Five Things You Need to Know About the Biopharmaceutical Research Ecosystem During COVID-19

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.

Some critics have claimed that this success is because the National Institutes of Health (NIH) use public funds to discover new therapies which are then just handed off to biopharmaceutical companies to be manufactured, packaged and monetized. This fundamental misunderstanding of the way drug development works has led to policy proposals that could seriously harm the U.S. research ecosystem and jeopardize its longstanding success.

Now more than ever, it is critical that both public and private assets can be brought to bear in addressing critical diseases such as COVID-19.

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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 kernel of scientific understanding requires additional research contributions from other scientists to determine whether that new scientific knowledge will inform the development of new research methods, technology platforms or treatments years or decades later. Academic, government and private industry researchers and scientists all contribute to the vast body of basic science research, and that knowledge is shared and expanded upon by scientists through peer-reviewed publications, scientific meetings, filing of patents and licensing of intellectual property (IP).

Because the NIH conducts limited research specifically related to drug development, without the investment of the biopharmaceutical industry the knowledge resulting from basic science research supported by NIH 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 upon 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.

"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]

— **DR. ANTHONY FAUCI** of National Institute of Allergy and Infectious Disease

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 transform discoveries from government-funded basic research 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. is the global leader of biopharmaceutical innovation is because the IP system promotes competition by ensuring each player excels 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, diagnostics companies and many others to stimulate progress in research and science to develop effective vaccines as well as diagnostics and treatment options critical to address COVID-19.

"We are the place that supports the scientific innovations that lead to these breakthroughs, and ultimately, to new therapies," Collins said in an interview. "But we need to be part of an ecosystem that includes the private sector and philanthropy and advocates for that in order for that to come true."

– DR. FRANCIS COLLINS, Director of the National Institutes of Health and Infectious Disease

https://news.bloomberglaw.com/pharma-and-life-sciences/research-not-heavy-hand-to-tamp-down-drug-costs-nihs-collins

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 increasing our understanding of 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.

In cases where public funding is provided, for example, to support clinical research or increase manufacturing capacity for potential new treatments and vaccines for COVID-19, some have called for the government to determine the price if the candidates are successful. This fails to recognize that reducing the incentives for the private sector to invest and take risks could have serious unintended consequences for future innovation.

In the face of the COVID-19 crisis, PhRMA member companies have committed to collaborating with a wide range of partners including working with various governments to ensure that when new treatments and vaccines are approved, they will be available and affordable for patients.[iv] Concerns that the biopharmaceutical industry will inappropriately price future vaccines or treatments are unfounded. During public health emergencies such as pandemics, the biopharmaceutical industry has a track record of responsible pricing and actively partnering with the government to ensure availability and affordability. Dr. Anthony Fauci has said he is not aware of any situation where companies priced vaccines out of reach in pandemic situations.[v]

Further, the Coronavirus Aid, Relief, and Economic Security (CARES) Act requires that products purchased by the federal government, such as vaccines and therapeutics developed using federal funds, will be acquired at a fair and reasonable price.[vi] As Speaker Pelosi described the provision, "The legislation protects against price-gouging of these medicines developed with taxpayer dollars by ensuring that the federal government will only pay a fair and reasonable price for coronavirus vaccines and drugs and providing HHS the authority to ensure that they are affordable in the commercial market."[vii] Any new additional policies that would set prices in the commercial market or make it less attractive to collaborate with the federal government would not only fundamentally set back the industry's ability to respond in a timely way to COVID-19 but would also deter companies from making long-standing investments needed to be able to respond quickly in times of future global health emergencies.

Rather than harming the highly successful U.S. biopharmaceutical research ecosystem and the patients who need innovative treatments, we should look to policies that will support patient access and affordability without undermining the 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
[iv] https://phrma.org/coronavirus
[v] 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/
[vi] Coronavirus Aid, Relief, and Economic Security (CARES) Act. Available at: https://www.congress.gov/bill/116th-congress/house-bill/748
[vii] " Pelosi Statement on Coronavirus Emergency Response Bill," March 4, 2020. Available at: https://www.speaker.gov/newsroom/3420