1980 Bayh-Dole Act
Frequently Asked Questions

- What is the purpose of the Bayh-Dole Act?
    - The Bayh-Dole Act created a uniform "technology transfer" process across federal research agencies, ensuring that federally funded research could move along the R&D pipeline.
    - The Bayh-Dole Act permits research institutions, other non-profit organizations, and small businesses to hold patents on inventions that stem from government-funded research, enabling them to license the rights to those inventions to private sector partners who can then invest the additional research & development needed to commercialize them.
    - This "technology transfer" mechanism created an environment in which U.S. science and technology flourished. Since 1980, university research alone has catalyzed over $1.3 trillion dollars in economic growth, 4.2 million jobs, and 11,000 start-ups that can be directly attributed to the Bayh-Dole Act's passage.
- What has the Bayh-Dole Act achieved since 1980?
    - The Bayh-Dole Act has had impacts across academia, industry, and the market. Here are a few examples of the Act's impact:
        - $1.9 trillion contributed to U.S. gross industrial output.
        - $1 trillion contributed to U.S. gross domestic product.
        - 6.5 million jobs supported.
        - Over 495,000 inventions disclosed, and over 126,000 U.S. patents issued.
        - Over 200 drugs and vaccines developed through public-private partnerships attributed to the Bayh-Dole Act.
        - According to the former President of NASDAQ, an estimated 30 percent of its value is rooted in university-based, federally funded research results, which might never have been commercialized had it not been for the Bayh-Dole Act.
- What are "march-in" rights?
    - As part of the Bayh-Dole Act, the government retains march-in rights that provide it the authority to require that the patent holder relicense their patent under any of the following specific circumstances:
        - "Such action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.
        - Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee or their licensees;
        - Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee or licensees; or
        - Such action is necessary because the agreement required by paragraph (i) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement."
- Does Bayh-Dole only apply to NIH?
    - No, the Act applies to technology transfer across the federal government, including the major Federal R&D funding agencies: the Department of Defense; the Department of Health and

Human Services , including the National Institutes of Health; the Department of Energy; NASA, and the National Science Foundation.

- Have march-in rights been exercised by the federal government?"
    - Both the Department of Defense and the NIH have been petitioned to use march-in, but to date, no federal agency has ever utilized its march-in rights. The NIH has been petitioned to do so eight times.
- What was NIH's "reasonable price" clause?
    - From FY90 to FY95, NIH added a "reasonable price" clause to its Cooperative Research and Development Agreements (CRADAs). Under this clause, a company taking an exclusive license to bring an NIH supported product to market could be compelled by the NIH to submit documentation showing that there was a "reasonable relationship" between the price of the product, the public investment into the product, and the health and safety needs of the public. Under the statute the terms "reasonable price" and "reasonable relationship" are not in the Bayh-Dole Act. In 1995 the decision was made to drop the reasonable price clause because NIH saw a steep decline in the willingness of companies and researchers to take part in collaborative research with Public Health Service (PHS) Scientists.
- Did Congress intend march-in rights to be applied to prescription drugs on the basis of pricing?
    - No. Based on both the testimony of the bill's sponsors and the plain language of the act, prices are not part of the legislation establishing or the legislative intent behind the Bayh-Dole Act. In fact, Senators Bayh and Dole have written that "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."
- What are the pros and cons of applying march-in rights to prescription drug pricing?
    - Pros:
        - Potentially lower prices for prescription drugs and other products that were researched and developed in part with federal funding.
    - Cons:
        - Lowered cooperation and collaboration between PHS Scientists and the private sector.
        - Lowered public benefit of medical breakthroughs as companies avoid taking on NIH-supported licenses.
        - Stifling of medical innovation as inventions begin to pile up in government stockpiles.
        - The proposed changes to Bayh-Dole pose a threat to academic research, potentially impeding scientists from exploring their ideas across all sectors and depriving them of opportunities that could serve as an additional pathway for research.
        - Harder time attracting and recruiting researchers to become PHS Scientists.
        - A return to a pre-Bayh-Dole Act market, where NIH-sponsored findings are stockpiled and the pace that the public would benefit from medical innovation is slowed.
        - Requiring federal research agencies to regulate product pricing would dilute their respective research-focused missions, compromising their contributions to scientific, medical, and public health progress.
- What would the march-in framework the Department of Commerce and NIST have proposed do?
    - The proposed framework marks a change in federal precedent, placing the NIH and other federal research agencies in the position of evaluating market prices and rescinding technology transfer agreements if a product price is deemed "unreasonable."