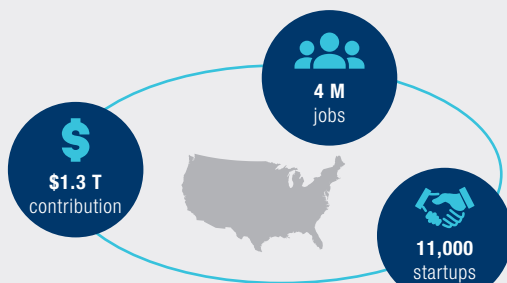


THE BAYH-DOLE ACT

The Law At-A-Glance

- Empowers universities, small businesses and non-profit institutions to take ownership of inventions made during federally-funded research, so they can license these basic inventions for further applied research and development and broader public use.
- Encourages private-sector investment needed to turn basic government-funded biomedical research into tested and approved products, requires these products to be manufactured domestically and ensures royalties for universities to further advance basic research and education.
- Allows the federal government to “march in” under limited circumstances, such as if a licensed invention is not being made available for public use. The law’s march-in provisions are not a mechanism for government regulation of market prices for innovative products.
- Enacted by Congress with strong bipartisan support to ensure basic innovations discovered through federal research are developed into real-life products, including approved therapies that reduce suffering, treat the sick and improve the lives of patients.

The Bayh-Dole Act has bolstered U.S. economic output by **\$1.3 trillion**, supported **4.2 million jobs**, and helped lead to more than **11,000 start-up companies**.



Source: Association of University Technology Managers

Bayh-Dole Act (1980)

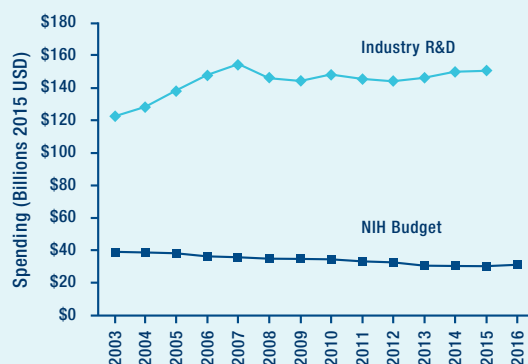
No new drugs or vaccines were commercialized when the government took patent rights away from inventing organizations.

More than 200 new drugs and vaccines developed through public-private partnerships.

BEFORE ◀ **AFTER**

Source: Government Accountability Office; Joseph Allen, IPWatchdog.com, June 2017

GLOBAL INDUSTRY R&D VS NIH BUDGET



Source: Evaluate Pharma; National Institutes of Health Budget Office

INNOVATION'S GOLDEN GOOSE

“Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980... More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.”

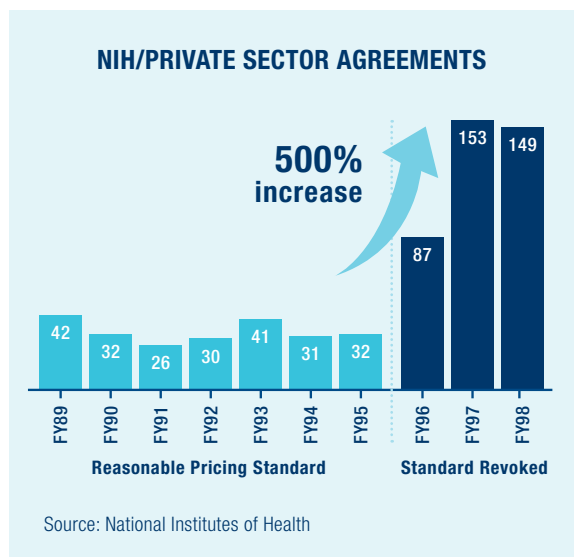
– The Economist

Preserving a Unique Public-Private Partnership for Future Innovation

The Bayh-Dole Act benefits the U.S. economy, taxpayers, consumers and patients, but certain activists are trying to undermine the law. Some want to force the government to “march-in” by arbitrarily tying prescription drugs prices in the U.S. to prices set in foreign countries. If successful, these efforts would stifle medical innovation, hurt small businesses, weaken military readiness and undermine decades of bipartisan consensus.

STIFLE MEDICAL INNOVATION

- **57%** of all new drugs are developed in the U.S. While other countries have great researchers and universities, they also impose price controls on medicines. Importing foreign prices controls will stifle innovation and deny patients the future cures they need.
- **In 1989**, the National Institutes of Health (NIH) adopted a “reasonable pricing” standard. It was revoked in 1995 because it was “a restraint on the new product development that the public identified as an important return of their research investment.”

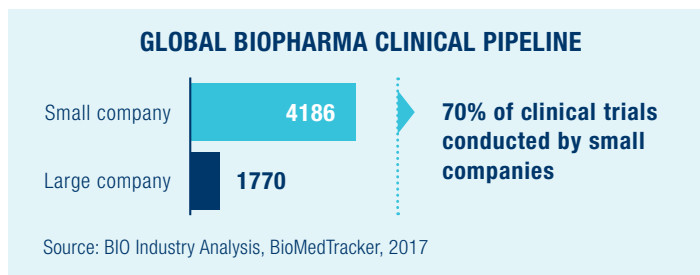


UNDERMINE BIPARTISAN CONSENSUS

- **On six different occasions** activists have tried to force the government to exercise its march-in rights because of drug prices. All six times, those efforts have been rejected by both Democratic and Republican Administrations.
- **In 2012**, NIH Director Francis Collins rejected a petition to exercise its march-in authority, stating the “extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available to physicians and patients.”

HURT SMALL BUSINESSES

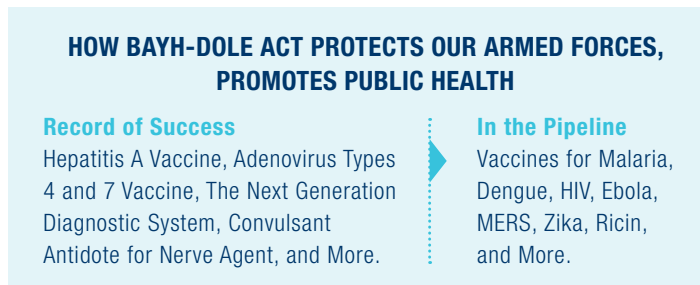
- **Approximately 70%** of university innovations are licensed to small companies, and the vast majority of all clinical trials are conducted by small biotech companies.



- **Biomedical innovation** is extremely expensive and time consuming. Weakening patent protections and adopting foreign price controls will make it harder for small companies to find the private capital they need to develop new cures.

WEAKEN MILITARY READINESS

- **The Armed Forces** face myriad threats, including infectious diseases and biological and chemical weapons. The Department of Defense (DoD) relies on private-sector partnerships to supply the resources and expertise needed to research, develop and manufacture critical medical countermeasures to treat and protect those serving in uniform.



- **Weakening the Bayh-Dole Act** will cripple the ability of the DoD to attract the private-sector partners necessary to protect our Armed Forces and the public’s health.

“Over the past decade we have seen a series of unpredicted naturally-occurring disease outbreaks...In each of these public health emergencies a number of major pharmaceutical companies stepped forward and at great costs...”

— Colonel Russel Coleman, former Joint Project Manager, Medical Countermeasure Systems