MONTANA BIOSCIENCE ALLIANCE
GROWTH · INNOVATION · ACCESS

INVESTOR BRIEFING · AUGUST 2026

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. The licensing window is open — and as of this briefing, no one has walked through it yet.

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

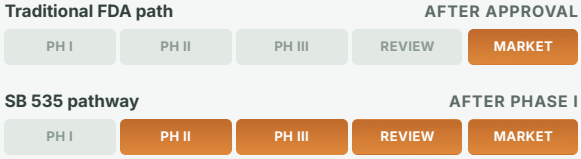
Why Montana, Why Now

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



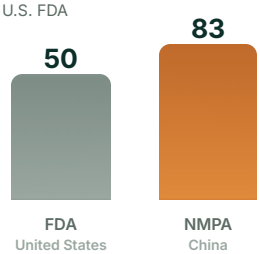
Copper marks the period in which patient revenue is possible. Structural comparison only — it does not imply a specific time or cost saving, which depend entirely on the individual program, its indication, and demand. Development-cost and timeline figures above reflect published Tufts CSDD-lineage estimates.

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 2026 — **Draft rules published**
DPHHS proposes 25 new rules (MAR Notice 2026-427.1) covering licensing and operating requirements for centers.

Apr 30 – May 8 2026 — **Hearing held, comment period closed**
Public hearing April 30; written comment closed May 8. Stakeholders testified on the licensing and safety framework.

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. Two received; none approved.

Open → — **First DPHHS center license · NEXT**
No Experimental Treatment Center has been licensed as of August 21, 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 August 21, 2026

- ✓ **Law in force; rules in force.** SB 535 effective May 12, 2025; ARM 37.106.3301–3325 effective July 25, 2026. No litigation challenging either has been filed.
- • **Zero centers licensed.** DPHHS has issued no Experimental Treatment Center license and has published no licensee roster or applicant count.
- • **Zero patients treated.** Clinics were described in July 2026 national coverage as outfitting treatment rooms and hiring medical directors, with treatment expected "in the coming months."
- • **Zero protocols approved.** The ETRB has received two treatment applications — a peripheral-neuropathy therapy from WinSanTor and an unnamed hearing-loss therapy — and has approved neither. Montana's rules set no fixed review timeline.
- ✓ **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 comparable bill has advanced elsewhere.

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 run the process yet.** Application mechanics, 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 expressly declined to implement this in the licensing rules (responses to comments 54–57), treating it as outside the scope of rulemaking. Collection, calculation, and enforcement mechanics remain open. DPHHS reports annually by September 1 on use of the funds.
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 MIT Technology Review and Science-Based Medicine has been skeptical, centering on profit from unproven drugs and unregulated pricing. 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 August 21, 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; 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.