# RIGHT TO TRY ACT — INVESTIGATIONAL INDIVIDUALIZED MEDICAL TREATMENTS (IIMT) AND NON-INVASIVE INVESTIGATIONAL DEVICE AMENDMENT

*Congressional Briefing Kit*

Roadmap & Strategic Plan • Messaging Sheet • Letter-of-Support Template

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# Section 1: Roadmap and Strategic Plan

## 1.1 Objective

Enact a narrow, bipartisan amendment to the federal Right to Try Act (21 U.S.C. 360bbb-0a, § 561B of the FD&C Act) to (a) authorize a parallel pathway for investigational individualized medical treatments (IIMTs)—which include drugs, biological products, and other advanced biological technologies—for patients with life-threatening conditions or severely debilitating illness, and (b) extend eligibility to certain non-invasive investigational medical devices—including AI/ML-enabled medical device software—so that eligible patients may access these technologies under the same statutory framework that currently applies only to eligible investigational drugs.

## 1.2 What the Statute Says Today

Section 561B of the FD&C Act currently authorizes eligible patients who have exhausted approved treatments to access certain eligible investigational drugs outside of clinical trials. The statute does not cover biological products, investigational individualized medical treatments, or medical devices of any kind. The proposed amendment would expand § 561B to encompass IIMTs (which include biological products) and non-invasive devices.

## 1.3Policy Rationale

- The 2018 Right to Try Act was a landmark patient-access law that authorizes eligible patients to access certain investigational drugs outside of clinical trials, but its scope is limited to eligible investigational drugs.
- The amendment clarifies that severely debilitating illness is in scope for IIMTs, addressing patients who are not strictly terminal but face profound morbidity—a population not reached by current § 561B, which applies only to life-threatening disease.
- Modern medicine increasingly relies on (i) genomics-driven individualized treatments (IIMTs)—including biological products and advanced biological technologies not covered by current law—and (ii) AI/ML-enabled medical device software that informs, prioritizes, or organizes therapeutic options without itself administering therapy.
- Excluding IIMTs (including biological products) leaves patients whose best option is a personalized therapy without the same access pathway as those seeking conventional investigational drugs.
- Excluding non-invasive devices creates an asymmetry: patients can access experimental drugs under Right to Try but not the software that helps clinicians choose which approved therapy to try. Because these non-invasive technologies do not introduce new hardware, implants, or surgery, and because they operate with a clinician in the loop, they

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present a risk profile comparable to—and in many cases lower than—the investigational drugs and biologics already covered by § 561B.
- The proposed amendment closes both gaps within a single vehicle, preserving all existing FDA oversight and adding targeted guardrails for each pathway.

## 1.4 Strategic Plan — Phased Approach

### *Phase I — Foundation and Stakeholder Alignment*

- Engage lead sponsors and original sponsors in House and Senate:
    - Senate: approach Sen. Ron Johnson (R-WI) and a Democrat or Independent partner who is active on innovation/cancer policy to replace former Sen. Donnelly. Consider members on HELP with oncology or digital health interest.
    - House: approach Reps. Andy Biggs (R-AZ) and Brian Fitzpatrick (R-PA) to reprise leadership; approach Rep. Mike Kelly (R-PA); recruit at least one Democratic original co-lead from Energy & Commerce (Health Subcommittee).
    - Map committees of jurisdiction: House Energy & Commerce (Health Subcommittee) and Senate HELP. Prepare member- and staff-level briefing decks; schedule Hill meetings.
- Secure letters of support from pediatric oncology physicians, patient advocacy organizations, and academic medical centers (see Section 3 template). Brief relevant trade associations and disease-focused coalitions; request neutral or supportive posture.
    - Scientific/Academic/Clinical validators: Society for Functional Precision Medicine; Dr. Anthony Letai (prominent cancer researcher) for a science-first perspective on urgency and feasibility; Leverage First Ascent's prospective and real-world evidence program as case examples of unmet need and patient benefit.
    - Patient advocacy: map and mobilize every group connected to First Ascent's network; secure named early supporters to feature in the sponsor press release.
    - Policy partners: engage the Goldwater Institute (RightToTry.org) for strategy counsel, state-law experience, and joint educational programming; align on device-specific facts and guardrails to avoid mixed messaging with drug-focused RTT narratives.
- FDA Engagement: Position the amendment as complementary to FDA's IDE, device expanded access, and CDS guidance. Request non-partisan technical input from:
    - HHS and FDA leadership (RFK, Jr. and Acting FDA director Kyle Diamantas)
    - CDRH leadership and the Digital Health Center of Excellence (listening session format) for informational dialogue; do not seek Agency endorsement.
    - OPP (Office of Policy) and OCL (Office of the Chief Counsel) for statutory construction and definitional hygiene (e.g., "non-invasive," "software as a device," relationship to § 520(o) non-device CDS).

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    - Offer to incorporate clarifying language the agency views as necessary for patient protections (e.g., IRB oversight acknowledgement, adverse event reporting pathway, no override of IDE where required). The goal is “no-objection technical assistance,” not overt endorsement.

### *Phase II — Introduction and Advancement*

- Introduction of standalone bill or inclusion as a rider in an appropriate FDA/user-fee or health vehicle.
    - Alternate if standalone not feasible: package into a bipartisan innovation, pediatric cancer, or AI-in-health title in a moving FDA or public health vehicle.
- Coordinate committee outreach, hearing witness identification, and Q&A preparation.
    - Committee Staff working sessions: House E&C Health; Senate HELP Health policy teams.
    - Goals: (i) confirm jurisdiction, (ii) secure informal review by Office of Legislative Counsel, (iii) align on neutral CBO exposure (access pathway should be budget-neutral).
- Track markup, floor activity, and conference, with rolling updates to coalition partners.

## 1.5 Key Messages (Preview)

- Narrow scope: the amendment covers only non-invasive investigational devices that have cleared early feasibility review and remain under IRB-approved investigation.
- Patient parity: closes an unintended gap that leaves device-dependent patients behind their drug-access peers.
- Preserves FDA authority: expressly does not displace or relax FDA oversight, IDE requirements, or expanded access pathways; non-preemption of stricter federal requirements is express.
- Clinician-in-the-loop: AI/ML-enabled medical device software in scope is informational; the treating clinician retains full therapeutic decision authority.

## 1.6 Risks and Mitigations

- Risk: concern that IIMT pathway lacks rigor. Mitigation: subsection (b) requires manufacturer compliance with all applicable Federal assurance laws, operation within an eligible health care facility, and patient meeting additional informed consent requirements.
- Risk: concern that the amendment expands access to hardware or implantable devices. Mitigation: the proposed statutory definition is limited to devices intended solely for non-invasive use and excludes any new or modified hardware component.

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- Risk: concern about AI/ML safety and autonomy. Mitigation: the in-scope software is limited to identification, prioritization, or management of individualized therapeutic options; clinician oversight is preserved; FDA pre-market frameworks are unchanged.
- Risk: preemption of state protections. Mitigation: non-preemption language preserves stricter state and federal requirements.

## 1.7 Metrics of Success

- Bipartisan lead sponsors identified in both chambers within 60 days.
- ≥ 10 letters of support from clinicians, patient organizations, and academic centers within 90 days.
- Committee hearing or markup within the current session.
- Introduction of technical-corrections package, if needed, prior to conference.

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# Section 2: One-Page Messaging Sheet

## Right to Try — IIMT's and Non-Invasive Devices Amendment

*Talking points for Hill meetings, coalition briefings, and press inquiries.*

### *The Ask*

Support a bipartisan amendment to the federal Right to Try Act to (1) authorize a new pathway for investigational individualized medical treatments (IIMTs)—which include drugs, biological products, and other advanced biological technologies—for patients with life-threatening conditions or severely debilitating illness, and (2) extend eligibility to certain non-invasive investigational medical devices—including AI/ML-enabled medical device software—while preserving FDA oversight in full.

### *Why It Matters*

- Patients with life-threatening or severely debilitating conditions who have exhausted approved options can currently obtain eligible investigational drugs under Right to Try but cannot obtain (a) personalized treatments incorporating biological products or advanced biological technologies tailored to their unique genomic profile, or (b) non-invasive AI/ML-enabled medical device software that could help clinicians tailor already-approved therapies.
- The merged amendment closes both gaps within a single, carefully scoped vehicle especially for patients whose best remaining option depends on AI/ML-enabled medical device software designed to inform, prioritize, or organize individualized treatment choices.

### *Core Messages*

- Two complementary narrow and targeted pathways, one vehicle: the IIMT pathway addresses personalized therapies (including biological products not currently covered); the device pathway addresses non-invasive AI/ML software with no new or modified hardware, no surgery, and no implantation.
- Same guardrails as today: eligible patients must meet the existing or expanded § 561B criteria; devices must have completed early feasibility review and remain under IRB-approved investigation; IIMTs must be provided in eligible health care facilities with additional informed consent.
- Clinician-in-the-loop: in-scope AI/ML-enabled medical device software supports, but does not replace, clinical judgment.
- FDA authority preserved: IDE, expanded access, PMA, 510(k), and all other FDA frameworks remain in force; the amendment does not preempt stricter federal or state requirements.

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- Bipartisan lineage: builds directly on the 2018 Right to Try Act and aligns with longstanding congressional interest in patient access and modern device pathways.

### *What the Amendment Does NOT Do*

- Does not authorize access to implantable, surgical, or hardware-based devices.
- Does not waive FDA review, Investigational Device Exemption (IDE) requirements, or expanded access.
- Does not create autonomous AI decision-making in clinical care.
- Does not preempt stricter federal, state, or institutional requirements.
- Does not waive Federal assurance requirements for IIMT providers.

### *Illustrative Use Case*

A pediatric patient with relapsed, refractory cancer has exhausted the standard of care. AI/ML-enabled medical device software, under an IRB-approved investigation and having completed early feasibility review, could help the treating oncologist prioritize among FDA-approved therapies based on the patient's own tumor biology. Today, the family can request an investigational drug under Right to Try but cannot request access to the software that would help choose which approved drug to try. The amendment fixes that asymmetry.

### *Contacts*

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## Section 3: Letter-of-Support Template

[Signer Letterhead]
[Date]

The Honorable [Name]
[Chamber and Committee, as applicable]

United States [Senate / House of Representatives]

Washington, DC [ZIP]

**Re: Support for the Right to Try Individualized Investigational Medical Treatments (IIMTs) and Non-Invasive Investigational Medical Devices Amendment**

Dear [Senator/Representative] [Last Name]:

On behalf of [organization / practice / institution], I write to express support for the proposed amendment to the federal Right to Try Act (21 U.S.C. 360bbb-0a). The current statute applies only to eligible investigational drugs. The proposed amendment would (1) authorize a new pathway for investigational individualized medical treatments (IIMTs)—which include drugs, biological products, and other advanced biological technologies—for patients with life-threatening conditions or severely debilitating illness, and (2) extend eligibility to certain non-invasive investigational medical devices, including AI/ML-enabled medical device software. The amendment also recognizes patients with severely debilitating illness—consistent with 21 C.F.R. § 312.81—so that access is not limited only to those with life-threatening disease.

[Organization] [describe mission in one sentence — e.g., advocates for pediatric cancer patients; treats adult patients with refractory solid tumors; represents academic medical centers working on individualized oncology]. In our experience, patients facing life-threatening or irreversibly debilitating conditions who have exhausted the standard of care frequently benefit from (a) personalized treatments incorporating biological products and advanced biological technologies informed by their unique genomic profile—not currently covered under Right to Try—and/or (b) tools that help clinicians prioritize among already-approved therapies based on the patient's own biology. These tools are increasingly embodied in non-invasive AI/ML-enabled medical device software that informs, but does not replace, the treating clinician's judgment.

The proposed amendment would close two unintended gaps in current law. Today, eligible patients can request only eligible investigational drugs under Right to Try—they cannot request investigational individualized treatments (including those incorporating biological products) tailored to their biology, or the non-invasive devices and software that can help their clinicians choose which approved therapy is most likely to work. The amendment:

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- Creates a new eligibility subsection for IIMTs—which include biological products and advanced biological technologies—requiring compliance with Federal assurance laws, operation within an eligible health care facility, and additional informed consent;
- Defines “eligible non-invasive medical device” narrowly—no new or modified hardware, no surgery, no implantation;
- Requires that covered devices have completed Phase I or equivalent early feasibility review and remain under IRB-approved investigation;
- Preserves FDA authority in full, including IDE, PMA, 510(k), and expanded access frameworks;
- Adds a guidance directive to ensure harmonization with IDE requirements under § 360j(g); and
- Does not preempt stricter federal, state, or institutional requirements.

For these reasons, [organization] respectfully urges you to support the amendment and to advance it through the committee of jurisdiction. We would welcome the opportunity to answer any questions or to provide additional clinical, scientific, or patient-perspective information.

Sincerely,

[Name]
[Title]

[Organization]

[Email] | [Phone]

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*Please return signed letters to: Jim Foote, CEO | jfoote@firstascentbio.com*

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