

The Biopharmaceutical Research Ecosystem: The Role of NIH and Industry in the Research and Development of New Medicines

America's biopharmaceutical companies are at the heart of a robust research and development (R&D) ecosystem that develops more innovative medicines than any other country in the world. Critical to this ecosystem is the working relationship between industry and government agencies like the National Institutes of Health (NIH), academic medical centers and community-based research sites to further the translation of basic research into lifesaving medicines. Many misunderstand the nature of the R&D process and the complementary roles the NIH, academic medical centers and community-based research sites play relative to the biopharmaceutical industry's role in the research and development of new medicines.

This fundamental misunderstanding of the way the R&D on medicines works threatens to undermine and even harm the U.S. research ecosystem and jeopardize its longstanding success. As the world continues to fight the ongoing COVID-19 pandemic, it is important to set the record straight about what roles are played in R&D. Now more than ever, it is critical that both public and private assets can be brought to bear in addressing critical unmet needs.

I Basic science research is conducted by both the public and private sectors and lays the foundation for our understanding about how the human body functions.

The goal of basic science research is to understand the function of newly discovered molecular compounds and cells, strange phenomena in the body or little-understood disease processes. Many times, this new knowledge requires additional contributions from other scientists before it can lead to breakthrough methods or treatments years or decades later. Academic, public and private industry scientists all contribute to the vast body of basic scientific discoveries, and that knowledge is shared and expanded upon by scientists through peer-reviewed publications, scientific meetings and licensing of intellectual property (IP).

I Because the NIH performs limited research directly related to clinical drug development, without the investment of the biopharmaceutical industry, the knowledge resulting from basic science research would generate many ideas for potential drugs and targets - but very few new medicines.

The biopharmaceutical industry's unique role in the research ecosystem is to utilize its scientific and industrial expertise to take the necessary risks to advance scientific research into safe and effective treatments that can be made available to patients. This highly complex process involves being able to manufacture drug substance and product that are well-tolerated and stable in the human body. The federal government cannot research, develop and manufacture vaccines and other new treatments without the resources, scientific expertise, R&D, manufacturing and technological platforms from private sector biopharmaceutical companies. A report from the Congressional Budget Office (CBO) highlighted the industry's robust investment in R&D, the complementary role public sector partners play in drug development and the impact that results for patients across the globe when they found that public-sector research and private R&D "are complements, not substitutes."ⁱ

As Dr. Anthony Fauci of National Institute of Allergy and Infectious Disease further explains, "We always need a pharmaceutical partner...I can't think of a vaccine, even one in which we've put substantial intellectual and resource input, that was brought to the goal line without a partnership with industry."ⁱⁱ

I Much of the success of the U.S. research ecosystem is due to the positive impact of the Bayh-Dole Act on public-private research collaboration.

Congress passed the Bayh-Dole Act in 1980 with bipartisan support to incentivize the private sector to make the substantial and risky investments needed to translate government-funded basic research into useful products. Bayh-Dole has helped lay the foundation for the robust and entrepreneurial U.S. R&D ecosystem. Before Bayh-Dole Act, not a single drug had been further developed utilizing patents generated with government funding. In contrast, since 1980, over 200 new drugs and vaccines have been developed through public private partnerships facilitated by the Act.^{iii,iv} The reason the U.S. produces more successful medicines than other countries is because our IP system promotes competition by ensuring each player exceeds at their role and is incentivized to take risks and share information throughout the process. Strategic public-private partnerships help support collaboration among governments, scientific institutions and biopharmaceutical, medical device and diagnostics companies, and many others to stimulate progress in research and science to develop new treatment options for patients.

I It is not solely a question of dollars invested. The NIH has a critical public health mission to uncover new knowledge that will lead to better health for everyone - and we should keep it that way.

The research grants NIH provide not only advance basic science research but also have a critical role to play in training future scientists, developing and supporting medical libraries, training medical librarians and other health information specialists and educating on the importance of prevention for maintaining good health.^v NIH-funded studies are imperative for understanding the natural history of diseases, identifying critical biomarkers and establishing clinical guidelines for best standard of care. Private sector companies regularly collaborate with NIH by providing funding and drug supplies, contracting with clinical trial networks to run industry-sponsored clinical trials and providing scientific expertise to those networks through advisory committees. However, similar to the way NIH cannot fulfill all of the responsibilities of the industry, the industry cannot fulfill all of NIH's responsibilities. Each member of the biopharmaceutical ecosystem plays a unique and vital role.

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It is important that public policies support the many forms of public- and private-sector collaboration that are so essential to ensuring that every element of the vibrant U.S. R&D ecosystem is working together to bring forth new treatments and cures and support the R&D of tomorrow's life-saving medicines. Through thoughtful, market-based approaches we can continue to support a thriving biomedical research ecosystem and allow the biopharmaceutical sector to continue to partner with the public sector to deliver innovative medicines and improve the lives of patients.

i CBO. [Research and Development in the Pharmaceutical Industry](#). April 2021.

ii Lerman D & A Siddons. "[Vaccine prices a flashpoint in coronavirus funding talks](#)," Roll Call. February 27, 2020.

iii Statement of Elmer B. Staats, comptroller general of the United States, Before the Committee on the Judiciary United States Senate, "S. 414-The University and Small Business Patent Procedures Act," May 16, 1979 <https://www.gao.gov/assets/100/99067.pdf>.

iv Chart based on an analysis from [AUTM](#)

v NIH, [Mission and Goals](#).

