Diana Harshbarger

(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.

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.

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 ''Right to Try for Individualized Treatments Act''.

SEC. 2. USE OF INVESTIGATIONAL INDIVIDUALIZED MEDICAL TREATMENTS BY PATIENTS DIAGNOSED WITH A LIFE-THREATENING DISEASE OR CONDITION OR SEVERELY DEBILITATING ILLNESS.

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

(1) by amending paragraph (1) to read as follows:

''(1) the term 'eligible patient' means—

''(A) in the case of a patient requesting an eligible investigational drug, a patient who has—

''(i) been diagnosed with a life-threatening disease or condition (as defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations));

''(ii) exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who—

''(I) is in good standing with the physician's licensing organization or board; and

''(II) will not be compensated directly by the manufacturer of such drug for so certifying; and

''(iii) provided to the treating physician written informed consent regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent; or

''(B) in the case of a patient requesting an investigational individualized medical treatment, a patient who has—

''(i) been diagnosed with a life-threatening disease or condition or severely debilitating illness (as such terms are defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations));

''(ii) considered approved treatment options, as certified by a physician, who—

''(I) is in good standing with the physician's licensing organization or board;

''(II) will not be compensated directly by the manufacturer of such treatment for so certifying; and

''(III) attests to the patient's life-threatening disease or condition or severely debilitating illness; and

''(iii) provided to the treating physician—

''(I) written informed consent regarding the eligible investigational drug or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent; or

''(II) as applicable, additional informed consent, regarding the investigational individualized medical treatment, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent;''; and

(2) in paragraph (2)(D), by striking ''and'' at the end;

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

(4) by adding at the end the following:

''(4) the term 'eligible health care facility' means a health care facility that is operating under the Federal assurance for protection of human subjects pursuant to section 491(a) of the Public Health Service Act;

''(5) the term 'investigational individualized medical treatment' means a drug or biological product for the patient based on an analysis of the patient's unique genomic profile, including their genomic sequence, human chromosomes, deoxyribonucleic acid, genes, gene products (such as enzymes and other types of proteins), or metabolites; and

''(6) the term 'additional informed consent' means consent attested to in writing by the patient's physician and a witness for an investigational individualized medical treatment that includes—

''(A) an explanation of the currently approved treatments for the patient's disease or condition;

''(B) the patient's attestation that the patient concurs with the assessment of their physician that all currently approved and conventionally recognized treatments are unlikely to prolong or improve their life;

''(C) clear identification of the specific proposed investigational individualized medical treatment the patient's physician recommends; and

''(D) a description, based on the physician's knowledge of the proposed treatment and the patient's disease, of the potential outcomes of the treatment.''.

(b) ELIGIBILITY FOR INVESTIGATIONAL INDIVIDUALIZED MEDICAL TREATMENT.—Section 561B of such Act (21 U.S.C. 360bbb–0a) is amended—

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

(2) by inserting after subsection (a) the following:

''(b) ELIGIBILITY FOR INVESTIGATIONAL INDIVIDUALIZED MEDICAL TREATMENT.—A manufacturer of an investigational individualized medical treatment that is in compliance with all applicable Federal assurance laws and regulations and is operating within an eligible health care

facility may make available such investigational individualized medical treatment, and an eligible patient may request access to such treatment from the eligible health care facility or manufacturer of such treatment, consistent with the requirements of this section. A manufacturer of an investigational individualized medical treatment is not required to make available such treatment to any patient.''.

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

(1) by inserting ''and investigational individualized medical treatments'' after ''Eligible investigational drugs'';

(2) by inserting ''or investigational individualized medical treatment'' after ''such eligible investigational drug'';

(3) by inserting ''or investigational individualized medical treatment'' after ''an eligible investigational drug''; and

(4) by inserting ''or investigational individualized medical treatments'' after ''investigational drugs''.

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

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

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

(A) in subparagraph (A), by striking ''subsection (c)(1)(A)'' and inserting ''subsection (d)(1)(A)''; and

(B) in subparagraph (B), by striking ''subsection (c)(1)(B)'' and inserting ''subsection (d)(1)(B)''.