

Senate Armed Services Committee Directs DoD to Reduce Drug Prices

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In its [Report](#) on the National Defense Authorization Act for Fiscal Year 2018, the Senate Armed Services Committee (the “Committee”) included an “Item of Special Interest” directing the DoD to exercise its rights under the Bayh-Dole Act “to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States” as compared to prices in foreign countries. This directive does not have the force of law, and was included as an item of special interest after an amendment to incorporate the clause into the NDAA failed. However, it represents an example of efforts to use the Bayh-Dole Act to influence drug product pricing.

Congress passed the Bayh-Dole Act in 1980 to address the stagnant state of innovation in the United States. The statute created a careful balance of public and private interests in inventions that receive government seed funding. This balance conveys to the inventor title to the invention and the ability to offer an exclusive license to private industry, while providing the government royalty-free use of the invention for government purposes and the ability to safeguard the public interest through the exercise of march-in rights. This balance spurred innovation, especially in the context of collaborations between universities and private industry. Universities were able to maintain title to their inventions, while licensing the invention to private industry who would bear the significant cost of commercializing an invention in exchange for the assurance that it could benefit from its exclusive license to the invention. This approach has been very successful. In 2014 alone,

university technology transfer programs resulted in 6,363 patents issued to universities, 5,435 licenses executed with private industry, and 965 new commercial product launches. By contrast, prior to the Bayh-Dole Act, universities receiving government funds secured fewer than 250 patents each year and only a small portion of such patents were successfully commercialized.

Against this backdrop, it is difficult to see how or why DoD would implement the Committee's directive.

- First, as reflected above, the Bayh-Dole Act has created a careful balance of interests. It seems unlikely that an agency charged with defending the country — not with making healthcare or patent policies — would interfere with this balance by effectively imposing rigid price controls on a particular class of products. Indeed, doing so could chill the progress in innovation that has been spurred by the Bayh-Dole Act and leave private industry less willing to undertake the significant investment of commercializing an invention. In addition, it would create an irrational inconsistency in how different industries are treated under the same statute.
- Second, even if the DoD were to attempt to implement the Committee's directive, the proposed action falls outside the current statutory framework. The Bayh-Dole Act only allows the government to grant third-party licenses in limited situations, and none of the situations involve or consider the price of the products incorporating the inventions. It is possible that if the directive is moved from an item of special interest in the Committee's Report into the NDAA itself, there could be new statutory authority under the Bayh-Dole Act to affect pricing. That said, such authority would only have the potential to apply to inventions conceived or reduced to practice with DoD funding during the relevant NDAA fiscal year and would not be retroactive. Further, any such authority would require re-authorization in the subsequent year's NDAA.
- Third, the Committee language appears to be well beyond that contemplated by the Bayh-Dole Act as it directs DoD to take action with respect to any invention that directly or indirectly received DoD funding. DoD's authority under the Bayh-Dole Act does not stretch to any invention that benefits from DoD funding. Instead, the Bayh-Dole Act only applies when an invention is first conceived or reduced to practice with the support of federal funding. Broadening DoD's authority could have catastrophic effects on private industry's willingness to share proprietary technology in any way with the U.S. Government.

Although the DoD lacks the proper policy foundation and statutory authority to implement the Committee's directive, contractors would be well advised to monitor continued attempts to influence pricing through the Bayh-Dole Act. Additionally, contractors should assess the intellectual property to which they hold title or an exclusive license to identify any inventions — whether in the drug product context or otherwise — that may be encumbered by the Bayh-Dole Act or may have benefitted from federal funding.

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