

July 7, 2023

U.S. Senate Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC, 20510

Dear Senate Health, Education, Labor and Pensions (HELP) Committee,

I write to you as the Executive Director of the Bayh-Dole Coalition, which represents academic research institutions, venture capitalists, and private sector companies that work together to bring federally funded inventions out of the laboratory and into the marketplace where they can benefit the public. Our coalition has serious concerns about the proposed “reasonable pricing” provision in the draft reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).

We’ve been down this road before, and it was a disaster. The proposed language would make the damage even greater than the last time this costly experiment was tried. Then the damage was limited to Cooperative R&D Agreements (CRADAs) with the National Institutes of Health or for exclusive licenses to NIH owned inventions. The proposed language includes grants to our research universities undermining their ability to license critical technologies for development. That would stifle university technology transfer at a time when we can least afford to do so. Given the present competitive and national security threat posed by China, the United States needs its full complement of technology transfer operations to be firing on all cylinders.

It’s worth revisiting the history of the “reasonable pricing” provision. In 1989, because of Congressional pressure, NIH added a provision to its Cooperative R&D Agreements and exclusive licenses stipulating that any resulting product demonstrates a “reasonable relationship between pricing of a licensed product, the public investment in that product, and the health and safety needs of the public.” What happened next was not a new era of cheaper drugs. Partnerships between private sector firms and the NIH collapsed,

undermining the development of new products and important scientific collaborations between our public and private sectors.

Under our unparalleled system for turning federally funded inventions into useful products under the Bayh-Dole Act, companies must assume considerable risk and expense to transform early-stage, federally-funded inventions into useful products. That journey is particularly daunting with drug development, where more than 80% of potential medicines entering clinical development fail, with those costs borne by the private sector.

When these projects fail, companies take the hit. Our unique system is driven by small entrepreneurial companies which must secure a long series of investments to bring a drug to market. These entrepreneurs can't be expected to make a binding legal commitment to NIH based on an undefined concept such as "reasonable pricing" for a product that doesn't even exist yet.

As the number of CRADAs collapsed, NIH convened a series of public meetings where not only companies, but NIH's own researchers reported the damage being inflicted because of the "reasonable pricing" provision. NIH obtained advice from its Directors' Advisory Committee, the Public Health Service Technology Transfer Policy Board and the NIH Technology Transfer Advisory Committee.

NIH reported:

"All three of these groups concluded that the clauses should not be permitted to impair NIH's ability to do collaborative research to improve public health. Further, these committees found that the NIH lacked the requisite legislative mandate or expertise to regulate prices and that such a role would conflict with its technology transfer mission." ([NIH News Release Rescinding Reasonable Pricing Clause](#))

Finally, on April 11, 1995, then NIH Director Harold Varmus announced the removal of the “reasonable pricing” clause, 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.”

He added:

“The clause attempts to address the rare breakthrough product at the expense of a more open research environment and more vigorous scientific collaborations. One has to have a product to price before one can worry about how to price it, and this clause is a restraint on the new product development that the public identified as an important return on their research investment.”

NIH showed the damage went beyond just CRADAs and licenses:

“The ‘reasonable pricing’ clause, however, discourages the execution of exclusive licenses and CRADAs and inhibits the ability of PHS scientists to obtain access to research materials and scientific expertise from their private sector counterparts, even outside the context of a license or a CRADA.”

Shortly thereafter, CRADAs with NIH showed an incredible rebound. But sadly, it doesn’t end there. Rather than admit their theory had been tried and failed, it was alleged that the problem was that NIH didn’t know how to count its own agreements. In response, under the Biden Administration, NIH issued a paper accompanied by graphs rebutting that assertion ([NIH on reasonable pricing and CRADAs 2021 revision](#))

We urge the Senate HELP Committee to prevent this troubling history from repeating itself. Our nation has benefited greatly from the collaboration between academia and industry, with federally-funded research producing life-saving technologies. The proposed

“reasonable pricing” language would erode one of the nation’s unique and historic policy achievements -- and it would do so at a moment when the country needs every possible advantage to drive economic growth, breakthrough innovation, and medical progress.

They say that the definition of insanity is doing the same thing over again while expecting a different result. We know what will happen if we impose a “reasonable pricing” clause on research agreements. There’s no excuse for going down this blind alley again. The last experiment was too costly to be repeated.

Sincerely,



Joseph P. Allen
Executive Director
Bayh-Dole Coalition