

June 30, 2023

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

Dear President Biden:

We write to urge you to reject [demands](#) to impose a “reasonable pricing clause” on therapies developed through life-saving partnerships between the National Institutes of Health (NIH) and private firms. Collectively, our organizations represent 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.

As you know, Senate Health, Education, Labor and Pensions Chairman Senator Bernie Sanders is threatening to stall Dr. Monica Bertagnolli’s nomination to lead the NIH until the administration agrees to “reinstate and strengthen a ‘reasonable pricing clause’ in all future collaboration, funding, and licensing agreements for biomedical research.”

We’ve been down this road before, and it was a disaster. Sen. Sanders is now urging your administration to not only reinstate this failed policy but to expand it beyond cooperative research agreements and licenses between the NIH and private-sector firms to include all research funding agreements. This would sweep in grants with 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.

Back in 1989, because of Congressional pressure, the NIH added a provision to its Cooperative R&D Agreements (CRADAs) 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 the system established by the Bayh-Dole Act, which you supported as a U.S. senator, 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.”

The 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.

Despite its clear failure, there were attempts by some in Congress to reimpose the disastrous “reasonable pricing” provision legislatively. Luckily, more reasonable members, like you, rejected that approach, not once, but twice. Now, with Senator Sanders’ ultimatum, you’re being asked to weigh in for a third time.

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 your Administration, NIH issued a paper accompanied by graphs rebutting that assertion ([NIH on reasonable pricing and CRADAS 2021 revision](#)).

Now, the fair pricing advocates are reduced to playing their final card -- alleging that those who disagree with them are corrupt. They made the same allegations against Senator Birch Bayh and Senator Robert Dole, who resisted attempts to undermine their namesake law. Those allegations continue despite the fact that Senators Bayh and Dole are no longer able to defend themselves. As you served many years with both men, who greatly valued your support in passing their legislation, there is no need to address that calumny here.

Mr. President, you have many hard decisions before you. Rejecting this attempt to intimidate you into restoring the failed "reasonable pricing" provision isn't one of them. We urge you to reject the latest attempt to steer our country down a road which only leads to a dead end. This is no time for our country to take such a disastrous wrong turn.

Sincerely,

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Bayh-Dole
COALITION

