United States Senate
WASHINGTON, DC 20510

VIA ELECTRONIC TRANSMISSION

December 20, 2023

President Joseph R. Biden
The White House
1600 Pennsylvania Ave., NW
Washington, DC 20500

Dear President Biden:

The American intellectual property system and research ecosystem are some of our country's greatest achievements. In fact, intellectual property rights were enshrined into our very Constitution by our founding fathers. These achievements have played a vital role in making the United States the global leader in the production of lifesaving medicines and other innovative new technologies. This success is largely due to policies enacted by Congress, for the public good, to ensure that federally-funded inventions can move from the laboratory to the marketplace.

Unfortunately, your Administration's recent announcement of a new policy framework, based on incorrect and inconsistent interpretation of the Bayh-Dole Act, is at odds with Congressional intent. The threat that government agencies will "march-in" and seize patents if prices exceed a vague and undefined threshold undermines the certainty that innovators need to make investments and bring complicated new technologies to market. The recent guidance will stop progress in its tracks with little discernible benefit to the public.

Senators Birch Bayh and Bob Dole recognized that the government does not develop new technologies on its own. For that, America relies on the private sector. Prior to enactment of the Bayh-Dole Act, the government retained the patents on federally funded inventions – and only 5% of those patents were ever licensed for use in the private sector.[1] Compare that to the benefits to society and the economy realized from this ecosystem just in 2022; $91.8 billion in research expenditures, 7,739 new U.S. patents issued, and 998 startups formed.[2]

The Bayh-Dole Act is designed and intended to incentivize the private sector to license inventions resulting from early-stage government-funded research and further develop those inventions into useful products. By allowing grant recipients such as universities to retain the title to the patents covering their inventions and enabling them to license the patents and the right to use those inventions to private sector partners, the Bayh-Dole Act has been hugely successful in facilitating the development of commercially available medical treatments and other products and maximizing taxpayer benefit for government-funded research.

Though Bayh-Dole allows the federal government to "march-in" and require additional licenses under a narrow set of circumstances, "march-in" was never intended to serve as a mechanism for regulating the pricing of any products. The law makes no reference to a "reasonable price" that

[1] Mittal, A. K. (2009). *Federal Research: Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions*. Available at: https://www.gao.gov/assets/gao-09-742.pdf.
[2] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf.

should be dictated by the government, and this omission was intentional.[3] In the nearly four decades that the Bayh-Dole Act has been in place, the National Institutes of Health (NIH) has denied every march-in petition based on pricing that has been submitted to the agency. In each case, NIH consistently concluded that the products subject to a march-in petition had reached practical application and met health or safety needs.

In an Op-Ed to the Washington Post, the bill's authors, Senators Birch Bayh and Bob Dole, stated:

> "The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product."[4]

Your Administration's misguided proposal could chill the private sector's willingness to enter into contractual agreements and licenses to the detriment of the American public.

Pricing restrictions on the private sector, as a condition of partnering with the government, has been tried before with disastrous results for patients and taxpayers. In 1989, the NIH imposed "reasonable pricing" conditions in all Cooperative Research and Development Agreements (CRADAs) between federal labs and outside parties to conduct research or development. The policy was revoked in 1995 after public meetings were held with companies, patient advocates and researchers, following which the agency concluded that these pricing conditions significantly chilled collaboration between the public and private sectors.[5] In his announcement of the decision, then Director of the NIH, Harold Varmus, M.D., said:

> "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 scientists without providing an offsetting benefit to the public. Eliminating the clause will promote research that can enhance the health of the American people."[6]

After the removal of the clause, there was a subsequent rebound in CRADAs.[7] Your Administration's latest action appears nakedly political, and it is the American public who will suffer. Nowhere more than in North Carolina, academic technology transfer is driving the innovation economy and benefitting society, with great commercial potential. Every year university research yields discoveries, jobs, new startups and small companies, and new drugs and vaccines. This policy raises substantial questions.

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[3] Bayh, B. and Dole, R. (2011). Our Law Helps Patients Get New Drugs Sooner. Washington Post op-ed. Available at: https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/.

[4] *Id.*

[5] National Institutes of Health. (1994). Reports of the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH_%20CRADA_Report_on_Reasonable-Pricing_Clause_1994.pdf.

[6] Press Release, NIH News, April 11, 1995. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf.

[7] https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf.

Your prompt attention to the following questions would be greatly appreciated.

1. What analysis has your Administration done to ensure that stakeholders will continue to invest and commercialize government funded research under this new framework?

    - Have research universities and other grant recipients communicated that this is sound policy?
    - Did your Administration consult with the NIH during the decision-making process? As you know, the NIH has rejected every march-in petition to date and in their 2016 rejection the agency stated that the use of march-in authority would not be an effective means of lowering the price.[8]
    - Have industry stakeholders such as energy, defense, and biopharma signaled that this policy gives them sufficient clarity to justify significant long-term investments?
    - Who from the investing community has your Administration worked with to ensure that venture capitalists will not be deterred from partnering with government and research universities?

2. Because certainty is so important for long-term investments, what benchmarks should investors and innovators rely on in determining pricing that will "pass muster" for your Administration?

    - Does your Administration have examples of what it considers "reasonable" pricing across industry sectors?
    - The guidance document explicitly asks if higher prices narrow the set of consumers who can afford a product. Would this apply, for example, to a biopharmaceutical product intended to treat a rare disease for a small number of patients? Or defense products where the federal government might be the only customer? What advice would you give to an innovator targeting a narrow customer base who may need a relatively high price to recoup their investment?
    - What assurances can your Administration give that consideration of reasonable pricing" will not be weaponized and used to pursue political agendas?

3. How will the Administration enforce its pricing factor in complicated pricing markets like the biopharmaceutical industry?

    - Will your Administration adjudicate a product's price based on the list price of the drug? Or the net price that the manufacturers actually receive? Or the patient out of pocket cost?
    - What analysis did your Administration rely on regarding the pharmaceutical pricing market – particularly misaligned incentives within the pharmaceutical supply chain and the existing rebate structure, which artificially increases list prices and arbitrarily limits access to prescription drugs due to the financial incentive associated with high-list price, highly-rebated products?

[8] Tabak, L. A. (2023, March 21). National Institutes of Health March-in Petition Rejection Letter. https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf.

Your Administration's proposed guidance will do profound harm to stakeholders in North Carolina as well as to U.S. competitiveness in general. I am therefore adamantly opposed and urge your Administration to reconsider.

Sincerely,

Thom Tillis
United States Senator