



Effect of the Inflation Reduction Act on Drug Innovation

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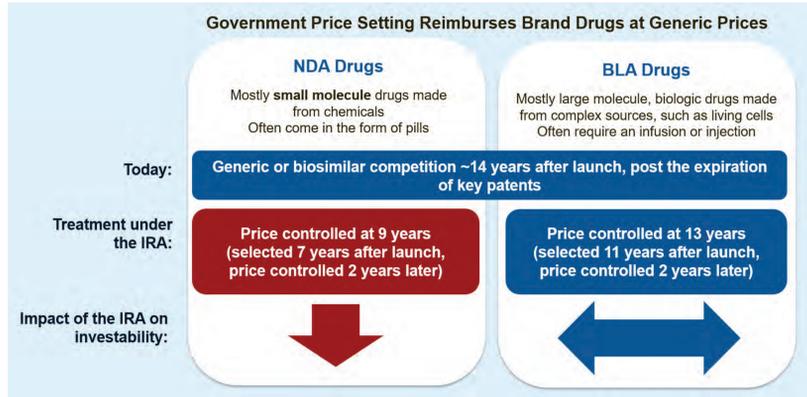
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BACKGROUND

The Inflation Reduction Act (IRA) introduced US drug price controls, granting the Centers for Medicare & Medicaid Services (CMS) authority to negotiate and set prices for selected high-expenditure drugs covered by Medicare.¹ The IRA differentiates between small-molecule drugs, which require a New Drug Application (NDA), and biologic (large-molecule) drugs, which require a Biological License Application (BLA). For small molecules, the IRA allows 9 years of market pricing before price controls apply in contrast, to the 13 years for biologics.² This distinction has raised concerns about its impact on pharmaceutical research and development (R&D) and market dynamics, particularly for small-molecule innovation (Figure 1).³

Figure 1. The IRA Introduces Government Price Setting for NDA (mostly small molecule) Drugs 9 Years After Launch vs 13 Years for BLA Drugs



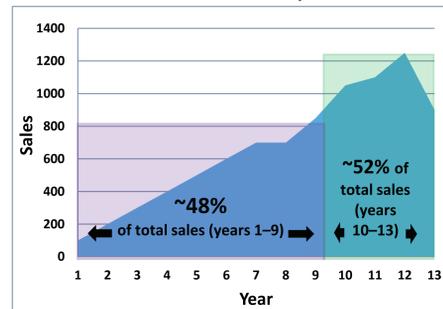
BLA: biological license application; IRA: inflation reduction act; NDA: new drug application

Studies and industry forecasts suggest that the shorter exclusivity window for small molecules may discourage investment in their development, as the expected period for recouping R&D expenditures is truncated vs biologics (Figure 2).⁴

An industry policy analysis predicted that the number of new small-molecule drug launches could decline by up to 20% in the coming decades; venture capital investment in small-molecule startups has shown a downward trend since late 2022, while biologics have attracted increased capital flows.

Although the IRA aims to expand patient access by reducing drug costs, there is concern that dampened small-molecule innovation could delay or limit access to novel therapies, especially in cardiovascular and infectious diseases, which rely heavily on small-molecule treatments.

Figure 2. Small Molecule Drug Sales Within First 13 Years of Launch (launched in 2007)



OBJECTIVES

We assessed the effects of the IRA's differential market exclusivity periods on drug innovation, focusing on small-molecule drug development, investment trends, and patient access to new therapies.

METHODS

A policy analysis was conducted using recent investment data, US Food and Drug Administration (FDA) drug approval statistics, and industry surveys, including trends in venture capital funding, pharmaceutical company R&D strategies, and case studies of pipeline changes since IRA enactment. Broader implications for patient care and market competition were also examined.

The READ method – Ready materials, Extract data, Analyze data, Distill findings – was applied to interpret policy documents, corporate statements, and public data, allowing for systematic extraction of actionable information from diverse sources.

Case study comparisons illuminated changes in R&D priorities, pipeline strategies, and investment flows since the IRA's enactment, carefully identifying units of analysis and connecting inputs to outcomes.

A stakeholder survey analysis was also conducted to incorporate industry and investor perceptions of incentives, strategic shift, and market expectations.

The broader context assessment evaluated secondary impacts on patient access, competition, and market structure by synthesizing professional commentary and economic forecasts.

RESULTS

A policy analysis of the IRA reveals distinct and measurable impacts on pharmaceutical investment, drug pipelines, R&D strategies, and broader market access, with especially pronounced effects in the small-molecule drug space compared to biologics.

Since the introduction of IRA-related legislation, funding for small-molecule drug development has declined by 70%. Pharmaceutical companies and investors have increasingly shifted focus toward biologic development, with three-quarters of surveyed venture capital firms planning to divest from small-molecule projects, leading to the cancellation or delay of early-stage small-molecule programs, especially in oncology and rare diseases.

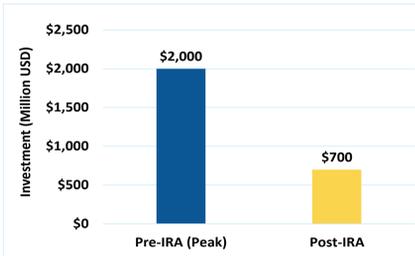
Small-molecule drugs, which account for most FDA approvals and prescriptions, are at risk of reduced innovation and diminished post-approval research, potentially limiting treatment options for underserved and elderly populations.

RESULTS

Since the introduction of IRA-related legislation, aggregate venture capital investments in small molecules declined 68% from \$2 billion to \$640 million post-IRA (Figure 3).

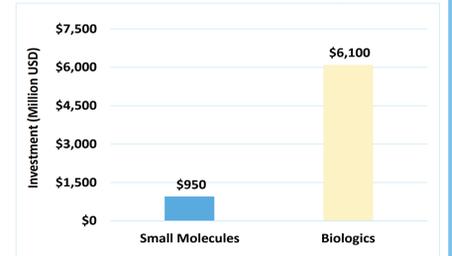
By contrast, investments in large molecules in 2024 were 10 times greater than those in small molecules (Figure 4).

Figure 3. Venture Capital Investment in Small Molecules – Pre- vs Post-IRA



IRA: inflation reduction act; USD: United States dollar

Figure 4. 2024 Venture Capital Investment in Small Molecules vs Biologics



USD: United States dollar

Additionally, 77% of surveyed investors believe the IRA's "pill penalty" disincentivizes small-molecule research (Table 1).

Table 1. Drug Pipeline and Investment Trends Post-IRA

Area	Trend/Change	Statistic
Small molecule VC funding	Down 68%	\$2B → \$640M
Biologic molecule funding	Stable/increased	10x greater
Investor concern ("pill penalty")	High (77%)	
Industry-funded post-approval trials	Down 38.4%	
Altered R&D/launch plans	Very high (87%)	
Early-stage VC rounds	No drop (trend)	

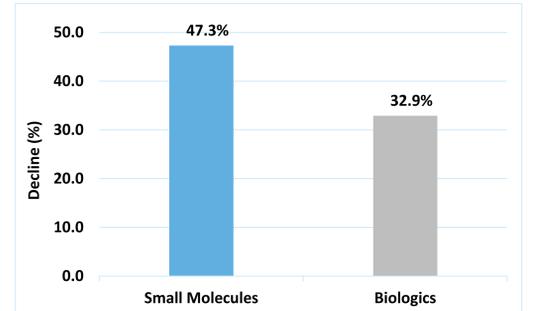
IRA: inflation reduction act; VC: venture capital

FDA Drug Approval and R&D Pipeline Changes

Industry-sponsored post-approval trials decreased by 38.4% on average after the IRA, including a -47.3% decline among small molecules and -32.9% for biologics (Figure 5).

For oncology, post-approval trials for small molecules fell disproportionately compared to biologics; models show a significant, sharper reduction for small-molecule clinical trials after IRA's passage (Table 2).

Figure 5. Decline in Post-Approval Trials Post-IRA



IRA: inflation reduction act

Since IRA, 87% of pharma executives report altering launch plans and prioritizing diseases with larger target populations or pan-indication potential (Table 2). Companies are shifting focus away from indication heavily reliant on Medicare reimbursement.

Patient Access and Market Competition

Reduced investment in small-molecule R&D may particularly affect elderly, cancer, and chronic disease populations who benefit from rapid innovation in oral or simple therapeutics.

The out-of-pocket cap for Part D patients is set at \$2,000/year, which may improve immediate patient affordability but also risks narrowing available treatments due to pipeline contraction.

Payer strategies have shifted, with increasing formulary restrictions and more rigid coverage controls in key therapeutic categories (Table 2).

Table 2. Post-IRA Investment and Innovation Impact: Small Molecules vs Biologics

Metric	Small Molecules	Biologics
Venture capital change post-IRA	-68% (\$2B to \$640M)	Up 10x vs small
Industry-sponsored post-approval trial drop	-47.30%	-32.90%
Investor belief IRA penalizes small molecules	77%	n/a
Executives reporting R&D/launch adjustment	87%	n/a
FDA post-approval oncology trial reduction	Sharper decline	Less affected
2025 VC deals > \$20M (trend)	Up/stable	Higher than small

FDA: food and drug administration; IRA: inflation reduction act; VC: venture capital

CONCLUSION

The IRA's shorter exclusivity period for small-molecule drugs undermines incentives for their development, resulting in reduced investment, fewer new therapies, and diminished competition. The policy may inadvertently restrict patient access to affordable and innovative treatments. Legislative remedies, such as equalizing exclusivity periods for small-molecule drugs through the Ensuring Pathways to Innovative Cures (EPIC) Act (March 2025), are needed to restore balance and sustain drug innovation across all therapeutic modalities.

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