

# RIGHT TO TRY — IIMTs and DEVICE AMENDMENT

*Staffer Two-Pager | Verbatim Draft Statutory Language*

## Suggested Draft Language for Amendment to the federal Right to Try Act

### Section 1. Short Title

This Act may be cited as the “Right to Try for Individualized Treatments and Non-Invasive Medical Devices Act.”

### Section 2. Definitions — Amendments to § 561B(a)

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

#### (1) Amend paragraph (1)

Strike existing paragraph (1) and insert the following:

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

*“(A) in the case of a patient requesting an eligible investigational drug or eligible non-invasive medical device, 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 or eligible non-invasive medical device, 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 or device for so certifying; and*

*“(iii) provided to the treating physician written informed consent regarding the eligible investigational drug or eligible non-invasive medical device, 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;”;*

**(2) Amend paragraph (2)(D)**

In paragraph (2)(D), strike “and” at the end.

**(3) Amend paragraph (3)**

In paragraph (3), strike the period at the end and insert a semicolon.

**(4)–(6) Add paragraphs (4) through (6)**

After paragraph (3), add 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, or other advanced biological technology (including but not limited to cell- or tissue-based therapy) 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, or other relevant individual biological characteristics; 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.”;*

**(7)–(8) Add device definitions**

After paragraph (6) (as added), add the following:

*“(7) the term ‘eligible non-invasive medical device’ means a medical device—*

*“(A) that is intended solely for non-invasive use and does not require any surgery or implantation for its operation;*

*“(B) that has successfully completed a Phase I (or equivalent early feasibility) clinical evaluation and remains under investigation in one or more clinical trials approved by an institutional review board; and*

*“(C) that may be comprised of software utilizing artificial intelligence (AI) or machine learning (ML) algorithms utilized in the identification, prioritization, or management of individualized therapeutic options and that does not include, require, or operate in conjunction with any new or modified hardware component, sensor, system, or apparatus as part of its investigational use; and*

*“(8) for purposes of paragraph (7), the term ‘hardware’ means any physical device, sensor, implant, or apparatus other than commercially available computer equipment used solely to run the software.”*

### Section 3. Eligibility for IIMT — New Subsection (b)

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.”***

**Effect:** After this section takes effect, the subsection structure of § 561B is: (a) Definitions, (b) Eligibility for IIMT, (c) Exemptions, (d) Outcomes, (e) Reporting, with (f) added in Section 7 below.

#### **Section 4. Exemptions — Amendments to Subsection (c)**

Section 561B(c) of such Act (21 U.S.C. 360bbb-0a(c)), as redesignated by section 3(1) of this Act, is amended—

##### **(1)–(4) conforming inserts for IIMTs**

(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”;

##### **(5) conforming inserts for devices**

(5) each place “eligible investigational drug” appears (as amended by paragraphs (1)–(4)), insert “or eligible non-invasive medical device” after such term.

##### **(6) new paragraph for device exemptions**

(6) by designating the existing text (as amended) as paragraph “(1)” and adding at the end the following new paragraph:

*“(2) Eligible non-invasive medical devices provided to eligible patients in compliance with this section are exempt from sections 360e, 360(k), and 360j(g) of this title, and parts 50, 56, and 812 of title 21, Code of Federal Regulations (or any successor regulations), provided that the sponsor of such eligible non-invasive medical device, or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible non-invasive medical device pursuant to this section, is in compliance with the applicable requirements set forth in sections 812.7 and 812.119 of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational devices.”*

## **Section 5. Conforming Amendments to Subsections (d) and (e)**

Section 561B of such Act (21 U.S.C. 360bbb-0a) is further amended—

### **(a) Subsection (d) (Outcomes)**

(1) In subsection (d), each place “eligible investigational drug” appears, insert “or eligible non-invasive medical device” after such term.

(2) Each place “investigational individualized medical treatment” should also appear per conforming edits, insert same as applicable.

### **(b) Subsection (e) (Reporting)**

(1) In subsection (e)(1), strike “The manufacturer or sponsor of an eligible investigational drug” and insert “The manufacturer or sponsor of an eligible investigational drug, investigational individualized medical treatment, or eligible non-invasive medical device.”

(2) In subsection (e)(2), each place “eligible investigational drug” appears, insert “or investigational individualized medical treatment or eligible non-invasive medical device” after such term.

### **(c) Cross-reference corrections**

(1) In subsection (e)(2)(A), strike “subsection (c)(1)(A)” and insert “subsection (d)(1)(A).”

(2) In subsection (e)(2)(B), strike “subsection (c)(1)(B)” and insert “subsection (d)(1)(B).”

**Note:** These cross-reference corrections reflect the redesignation of former subsection (c) (Outcomes) to subsection (d) effected by section 3 of this Act.

## **Section 6. Section Heading Amendment**

The section heading for section 561B of such Act is amended by striking “RIGHT TO TRY” and all that follows through “DRUGS” and inserting:

***“RIGHT TO TRY FOR INVESTIGATIONAL DRUGS AND INVESTIGATIONAL INDIVIDUALIZED MEDICAL TREATMENTS AND NON-INVASIVE MEDICAL DEVICES”***

## **Section 7. Guidance — New Subsection (f)**

Section 561B of such Act (21 U.S.C. 360bbb-0a) is amended by adding at the end the following new subsection:

***“(f) GUIDANCE.—The Secretary shall, as appropriate, issue guidance regarding the application of this section to non-invasive medical devices, including to ensure appropriate harmonization with requirements applicable to investigational device exemptions under section 360j(g) of this title and related regulations.”***

## Summary of Changes

*Current law: Section 561B (21 U.S.C. § 360bbb-0a) applies to an “eligible investigational drug” (as defined in statute), not to biological products or devices.*

- **IIMT pathway (proposed):** Expands § 561B to cover investigational individualized medical treatments (IIMTs)—defined to include drugs, biological products, or other advanced biological technology based on analysis of a patient’s unique genomic profile. Inserts definitions for “eligible health care facility,” “investigational individualized medical treatment,” and “additional informed consent” as new paragraphs (4)–(6). Creates new subsection (b) establishing IIMT eligibility. Redesignates existing (b)–(d) as (c)–(e).
- **Patient eligibility expansion (IIMT):** Expands patient eligibility for IIMTs to include “severely debilitating illness” in addition to “life-threatening disease” (using 21 C.F.R. § 312.81 definitions), while the drug and device branch under paragraph (1)(A) remains aligned to “life-threatening disease or condition” unless otherwise amended.
- **Device pathway (proposed):** Adds definitions for “eligible non-invasive medical device” (paragraph (7)) and “hardware” (paragraph (8)) in § 561B(a). Conforming edits to paragraph (1)(A) extend “eligible patient” to include device-seeking patients.
- **Exemptions (c) (proposed):** IIMT conforming inserts throughout existing exemption text. New paragraph (c)(2) exempts qualifying devices from 21 U.S.C. §§ 360e, 360(k), 360j(g) and 21 C.F.R. parts 50, 56, 812, conditioned on compliance with 21 C.F.R. §§ 812.7 and 812.119.
- **Outcomes and reporting (d)–(e) (proposed):** Conforming inserts extend clinical-outcomes and manufacturer reporting obligations to IIMTs and non-invasive devices; corrects internal cross-references to reflect redesignation.
- **Section heading (proposed):** Amended to reference investigational drugs, IIMTs, and non-invasive medical devices.
- **Guidance (f) (proposed):** Directs the Secretary to issue guidance on applying § 561B to non-invasive medical devices, with harmonization to IDE requirements under § 360j(g).

*The amendment does not alter FDA pre-market authority or requirements outside the § 561B access pathway*

## Key Cross-References

- 21 U.S.C. § 360bbb-0a (§ 561B of the FD&C Act) — federal Right to Try Act
- 21 C.F.R. Part 812 — Investigational Device Exemptions (IDE)
- 21 C.F.R. Parts 50 & 56 — Human subjects protection; Institutional Review Boards
- 21 C.F.R. §§ 812.7, 812.119 — Sponsor/investigator compliance for investigational devices
- 21 U.S.C. § 360e — Premarket approval (PMA)
- 21 U.S.C. § 360(k) — Premarket notification (510(k))
- 21 U.S.C. § 360j(g) — Investigational Device Exemptions