SENATE BILL 535 — RIGHT TO TRY, EXPANDED

The First U.S. Market for Post–Phase I Therapies

Montana is the only state where a biologic, drug, or device that has cleared Phase I safety trials can generate revenue at the bedside, years before full FDA approval. The implementing rules took effect July 25, 2026. A review board has approved its first protocol and the first center license applications are in — but as of this briefing, no center has been licensed.

1st
STATE IN THE NATION TO LICENSE POST–PHASE I TREATMENT

25
IMPLEMENTING RULES IN FORCE SINCE JULY 25, 2026

2%
OF NET ANNUAL PROFITS TO PATIENT ACCESS, PER STATUTE

0
CENTERS LICENSED TO DATE — THE FIELD IS STILL OPEN

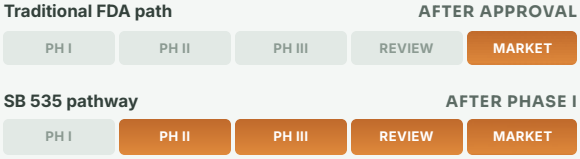
Why Montana, Why Now

Traditional U.S. drug development runs **10+ years and over a billion dollars** before a therapy reaches its first paying patient. SB 535 changes where in that sequence revenue can begin. Once a treatment has completed phase 1 and is not yet FDA-approved for general use — and either remains in an FDA-approved trial or carries a demonstrated safety record from a qualified medical institution — a licensed Montana **Experimental Treatment Center** can administer it to eligible, informed, cash-pay patients — creating early commercial revenue and real-world clinical experience while the FDA process continues.

- **Earlier revenue.** Convert part of the pre-approval burn window into revenue-generating clinical experience.
- **First-mover jurisdiction.** No other state offers this pathway, and the leading imitator has stalled — early entrants define the ecosystem.
- **GMP-ready infrastructure.** The planned Montana Innovation Corridor Gateway includes a manufacturing floor built for SB 535 firms.
- **Real safety guardrails.** Five-member conflict-free review boards, informed consent, and five-day adverse-event reporting keep the framework credible to patients, payers, and press.

When Patient Revenue Can Begin

Structural comparison — traditional FDA path vs. the SB 535 pathway



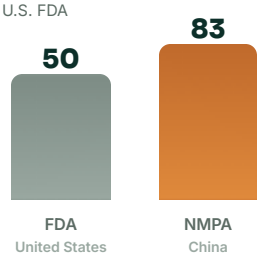
Copper marks the period in which patient revenue is possible. Structural comparison only — it does not imply a specific time or cost saving, which depend entirely on the individual program, its indication, and demand. Development-cost and timeline figures above reflect published Tufts CSDD-lineage estimates.

The Competitive Stakes

Regulatory speed has become a competitiveness issue. **China's NMPA approved 83 new drugs in 2024 to the FDA's 50**, and China's share of **new commercial clinical trials** climbed from 8% in 2013 to **30% in 2024**, just behind the United States at 35%. Economist Alex Tabarrok has called SB 535 **"the most important regulatory innovation in drug approval in my lifetime."** Montana's bet is that regulatory design — not just R&D spend — is where American biotech competitiveness is won back.

New Drug Approvals, 2024

China's regulator vs. the U.S. FDA



Not a like-for-like measure: NMPA's 83 includes imported drugs already approved elsewhere; FDA's 50 counts novel CDER approvals. Trial-share figures: IQVIA Institute, Global Trends in R&D 2025.

IMPLEMENTATION

From Statute to Operating Framework

How the Framework Was Built

May 12 2025 — **SB 535 signed into law, effective on passage**
Ch. 621, 69th Legislature. Montana becomes the first state to authorize licensed experimental treatment centers for post–Phase I therapies. Senate 39–9; House 49–48 on reconsideration.

Apr 10 – May 8 2026 — **Draft rules published, heard and commented on**
DPHHS proposes 25 new rules (MAR Notice 2026-427.1). Public hearing April 30; written comment closed May 8.

Jul 25 2026 — **Final rules adopted and in force**
MAR Notice 2026-427.2 (Montana Administrative Register, Issue 14, July 24, 2026) adopts ARM 37.106.3301–3325 effective July 25 — 12 rules as proposed, **13 modified**.

Jul 25 2026 — **First private review board announced**
The Montana Experimental Treatment Review Board — operated by Montana Governance Services Inc., a subsidiary of Infinita, and expressly not a state body — begins accepting treatment applications at a $12,500 review fee.

Aug 26 2026 — **First protocol approved, with conditions**
The ETRB unanimously approves Parley Neurotech's hearing-loss combination therapy (Review Decision Letter RDL-2026-001). The approval takes effect only at centers that designate the board, and only once its conditions are confirmed met.

Sep 2026 — **First center license applications reported**
DPHHS's statutory report confirms no center licensed as of September 1. The department tells national press that two license applications are pending.

Open → — **First DPHHS center license · NEXT**
No license has been announced as of November 19, 2026, and no patient has been treated. The application pathway is live: $10,000 application fee, $5,000 annual renewal.

What a Licensed Center Must Have

Governance

- Administrator overseeing daily operations, staff orientation and training, credentialing, and licensure compliance; may serve multiple commonly-owned centers
- Medical Director holding a **current license in good standing with the Montana Board of Medical Examiners**; serves as safety officer
- **Changed at adoption:** the three-year internal-medicine residency and one-year Montana-licensure tenure requirements were struck — relevant specialty licensure now qualifies
- Full disclosure of prior facility and staff safety history

Review Board

- **Changed at adoption:** minimum raised from four to **five members**, to prevent deadlock
- Must include a Montana-licensed physician, a researcher with clinical outcome data expertise, and an ethicist
- No personal, financial, employment, or ownership interest in the center reviewed
- Meets at least monthly; approves every protocol; publishes an annual public report including **aggregate treatment outcome data**

Patient Safeguards

- Written consent detailing treatment, trial phase and all costs, plus the full text of **50-12-110, MCA (immunity from suit)** and the center's grievance policy
- **Changed at adoption:** documentation that the patient **evaluated** other FDA-approved options — "attempted" was deliberately removed
- **Changed at adoption:** history and physical within **30 days** of treatment initiation, not 12 months, plus pre-treatment screening
- Serious adverse events reported to the department **and** the review board within five days; hospital transfer agreement required

Licensure & Reporting

- $10,000 license application; $5,000 annual renewal (SB 535 §1)
- **Changed at adoption:** annual quality and adverse-event report due **February 1**, not January 31, via the electronic licensing system; late filing may reduce the license to provisional
- Inpatient defined as admitted to or residing at the facility **24 hours or more** — this determines inpatient vs. outpatient licensure
- Off-site administration permitted where the review board finds the treatment **safe for delivery outside the center**, with rural access expressly considered

⚑ **Thirteen of the twenty-five rules changed between proposal and adoption.** Any diligence memo, vendor pitch, or legal summary built on the April 2026 draft — including several published client alerts — is now out of date on medical-director qualifications, board size, the alternatives standard, the history-and-physical window, and the reporting deadline.

DILIGENCE

Where Things Stand, and What Is Unresolved

Status as of November 19, 2026

- [x] **Law in force; rules in force.** SB 535 effective May 12, 2025; ARM 37.106.3301–3325 effective July 25, 2026. We are not aware of litigation challenging either.
- [x] **One protocol approved, with conditions.** On August 26 the ETRB approved Parley Neurotech's hearing-loss combination therapy (RDL-2026-001). It is usable only at a licensed center that designates the board, once the board confirms its conditions are met. No decision has been announced on WinSanTor's peripheral-neuropathy application. Montana's rules set no fixed review timeline.
- [ ] **Zero centers licensed; two applications reported.** DPHHS's statutory report confirmed no licensed center as of September 1, and none has been announced since. The department told Politico and Business Insider in September that two license applications were pending. It publishes no applicant names.
- [ ] **Zero patients treated.** An approved protocol cannot be delivered until a licensed center exists.
- [x] **First-mover position is holding.** New Hampshire HB 1734, the leading copycat, was amended down to a study committee and died in conference on May 21, 2026. No other state has enacted a comparable law.

Open Risks a Diligence Process Will Raise

FEDERAL PREEMPTION	**Unresolved, and no safe harbor exists.** The FDA has taken no public position on Montana's framework — as a matter of policy it does not comment on state legislation. Goodwin Procter (August 4, 2026) frames the live questions as whether FDA could exercise enforcement authority over uses authorized under Montana law, and to what extent federal law preempts the state framework; it offers no answer. Analysts including Chris Robertson (Boston University) note that informal federal forbearance could reverse with a change of administration.
NO LICENSEE PRECEDENT	**Nobody has completed the process yet.** Two applications are in review, but DPHHS review timelines, inspection posture, and the practical bar for board composition and transfer agreements are all untested. First movers absorb that uncertainty; they also set the template.
THE 2% MECHANISM	**Statutory, not regulatory — and undefined.** SB 535 §2 requires a center to allocate 2% of net annual profits to support access to experimental treatments and health care. DPHHS declined to define or implement this in the licensing rules, treating it as outside the scope of rulemaking. Collection, calculation, and enforcement mechanics remain open. DPHHS reports annually by September 1; its first report showed no account activity.
REPUTATIONAL CONCENTRATION	**The loudest advocates are a narrow group.** The only operating review board is run by an Infinita subsidiary and funded by $12,500 applicant fees — a structure critics have flagged as a conflict. National coverage in Politico, Business Insider, MIT Technology Review and Science-Based Medicine has been skeptical, centering on profit from unproven drugs, unregulated pricing and who wrote the law. Serious institutional capital will ask how the Alliance is differentiated from that ecosystem.
CLINICAL & PRICING	**Phase I clears safety in a narrow sense only.** Harvard's Aaron Kesselheim notes roughly one in six drugs that pass Phase I later surface safety problems. Prices are unregulated and insurance coverage is not established, which puts demand, reimbursement, and adverse-event exposure squarely in the underwriting question.

The Economic Thesis for Montana

SB 535 gives Montana something no other state can currently offer: a lawful point at which a clinical-stage asset can begin earning. Paired with GMP-ready manufacturing, a defined licensing path now actually in force, and a statutory tie between commercial success and rural health access, it makes the state a distinctive home for clinical-stage companies. The framework is built; the operating precedent is not. That gap is the opportunity and the risk in the same sentence.

> *"Montana's SB535, signed into law in May 2025, is the most important regulatory innovation in drug approval in my lifetime."*
>
> ALEX TABARROK · MARGINAL REVOLUTION, JUNE 16, 2026

Prepared by the Montana BioScience Alliance for informational purposes. Current as of November 19, 2026. Summarizes SB 535 (2025, Ch. 621) and the implementing rules ARM 37.106.3301–3325 as adopted by MAR Notice 2026-427.2, effective July 25, 2026. Primary sources: the DPHHS notices of proposal and adoption; the DPHHS SB 535 annual report of September 1, 2026; Montana ETRB Review Decision Letter RDL-2026-001; IQVIA Institute Global Trends in R&D 2025; DIA Global Forum on 2024 NMPA approvals; Goodwin Procter, August 4, 2026. This briefing does not constitute legal, investment, or medical advice, nor an endorsement of any treatment, company, or provider. Experimental treatments under SB 535 are cash-pay and are not FDA-approved. No Experimental Treatment Center has been licensed and no patient has been treated under this law as of this printing; nothing here should be read as a representation that operating capacity exists today. Development-cost and revenue-timing comparisons are structural and illustrative, not forecasts. Verify current requirements with DPHHS and qualified counsel before acting.