessary to en-
23 sure effective controls against diversion at such
24 research sites.”.

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

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

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

7 “(2)(A) If a person is registered to conduct re-
8 search with a controlled substance and applies for a
9 registration, or for a modification of a registration,
10 to conduct research with a second controlled sub-
11 stance that is in the same schedule as the first con-
12 trolled substance, or is in a schedule with a higher
13 numerical designation than the schedule of the first
14 controlled substance, a new inspection by the Attor-
15 ney General of the registered location is not re-
16 quired.

17 “(B) Nothing in this paragraph shall prohibit
18 the Attorney General from conducting any inspec-
19 tion if the Attorney General deems it necessary to
20 ensure that the registrant maintains effective con-
21 trols against diversion.”.

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

1 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES
2 NEWLY ADDED TO SCHEDULE I.—If a person is con-
3 ducting research on a substance at the time the substance
4 is added to schedule I, and such person is already reg-
5 istered to conduct research with a controlled substance in
6 schedule I, then—

7 “(1) the person shall, not later than 90 days of
8 the scheduling of the newly scheduled substance,
9 submit a completed application for registration or
10 modification of existing registration, to conduct re-
11 search on such substance, in accordance with the
12 regulations issued by the Attorney General;

13 “(2) the person may, notwithstanding sub-
14 sections (a) and (b), continue to conduct the re-
15 search on such substance until the person withdraws
16 such application or until the Attorney General serves
17 on the person an order to show cause proposing the
18 denial of the application pursuant to section 304(c);

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

1 “(4) if the person sends a copy of the applica-
2 tion referred to in that paragraph to a manufacturer
3 or distributor of such substance, receipt of such copy
4 by such manufacturer or distributor shall constitute
5 sufficient evidence that the person is authorized to
6 receive such substance.”.

7 (f) TREATMENT OF CERTAIN MANUFACTURING AC-
8 TIVITIES AS COINCIDENT TO RESEARCH.—Such section
9 302 (21 U.S.C. 822) is further amended by adding at the
10 end the following new subsection:

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

13 “(1) IN GENERAL.—Except as specified in
14 paragraph (3), a person who is registered to perform
15 research on a controlled substance may perform
16 manufacturing activities with small quantities of
17 that substance, including activities listed in para-
18 graph (2), without being required to obtain a manu-
19 facturing registration, if such activities are per-
20 formed for the purpose of the research and if the ac-
21 tivities and the quantities of the substance involved
22 in those activities are stated in—

23 “(A) a notification submitted to the Attor-
24 ney General under section 303(l);

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

4 “(C) a notification to the Attorney General
5 that includes the registrant’s name and an at-
6 testation that the research to be conducted with
7 the small quantities of manufactured substance
8 is consistent with the scope of the research that
9 is the basis for the registration.

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

12 “(A) processing the substance to create ex-
13 tracts, tinctures, oils, solutions, derivatives, or
14 other forms of the substance consistent the in-
15 formation provided as part of a notification
16 submitted to the Attorney General under sec-
17 tion 303(l) (21 U.S.C. 823(l)) or a research
18 protocol filed with the application for registra-
19 tion approval; and

20 “(B) dosage form development studies per-
21 formed for the purpose of satisfying FDA regu-
22 latory requirements for submitting an investiga-
23 tional new drug application.

24 “(3) EXCEPTION REGARDING MARIHUANA.—

25 The authority under paragraph (1) to manufacture

1 substances does not include authority to grow mari-
2 huana.”.

3 (g) TRANSPARENCY REGARDING SPECIAL PROCE-
4 DURES.—Section 303 of such Act (21 U.S.C. 823) is fur-
5 ther amended by adding at the end the following new sub-
6 section:

7 “(m) TRANSPARENCY REGARDING SPECIAL PROCE-
8 DURES.—

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

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

21 “(B) the process and criteria that shall be
22 applied to applications to conduct research with
23 such substances; and

24 “(C) how such process and criteria differ
25 from those applicable to applications to conduct

1 research with other controlled substances in the
2 same schedule.

3 “(2) TIMING OF POSTING.—The Attorney Gen-
4 eral shall make such information public upon mak-
5 ing such determination, regardless of whether a
6 practitioner has submitted such an application at
7 that time.”.

8 **SEC. 3. CURRENTLY ACCEPTED MEDICAL USE WITH SE-**
9 **VERE RESTRICTIONS.**

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

13 “(7)(A) Subject to subparagraph (B), the term
14 ‘currently accepted medical use with severe restric-
15 tions’, with respect to a drug or other substance, in-
16 cludes a drug or other substance that is an active
17 moiety or active ingredient (whether in natural or
18 synthetic form) of an investigational new drug for
19 which a waiver is in effect under section 505(i) of
20 the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 355(i)) or section 351(a)(3) of the Public
22 Health Service Act (42 U.S.C. 262(a)(3)) and that
23 the Secretary—

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

4 “(ii) authorizes for expanded access under
 5 subsection (b) or (c) of section 561 of the Fed-
 6 eral Food, Drug, and Cosmetic Act (21 U.S.C.
 7 360bbb), either alone or as part of a thera-
 8 peutic protocol, to treat patients with serious or
 9 life-threatening diseases for which no com-
 10 parable or satisfactory therapies are available.

11 “(B) A drug or other substance shall not meet
 12 the criteria under subparagraph (A) for having a
 13 currently accepted medical use with severe restric-
 14 tions if—

15 “(i) in the case of a drug or other sub-
 16 stance described in subparagraph (A)(ii)—

17 “(I) the Secretary places the ex-
 18 panded access or protocol for such drug on
 19 clinical hold as described in section 312.42
 20 of title 21, Code of Federal Regulations (or
 21 any successor regulations);

22 “(II) there is no other investigational
 23 new drug containing the drug or other sub-
 24 stance for which expanded access has been
 25 authorized under section 561(a) of the

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

3 “(III) the drug or other substance
4 does not meet the requirements of sub-
5 paragraph (A)(i); or

6 “(ii) the drug or other substance is an ac-
7 tive moiety or active ingredient (whether nat-
8 ural or synthetic) of an application approved
9 under section 505 of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 355) or section
11 351 of the Public Health Service Act (42
12 U.S.C. 262).”.

13 (b) AUTHORITY AND CRITERIA FOR CLASSIFICATION
14 OF SUBSTANCES.—Section 201(j) of the Controlled Sub-
15 stances Act (21 U.S.C. 811(j)) is amended—

16 (1) in paragraph (1), by inserting “a drug des-
17 igned as a breakthrough therapy under section
18 506(a) of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 356(a)), or a drug authorized for ex-
20 panded access under subsection (b) or (c) of section
21 561 of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 360bbb)” after “subsection (f),”; and

23 (2) in paragraph (2)—

24 (A) in subparagraph (A), by striking “;
25 or” and inserting a semicolon;

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

4 (C) by adding at the end the following:

5 “(C) the date on which the Attorney Gen-
6 eral receives notification from the Secretary of
7 Health and Human Services that the Secretary
8 has designated a drug as a breakthrough ther-
9 apy under section 506(a) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 356(a)) or
11 authorized a drug for expanded access under
12 subsection (b) or (c) of section 561 of the Fed-
13 eral Food, Drug, and Cosmetic Act (21 U.S.C.
14 360bbb); or

15 “(D) the date on which the Attorney Gen-
16 eral receives any written notification dem-
17 onstrating that the Secretary, before the date of
18 enactment of this subparagraph, designated a
19 drug as a breakthrough therapy under section
20 506(a) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 356(a)) or authorized a
22 drug for expanded access under subsection (b)
23 or (c) of section 561 of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 360bbb).”.

○