The Vital Importance of the Bayh-Dole Act to America's Life-sciences Innovation System

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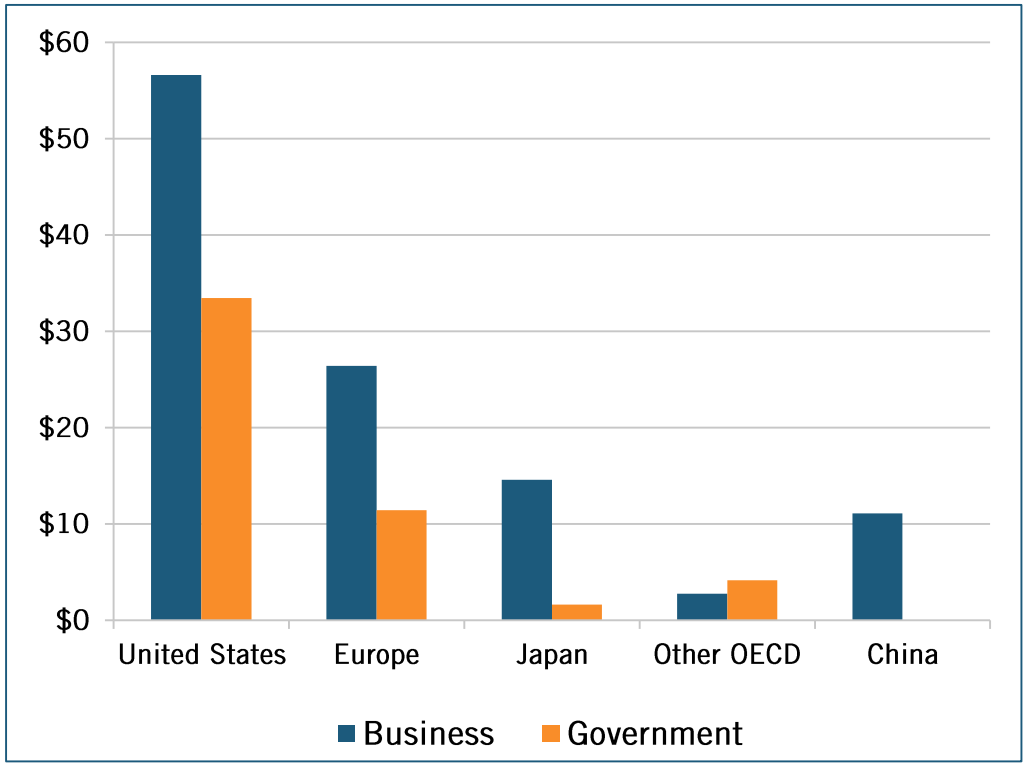
About ITIF

- The world's leading science and technology policy think tank.
- Supports policies driving global, innovation-based economic growth.
- Focuses on a host of issues at the intersection of technology innovation and public policy across several sectors:
  - Innovation and competitiveness
  - IT and data
  - Telecommunications
  - Trade and globalization
  - Life sciences, agricultural biotech, and energy

U.S. Leads in Global Life-sciences R&D and Innovation

Business and Government Investment in Pharmaceutical R&D (in Billions), 2017



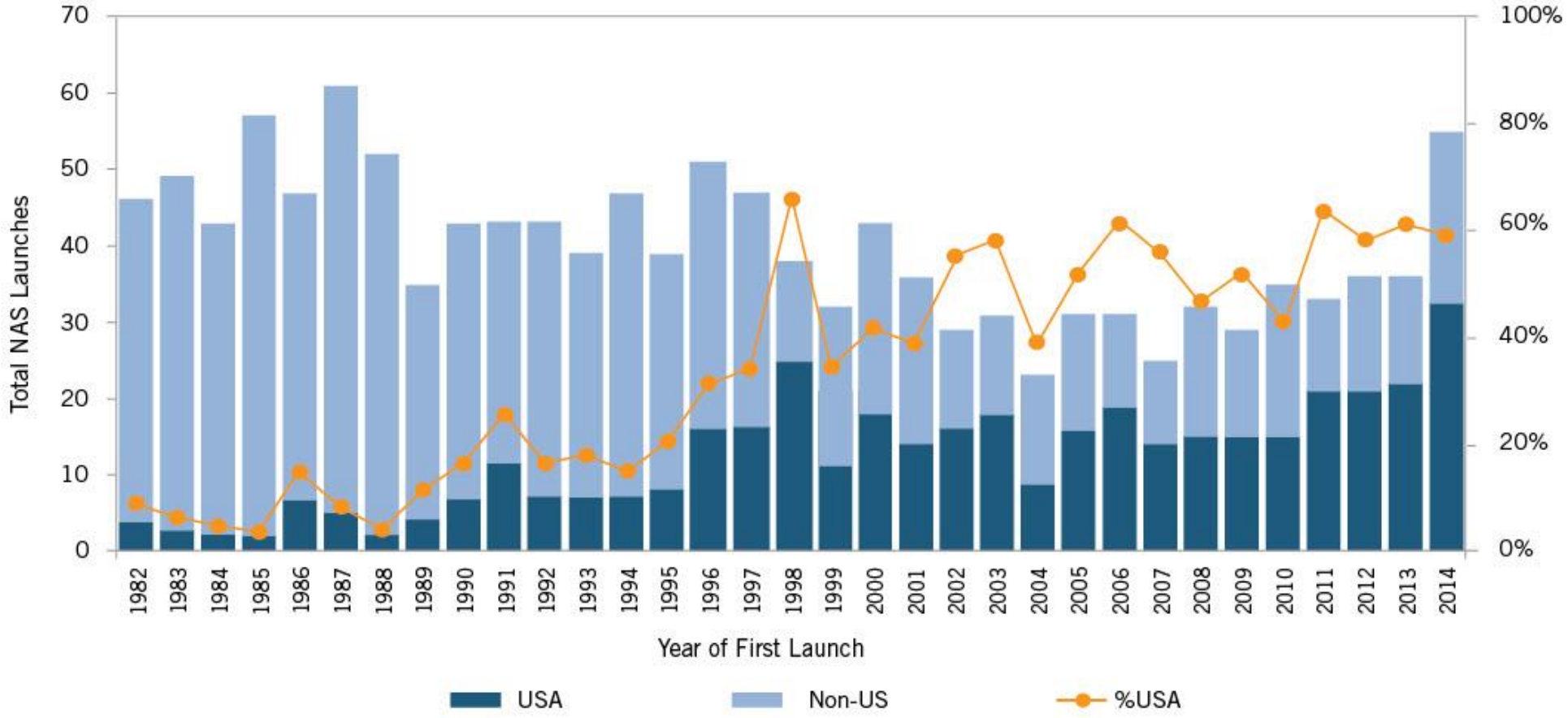
Number of New Chemical or Biological Entities Produced, 1997-2016

Region	1997-2001	2002-2006	2007-2011	2012-2016	Total
U.S.	84	67	65	88	304
Europe	79	46	52	75	252
Japan	29	21	20	32	102
Other	4	14	12	38	64

Source: ITIF, "How to Ensure That America's Life-Sciences Sector Remains Globally Competitive"

But It Wasn't Always That Way

U.S. Share of New Active Substances (NAS) Launched First on World Market



Source: John K. Jenkins, M.D., "CDER New Drug Review: 2015 Update

Keys to U.S. Life-sciences Innovation Leadership

1. Robust public/private investment in biomedical research.
2. Strong incentives to encourage investment.
   (e.g. R&D tax credit, Orphan Drug Tax Credit)
3. Effective regulatory/drug approval system (e.g., PDUFA).
4. Pricing/reimbursement system allowing innovators to earn sufficient revenues to support research.
5. Robust IP rights/protections, including the Bayh-Dole Act.

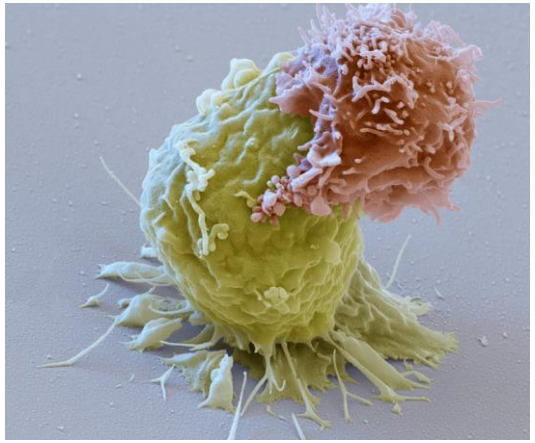


Image of a CAR-T cell (reddish) attacking a leukemia cell (green).

Source: ITIF, "Why Life-Sciences Innovation is "Politically Purple"—And How Partisans Get It Wrong"

The Bayh-Dole Act

- Bipartisan legislation, passed in 1980, giving universities rights to IP generated from federal funding.

What drove Congress to enact Bayh-Dole?

- Faltering commercialization of federally funded research.
- Faltering U.S. economic competitiveness in late 1970s.

The Bayh-Dole Act: Impact

- Led to a 10-fold increase in academic patenting in first 20 years; over 80,000 patents and 12,000 start-ups resulting from academic tech transfer.
- Over 200 drugs and devices developed through public-private partnerships facilitated by the Bayh-Dole Act.
- *The Economist: "Possibly the most inspired piece of legislation to be enacted in America over the past half-century."*

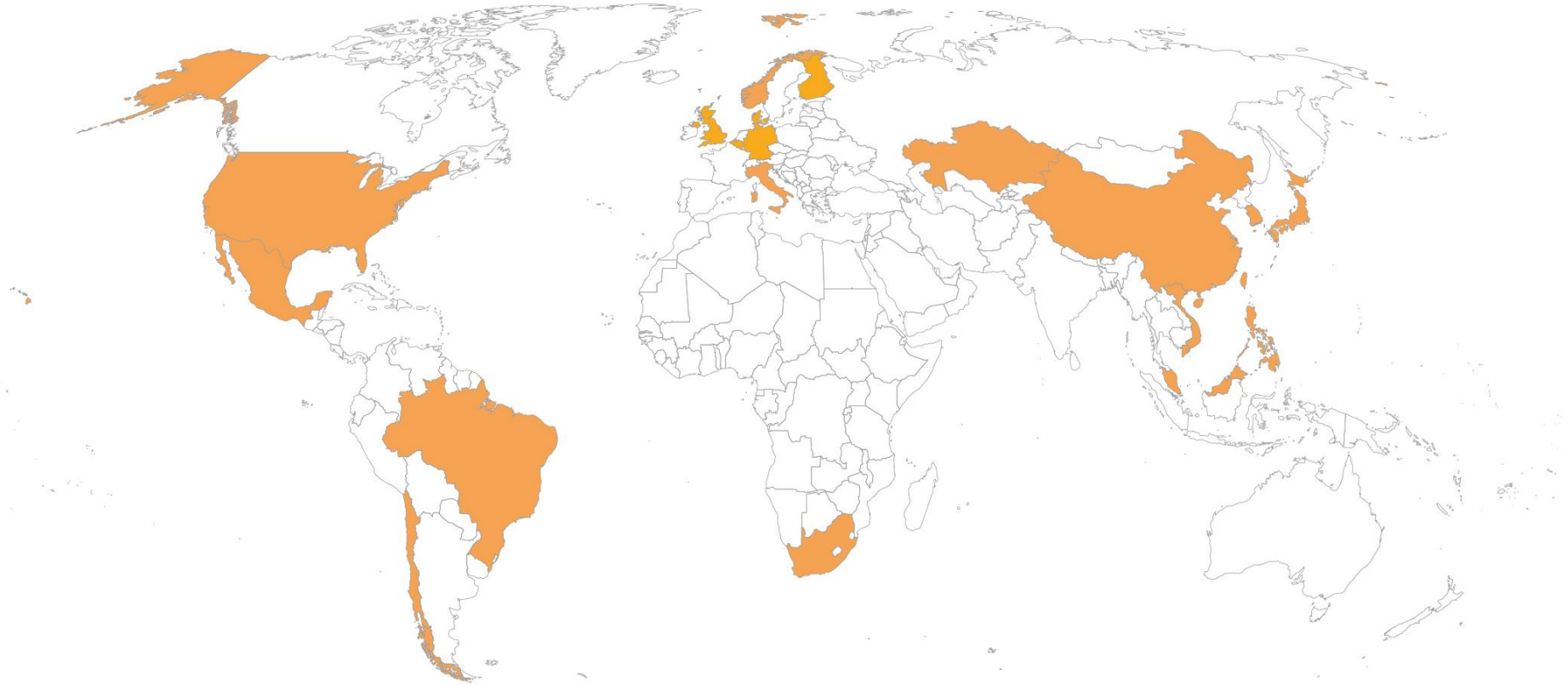
OPINION

Innovation's golden goose

The reforms that unleashed American innovation in the 1980s, and were emulated widely around the world, are under attack at home

The Bayh-Dole Act: Emulated By Countries Worldwide

Sample Countries That Have Enacted Bayh-Dole-like Legislation



Complementary Roles of Key Actors in U.S. Life-sciences System

- **Federal government:** Funds basic research (NIH: $39B) identifying underlying mechanisms of disease/promising points of intervention.
- **Universities:** Conduct $38B of life-sciences research annually, creating new knowledge/discoveries often licensed to private sector.
- **Private sector:** Invests $90B in R&D/clinical trial activities required to turn basic life-sciences discoveries into new drugs, devices, therapies.

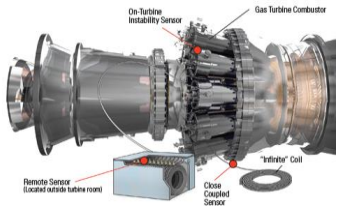
$100 of private investment for every $1 of public investment to a new drug.

Sources: ITIF, "The Bayh-Dole Act's Vital Importance to the U.S. Life-sciences Innovation System";
Chatterjee and Rohrbaugh, "NIH Inventions Translate Into Drugs and Biologics With High Public Health Impact"

Bayh-Dole Case Study: CardioMEMS

- Mid-1990s: Dr. Mark Allen receives $500K ARL grant to develop sensors for jet turbines.
- Patents awarded in 1999, assigned to GATech.
- 2000: Begins working with colleagues to adapt wireless MEMS sensors for human body.
- 2001: Incorporates CardioMEMS, for remote pulmonary artery monitoring, attracts $50M VC.
- FDA approved in 2005; users have experienced a 37% reduction in heart failure hospitalizations.

United States Army Research Laboratory



DISCOVER INNOVATE ARL TRANSITION

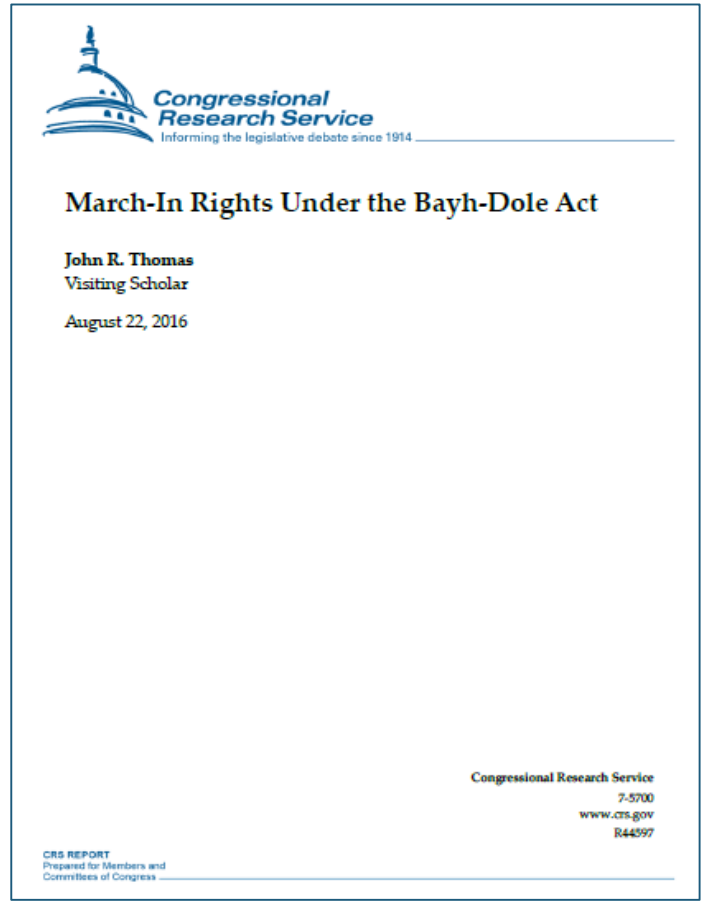
Georgia Tech

cardiomems

Bayh-Dole March-In Rights

Under certain circumstances, the government retains the right to "march-in" and require patent holders to grant licenses:

- If the contractor fails to take effective steps to achieve practical application of the subject invention;
- If the product can't be substantially U.S.-manufactured;
- If contractor can't meet requirements for public use specified by federal regulations;
- If action needed to alleviate health or safety needs which aren't "reasonably satisfied" by the patent holder.


Congressional Research Service
Informing the legislative debate since 1914

March-In Rights Under the Bayh-Dole Act

John R. Thomas
Visiting Scholar

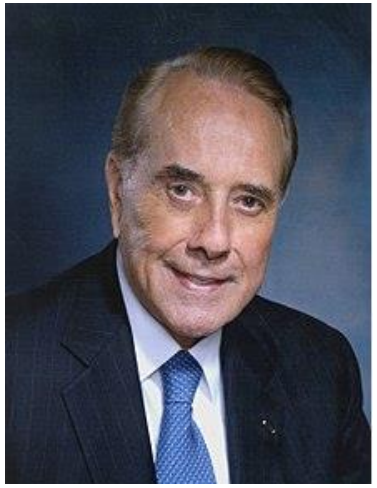
August 22, 2016

Congressional Research Service
7-5700
www.crs.gov
R44557

CRS REPORT
Prepared for Members and Committees of Congress

Source: CRS, "March-In Rights Under the Bayh-Dole Act"

March-in Rights Not Intended to Address Pricing



"Bayh-Dole did not intend that government set prices on resulting products.

The law makes no reference to a reasonable price that should be dictated by the government.

This omission was intentional."

The Washington Post

Our Law Helps Patients Get New Drugs Sooner

As co-authors of the Bayh-Dole Act of 1980, we must comment on the March 27 op-ed article by Peter Arno and Michael Davis about this law.

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.

For every $1 spent in government research on a project, at least $10 of industry development will be needed to bring a product to market. Moreover, the rare government-funded inventions that become products are typically five to seven years away from being commercial products when private industry gets involved. This is because almost all universities and government labs are conducting early-stage research.

Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a **reasonable** price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.

The article also mischaracterized the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.

The law we passed is about encouraging a partnership that spurs advances to help Americans. We are proud to say it's working.

BIRCH BAYH

BOB DOLE

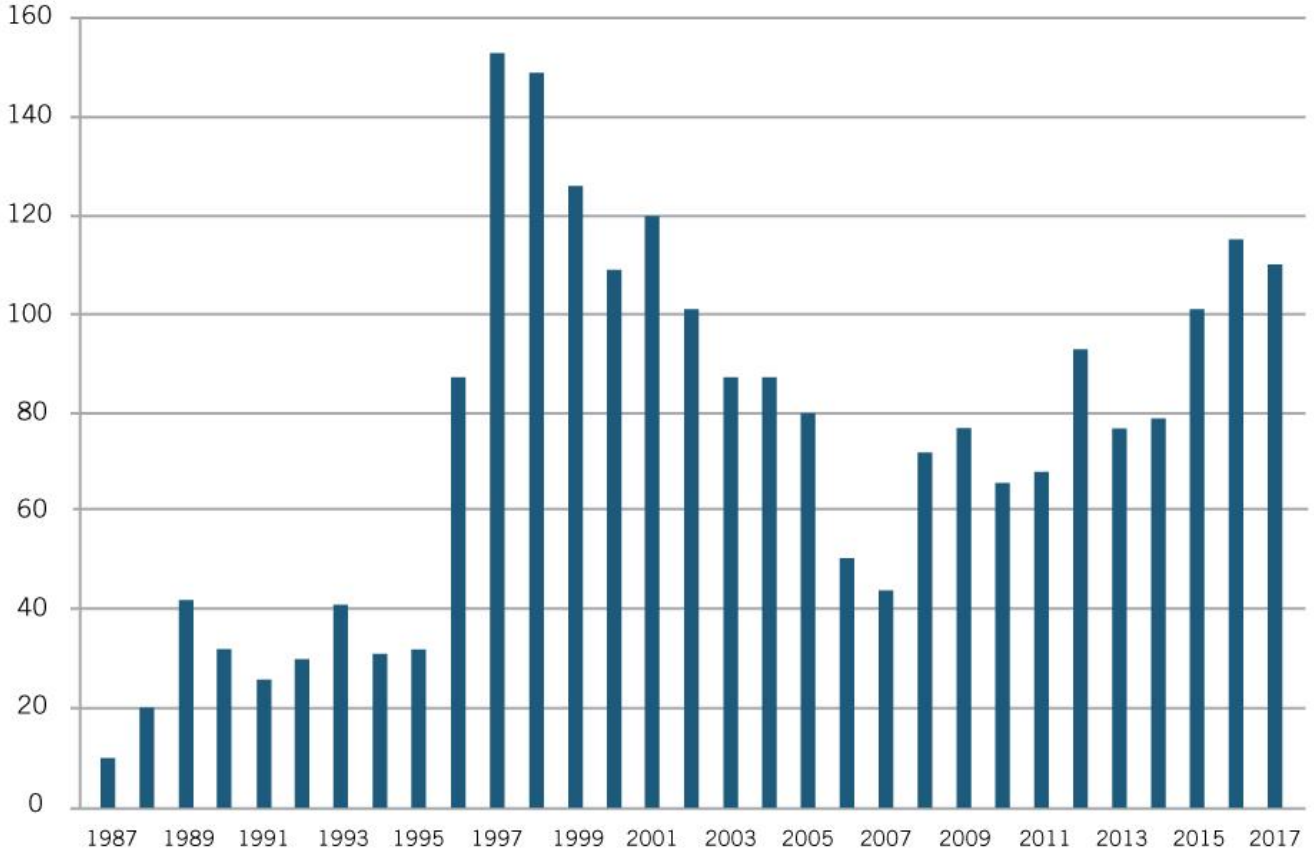
Washington

Inclusion of "Reasonable Pricing" Clause Stunted Innovation

NIH imposed "reasonable price" requirements on CRADAs in 1990; NIH repealed then in 1995.

Varmus: "The pricing clause has driven industry away from potentially beneficial scientific collaborations."

NIH New CRADAs Per Fiscal Year, 1987-2017



Source: NIH Annual Reports; Joseph Allen, "Compulsory Licensing for Medicare Drugs– Another Bad Idea from Capitol Hill"

Conclusions

1. U.S. life-sciences leadership is the result of conscientious policy choices that need to be sustained.

2. The Bayh-Dole Act is working effectively, and as intended, enabling valuable financial support for America's research universities.

3. Application of march-in rights to control drug prices not intent of law and would undermine U.S. life-sciences system.

Thank You!

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