Public-Private Partnership: Mobilizing taxpayer contributions to offer free-market solutions to high drug prices

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Abstract

High drug prices remain a significant concern despite decades of measures to address it. Most would agree that one path to lower prices is innovation; therefore, the government has often implemented incentives or regulations to promote innovation and market competition. To this end, the government has enacted programs to expedite the approval process or increase profitability for pharmaceutical companies. However, instead of improving competition and drug prices, the measures ultimately reduce approval standards for certain therapeutic areas or inadvertently permit high prices. An often-overlooked fact is that the patients purchasing those drugs invested in their successful discovery and development through taxes. This increases the obligations of the government to devise safe and effective plans for encouraging innovation while addressing drug prices. The solution begins with expanding the government's role in late-stage clinical development through associations with the private sector, especially small pharmaceuticals.

Introduction

Patients and politicians often argue that drug prices are too high. When patients struggle to pay for the medications they need to survive or thrive, their argument weighs more heavily. At the same time, many overlook the fact that patients and tax-paying citizens make a tremendously consequential contribution to drug development by supporting basic research. This contribution offers further rationale for the claim of high drug prices and repositions government obligation from regulating business or offering grants and incentives to ensuring that constituents benefit from their growing investment towards drug development. Here, I discuss free-market solutions to high drug prices that will mobilize small pharmaceuticals and ultimately ensure that taxpayers truly benefit from their contribution from both a health and financial standpoint.

Overlooked tax-payer contribution to drug development

Prescription drugs are costly in America. For example, the post-rebate prices of brand-name drugs like Lantus, a long-acting insulin, and Advair, an asthma drug, are 3-4 times higher than in the rest of the world [1]. However, patient contribution to privatized drug development might be an important reason why the claim that prices are high rings more true. The public sector and its tax-paying citizens invest a tremendous amount of money into research that is crucial to drug development.

Although the need for foundational research is intuitive, the scale of the intellectual contribution is astounding. According to an article from 2018 investigating the contribution of academic research funded by the National Institutes of Health (NIH), 210 drugs approved between 2010-2016 were associated with over 2 million publications [2]. This includes research about the disease, the drug target, the drug's performance in preclinical models, the appropriate readouts of drug response in the clinic, and the various methodologies or tools used to develop and evaluate the drug. However, the most astounding statistic is the amount of NIH funding that underlies this intellectual contribution, because over 600,000 of the publications were associated with at least one NIH-funded project [2]. This amounted to nearly $115.2 billion of support from the public sector to drug development [2].

Much to the concern of taxpayers, this total accounted for nearly 25% of the tax dollars that went to the NIH between 2000-2016 [3]. In most cases, taxpayers can expect to directly benefit from their contributions, whether through infrastructure, sanitation or security. This does not seem to be the case with research, even research with clinical implications. Instead, the taxpayer must pay significantly more to reap any benefits because of high drug prices. This is the result of for-profit pharmaceutical companies

completing the costly process of turning this information about drugs and drug targets into successful products.

Questionable trend in drug approval standards

To the credit of pharmaceutical companies, NIH-funded academic research has not particularly helped them with high failure rates. According to an article from 2016 investigating drug failure in late-stage clinical development, merely 36% of investigational therapeutic agents that entered a phase III trial between 1998 and 2008 were approved in the US [4]. The failure rate is much worse than 64% for certain therapeutic areas [4]. Therefore, companies frequently fail in the late stages of clinical development, often after incurring the cost of both preclinical and early clinical testing.

Concerns about public investment in drug development increase when evaluating the government's efforts to help pharmaceutical companies meet taxpayer needs [5–7]. The government has created an industry where reducing standards is the best path to innovation, but the risk of a harmful drug or cost of an ineffective drug is too great [5–9]. Instead, researching more personalized treatment plans, improving preclinical testing, and integrating genetic studies with phenomics to anticipate long-term clinical outcomes earlier on will promote innovation by improving the chances of success [10–12]. These better-suited approaches happen to highlight the importance of basic research and, in turn, the investment of taxpayers towards government-supported research. One might term this an "early investment" in the final product marketed by pharmaceutical companies – an investment the government should look to ensure that taxpayers benefit from.

"Competitive" solutions in a free market

Would not increasing the government's role in drug development, especially late-stage clinical development, present an opportunity to address this concern? For example, the Department of Defense has been able to reasonably invest in weapons systems development by contracting different companies over the years [13]. In stark contrast, the NIH has allowed industry to take control of drug development through various licensing strategies from academia to industry [14]. A measured step towards drug development by the NIH would positively change the landscape of both drugs and drug prices.

Broadly speaking, the NIH should increase economic support to small pharmaceutical companies to expand the existing free market that is dominated by patent-based monopolies held by large pharmaceuticals. In fact, through strategic acquisitions of small companies in bankruptcy and patent settlements to keep generics off the market, only a few large companies hold the rights to sell drugs and therefore do so at extremely high prices [4,15]. The demonstrated benefit to patients of supporting small companies might provide additional reasoning to expand them [16,17].

However, the investments in small pharmaceutical companies must also consist of a transaction that returns a portion, if not all, of the early investment which now includes funds supporting the programs. The capital from this transaction can then be allocated to both these new initiatives and further research. This would facilitate a potentially sustainable flow of capital into both translational and basic research supported by the NIH for the benefit of even more patients. Therefore, supporting small pharmaceuticals through strategic partnerships or by owning and maintaining manufacturing licenses would allow the NIH to ensure that taxpayer funds for research supporting drug development are put to their best possible use.

Strategic partnerships

A specific initiative would be partnering with small pharmaceutical companies in later clinical stages. The Biomedical Advanced Research and Development Authority in the Department of Health and Human Services has in the past partnered with Merck to develop Ebola vaccines that were instrumental in controlling the Congo Ebola outbreak in 2018, and then Achaogen to develop antibiotics for the growing problem of drug-resistant bacterial infections [18,19]. Another recent initiative, DRIVe looks to invest in companies for equity [20,21]. Since acquisitions by large companies would deter the initiative's intended benefit to the market, partnership terms should prohibit buy-outs by large pharmaceuticals but include setting fair prices [4]. Notably, price negotiations would occur within the context of a partnership and not as an independent regulatory practice. Although the company would be losing a share of the profits, development costs would significantly decrease because of government investment. For some companies, the investment will expedite development, while for others the investment might save them from bankruptcy. For this reason, low prices are a reasonable expectation. Additionally, consumers cannot deny that the most significant selling points for small companies will be lower prices and government sponsorship, especially in the face of the more well-known names of large pharmaceuticals. Despite the gains, companies are likely to have the upper-hand in project discussions and financial

negotiations, leaving the government with the most risk. Nevertheless, the expertise exists within academia to significantly reduce this risk.

Owning and maintaining manufacturing licenses

This initiative would permit a drug discovered by small pharmaceutical companies to be licensed to the NIH [14]. Licensing fees to small companies will provide them with a stable source of income while they develop and test other drugs into the market. Further increasing competition, one can expect the government to constrain the price of their drug more reasonably than a private, for-profit pharmaceutical, and the absence of a royalty would make this even more practical. Low-potential drugs might be a major concern for licensing because of the absence of a royalty; therefore the program should require a rigorous review process highlighting the individual profiles of the candidates [12]. The question then becomes whether the government has the resources to develop drugs. A likely concern will be that the level of government spending required to fund drug development could contribute to significant inflation. To avoid burdening taxpayers with a higher cost of living or even taxes, this initiative should rely on long-term returns and grow gradually. Transferring some of the drug development load from industry to the government is the best way to ensure that both patients and taxpayers get value for their money.

Outcomes

Both initiatives seek to ensure that large pharmaceuticals never rely on high-profit margins when it comes to designing new drugs. Importantly, both help small pharmaceuticals avoid bankruptcy through revenue streams much earlier in the drug development process. With the possibility of a competitive drug being put forth by small pharmaceuticals or even the government at a fair price, market prices will likely decrease. Money will also find its way back to the public sector via sales revenue to support the initiatives and more basic research. Most importantly, the desired outcome of these initiatives is a more competitive pharmaceutical industry in which both large and small companies are developing more novel and successful drugs at lower prices for taxpayers and patients. Individually, both Moderna, a small company, and Pfizer have helped manage COVID-19 through their application of the same groundbreaking mRNA vaccine technology. A similarly great demand for treatments and cures continues to exist in most therapeutic areas.

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