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TURNING POLICY INTO STRATEGY: HOW ONE BIG BEAUTIFUL BILL ACT (H.R.1) CAN RESHAPE THE FUTURE OF BIOTECH

Abstract: The 2025 U.S. House Bill H.R.1 introduces sweeping reforms that go beyond tax restructuring—they signal a fundamental shift in how biotech companies must think about innovation, compliance, and strategic growth. This report decodes the most biotech-relevant provisions of H.R.1, including R&D tax relief, orphan drug pricing, telehealth policy, AI funding, agri-biotech grants, and workforce development. Drawing from expert commentary and economic impact estimates, the analysis reframes each policy lever into an actionable strategy. Whether you're leading a startup or steering a large diagnostics firm, this guide helps translate complex legislation into clear opportunities—and cautions—so you can align early and lead with confidence in a fast-changing regulatory landscape.

This summary is for informational purposes only and does not constitute tax, legal, or financial advice. For guidance specific to your situation, consult a licensed professional.

In 2025, the passage of H.R.1 triggered ripple effects across the U.S. healthcare and biotech ecosystem. Designed to reshape tax codes, streamline government programs, and reorient funding priorities, the bill offers both opportunities and hidden minefields for biotech firms. This guide decodes the implications of key H.R.1 sections and reframes them as actionable insights.

Section: USDA research funding and agri-biotech collaboration

The bill allocates increased support to agricultural research programs under USDA, which could unlock more funding opportunities for biotechnology companies working in crop science, genetic editing, and sustainable agriculture. Although this section isn't headline-grabbing, it's still a key enabler for long-term scientific progress.

- Funding may support bioengineering innovations related to drought resistance or pest tolerance.
- The impact is indirect but meaningful, especially for companies plugged into USDA grant mechanisms.
- Competitive pressure for grants may limit access for smaller firms without academic partners.
- The timeline begins in 2025 and follows USDA's budget allocation cycles.

Recommended actions:

- Biotech firms should monitor USDA's NIFA and AFRI programs.
- Form partnerships with agricultural universities or USDA-affiliated research labs.
- Target projects aligned with federal sustainability and climate-smart agriculture priorities.

Section: DOE investment in AI models with biotech potential

The inclusion of "transformational AI models" within DOE funding priorities focuses primarily on energy but could spill over into biotech—especially where large-scale modeling applies to genomics or protein folding.

- Al-heavy biotech firms could benefit by repurposing infrastructure or tools developed under this program.
- The actual biotech impact will depend on inter-agency collaboration between DOE and HHS/NIH.
- The funding period is expected from 2025 to 2028.

Recommended actions:

- Follow DOE announcements and watch for opportunities to propose AI collaborations.
- Engage with OSTP or NSF AI working groups to anticipate future crossover funding.
- Build internal capacity for large model deployment relevant to molecular biology or drug design.

Section: Full expensing of R&D activities

This provision reverses the previously mandated amortization of R&D expenditures and allows companies to fully deduct qualified R&D in the same year it occurs. This is a direct financial win for biotech firms investing in innovation.

Short-term cash flow improvement for both startups and established players.

- Long-term boost to overall R&D investment and investor confidence.
- Critics argue it may raise the fiscal deficit and favor larger firms with more R&D spending.

Recommended actions:

- Rework financial planning to incorporate tax savings.
- Consult with tax counsel to understand eligibility and documentation standards.
- Use savings to accelerate pipeline progress or extend runway.

Section: Orphan drug pricing clarification under Medicare

The bill clarifies which orphan drugs are exempt from price negotiations under Medicare, a point of contention since the IRA passed. It narrows the exemption to single-indication orphan drugs.

- This could discourage development of multi-indication orphan drugs.
- Innovators in rare disease biotech may find diminished pricing power under Medicare.
- Some critics argue this helps curb overuse of the orphan drug designation.
- CMS will implement the pricing rule changes beginning in 2026.

Recommended actions:

- Conduct a portfolio review of orphan-designated assets.
- Update market modeling to reflect potential pricing changes.
- Engage with BIO and other coalitions to influence CMS implementation.

Section: Telehealth safe harbor extension

The bill makes permanent a pandemic-era provision allowing high-deductible health plans (HDHPs) to cover telehealth services without patients first meeting deductibles. This affects diagnostics and digital health tools.

- Supports continued growth in direct-to-consumer (DTC) diagnostic platforms.
- Reinforces virtual care as a core channel for chronic disease management.
- The policy becomes permanent starting in 2025.

Recommended actions:

- Integrate diagnostic solutions with virtual care delivery.
- Monitor payer reimbursement policies to align product offerings.
- Ensure digital tools meet data privacy and HIPAA standards.

Section: Expansion of workforce Pell Grants

The bill expands Pell Grant eligibility to cover job training programs, including those tied to biotechnology manufacturing and lab skills.

- Enhances talent availability for growing biomanufacturing sectors.
- Could reduce onboarding and training costs for biotech employers.
- Schools must be certified; biotech firms must coordinate with accredited institutions.
- Implementation will begin with FY2026 budgets.

Recommended actions:

- Partner with local colleges to help design eligible training programs.
- Offer internships or co-ops linked to Pell-funded certifications.
- Engage workforce development boards to secure funding alignment.

Final Thoughts

H.R.1 isn't just tax reform—it's a strategic signal. While some provisions carry risk or ambiguity, smart biotech firms can turn these shifts into growth vectors. Like in <u>Bio Medix's story</u>, success often hinges on early collaboration across departments—from R&D and finance to policy and marketing.

The bridge from policy to strategy is there. It just takes someone to build it.

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Our Team at Biotech Bridge Media

Biotech Bridge Media offers a **comprehensive service package** by integrating business consulting, regulatory, and quality management expertise. In collaboration with **Dr. Srilekha Deka (Script Molecular) and Dr. Jaspreet Seth, QuRA Solutions**, we provide end-to-end solutions, including new product development, regulatory compliance, quality management, and market strategy. Whether you're navigating FDA regulations, implementing ISO standards, or launching a new diagnostic assay, our combined team ensures seamless integration of business, regulatory, and quality frameworks.

Krishnan Allampallam, PhD, MBA, Founder/Owner Biotech Bridge Media,

I started BBM with the goal of helping very busy leaders with ad-hoc small projects they want to do but don't have the resources nor do they have the time to coach a new member. With 25+ years of experience in the biotech industry with a strong technical and business background, I can start on day one running. I can help with the following strategic product management, market research in biotechnology, pharma market space, content development for multi-channel digital marketing branding, product launch planning and execution, sale enablement, sales collaterals, training, technical training

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Srileka, MD, PhD, Chief Scientific Officer at Script Molecular, Regulatory Consultant Srileka, an experienced healthcare executive and a highly skilled scientist with two decades of experience in the biotechnology and molecular device industry. Having worked with small start-ups as well as large companies like Roche, Srilekha has multiple successful submissions to FDA [510(k)] and other regulatory agencies. She led the teams through successful ISO13485 certification and rapid launch of RUO assays. With a rich background of clinical medicine and scientific research, she is enthusiastic about leveraging her knowledge for advancement of diagnostics for improved treatment and disease outcomes in patients.

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Jaspreet, a dynamic professional with proven experience (20 yrs) in Quality Systems Regulations, Clinical Research Compliance, College of American Pathologists (CAP) accreditation, Good Clinical Laboratory Practices (GCLP), Quality Assurance, Quality Control, assay and process validations, and customer support experience.

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