

## Time for tech transfer law to change? U-M doctor looks at history of Bayh-Dole and says yes

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The law that has helped medical discoveries make the leap from university labs to the marketplace for more than 30 years needs revising, in part to ensure the American people benefit from science their tax dollars have paid for, says a University of Michigan Medical School physician and medical historian.

In a new commentary in the *New England Journal of Medicine*, Howard Markel, M.D., Ph.D., director of the U-M Center for the History of Medicine, looks at the fluke-ridden history of how the law known as Bayh-Dole Technology Transfer Act was passed in 1980. The law made it much easier for research findings made by academics to be patented, licensed by companies and commercialized.

The haphazard history of Bayh-Dole, and the issues and risks that have arisen since it was passed, suggest it is time to re-examine and revise the law, says Markel.

The need for more modern guidance of the process known as technology transfer, and the conduct of ethical and socially just partnerships between academia and industry, was reflected in the recent unanimous Supreme Court ruling that barred the patenting of <a href="https://example.com/human\_genes">human\_genes</a> – though allowed other patents of gene-related discoveries, Markel says.

He traces the history of the Bayh-Dole law, which allows universities and



other institutions that receive federal research dollars to grant exclusive licenses to companies that wish to commercialize discoveries made by academic researchers.

Initially conceived as a way to help the United States economy at a time when industry was struggling to keep up with German and Japanese innovation, the proposal only became law because of last-minute wrangling during the final days of a lame-duck Congressional and presidential term.

"The Bayh-Dole Act has had such far-reaching influence in both academia and American society, but it certainly is not a law that should be set in stone," says Markel. "The very passage of the act was based on a series of quirky, historically improbable events, and random and entropic processes. There have been many great things and grave problems that have emerged since the passage of Bayh-Dole, but because the landscape of biotechnologies in universities and industry has evolved so far, so fast, it's time to have a rational, serious dialogue about revising it to reduce the risks the law has created."

Markel notes that partnerships between industry and academia are important, and is not calling for a separation of the two spheres.

Rather, he feels that more consideration needs to the ethics of industry/academic interaction, the need for continued support of basic research, scientific data sharing, and the payback for American taxpayers whose dollars support research before commercialization.

"We're all paying for these discoveries, which can lead to profits for the individual researchers, their institution and the company that commercializes the idea," he says. "But the one investor that can be left out of the profit equation is the American taxpayer."



## More information:

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