

119TH CONGRESS
2^D SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to authorize the use of investigational individualized medical treatments by patients diagnosed with a life-threatening disease or condition or severely debilitating illness, and for other purposes.

IN THE SENATE OF THE UNITED STATES

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize the use of investigational individualized medical treatments by patients diagnosed with a life-threatening disease or condition or severely debilitating illness, 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 “Right to Try for Indi-
5 vidualized Treatments Act”.

1 **SEC. 2. USE OF INVESTIGATIONAL INDIVIDUALIZED MED-**
2 **ICAL TREATMENTS BY PATIENTS DIAGNOSED**
3 **WITH A LIFE-THREATENING DISEASE OR**
4 **CONDITION OR SEVERELY DEBILITATING ILL-**
5 **NESS.**

6 (a) DEFINITIONS.—Section 561B(a) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0a(a))
8 is amended—

9 (1) by amending paragraph (1) to read as fol-
10 lows:

11 “(1) the term ‘eligible patient’ means—

12 “(A) in the case of a patient requesting an
13 eligible investigational drug, a patient who
14 has—

15 “(i) been diagnosed with a life-threat-
16 ening disease or condition (as defined in
17 section 312.81 of title 21, Code of Federal
18 Regulations (or any successor regula-
19 tions));

20 “(ii) exhausted approved treatment
21 options and is unable to participate in a
22 clinical trial involving the eligible investiga-
23 tional drug, as certified by a physician,
24 who—

1 “(I) is in good standing with the
2 physician’s licensing organization or
3 board; and

4 “(II) will not be compensated di-
5 rectly by the manufacturer of such
6 drug for so certifying; and

7 “(iii) provided to the treating physi-
8 cian written informed consent regarding
9 the eligible investigational drug, or, as ap-
10 plicable, on whose behalf a legally author-
11 ized representative of the patient has pro-
12 vided such consent; or

13 “(B) in the case of a patient requesting an
14 investigational individualized medical treatment,
15 a patient who has—

16 “(i) been diagnosed with a life-threat-
17 ening disease or condition or severely de-
18 bilitating illness (as such terms are defined
19 in section 312.81 of title 21, Code of Fed-
20 eral Regulations (or any successor regula-
21 tions));

22 “(ii) considered approved treatment
23 options, as certified by a physician, who—

1 “(I) is in good standing with the
2 physician’s licensing organization or
3 board;

4 “(II) will not be compensated di-
5 rectly by the manufacturer of such
6 treatment for so certifying; and

7 “(III) attests to the patient’s life-
8 threatening disease or condition or se-
9 verely debilitating illness; and

10 “(iii) provided to the treating physi-
11 cian—

12 “(I) written informed consent re-
13 garding the eligible investigational
14 drug or, as applicable, on whose be-
15 half a legally authorized representa-
16 tive of the patient has provided such
17 consent; or

18 “(II) as applicable, additional in-
19 formed consent, regarding the inves-
20 tigational individualized medical treat-
21 ment, or, as applicable, on whose be-
22 half a legally authorized representa-
23 tive of the patient has provided such
24 consent;” and

1 (2) in paragraph (2)(D), by striking “and” at
2 the end;

3 (3) in paragraph (3), by striking the period at
4 the end and inserting a semicolon; and

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

6 “(4) the term ‘eligible health care facility’
7 means a health care facility that is operating under
8 the Federal assurance for protection of human sub-
9 jects pursuant to section 491(a) of the Public
10 Health Service Act;

11 “(5) the term ‘investigational individualized
12 medical treatment’ means a drug or biological prod-
13 uct for the patient based on an analysis of the pa-
14 tient’s unique genomic profile, including their
15 genomic sequence, human chromosomes,
16 deoxyribonucleic acid, genes, gene products (such as
17 enzymes and other types of proteins), or metabolites;
18 and

19 “(6) the term ‘additional informed consent’
20 means consent attested to in writing by the patient’s
21 physician and a witness for an investigational indi-
22 vidualized medical treatment that includes—

23 “(A) an explanation of the currently ap-
24 proved treatments for the patient’s disease or
25 condition;

1 “(B) the patient’s attestation that the pa-
2 tient concurs with the assessment of their phy-
3 sician that all currently approved and conven-
4 tionally recognized treatments are unlikely to
5 prolong or improve their life;

6 “(C) clear identification of the specific pro-
7 posed investigational individualized medical
8 treatment the patient’s physician recommends;
9 and

10 “(D) a description, based on the physi-
11 cian’s knowledge of the proposed treatment and
12 the patient’s disease, of the potential outcomes
13 of the treatment.”.

14 (b) ELIGIBILITY FOR INVESTIGATIONAL INDIVIDUAL-
15 IZED MEDICAL TREATMENT.—Section 561B of such Act
16 (21 U.S.C. 360bbb–0a) is amended—

17 (1) by redesignating subsections (b) through (d)
18 as subsections (c) through (e), respectively; and

19 (2) by inserting after subsection (a) the fol-
20 lowing:

21 “(b) ELIGIBILITY FOR INVESTIGATIONAL INDIVID-
22 UALIZED MEDICAL TREATMENT.—A manufacturer of an
23 investigational individualized medical treatment that is in
24 compliance with all applicable Federal assurance laws and
25 regulations and is operating within an eligible health care

1 facility may make available such investigational individual-
2 ized medical treatment, and an eligible patient may re-
3 quest access to such treatment from the eligible health
4 care facility or manufacturer of such treatment, consistent
5 with the requirements of this section. A manufacturer of
6 an investigational individualized medical treatment is not
7 required to make available such treatment to any pa-
8 tient.”.

9 (c) EXEMPTIONS.—Section 561B(c) of such Act (21
10 U.S.C. 360bbb–0a(c)), as redesignated by subsection
11 (b)(1) of this section, is amended—

12 (1) by inserting “and investigational individual-
13 ized medical treatments” after “Eligible investiga-
14 tional drugs”;

15 (2) by inserting “or investigational individual-
16 ized medical treatment” after “such eligible inves-
17 tigational drug”;

18 (3) by inserting “or investigational individual-
19 ized medical treatment” after “an eligible investiga-
20 tional drug”; and

21 (4) by inserting “or investigational individual-
22 ized medical treatments” after “investigational
23 drugs”.

24 (d) CONFORMING AMENDMENTS.—Section 561B of
25 such Act (21 U.S.C. 360bbb–0a) is amended—

1 (1) in the section heading, by inserting “**AND**
2 **INVESTIGATIONAL INDIVIDUALIZED MEDICAL**
3 **TREATMENTS**” after “**DRUGS**”; and

4 (2) in subsection (e)(2), as redesignated by sub-
5 section (b)(1) of this section—

6 (A) in subparagraph (A), by striking “sub-
7 section (c)(1)(A)” and inserting “subsection
8 (d)(1)(A)”; and

9 (B) in subparagraph (B), by striking “sub-
10 section (c)(1)(B)” and inserting “subsection
11 (d)(1)(B)”.