

MARCH-IN RIGHTS FRAMEWORK EXPANSION THREATENS AMERICA'S LEADERSHIP IN MEDICAL INNOVATION



Developing New Medications is Risky and Costly

Drug development is one of the riskiest industries for investments.

Only **1 OUT OF EVERY 10 DRUGS** that makes it into clinical trials is approved by the FDA.¹

Developing new medications is a costly investment — at over **\$2 BILLION.**^{2,3}

Government Interest Has a Modest but Minor Contribution to Product Approvals and Public Health

Only **8%** of all products approved in the past decade were associated with public funding.⁴

Federal funding — most commonly used for basic research— can lead to patents contributing to future products. But no medication has gained FDA approval without significant private-sector investment— to the tune of \$67 invested by the private sector for every \$1 from public funds.⁵

The public sector contributes important discoveries, but legally controlling patents (e.g., every patent is subject to Bayh-Dole) account for only 1% of all products approved by the FDA.⁵

The Proposed Change is Based on a Faulty Premise that Ignores Market Competition in the U.S.

MORE THAN 92% of all prescriptions filled in the United States are generic medications and saved the U.S. healthcare system **\$408 BILLION** in 2022.^{6,7}

The growing biosimilar market has saved over **\$7 BILLION** for the U.S. health care system and is projected to save **\$180 BILLION** in the next five years.^{8,9}

New treatments, on average, have less than a year on the market before therapeutic alternatives are available and market-based competition for preferred formulary tiering and rebates create competition among these innovations.¹⁰



External Factors Distort Patient Accessibility and Out-of-Pocket Costs

For every **\$1** spent on medications, **\$0.50 GOES TO ORGANIZATIONS** that do not invest in research. Payers, middlemen, and others in the supply chain are profiting without investments to develop these medications.¹¹

Insurance-based costs due to deductibles, copays, and co-insurance distort the cost of medications for patients.

Copayments for 28% of patients cost more than the total cost of their medication.¹²

Maintaining an Ecosystem that Supports Research and Development Benefits Patients, Universities, and Economics

The biopharmaceutical sector serves as a bedrock of innovative jobs by supporting more than **4.4 MILLION** American jobs and directly providing at least **900,00 HIGH-PAYING JOBS.**¹³

Overriding existing patent laws for even 10% of all medications would have a material impact on the US GDP (↓0.2%), consumer benefits (↓\$152.3 billion), and 445,00 fewer jobs over 30 years.¹⁴

Chipping away at the research ecosystem would affect industry but also universities, communities, and the economies that they support.



¹BIO. Clinical Development Success Rates and Contributing Factors 2011-2020. Available at: <https://www.bio.org/clinical-development-success-rates-and-contributing-factors-2011-2020>

²Tufts Center for the Study of Drug Development. Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. November 18, 2014. Available at: https://f.hubspotusercontent10.net/hubfs/9468915/TuftsCSDD_June2021/pdf/cost_study_background.pdf.

³Deloitte. Seize the Digital Momentum. Measuring the Return from Pharmaceutical Innovation. January 2023. Available at: <https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-seize-digital-momentum-rd-roi-2022.pdf>

⁴Schulthess D, Bowen HP, Popovian R, Gassull D, Zhang A, Hammang J. The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals. Therapeutic Innovation & Regulatory Science. 2022; 57:160-169. Available at: <https://link.springer.com/article/10.1007/s43441-022-00451-8>.

⁵Vital Transformation. Who Develops Medicines? An Analysis of NIH Grants. May 10, 2021. Available at: <https://vitaltransformation.com/2021/05/who-develops-medicines-an-analysis-of-nih-grants/>.

⁶Association for Accessible Medicines. The U.S. Generic & Biosimilar Medicines Savings Report. <https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf>

⁷IQVIA. The Use of Medicines in the US 2023: Usage and Spending Trends and Outlook to 2027. May 2, 2023. Available at: <https://www.iqvia.com/insights/the-iqvia-institute-reports-and-publications/reports/the-use-of-medicines-in-the-us-2023>

⁸Ibid.

⁹IQVIA. Biosimilars in the United States 2023-2027. January 2023. Available at: <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/biosimilars-in-the-united-states-2023-2027/iqvia-institute-biosimilars-in-the-united-states-2023-usl-orb3393.pdf>

¹⁰DiMasi JA, Faden LB. Competitiveness in follow-on drug R&D: A Race or Imitation? Nature Reviews Drug Discovery. 2011;10(1):23-27. Available at: <https://www.nature.com/articles/nrd3296>.

¹¹BRG Research. The Pharmaceutical Supply Chain, 2013-2020. January 7, 2022. Available at: <https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/>

¹²Van Nuys K, Joyce G, Ribero R, Goldman D. Overpaying for Prescription Drugs: The Copay Clawback Phenomenon. March 12, 2021. USC Schaeffer Center for Health Policy & Economics. Available at: <https://healthpolicy.usc.edu/research/overpaying-for-prescription-drugs/>

¹³We Work for Health. 20218. Available at: <https://www.weworkforhealth.org/in-the-states>.

¹⁴FTI Consulting. The Role of Intellectual Property in the Biopharmaceutical Sector 2022. September 21, 2022. Available at: <https://www.ifpma.org/publications/the-role-of-intellectual-property-in-the-biopharmaceutical-sector/>