Senator King's Compulsory Licensing Amendment Is Bad Law and Bad Policy

Summary

Senator Angus King added an amendment to the Committee Report for the National Defense Authorization Act that directs the Department of Defense (DOD) to use two provisions of the Bayh-Dole Act (P.L. 96-517, as amended) to issue compulsory licenses for any drug arising from DOD-funded research, if such drug is priced "higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States."

This amendment is based on a long-discredited theory of how the Bayh-Dole Act operates that has been repeatedly rejected over the years by the National Institutes of Health under both Republican and Democratic Administrations, and most recently by the Department of Defense itself.

If not removed, the amendment would undermine public/private sector R&D partnerships, and thereby inflict considerable damage to a system that has long helped drive the U.S. economy and make America the world's beacon of biomedical innovation. While the intent of the amendment is to enhance access to new medicines for patients in need, ironically its impact would be that fewer new drugs would be developed to protect the public health. And for a variety of practical and legal reasons, it would do little if anything to enhance access to even today's existing drugs.

The King Amendment must not be included in any final DOD authorization bill or accompanying report language.

The King Amendment Would Undermine the Success of the Bayh-Dole Act

The purpose of the Bayh-Dole Act is to encourage the commercial development of federally-funded inventions by decentralizing the ownership and management of inventions away from government bureaucracies in Washington, D.C., and to the universities and small businesses that discover them in the course of their research. The law also allows federal laboratories flexibility in how they license the inventions they discover.

Before Bayh-Dole, the government took ownership of all such inventions, offering

them to any and all third parties under non-exclusive licenses. *The Comptroller General found that, as a result of this non-exclusive approach, not a single new drug had been developed based on federally-funded research*. A key objective of the law was to allow federally-funded grantees and contractors to take ownership of inventions they develop with such funding, and to license such inventions on either an exclusive or non-exclusive basis to third parties for purposes of further commercial development. The law also created a uniform patent policy across all agencies, replacing more than 20 inconsistent policies that were then in place.

To guard against potential abuse of this new system, Congress incorporated into Bayh-Dole a government "march-in" provision. Under this authority, if a Federal funding agency determines that good faith efforts are not being made by a licensee to bring an invention to "practical application" so that it is "available to the public on reasonable terms," the funding agency can insist that additional licenses be issued to others so that the invention can be made more readily available. March-in rights also can be used in public health or other national emergencies, if the licensee is unable to manufacture enough product to meet such public needs. The law also gives federal agencies a royalty-free license to practice such inventions themselves for use by the federal government.

Importantly, these march-in and government use authorities are discretionary, permitting funding agencies to balance all appropriate factors when considering whether to utilize such authorities and to what extent.

Since passage of the law in 1980, more than 200 federally-funded inventions have been developed into marketed new drugs and vaccines through public-private technology licensing and partnerships. Publicly-funded inventions generate more than two new start-up companies and new products every day. A recent economic impact study found that over 20 years (1996- 2015) the law contributed up to **$1.33 trillion** to the U.S. economy, while supporting more than **4 million** well-paying jobs. No other country comes close to matching these numbers. The Economist Technology Quarterly said: ***"Possibly the most inspired piece of legislation to be enacted in America over the past half century was the Bayh-Dole Act of 1980… More than anything, this simple policy helped to reverse America's precipitous slide into industrial irrelevance."***

The King amendment puts this success at grave risk by mandating an inflexible and counterproductive licensing approach that is inconsistent with how Bayh-Dole operates across the federal government – thus undermining the key objectives of this enormously successful law.

Pricing Is Not a Basis for March-In under Bayh-Dole

Over the last two decades, it has been claimed repeatedly by certain activist groups that the Bayh-Dole Act authorizes the government to issue compulsory licenses whenever a product's price is higher than it may think is warranted. Both Senators Bayh and Dole have made clear in the past that this view is a gross misinterpretation of their law. They have stated that their law only gives agencies the authority to march-in if a product isn't available for public use. There also is no reference to pricing as a basis for "marching in" in either the statute or its legislative history.

Despite this history, a march-in petition was filed in 2004 with the National Institutes of Health (NIH), urging the agency to issue compulsory licenses for the AIDS drug Norvir, based on its price. Senator Bayh testified at the ensuing NIH public meeting on the petition, stating that the language of the petition deliberately misquoted the legislative history of Bayh-Dole and adding that, if Congress wanted the law to serve as a mechanism to control prices of commercially available products, it would have to amend the statute to provide such authority and to define what a "reasonable price" means. That, of course, has never been done, despite the fact that Congress has repeatedly considered and rebuffed efforts by critics of the law to do just that.

NIH correctly rejected the Norvir petition. And over the next 13 years, federal agencies have been petitioned four more times to issue compulsory licenses based on the price of commercially available medicines (a second march-in petition against Norvir, one against Latanoprost, and two against Xtandi). In every instance, and in both Republican and Democratic Administrations, these petitions were denied on the grounds that Bayh-Dole does not permit march-in by the government on the basis of price where the product is otherwise being made commercially available by the licensee.

Most directly on point with the King amendment, in June 2016 NIH Director Francis Collins and then HHS Secretary Sylvia Burwell dismissed a march-in petition against the prostate cancer drug Xtandi. The petition argued that, because the drug is sold at a higher price in the United States than abroad, it met the march-in criteria of Bayh-Dole. In his denial letter, Dr. Collins directly addressed the contention that price, not market availability, is a march-in trigger. Citing the petition's own data, the letter states:

> *"... **Xtandi is broadly available as a prescription drug. Your letter states that***

sales of enzalutamide increased 77% from Fiscal Year 2013 to Fiscal Year 2014…, however, it provides no information and no information was identified from public sources that enzalutamide is currently or will be in short supply.

"In view of the above information presented in your letter and your follow-up correspondence and public information identified by the NIH, we decline to proceed with the government's march-in authorities at this time or utilize the government's license to the patents."

A similar march-in petition against the same drug also was filed with the Department of Defense, which was denied by that agency as well.

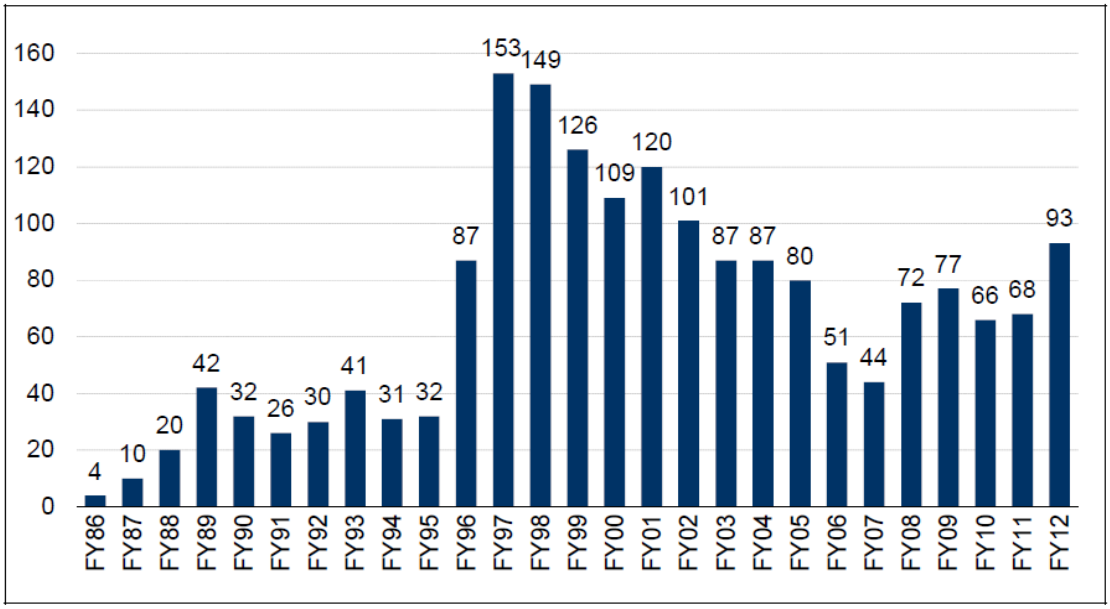
The King amendment is not the first attempt to force a price control formula into licensing and collaborative R&D agreements between government-funded research institutions and private companies. Similar Congressional pressure was applied in the early 1990s, forcing NIH to include a "reasonable pricing" provision in its agreements with licensees and collaborators. The provision led to a significant decline in NIH's public-private partnerships, as commercial parties justifiably were unwilling to invest in the risky, lengthy, and expensive development of federally-funded inventions with the threat of compulsory licensing of their products to competitors hanging over their heads.

In response, then NIH Director Harold Varmus revoked the provision in 1995, explaining: ***"the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public. […].One has to have a product to price before one can worry about how to price it, and this clause is a restraint on the new product development that the public identified as an important return on their research investment."*** [1]

Two years after Dr. Varmus intervened, NIH-industry cooperative research agreements were up more than 500% (Fig. 1). Since that experience, NIH has been adamantly opposed to including "reasonable pricing" provisions in its licenses or cooperative agreements, viewing them as counterproductive to the development of new drugs to meet patient needs.

[1] https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

Figure 1. NIH CRADAs



Source: National Institutes of Health, Office of Technology Transfer http://www.ott..nih.gov/about_nih/statistics.html.

The King amendment would have the same disastrous results at the Department of Defense that the previous attempt had at NIH.

The King Amendment Would Disproportionately Harm Small Businesses

Some of the greatest damage of the amendment will fall on small companies, the backbone of our vibrant, uniquely American biotechnology industry, and many of which form around academic inventions. About 70% of university inventions are licensed to small companies, and unlike other countries, about half of the new drugs developed in the United States originate in small businesses.

It has been estimated that companies spend $100 dollars on development for every $1 the government spent supporting the basic research leading to the invention. That is not surprising, because federally-funded research typically is at a very early stage of development, and focused more on ideas or potential targets than actual products. Under the Bayh-Dole system, the private sector assumes virtually the entire business risk and expense of product development and commercialization. And in drug development, that burden is considerable.

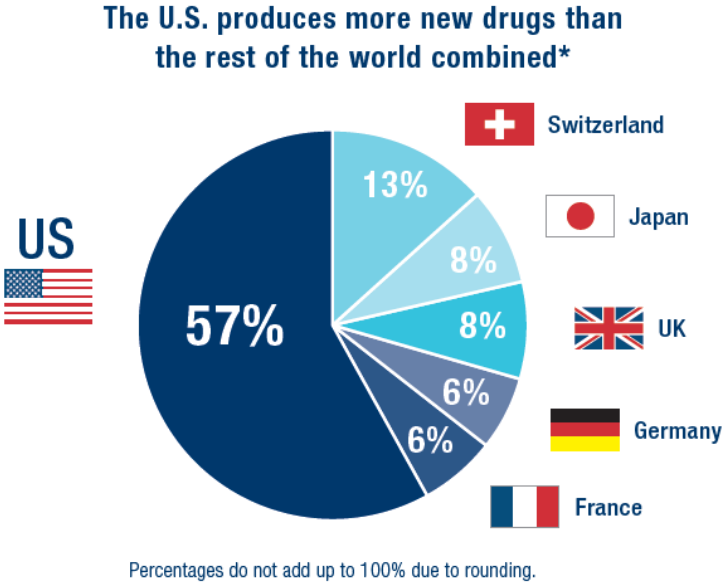
Developing a new drug is estimated to cost companies between $1 and $2 billion dollars, requiring more than a decade for development. Of every 10,000 compounds being investigated for potential medical use, about 250 make it to

preclinical testing, five proceed to clinical trials, and just one enters the marketplace as an approved drug. Of these approved drugs, many never recover their own cost of development, and thus the pricing on a few successful drugs must pay for the investments in all the others, including all those that failed in the pipeline.

What venture capitalist would fund or invest in a life science start-up built around a federally-funded invention if the King amendment passed? After assuming all the risks of development, a start-up could see the Department of Defense forced to grant compulsory licenses to its competitors (including much bigger companies) under Senator King's mandatory formula.

The King Amendment Would Import Foreign Prices Control on American Innovation and Jeopardize America's Global Advantage in the Life Sciences

The United States is the undisputed world leader in the life sciences. Nearly 60% of all new medicines are developed right here in the United States – more than in all other nations combined. U.S.-based companies and investors spend more than $70 billion each year on domestic biomedical research, more than twice the amount of the entire NIH annual budget, and these biopharmaceutical companies reinvest a higher percentage of their revenues back into R&D than any other industry in America.



While other countries also have great research universities and companies, there is one key distinction that sets the United States apart and is why America leads the world in biomedical innovation – virtually all other countries impose arbitrary

price controls on new medicines. These foreign price controls undervalue the fruits of American ingenuity and invention, and reduce investment in new medicines in those countries. It has been estimated that, had the United States adopted European-style price controls on new drugs over the past two decades, the world would have 117 fewer innovative medicines on the market today.

The King Amendment would, essentially, import these foreign price controls on American biomedical innovation and jeopardize our global advantage in this critically important technological field. More important, it would harm patients around the world urgently hoping for relief from currently untreatable or incurable diseases, as many investors might see developing new drugs as simply no longer worth the effort.

The King Amendment Is Unlikely to Make Products More Available to Patients

Even if DOD issued licenses to practice the invention to other companies, there are several practical considerations that are likely to limit the benefit to the public or the government from such actions. First, DOD cannot waive any of the requirements of the Federal Food, Drug & Cosmetic Act, which govern the approval of all drugs sold in the United States. Any such licensee would need to either (1) go through its own extensive R&D and regulatory approval process, which could take a decade or more at substantial expense, or (2) wait until a generic or biosimilar drug application can be submitted and approved after the expiration of the applicable reference product data exclusivity provided under federal law. Further, marketed products often incorporate additional patented inventions that were not funded with federal research dollars – and thus any DOD-issued license could not reach other patents essential to making the product.

Whatever the scenario, the process of bringing an alternative product to market under a DOD-issued compulsory license likely would consume years of expensive product development, regulatory review, and litigation in the courts.

Further, there is no guarantee that any such competitor, once on the market, would substantially lower its price. In fact, as the federal government has reported, substantial market discounts are unlikely until there are at least three competitors on the market for a particular drug. Thus, instead of helping patients, the King Amendment is more likely to simply shift sales from one private company to another.

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The King amendment is bad law and bad policy, and must be rejected.