

# US Medicine Pricing Policy Changes: Impact on the Full Biopharmaceutical Investment Ecosystem

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## Background

- The US is undergoing its most significant pharmaceutical pricing reform in decades. The Inflation Reduction Act (IRA, 2022) introduced Medicare drug price negotiation for the first time. More recently, proposed Most Favoured Nation (MFN) pricing policies - GENEROUS (Medicaid), GLOBE and GUARD (Medicare Parts B and D) — would link US prices to international reference prices, potentially compressing revenues further.
- The US is the world's largest pharmaceutical market and a principal engine of global R&D investment. Revenue reductions risk unintended consequences for innovation, but assessing those consequences requires an accurate understanding of how the biopharmaceutical investment ecosystem actually works and how investors respond to policy signals.
- That understanding is currently limited.** Existing policy impact models (e.g., that developed by the Congressional Budget Office, CBO) rely on simplified assumptions about investment decision-making that may not reflect the diversity and complexity of the real ecosystem.

## Aim

To characterise the biopharmaceutical investment ecosystem across its full range of stakeholders, and to assess how US pricing policies, including the IRA and proposed MFN policies, would influence investment decisions in practice.

## Methods

- A **targeted literature review** mapped the innovation ecosystem across R&D stages, investor types, and partnership dynamics (2019-2024 pipeline and approval data from Citeline PharmaProjects; funding data from PitchBook).
- Semi-structured interviews** were conducted with 19 investors (June-August 2024): 7 venture capital (VC) investors; 3 corporate venture capital (CVC) investors; 2 private equity (PE) investors; 4 small biopharmaceutical companies; 3 large biopharmaceutical companies.

Interviews were recorded, transcribed, and thematically coded across six domains: ecosystem characterisation; investment type; risk and capital mobility; decision-making; R&D costs; and IRA impact. Findings were organised against the four key assumptions of the CBO model.

## Results (1)



### The ecosystem is diverse, complex, and collaborative

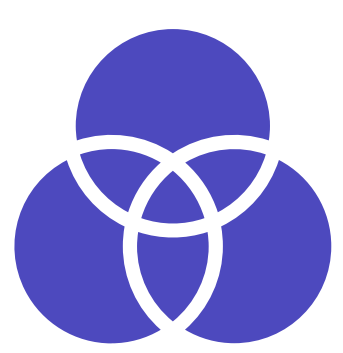
Early-stage R&D is driven by small companies and start-ups supported by VC. Most assets (~70%) are developed and launched through partnerships. Financial investors make company-level, portfolio-based decisions. A single homogeneous "firm" cannot represent this landscape.

### Risk tolerance and decision-making vary widely across investor types

Early-stage VCs accept high technical risk and diversify broadly; late-stage VCs navigate manufacturing and market access challenges. Small companies plan for early exits; large companies prioritise avoiding late-stage failures. Rising R&D costs affect firms unequally and these differences matter for how policy shocks propagate through the ecosystem.



### Investment decisions are multi-dimensional: revenue is necessary but not sufficient



Investors require ROI thresholds of 3x or more, not simply a positive return. Strategic fit, unmet need, therapeutic area, asset type, and regulatory landscape all shape decisions. This means the innovation impact of revenue-reducing policies may be larger than simple financial models suggest.

### The number of newly approved drugs is an inadequate measure of innovation

First approvals miss two critical dimensions. Indication expansions - around 65% of oncology approvals - are a major source of treatment advances yet invisible to models counting only novel drugs; post-approval R&D may be hard hit by revenue-reducing policies, but this is not captured. Second, drugs are not equal in health impact: without accounting for the type and value of drugs likely to be lost, it is impossible to identify which patients bear the greatest burden, or whether approval counts are even a meaningful proxy for what policymakers should care about.



## Results (2)

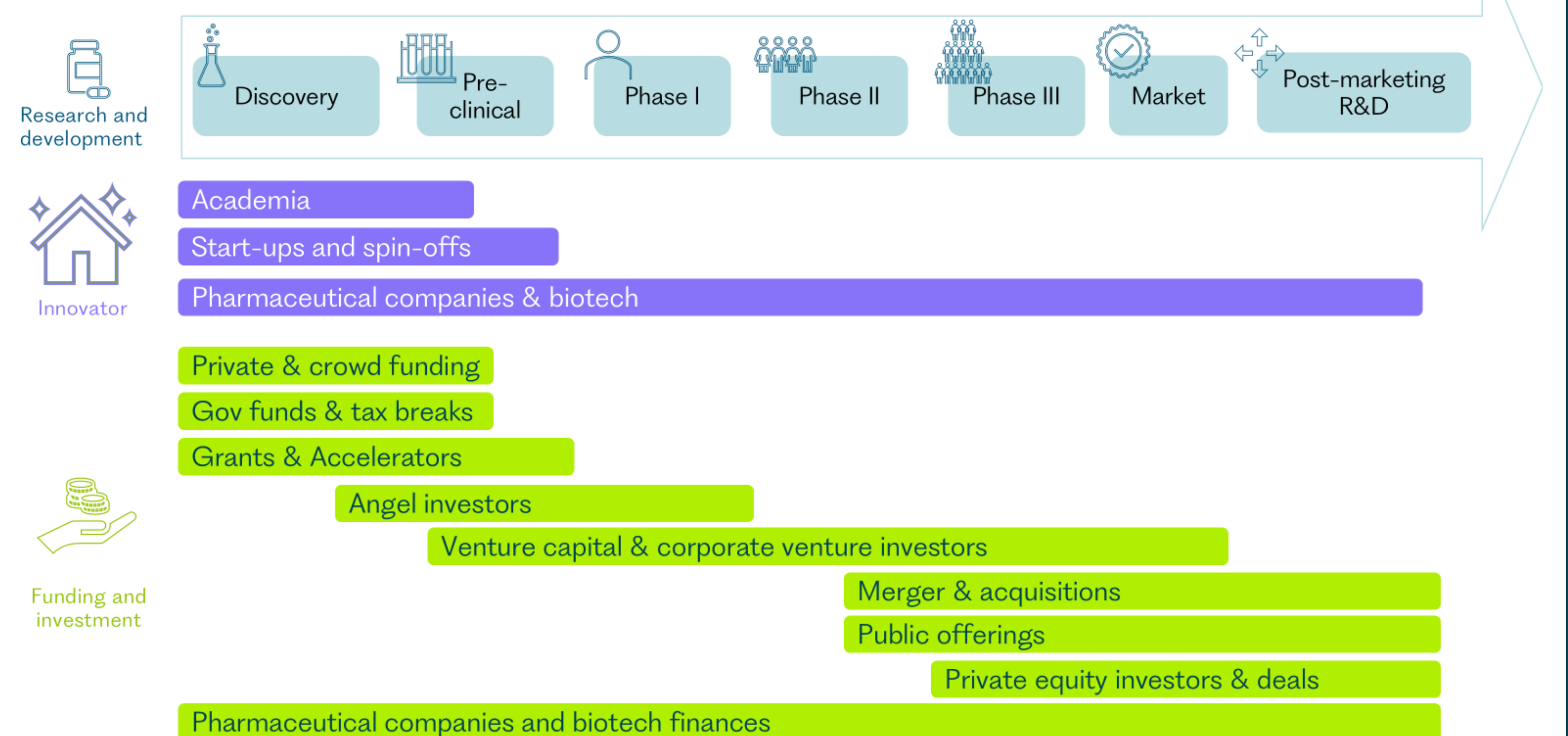


Figure 1. A graphical representation of the innovation investment ecosystem

## Discussion & Conclusion

- The biopharmaceutical investment ecosystem is substantially more complex than is typically assumed in policy impact assessments.
- It comprises diverse actors, including VCs, CVCs, private equity, small and large biopharma, each with distinct risk profiles, investment horizons, and responses to pricing policy.
- The IRA has already changed investor behaviour. Post-approval clinical trials for small molecules fell 47% and early-stage VC investment in small molecules dropped 70%. Furthermore, effects are not uniform; investment is being steered away from orphan indications, indication extensions, and Medicare-relevant therapeutic areas.
- MFN pricing could compress revenues further, with consequences that current policy models are ill-equipped to predict.
- Policy models, including those used by the CBO, should be strengthened to reflect the full ecosystem, capture post-approval R&D impacts, and measure innovation in terms of health benefit rather than drug counts alone.

Read the journal article

