Bayh-Dole COALITION

Celebrating the past. Protecting the future.

July 16, 2024

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Director
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Lawrence A. Tabak
Principal Deputy Director
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Dear Director Bertagnolli and Deputy Director Tabak:

Thank you for providing an opportunity for public comments on your proposed plan to "promote access to products stemming from taxpayer-funded inventions" created through NIH intramural R&D.

The Bayh-Dole Coalition is a diverse group of innovation-oriented organizations and individuals committed to celebrating and protecting the public/private sector technology transfer system under which NIH and other agencies license their inventions. Our members represent research universities, large and small companies, venture capital and other stakeholders in the U.S. innovation system, so our comments reflect what we heard from our members regarding the pending proposal.

Fueled by the Bayh-Dole Act, the Federal Technology Transfer Act, and other pathbreaking technology transfer statutes, the United States has become the undisputed world leader in the life sciences. We are also the leader in helping the less fortunate access needed medical care, both here and abroad. We should do everything that we can to make the world a safer, healthier place, but that can only be done if our model for translating early-stage government-supported inventions into useful products is preserved.

Before delving into the proposed policy, there are several factors that must be considered in evaluating its impact. We should not forget that under our system, it is the private sector that assumes the risk and burden of commercialization. Many times, agencies like NIH are relying on small companies to develop their early-stage inventions into useful products. This is a long, expensive process with daunting odds against success. Nevertheless, our system of public/private sector partnerships has made the United States the nation others depend upon to protect their health. Clearly, the Bayh-Dole system is working.

We support the NIH's goal of ensuring that products incorporating its inventions are available, affordable, and acceptable to consumers and patients. However, to our knowledge NIH has never raised concerns that inventions arising from its intramural programs have not been available or affordable to consumers, creating a need for the licensing requirements laid out in the current proposal.

For example, the December 2022 NIH-commissioned study "Public Health & Economic Impact Study of NIH Intramural Technology Transfer Licensing" documents a plethora of benefits of NIH-generated technology to public health, healthcare costs, company formation, job creation and other parameters without any indication that the public is struggling to access these products because they are unaffordable or inaccessible.

It should also be noted that agencies like NIH often find it difficult to identify even one company interested in taking a license to their inventions. Keeping that in mind, we should be very cautious about adding additional burdens and uncertainties to the process. When that was done in the past, the result was disastrous.

For example, from 1990 to 1995, NIH attempted to address concerns about high drug prices by adding a "reasonable pricing clause" to its Collaborative Research and Development Agreements (CRADAs) and exclusive licenses. Under the clause, a company attempting to bring an NIH invention to market could be required to submit documentation showing a "reasonable relationship between the pricing of the product, the public investment in that product, and the health and safety needs of the public."

Soon NIH began to receive reports from companies and researchers about the negative impact of the reasonable pricing clause. NIH held two public meetings in 1994 with companies, patient advocates, and researchers, which came to a consensus that entrepreneurs were avoiding collaborations with the NIH because of the pricing clause. As a result, NIH Director Varmus in 1995 announced the removal of the clause from CRADAs and exclusive licenses, saying it had accomplished no public benefit and was only preventing important NIH/industry partnerships from being created. With the clause rescinded, partnerships soon revived and a number of important therapeutics were commercialized, protecting public health here and abroad.

With that costly lesson in mind, care must be taken so that the proposed NIH licensing policies do not inadvertently recreate the collaboration-chilling effects of unsuccessful past initiatives, thereby hindering the development of new treatments.

Flexibility will also be necessary to account for differences in the licensed technology as well as the parameters and scope of the license. For example, approximately two thirds of NIH licenses are for research tools such as assays, tests, reagents, biological materials, samples, cell lines, and animal models. These are for use by academic and corporate research departments and are not normally incorporated in consumer products. Thus, the question of whether research tools are affordable or acceptable to patients and underserved communities seems irrelevant and nonsensical.

As another example, NIH reports that the majority of its licenses are non-exclusive, meaning that most NIH licensing transactions allow for competition between multiple licensees and have a significantly more limited scope than a worldwide exclusive license. It seems to make little sense to impose the cost and uncertainty of an access plan on non-exclusive licenses.

Further, NIH should consider the relative contribution of its licensed technology to the end product. An NIH invention may be a central component of a commercial product developed by a licensee, or it may be a small part that needs to be combined with other, privately developed technologies in order to create a new therapy.

Through its access plan proposal, NIH seeks greater influence and control over the commercial planning of its licensees, but why should NIH have such leverage when its contribution to the final product is slight?

A critical factor that should be noted that is missing from the document is that licensees are paying NIH for high risk, early-stage discoveries. The tone implies that licensees are receiving a special benefit at public expense. In reality, licensees are risking their own money, time and resources on discoveries that are much more likely to fail than succeed. And when that happens, it is the licensee, not NIH, that takes the hit.

With that in mind, what is the quid pro quo for your licensees under the new guidelines? In one part of the proposed "access plans," NIH suggests that licensees should agree "to sell a designated volume of product to the U.S. Government or another designated entity on a cost-plus basis," or to "keep prices in the U.S. equal to those in other developed countries." Such clauses significantly increase the burden on the licensee.

If the government wants to impose such terms on the company assuming the risk of the transaction, it's only fair to ask: What additional value is NIH bringing to the deal?

There is no indication that NIH will lower or forego royalties if licensees adopt the new criteria. NIH is not committing any new funds for developing the product. What new benefit is NIH bringing to the table in exchange for its licensees agreeing to accept the proposed policy changes, many of which make their burdens even heavier? Such an imbalance undermines the fundamental premise that we are forming partnerships between the public and private sectors, not building one-way streets.

Finally, we must note that your proposal was issued at a time when industry confidence in the government as a reliable research partner is at a low ebb because of the pending march-in guidelines, which seek to change the Bayh-Dole Act without the consent of Congress.

Under the Administration's proposal, anyone can petition the funding agency to march in to license copiers if they allege that a product is "unreasonably priced," a completely undefined term. When issuing the guidelines, the Administration made it clear this shift is primarily aimed at asserting arbitrary price controls on new drugs based on NIH-funded patents.

If the government seeks to ignore the criteria of a 45-year-old statute, what's to prevent it from exploiting the many ambiguous terms in your pending licensing guidelines to pull the rug out from under a company that's developed a successful product after expending hundreds of millions (or even billions) of its hard-earned dollars?

For example, what happens if NIH rejects the access plan that's submitted once a licensed product enters Phase III trials or an equivalent stage of development? Is the license terminated? What recourse does a licensee have if they feel your objection is unwarranted? Lack of certainty about the rules is the greatest threat to innovation, particularly in relationships like this when the party bound by the new terms is the one assuming the vast majority of the risk.

These fears are exacerbated when NIH lists having licensees commit to "keep prices in the U.S. equal to those in other developed countries" as its first recommendation under "Promoting equitable access and affordability in product development." NIH certainly knows that equating foreign and domestic drug pricing, while a favorite slogan of those attacking our system, is not always under the control of its licensees.

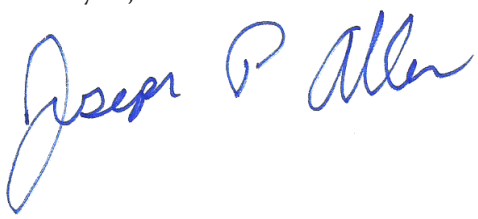
NIH has wide latitude to create the terms by which it licenses inventions arising from intramural R&D, but that must be done very carefully. It's reasonable to assume that if these guidelines are adopted, pressure will be placed on those receiving NIH extramural funding to fall in line.

For the reasons listed above, at this point there is little confidence in how the proposed policy will be applied. It is not even clear why it is needed.

NIH correctly notes that "*its licensees, their partners, and the public will need confidence around what this policy requires and the standards that would be used to evaluate plans.*"

There needs to be much more detail — and thought — given to the impact of this document on the willingness of private companies to spend their money to license NIH-funded inventions. Without that, there are no products to access.

Thank you,



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