Improving the Incentive to Innovate

An important benefit of the 21st Century Cures bill

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Key Points

Innovations in the pharmaceutical industry significantly improve health outcomes for patients and make important contributions to the U.S. economy, including creating high-paying jobs.

However, the combination of shortening effective patent lives and rising development costs are dis-incenting future pharmaceutical research in the U.S. that, if left unchecked, will diminish future innovations for patients and reduce the vibrancy of the U.S. economy.

Provisions in the 21st Century Cures bill would help address these problems. If enacted, these provisions will accelerate the approval process for innovative pharmaceutical drugs and, therefore, extend the effective patent lives for new pharmaceutical innovations.

Extending pharmaceuticals effective patent life stimulates greater investment, and ultimately, innovation in the U.S. to the benefit of patients and overall economic growth.

Since the *21st Century Cures bill* was launched in 2014, the U.S. House Committee on Energy and Commerce has held hearings, hosted roundtable discussions across the country, issued white papers, and, in a rare bipartisan vote, the Committee unanimously approved the bill on May 21, 2015. As of June 2015 the *bill* looks destined for approval by the full U.S. House of Representatives sometime later in the year. A bill that addresses similar issues is also under consideration in the U.S. Senate Committee on Health, Education, Labor, & Pensions.

Key pro-growth reforms contained in the *21st Century Cures bill*, particularly those reforms that accelerate the FDA approval process, will improve the incentives for continued pharmaceutical innovation in the U.S., supporting an industry where the U.S. is already the global leader. Accelerating the FDA approval process extends the effective patent life of innovative pharmaceutical drugs and addresses the diminishing incentives to develop new and innovative therapies in the U.S.

Studies illustrate that policies that increase the incentive for pharmaceutical research & development (R&D) encourage increased R&D activities, and greater R&D is associated with both stronger economic returns and increased medical innovation. As a result, passing these reforms that streamline the FDA approval process will help improve the lackluster economic performance of the U.S. and help improve the welfare of patients by creating new, or more effective, pharmaceutical therapies.

The Pharmaceutical Industry

Effective economic regulations should account for the public interest goal(s) that justify regulating the activity, and the economic fundamentals of the regulated industry. In the case of the pharmaceutical industry, the public interest goals are to ensure the safety and efficacy of medicines. It is also in the public interest that pharmaceutical manufacturers have the opportunity to cover their costs of capital from developing an innovative drug therapy, and, as a result, ensure that innovative pharmaceutical companies have an incentive to invest in the risky, time-intensive drug development process.

A cursory review of the pharmaceutical industry illustrates that, despite regulatory flaws that are increasing the disincentives for innovation over time, the industry has been creating great value for patients, and making large contributions to the U.S. economy.

From a patient perspective, continued innovation in the pharmaceutical sector is improving the health of millions of Americans every year. Take cancer for instance. Cancer death rates have declined nearly 22 percent since their peak in the 1990s.[1] Approximately 83 percent of the gains in cancer survival rates are attributable to new treatments that include more effective cancer medicines.[2] Similar gains in survival rates and improved quality of life benefits have accrued from medicines that more effectively manage HIV/AIDS. For patients with Hepatitis C, pharmaceutical medicines can now effectively eliminate the disease altogether. Perhaps nowhere are the benefits greater than advances in vaccines.

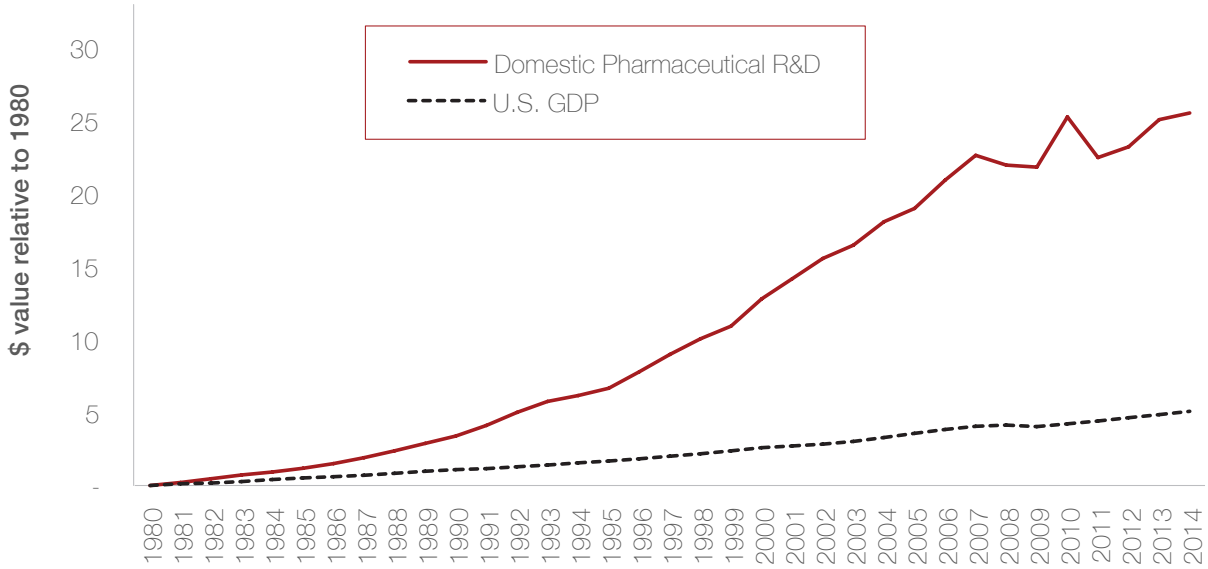
> Vaccines given to infants and young children over the past two decades will prevent 322 million illnesses, 21 million hospitalizations and 732,000 deaths over the course of their lifetimes, according to a new report from the Centers for Disease Control and Prevention.
>
> Vaccines also will have saved $295 billion in direct costs, such as medical expenses, and a total of more than $1.3 trillion in societal costs over that time…[3]

Compared to the rest of the world combined, the U.S. holds the intellectual property rights to the majority of new medicines.[4] And, thanks to the past success, the near-term prospects of the U.S. pharmaceutical industry are bright. For instance there are currently more medicines under development in the U.S. than in the rest of the world combined due, in large part, to the strong intellectual property protections offered in the U.S. These achievements are also manifested in the large amount of money that is being invested into new pharmaceutical research. Importantly, research-intensive industries are associated with higher wages and better jobs.

According to PhRMA, their member companies invested $41 billion into U.S. based R&D activities in 2014,[5] which represents the majority of all biopharmaceutical R&D spending in the U.S.[6] In fact, the U.S. pharmaceutical sector accounts for the single largest share of all U.S. business R&D, representing about 20 percent of all domestic R&D funded by U.S. businesses, according to 2010 data from the National Science Foundation.[7] The Congressional Budget Office (CBO) has also documented that the pharmaceutical industry is one of the most research-intensive industries. According to the CBO "pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm."[8]

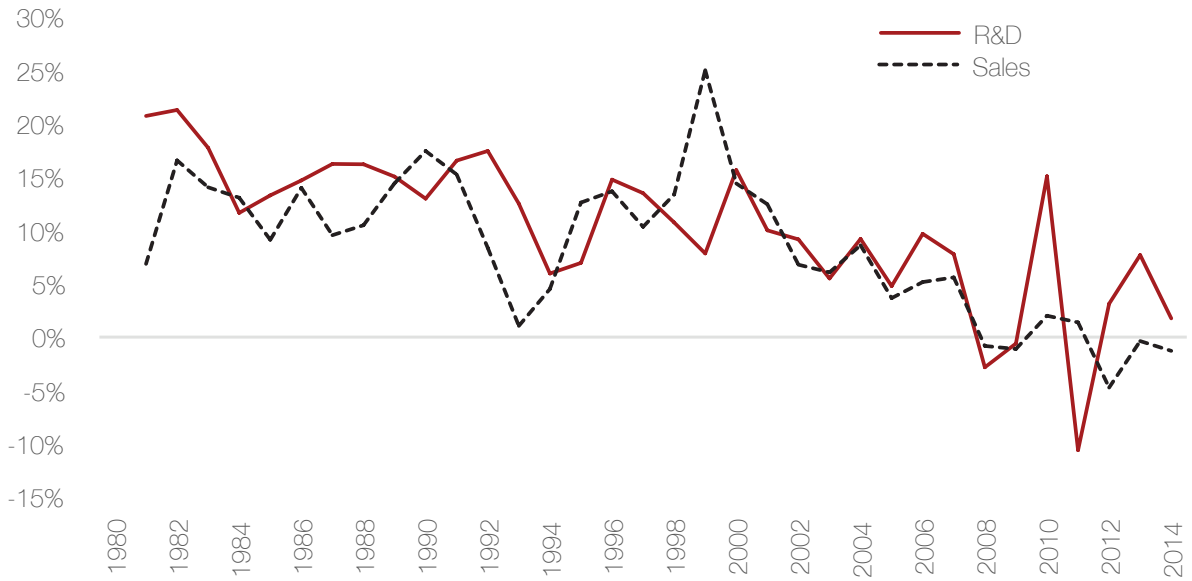
The extraordinary historical growth in U.S. based pharmaceutical R&D can be visualized by comparing its growth to the growth in the overall U.S. economy. Compared to 1980, the U.S. economy as of 2014 was five times larger. In comparison, the amount of money spent on U.S. based pharmaceutical R&D was over 25 times as large in 2014 compared to the expenditures made in 1980, see Figure 1. The U.S. pharmaceutical has been, over the long-term, a significant growth industry.

Figure 1
Growth in U.S.-Based Pharmaceutical R&D Compared to U.S. Economic (GDP) Growth 1980–2014



Not surprisingly, the growth in the industry's R&D spending is closely tied to its growth in total revenues, see Figure 2. Figure 2 illustrates the generally close relationship between the change in total domestic sales revenues earned by the pharmaceutical industry and the change in the amount of resources that have been invested in new innovative medicines. This close relationship is due to the generally stable share of revenues that the pharmaceutical industry plows back into R&D. On average over the 1980 to 2014 period, domestic pharmaceutical R&D as a percentage of sales has been 18.8 percent. The smallest share of revenues devoted to R&D was 13.1 percent (in 1980) and the highest share was 23.4 percent (in 2014).

Figure 2
Percentage Growth in U.S. Based Pharmaceutical R&D Compared to Estimated Pharmaceutical Sales
Domestic Industry
1981–2014



A continuation of the past robust growth in innovations are in jeopardy, however, due to the combination of slowing industry revenues, the rising cost of developing a new therapy, and the shortening effective patent life for new innovative medicines.

The developing problem of slowing pharmaceutical revenues is beginning to impact industry R&D activities—see the declining rate of growth in pharmaceutical R&D expenditures and sales evident since the mid-2000s in Figures 1 & 2. Table 1 presents the data for these trends. While domestic R&D sales outpaced GDP growth over the entire 1980—2014 period, there has been a pronounced slowdown since 2007. Looking at eight year periods for comparison, whereas the average annual revenue growth was increasing at a double-digit pace in the 1980s and 1990s, it slowed beginning in 2000, and has turned negative over the 2007 to 2014 period.

Table 1
Compound Average Annual Growth Rates in Domestic Pharmaceutical Industry Sales Compared to the Compound Average Annual Growth Rate in U.S. GDP
1980–2014

	Est. Domestic Sales	GDP
1980 - 2014	8.26%	5.45%
1986-93	10.82%	5.95%
1993-00	13.28%	5.91%
2000-07	6.87%	5.01%
2007-14	-0.73%	2.68%

While the slowdown in pharmaceutical domestic revenues was also accompanied by slower overall economic growth in the U.S., the decline in pharmaceutical sales has been much steeper. The slower revenue growth, when coupled with the rising costs of developing new drugs, portends less R&D (and therefore less innovation) in the future without policy changes to address these problems. And, the estimated total R&D cost per drug is expensive. According to an analysis performed by Matthew Herper (2013) these estimated costs per drug are approximately $5.5 billion. Specifically,

> Using data from the Innothink Center for Research in Biomedical Innovation, I tabulated the number of brand new drugs launched by 98 publicly-traded biotechnology and drug companies over the past decade. Then, using FactSet Systems, I tallied each company's research and development spending over the ten years preceding their most recent drug approval. Then I divided the second number by the first.[9]

It is noteworthy that Herper's results illustrate the large impact on costs created by drug failures. Based on his methodology, Herper found that companies that launched only one drug had an average (specifically median) cost of $351 million compared to an average cost of $5.5 billion for companies that had eight to 13 drugs approved. The difference in costs are due to how failures are taken into account. As Herper describes, "For every small company that succeeds, there are many more that fail. A big pharmaceutical company carries that weight of failure, with both its successes and its failures on the books."[10] The true cost of capital for a pharmaceutical company includes the costs of failures, of course. Consequently, based on Herper's analysis, the total cost for developing one successful drug is $5.5 billion.

Rising costs, coupled with slowing revenue growth, is a negative sign for continued industry innovation—to the detriment of the health of patients.

Effectively Regulating the Pharmaceutical Industry

Despite the value created by the pharmaceutical industry, regulatory barriers are creating unnecessary, and worsening, obstacles that are beginning to inhibit success.

Effectively regulating the pharmaceutical market requires a difficult balancing act. Starting with the FDA, FDA regulations must ensure pharmaceutical medicines are safe and effective; but, the regulations should minimize the disincentives to innovation by ensuring the regulatory burdens are neither excessively costly, nor cause excessive or unnecessary time delays.

Complying with the FDA's safety and effectiveness standards typically includes running pre-clinical trials, running clinical trials, and submitting proprietary manufacturing data to the FDA. Of course all of these activities occur after the company has spent years discovering the new drug in the first place. Accounting for all of these activities it takes, on average, 12 years to develop a new drug according to the California Biomedical Research Association.[11] The Pharmaceutical Research Manufacturers Association (PhRMA) estimates that the drug development process takes 10 to 15 years.[12]

The ability for pharmaceutical companies to benefit from their patent rights is also important. The purpose of the U.S. patent system is to encourage greater innovation by creating secure property rights for innovative firms and individuals. As applied to the pharmaceutical industry, patents establish exclusivity rights over a new innovative pharmaceutical product for a predetermined period. While on patent, the innovative pharmaceutical company has the exclusive right to make, use, and sell the patented drug therapy. These exclusivity rights empower the innovator drug company with the opportunity to recoup its large R&D costs by charging prices that are higher than the prices charged by a firm that only incurred production costs – or exclusivity prices.

As discussed in PRI's briefing paper, "Why Pharmaceutical Prices Drop Once Drugs Are Off-Patent", it is the ability to charge exclusivity prices that creates the opportunity for the innovative drug manufacturer to recoup its costs of capital.[13] A competitive rate of return on capital, adjusted for risk, ensures that investors will be willing to invest their money with the pharmaceutical industry, a business where failure is the norm, and a small number of medicines pay for all of the R&D. However, it is also imperative that the patent regulations balance the need to provide innovative pharmaceutical companies adequate time to recoup its cost of capital with the need to promote a competitive generic market once the innovative pharmaceutical company has had ample time to recoup these costs.

The lifespan of a patent in the U.S. is 20 years from the date on which the patent is issued. And, herein creates the problem for the innovative pharmaceutical industry.[14] Once a patent for a new medicine is obtained, the innovative pharmaceutical company must then obtain regulatory approval from the FDA—the extensive, and time intensive, regulatory approval process that ensures the new drug's safety and efficacy does not begin until after the patent has been issued. This process creates a separation between the statutory lifespan of a patent (20 years) and the effective patent life for the new innovative medicine, which is the amount of time a new therapy is still on patent and has been cleared for sale to patients by the FDA. Effectively, the time spent complying with the FDA regulatory approval process is shortening the effective lifespan of patents obtained by innovative pharmaceutical companies compared to patents obtained by other high-tech industries.

Although drug manufacturers can extend the patent for up to five years to recoup some of the patent lifespan lost during the FDA regulatory approval process (under the Patent Term Restoration Program), even with this program typically patents for branded pharmaceutical drugs expire after being available to patients for only 11.5 years—about 58 percent of the statutorily defined patent life.[15] Furthermore, this lifespan is significantly shorter than the effective lifespan for innovative pharmaceuticals in the past.

Research by Magazzini et al. (2012) estimate that the effective patent life in the U.S. has declined 1.8 months per year between 1993 and 2007, and 1.6 months per year in the EU-15.[16] Confirming this downward trend in the effective patent life for pharmaceutical medicines, back in 1968 "most drugs had an effective patent life of about 17 years", according to Josh Bloom (2012).[17] Put another way, the current effective patent life of an innovative drug is now 32 percent shorter than the effective patent life in 1968.

When coupled with the now higher cost of developing innovative therapies ($5.5 billion) this combination reduces the ability of an innovative manufacturer to cover its cost of capital. The inability to cover its cost of capital discourages investment in these firms reducing the total amount of pharmaceutical R&D activities to the detriment of patients and the economy.

There are many options for effective reform. The commonality across many of these options is the need to expand the effective patent life for innovative drug manufacturers—the ideal reform expands the effective patent life for the broadest number of innovative medical therapies. One pathway for expanding the effective patent life for drugs is to shorten the FDA approval process, while still assuring the safety and efficacy of the new therapies—this is the path chosen by the *21st Century Cures bill*.

Among the many other provisions, *Title II* of the *21st Century Cures bill* expedites the FDA approval process through provisions such as:

- Expanding the accelerated drug approval plan beyond its current application to patients with life threatening or untreated diseases;
- Establishing a "streamlined data review program" that creates a pathway to review an existing drug or biologic for a new qualified indication; and,
- Creating new streamlined pathways for the approval of antibiotics and vaccines.

By shortening the FDA approval process, the reforms help expand the effective patent life for those drugs covered by these provisions. While the relief is narrower than the ideal, and important reforms (such as offering innovative firms data exclusivity) are not considered,[18] the reforms are an improvement over the current regulations and provide short-term and long-term benefits for patients and the broader economy.

Patients benefit in the short-term by having access to the latest therapeutic options faster. In the long-term, expediting the FDA approval process reverses the recent declines in the effective patent life of branded pharmaceuticals. Expanding the effective patent life for pharmaceuticals increases the amount of resources that manufacturers are able to devote toward the time-intensive and risky drug development process. For instance, Grootendorst and Di Matteo (2007) found that after Canada extended the effective patent lives of patented drugs, R&D spending in Canada increased by $4.4 billion.[19]

By encouraging greater R&D, patients will benefit from the greater incentive for companies to develop more effective medicines in the future. Encouraging greater R&D expenditures will also help accelerate the growth across the innovative pharmaceutical industry—an industry that is critical to the long-term health of our economy.

The pharmaceutical industry annually generates around $790 billion in economic activity, supports a total of 3.4 million jobs, and pays its workers over $110 thousand a year on average (more than double the U.S. average).[20] The slowing growth prospects of the industry, if they were to become a long-term problem, threatens the growth in this industry that has traditionally been an important economic growth driver. The provisions in the *21st Century Cures bill* that streamline the FDA approval process will help reverse these slowing growth prospects and benefit the U.S. economy's broader prospects.

Concluding Thoughts

Discovering innovative drug therapies is becoming harder, more time intensive, and more costly. However, given the complexity of these diseases, the benefits to patients from successfully developing these new therapies is great. The effective patent life of new drugs has been shortening for several decades, however, which diminishes the ability of pharmaceutical companies to continue developing innovative therapies to address these more complex health threats.

The *21st Century Cures bill* contains provisions that will expedite FDA approval of new drugs helping to reverse the longer-term decline in the effective patent life for new pharmaceutical drugs. Should such changes become law, the incentives to engage in pharmaceutical R&D in the U.S. will improve. The expected outcome from this reform is not only a stronger economy; due to these reforms the companies will be able to devote greater R&D expenditures for patients in need of new therapies, and consequently, increase overall patient health outcomes.

Endnotes

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