August 18, 2023

Dr. Lyric Jorgenson
Acting Associate Director for Science Policy
National Institutes of Health
Office of Science Policy
6705 Rockledge Dr. #750
Bethesda, MD 20817

Dear Director Jorgenson:

I appreciate the opportunity to comment on the importance of private sector investment in prescription drug research and development and its relationship to NIH funding.

The Institute for Policy Innovation is a non-profit, non-partisan public policy "think tank" based in Irving, Texas, and founded in 1987 to research, develop and promote innovative and non-partisan solutions to today's public policy problems. IPI is supported wholly by contributions from individuals, businesses and non-profit foundations.

By way of background, I am a resident scholar with IPI. I am also a past president of the Health Economics Roundtable for the National Association for Business Economics, the largest trade association of business economists. And I currently serve as Chair of the Texas Advisory Committee to the U.S. Commission on Civil Rights.

Comparing Federal Funding for Research and Development: The Pharmaceutical Industry vs. the Clean Energy Industry

There is a small but vocal and influential group of people who have increasingly pushed the narrative that most research and development funding for prescription drugs in the United States comes from the government. While the federal government does provide some funding, primarily for initial drug research—as well as medical devices and other health care-related research—the private sector pharmaceutical companies provide the lion's share of R&D funding.

At a House Committee on Oversight and Reform meeting in January 2019, U.S. Representative Alexandria Ocasio-Cortez (D-NY) claimed, "the public is acting as early investor, putting tons of money into the development of drugs that then become privatized, and then they [the public] receive no return on the investment that they have made." Similar assertions have been made by other progressive elected officials and think tanks.

It's a strange argument given that this very week President Joe Biden toured the country boasting the one-year anniversary of the Inflation Reduction Act (IRA), which is pouring hundreds of billions of taxpayer dollars into funding basic research and development for various types of clean energy projects and products.

For example, Reuters reports, "While the biggest impacts will begin in 2024 and 2025, there have been more than 270 new clean energy projects announced since its [the IRA] passage, with

investments totaling some $132 billion, according to a Bank of America analyst report." And that's just the beginning.

Goldman Sachs recently released a report claiming the real cost of the IRA over 10 years will be $1.2 trillion, more than three times the initial estimate of $391 billion. According to Goldman, its estimate includes "electric vehicles (difference: $379 billion), green energy manufacturing ($156 billion), renewable electricity production ($82 billion), energy efficiency ($42 billion), hydrogen ($36 billion), biofuels ($34 billion) and carbon capture ($31 billion)."

We should also mention $39 billion in taxpayer-provided funding for the semiconductor industry—which has many very profitable companies—provided in the CHIPS and Science Act, which passed last summer.

The president and other progressives refer to all of these taxpayer-provided subsidies as "investments."

Countless for-profit companies, with many wealthy investors (and political donors), will benefit from these taxpayer-provided subsidies. Some of those companies may survive and reap hefty profits. Most will likely end up filing for bankruptcy, as the electric bus company Protera has recently done. And yet we never hear progressives complain that taxpayers may "receive no return on the investment that they have made" in clean energy.

While the government will use the subsidies to impose regulatory strings on the receiving companies, there is no indication yet that the government intends to impose price controls on the clean energy companies, as the White House proposes to do with prescription drugs.

In fact, the clean energy industry, with all of its branches, could not survive without massive government subsidies. The U.S. pharmaceutical industry has thrived for decades almost entirely on private sector funding. And the health of patients around the world has benefited from those investments.

How much has the pharmaceutical industry invested? About $1.1 trillion since 2000. But the funding pace is accelerating. While members of the Pharmaceutical Research and Manufacturers Association (PhRMA) invested $50.7 billion in R&D in 2010, that annual investment doubled to $102.3 billion by 2021.

Determining how much the National Institutes of Health (NIH) provides in basic research funding is complicated because money is fungible and can be used for a number of purposes that may or may not directly result in the discovery of a new molecule.

A 2019 study titled "Public sector financial support for late stage discovery of new drugs in the United States: cohort study" found, "Over the 10 year study period [2008-2017], the FDA approved 248 drugs containing one or more new molecular entities. Of these drugs, 48 (19%) had origins in publicly supported research and development and 14 (6%) originated in companies spun off from a publicly supported research program."

A 2020 research paper titled "Public research funding and pharmaceutical prices: do Americans pay twice for drugs?" reviewed several studies, concluding:

> "Detailed case studies reveal that public support has played at least some role in virtually all of the 26 most clinically and commercially significant drugs and drug classes approved over the past several decades. … But in a large majority of cases, the public sector's contribution to new drugs has been in the form of early scientific findings, unrelated to current or potential applications. The public sector supported key basic research for 19 of the 26 'transformative' drugs and drug classes cited above, contributed to the actual discovery of a new therapy in just 11, and could claim sole discovery credit in only four cases."

So, yes, NIH funding plays a role in basic research, but it's the innovator pharmaceutical companies that take a new molecule, or sometimes just a concept, and turn that into a product, guide it through the often very expensive clinical trials and time-consuming FDA approval process, manufacture the new drug, package, distribute and market it to health care providers and patients.

Of course, there are a number of factors that determine whether those drugs will actually make it to market. The Congressional Budget Office says, "Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA."

No one reimburses the drug companies for the 88 percent of drugs entering clinical trials that don't make it to market. And of those that do make it to market, only a handful are very profitable. But it is those very profitable drugs that cross-subsidize the ones that don't make it to market. Yet it's those profitable drugs that the government is targeting for price controls.

One more point. For the past two decades, the innovator drug companies have increasingly begun to target diseases that affect a relatively small percentage of the population—say, perhaps only 25,000 to 100,000 people—often referred to as "orphan drugs." In those cases, the companies do not have the ability to spread the cost of creating those drugs over millions of patients. The smaller the patient population, the higher the cost, relatively speaking.

In conclusion, it is true the government funds some initial work in identifying new molecules and therapies. But that funding pales in comparison to the cost, time and effort it takes to bring a new drug to market. Most investigational drugs won't make it. When that happens, it is the pharmaceutical industry and its investors who lose money, not taxpayers.

By contrast, the federal government is pouring hundreds of billions of taxpayer dollars into multiple clean energy projects. Most of those clean energy companies will fail. If a drug company were to fail, investors would lose their capital. When government-backed clean energy companies fail, taxpayer money is lost. If Rep. Ocasio-Cortez really wants to discover where "the public is acting as early investor," but then "receive no return on the investment that they have made," she should turn to the clean energy industry rather than the pharmaceutical industry.

Sincerely,

Merrill Matthews, Ph.D.
Resident Scholar
Institute for Policy Innovation