

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. Many misunderstand the nature of the R&D process and the role that the National Institutes of Health (NIH) plays relative to the biopharmaceutical industry's role in the discovery and development of new medicines. This fundamental misunderstanding of the way drug development works threatens to seriously undermine and even harm the U.S. research ecosystem and jeopardize its longstanding success. As the world faces a public health emergency of unprecedented proportions and the industry is collaborating across the biopharmaceutical research system and working around the clock to deliver solutions for patients, it is important to set the record straight. In particular, now more than ever, it is critical that both public and private assets can be brought to bear in addressing diseases such as COVID-19.

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, government and private industry scientists all contribute to the vast body of basic science discoveries, and that knowledge is shared and expanded upon by scientists through peer-reviewed publications, scientific meetings and licensing of intellectual property (IP).

Because the NIH does limited research related to drug development, without the investment of the biopharmaceutical industry, the knowledge resulting from basic science research would generate many ideas for potential drugs and drug 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 build on and further advance basic science research into safe and effective treatments that can be made available to patients. 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. As Dr. Anthony Fauci of National Institute of Allergy and Infectious Disease (NIAID) 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."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 discoveries into useful products. Bayh-Dole has helped lay the foundation for the robust and entrepreneurial U.S. R&D ecosystem. Prior to enactment of the Bayh-Dole Act, the government retained the patents on federally-sponsored inventions – and only 5% of those patents were ever used in the private sector.ⁱⁱ The reason the U.S. produces more successful medicines than other countries is because the 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 to address unmet need.

It is not solely a question of dollars invested. 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.

Imagine the loss for the advancement of public health if the NIH was solely focused on developing new therapeutics. Through the research grants NIH provides, they 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.ⁱⁱⁱ NIH-funded studies are critical 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.

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 research and development 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 in unprecedented ways.

ⁱ Lerman D & A Siddons. "Vaccine prices a flashpoint in coronavirus funding talks," Roll Call. February 27, 2020. Available at: <https://www.rollcall.com/2020/02/27/vaccine-prices-a-flashpoint-in-coronavirus-funding-talks/>

ⁱⁱ Government Accountability Office (GAO). (2009). Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions. Available at: www.gao.gov/products/GAO-09-742.

ⁱⁱⁱ <https://www.nih.gov/about-nih/what-we-do/mission-goals>

