



AUTM CEO Stephen Susalka Comments at NIST Public Webinar on Proposed Changes to Bayh-Dole Regulations

WASHINGTON, DC, February 25, 2021 – My name is Steve Susalka and I’m the CEO of AUTM - a non-profit leader in efforts to move academic research innovations from the lab to the marketplace. Our community consists of 3,000 members who work in more than 800 universities, research centers, hospitals, businesses and government organizations around the globe.

Without a doubt, the Bayh-Dole Act has been instrumental in transforming early-stage discoveries into the products and services of tomorrow. Whether it’s a fire-fighting drone putting out wildfires, the intranasal FluMist dose you give to your child in lieu of a shot, or even your high-definition TV – each arose from early-stage research catalyzed by the Bayh-Dole Act.

It’s important to note that while universities and other nonprofits foster these innovations, they do **NOT** manufacture or sell the resulting products. That is accomplished by licensing that invention to a company that incurs all the future risk of advancing that innovation to a final product that is sold to the public. It’s AUTM’s mission to support that process - called technology transfer – and facilitate the translation of those early-stage ideas into the products and services of tomorrow.

History is our guide here. Before Bayh-Dole, as one example, not a single drug was commercialized when the patent rights were taken from the inventing institution by the government. Not a single one. Contrast that with today, when, according to Stevens and Rohrbaugh, more than 250 FDA approved drugs, vaccines, and in vivo diagnostics were discovered in whole or in part from academic institutions and have been licensed to industry - the majority of which benefited from a small amount of federal funding.

To that end, today we want to comment on the proposed march-in rights clarification.

As you may have heard, the march-in right provision has been wrongly proposed as a tool to control prices, when in fact there is no legal or historical basis for that approach. In order to keep Bayh-Dole strong and combat the inappropriate implementation of march in rights, we recommend removing both the word “exclusively” and the phrase “of the contractor” in proposed provision 401.6(e).

This revised provision will add certainty to those companies that are licensing groundbreaking inventions out of universities and other non-profits. In the absence of this type of assurance, these inventions likely will never make it to the market for the good of society. If potential licensees and their investors become averse to taking on the risks involved in developing and commercializing federally funded inventions, then pricing becomes a moot point because there will be no product to price. Let’s not reverse these decades of progress. Thank you.