



THE TEXAS POLICY VOICE FOR HEALTHCARE AND BIOSCIENCE

Opinion Editorial

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U.S. medical progress is in jeopardy

Attempts to undermine public-private partnerships could erode the financial foundation of R&D.

Every day patients from around the country arrive in North Texas desperate for help, anxious for answers and hopeful for a cure. They come here for world-class medical treatment and to participate in one of the many clinical trials underway for a range of diseases from Alzheimer's to cancer.

For anyone who has watched a loved one desperate for a cure, these trials can provide a hopeful therapeutic option. They also provide those suffering from chronic disease with another chance at relief. Clinical trials are vital part of the Food and Drug Administration process to approve treatments.

Through partnerships with pharmaceutical and device companies and places like Mary Crowley Cancer Research Center or the Dallas VA Medical Center, researchers can study new treatments, like a new drug or medical device, to make sure it is safe and effective before receiving FDA approval. But this progress is in jeopardy because of recent attempts to misuse the regulatory process and reverse the effects of the laws that underpin such medical innovation.

A cornerstone of research and development activity is public-private partnerships. The startup costs for innovators are extraordinary and often come with significant risk. And the government does not typically have the entrepreneurial capacity to move quickly and nimbly. That's why more than four decades ago, Congress passed the Bayh-Dole Act. The bipartisan duo of U.S. senators who authored it, Evan Bayh and Bob Dole, wrote in an op-ed for The Washington Post at the time that they aimed to "spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner."

The act ensured that academic institutions, small businesses and nonprofit organizations that received federal research grants could license their R&D to the private sector to further develop and commercialize their discoveries. Where previously the government retained the patents, this new model incentivized the private sector to collaborate with institutions and bring those discoveries to market.

The innovation that has flourished in the past 40 years has been astonishing, and the rapid pace of development of the COVID-19 vaccine is just the most recent example.



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Now, some members of Congress and activist groups have petitioned the federal government, asking it to invoke a clause that was built into the legislation to allow the government to “march in” and relicense patents that originated from federally funded research. The intent was clear and limited: if a licensed invention was sitting on the shelf and not being commercialized, the government wanted to be able to march in and leverage it for the greater good.

But those calling for the government to march in now are twisting the intent of the legislation. And this distortion could have a chilling effect on the pace of innovation and discovery moving forward.

While their purported goal of reducing the cost of prescription drugs is notable and one that requires focus, their process for getting there would damage the research juggernaut the legislation has inspired.

Prior to Bayh-Dole, just a handful of the patents the government retained were ever licensed. Scientific discovery and innovation languished. But now, academic institutions have built commercialization into their overall model, actively turning their research into tangible discoveries.

If the private sector loses the incentive to commercialize, Bayh-Dole loses its teeth and research could revert to languishing in laboratories instead of making its way to pharmacy shelves. This would ultimately increase the cost of prescription drugs and halt the development of untold discoveries under development – having the reverse effect petitioners claim to want.

Texas would be especially hard hit. Since 2004, more than 17,000 clinical trials have been conducted here, with more than 2,500 currently underway. This equates to a lot of innovation – and a lot of economic growth. A recent study from the Pharmaceutical Research and Manufacturers of America found that \$76.5 billion in economic activity in Texas was supported by biopharmaceutical research companies. Clearly the health of our economy – and more importantly the health of Texans – would be adversely affected by such moves.

We call on all lawmakers, especially the members of our Texas congressional delegation, to stand up for and defend public-private partnerships by preserving the 40-year precedent and intent of Bayh-Dole and rejecting petitions that call for misuse of march-in authority. The future of innovation and the health of our economy depend on it.