Bayh-Dole COALITION

Issue Brief: Biden's NIH Licensing Guidelines Imperil New Medicines

January 2025

Days before leaving office, the Biden Administration issued new guidelines for licensing NIH-made inventions. Despite warnings from those experienced in commercialization that the guidelines condemn promising medical breakthroughs from being developed, they were finalized with the claim they would expand patient access to new drugs, vaccines, and medical devices. Unfortunately, the guidelines are likely to prevent promising discoveries from helping long-suffering patients.

The guidelines go well beyond what the law mandates.

Before 1980, few NIH inventions were turned into useful therapies. Congress effectively addressed the problem by enacting key laws, including the Bayh-Dole Act of 1980, that have been foundational in facilitating the commercialization of products to the benefit of patients. These laws are the lifeblood of our biomedical research ecosystem in the U.S., which is built on a system of technology transfer that recognizes appropriate incentives for public-private collaboration need to be in place to ensure discoveries made or funded by NIH do not simply remain on the shelf, not benefiting anyone.

The technology transfer system that these laws support allows inventions patented by federal research laboratories, like NIH, to be licensed to the private sector, and also allows universities around the country to own the patents on the inventions coming out of their federally-funded research programs. In both cases, it is the private sector that undertakes the risk and expense of commercial development. Breakthroughs in treatments for cancer, brain injuries, HIV/AIDS, and many other maladies are the result of this system, fueling the United States' undisputed leadership in the life sciences.

The guidelines address technology transfer of inventions made by NIH at federal laboratories. Initially, Congress wanted to ensure that potential licensees of government-owned patents in all sectors were serious about commercialization, so it required applicants seeking to license government-funded discoveries to submit "a plan for development and/or marketing of the invention."

However, the new guidelines expand that simple instruction far beyond Congress' original intent by requiring potential licensees of NIH patents to also address how resulting products will be *available, affordable, acceptable, and sustainable*. Each has an extensive list of aspects that licensees must address.

Access plans can now be used against the licensee.

Under the Bayh-Dole Act, if a licensee fails to develop an invention in good faith, the university or federal laboratory can revoke the license. But the NIH guidelines allow the bureaucracy to second-guess purely business decisions like how a resulting product is priced, distributed, or maintained. The law does not give NIH that authority.

In addition, the guidelines provide that licensees "are expected" to submit a publicly available update of their access plan three months after the Food and Drug Administration approves a new therapy. If it doesn't like some aspect of that report, NIH can revoke the license even though the company may have invested millions — or billions — of dollars in development.

Further, the Bayh-Dole Act appropriately stipulates that commercialization plans are confidential. Critics have long wanted access to find loopholes to attack the licensee so others can copy the product. Opening the door for such abuse makes NIH an unreliable partner for the entrepreneurial companies that drive our economy.

The guidelines are anti-small business.

The brunt of complying with the new guidelines falls on innovative small companies, which drive U.S. innovation. According to NIH:

> *"For the past several years, over 50% of NIH's license agreements and nearly all of the product commercialization deals have been with small businesses as a result of NIH's licensing practices, which favor small companies. Increasingly, breakthrough products based on NIH discoveries emanated from working with small to mid-sized companies, entrepreneurs, venture capitalists and angel investors."*

Turning an NIH-funded invention into a useful product is a daunting, high-risk task. A recent study found that of the 18 innovative new therapies developed over the past 20 years involving government-funded inventions, *the company invested 66 times as much money as NIH spent supporting the research leading to the patent.*

Even when successful, it may take the licensee decades or more to turn a profit. And about 90% of the time, the technology dies in the development pipeline. When they do, industry, not NIH, takes the hit. That's why it's already hard to find even one company interested in obtaining an NIH license. By making the process more bureaucratic and riskier, companies large and small may shun NIH inventions.

Companies walked away when NIH tried to set product prices.

NIH has tried once before to micromanage the prices of products based on its inventions. It was a disaster.

Under political pressure, NIH tried to force licensees to accept a "reasonable pricing" clause in the 1990s. Rather than lowering drug prices, NIH partnerships collapsed. Then NIH Director Harold Varmus repealed the policy, stating:

> *"An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS (public health service) scientists without providing an offsetting benefit to the public. Eliminating the clause will promote research that can enhance the health of the American people."*

The U.S. leads the world in turning NIH discoveries and government-funded inventions into useful products. Many people are alive today because these inventions did not wither on the vine but rather were commercialized to help fight disease here and around the world. The new licensing guidelines jeopardize the success of this system.

The new Administration should immediately rescind them.