

118TH CONGRESS
1ST SESSION

S. _____

To amend the Controlled Substances Act to define currently accepted medical use with severe restrictions, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. BOOKER (for himself and Mr. PAUL) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Controlled Substances Act to define currently accepted medical use with severe restrictions, 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. CURRENTLY ACCEPTED MEDICAL USE WITH**
4 **SEVERE RESTRICTIONS.**

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

8 “(7)(A) Subject to subparagraph (B), the term
9 ‘currently accepted medical use with severe restric-
10 tions’, with respect to a drug or other substance, in-

1 includes a drug or other substance that is an active
2 metabolite, moiety, or ingredient (whether in natural
3 or synthetic form) of an investigational new drug for
4 which a waiver is in effect under section 505(i) of
5 the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 355(i)) or section 351(a)(3) of the Public
7 Health Service Act (42 U.S.C. 262(a)(3)) and that
8 the Secretary—

9 “(i) designates as a breakthrough therapy
10 under section 506(a) of the Food Drug and
11 Cosmetic Act (21 U.S.C. 356(a)); or

12 “(ii) authorizes for expanded access under
13 subsection (b) or (c) of section 561 of the Fed-
14 eral Food, Drug, and Cosmetic Act (21 U.S.C.
15 360bbb), either alone or as part of a thera-
16 peutic protocol, to treat patients with serious or
17 life-threatening diseases for which no com-
18 parable or satisfactory therapies are available.

19 “(B) A drug or other substance shall not meet
20 the criteria under subparagraph (A) for having a
21 currently accepted medical use with severe restric-
22 tions if—

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

1 “(I) the Secretary places the ex-
2 panded access or protocol for such drug on
3 clinical hold as described in section 312.42
4 of title 21, Code of Federal Regulations (or
5 any successor regulations);

6 “(II) there is no other investigational
7 new drug containing the drug or other sub-
8 stance for which expanded access has been
9 authorized under section 561(a) of the
10 Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 360bbb(a)); and

12 “(III) the drug or other substance
13 does not meet the requirements of sub-
14 paragraph (A)(i); or

15 “(ii) the drug or other substance is ap-
16 proved under section 505 of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 355) or
18 section 351 of the Public Health Service Act
19 (42 U.S.C. 262).”.

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

23 (1) in paragraph (1), by inserting “a drug des-
24 ignated as a breakthrough therapy under section
25 506(a) of the Food Drug and Cosmetic Act (21

1 U.S.C. 356(a)), or a drug authorized for expanded
2 access under subsection (b) or (c) of section 561 of
3 the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 360bbb)” after “subsection (f),”;

5 (2) in paragraph (2)—

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

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

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

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

21 “(D) the date on which the Attorney Gen-
22 eral receives any written notification dem-
23 onstrating that the Secretary, before the date of
24 enactment of this subparagraph, designated a
25 drug as a breakthrough therapy under section

1 506(a) of the Food Drug and Cosmetic Act (21
2 U.S.C. 356(a)) or authorized a drug for ex-
3 panded access under subsection (b) or (c) of
4 section 561 of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 360bbb).”;

6 (3) in paragraph (3), by inserting “or para-
7 graph (4)” after “paragraph (1)”; and

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

9 “(4) With respect to a drug moved from schedule I
10 to schedule II pursuant to paragraph (1) and the expe-
11 dited procedures described under this subsection, if the
12 drug no longer has a currently accepted medical use with
13 severe restrictions and the Secretary of Health and
14 Human Services recommends that the Attorney General
15 control the drug in schedule I pursuant to subsections (a)
16 and (b), the Attorney General shall, not later than 90 days
17 after receiving written notification from the Secretary,
18 issue an interim final rule controlling the drug in accord-
19 ance with such subsections and section 202(b) using the
20 procedures described in paragraph (3) of this subsection.”.