THE BAYH-DOLE ACT:
Spurring American Biopharmaceutical Innovation

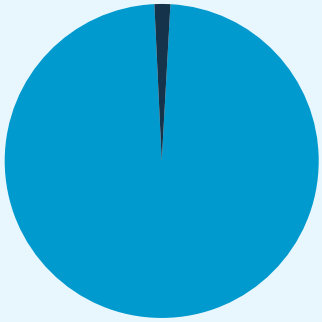
Congress passed the Bayh-Dole Act in 1980 with strong bipartisan support, creating a framework where researchers receiving federal funds could patent their inventions and license them to private companies so they could continue to research and develop them into products that benefit the public. This landmark legislation ensures that innovative ideas are protected and brought to market. It has contributed nearly $2 trillion to the U.S. economy and supported 6.5 million jobs.

Without the Bayh-Dole Act and significant investments and financial risks shouldered by the private sector, any knowledge gained through government-supported research would generate interesting ideas but very few new products.

Development of New Medicines Relies on Private Sector Expertise and Investment

Of the 18 FDA-approved medicines with patents linked to National Institutes of Health (NIH) grants from the year 2000, total private investment exceeded NIH funding by orders of magnitude: $44.2 billion in private investment compared to $670 million in NIH funding.

Private vs NIH investment for products with NIH-linked patents



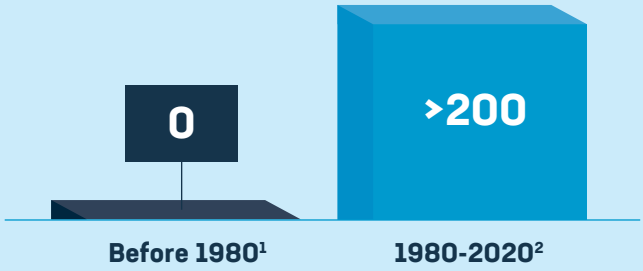
98.5%
Private Investment

1.5%
NIH Investment

Note: Findings based on an analysis by Vital Transformation

Before Bayh-Dole, not a single drug had been further developed utilizing patents generated with government funding. In contrast, since 1980 over 200 new drugs and vaccines have been developed through public-private partnerships facilitated in part by Bayh-Dole.

Cumulative number of approved medicines built on government-funded research



The Bayh-Dole Act was never intended to be a mechanism to regulate medicine prices.

Under Bayh-Dole, the federal government has the right to "march in" under a narrow set of circumstances. This would require patent holders to license their inventions to additional companies if the original licensee isn't making good-faith efforts to develop the technology into a usable, real-world product. The NIH has noted that price is not included in the law as a circumstance warranting exercise of march-in provisions. Using this Bayh-Dole provision for price regulation could stifle the same innovation this policy was designed to help accelerate.

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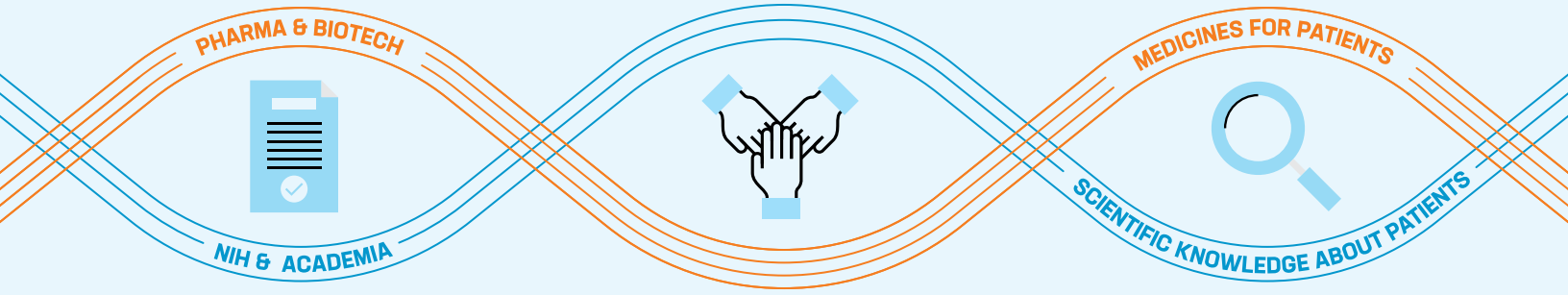
Public-Private Collaboration Fuels the U.S. Biopharmaceutical Ecosystem



Patents and Licenses:

Patents allow researchers to protect and license their inventions for further development and potential commercialization, enabling the U.S. biomedical research and development ecosystem to lead the world in biopharmaceutical progress.

Exchange of Scientific Knowledge:

Private industry, academic and government scientists work to understand the function of newly discovered molecular compounds and cells or little-understood disease processes. This knowledge is shared in peer-reviewed publications, scientific meetings, patents and licensing of intellectual property. This exchange of scientific knowledge fuels the creation of ideas for new medicines.

Research Collaboration:

Industry, academic and government scientists collaborate on research questions, but the biopharmaceutical industry takes the risks to advance basic scientific research into safe and effective treatments and cures for patients through further research and commercialization.

"Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector. The purpose of our act was to spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner."

Sen. Birch Bayh and Sen. Bob Dole
in 2002

"Many lawmakers want the government to use march-in rights to seize brand-name drug patents and relicense them to generic manufacturers. They have good intentions…But if companies fear that the government will intervene after years of expensive R&D, they will not invest in the first place."

Carol Mimura,
Assistant Vice Chancellor for Intellectual Property & Industry Research Alliances at the University of California, Berkeley

"Bayh-Dole's authors made clear: March-in rights are not to be used for government price controls. March-in rights are a backstop to ensure that private sector licensees put technologies to work benefiting society."

Walt Copan,
Former director of the National Institute of Standards and Technology

1. Statement of Elmer B. Staats, comptroller general of the United States, Before the Committee on the Judiciary United States Senate, "S. 414-The University and Small Business Patent Procedures Act," May 16, 1979 https://www.gao.gov/assets/100/99067.pdf

2. Chart based on an analysis from AUTM

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