



(Original Signature of Member)

119TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

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.

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IN THE HOUSE OF REPRESENTATIVES

Mrs. HARSHBARGER introduced the following bill; which was 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)”.