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Effective Biomedical Public-Private Partnerships Are About Innovation, Not Lower Drug Prices

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There is fascination of late with the prospect of exercising Bayh-Dole Act "march-in rights," primarily as a means of reducing the price of expensive drugs that have been discovered or developed with federal funds. In recently published pieces in *Health Affairs Forefront* and elsewhere, some contend that the intended public health benefits of biomedical public-private partnerships will be realized only if the drug prices paid by consumers are reduced prior to patent expiry.

We believe that this rather narrow characterization is wrong. It ignores both the extraordinary impact on innovation that Bayh-Dole has spurred over the four decades since its passage and the price reductions that occur with the introduction of generic drugs following a period of market exclusivity.

Before addressing the controversy over march-in rights, it is important to recognize the inherent value of biomedical public-private partnerships. These collaborations often are the best way to make meaningful scientific and clinical progress in challenging areas such as treatments for neurodegenerative disorders. But they must be structured properly to establish clear goals from the outset that reflect the respective skills and resources of the parties. This should include aligning incentives, operating under transparent governance and reporting procedures, and ensuring mutual accountability.

Some believe that you can have your cake, and eat it too, as there is no definitive proof that innovation will be harmed if prices are substantially reduced. If one or two drugs were made available at lower prices following the exercise of march-in rights, this would establish a worrisome precedent; it would not, however, have the deleterious impact that would follow widespread price cuts in the United States, as would occur under a version of House Speaker Nancy Pelosi's HR 3. While it is impossible to know precisely the adverse impact on innovation that would follow price cuts (draconian or not), we do know that biopharmaceutical companies earn the vast majority of their profits in the United States, that venture capitalists invest in high-risk opportunities only if there is the prospect of a solid return on that investment in the event of success, and that venture-backed or venture legacy companies (for example, publicly traded companies that were backed by venture firms in their early years) play a huge role in discovering and developing new medicines.

In addition, there are a number of studies that bear (at least indirectly) on this question and suggest that biomedical innovation would be harmed over time by lower prices. For example, researchers and scholars have found that the 2003 Medicare Part D drug benefit has led to increased sales revenues and profitability, even with negotiated discounts; that this sales revenue growth has resulted in a concomitant increase in biopharmaceutical research and development (R&D) spending; that biopharmaceutical R&D spending also grows as expectations of profitability from product pipeline candidates with likely Medicare Part D coverage becomes evident, and that stock prices reflect this expectation; and that there are significant increases in biopharmaceutical pre-clinical and clinical spending for those drug classes that are most likely to be covered by Medicare Part D. Critics contend that pharmaceutical companies earn too much money, but in fact the industry's return on equity is less than the return of many others, including the technology sector. Taken together, these studies show that reimbursement leads to profits, profits lead to research, and research leads to new drugs.

The Bayh-Dole legislation (officially, the Patent and Trademark Law Amendments Act of 1980) was not intended to give the federal government access to low-cost drugs; it was to permit licensing of publicly funded university research inventions to private enterprises that would then develop them into commercially useful products. The university retains ownership of the underlying intellectual property and receives royalties if the licensee is successful. Bayh-Dole has met with great success, as more than 200 new medicines have been developed and made available to patients under its aegis in the past four decades.

Importantly, Bayh-Dole march-in rights—which allow the federal government to force licensure on reasonable terms to a third party—are to be exercised under the law only if the original licensee has failed to make practical application of the invention, or where public health and safety needs are not being met. This is why, when the National Institutes of Health (NIH) has addressed the question of whether it should exercise march-in rights because of the price of a medicine, it has repeatedly declined to do so:

"We are wary…of forced attempts to influence the marketplace…particularly when such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies. The NIH agrees…that the extraordinary remedy of march-in is not an appropriate means of controlling prices."

Former NIH Director Dr. Francis Collins has expressed a similar view, noting during a US Senate Appropriations Subcommittee hearing that the Bayh-Dole statutory language "does not appear to have really been designed to be utilized in a fashion where the price is the obstacle."

It is critical to consider the benefits of Bayh-Dole in concert with the development of the generic drug industry that was spurred by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) and more recently the Biologics Price Competition and Innovation Act of 2010 (BPCIA). Underlying each of these statutes was the decision to provide a period of protection from copying that is sufficiently long to incentivize investment and allow for a level of profitability that adequately rewards risk taking and funds future research. One will search the legislative history in vain for any hint that these congressional actions were taken to fill some perceived gaping hole in the rules established by Bayh-Dole and impose de facto price controls.

As patent terms and regulatory exclusivities end, most drugs (whether or not discovered with public funds) face generic competition and prices fall accordingly. In concert, Hatch-Waxman and BPCIA established the foundational legal basis for the US biopharmaceutical industry. While one can identify particular cases where product exclusivity extends longer than is optimal either because of multiple patent filings or settlements of patent disputes with generic firms, the average period of market exclusivity is only about 12 years. As such, this framework broadly promotes an equilibrium that supports private investment in innovation as well as patient access.

Bayh-Dole has spurred an extraordinary collaboration among government, industry, and academia that has and will continue to foster biomedical innovation. Those who press to apply its provisions for short-term price reductions are misguided. We should instead continue to rely on the competitive market forces that are evident upon patent expiry and the accompanying generic drug approval and launch.

Authors' Note

John Osborn holds a limited partnership interest in a Warburg Pincus fund, which includes domestic and international health care investments, and through his retirement fund holds shares of biopharmaceutical companies including Abbott Labs, Johnson & Johnson, Medtronic, and ThermoFisher Scientific. Osborn is employed by Hogan Lovells, which represents biopharmaceutical companies in various legal matters. David Beier holds shares in three biopharmaceutical companies (Amgen, Infinity Pharmaceuticals, and Arcus) and holds interests in the life sciences sector through a venture fund at Bay City Capital, and from a Special Purpose Vehicle in Twist Bioscience. The University of California, San Francisco and the University of Washington have benefitted over the years from out-licensing biopharmaceutical discoveries to private companies.

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