

**Testimony of
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**Before the
United States House of Representatives,
House Committee on Government Oversight and Reform**

**Hearing on
“HIV Prevention Drug: Billions in Corporate Profits
After Millions in Taxpayer Investments”**

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Washington, DC

Good afternoon Chairman Cummings, Ranking Member Jordan, and members of the Committee; thank you for inviting me to share the views of the Information Technology and Innovation Foundation (ITIF) on the issue of the relationship between drug prices, intellectual property (IP), and the U.S. biomedical innovation system.

ITIF is an independent, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized as the world's leading science and technology think tank, ITIF's mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress.

THE UNITED STATES LEADS THE WORLD IN LIFE-SCIENCES INNOVATION

As ITIF documented in its report “How to Ensure That America’s Life-Sciences Sector Remains Globally Competitive,” the United States leads the world on a number of life-sciences innovation measures, from R&D investment to high-impact scientific publications to innovative new drug launches (i.e., number of new chemical or biological entities).¹ U.S. life-sciences leadership starts with secure intellectual property rights (IPR) and robust public and private investment in life-sciences R&D, which is essential because developing a new pharmaceutical compound takes an average of 12 to 14 years of research, development, and clinical trials at a cost of an estimated \$2.6 billion.² As an innovation-based industry, the U.S. life-sciences sector is extremely research-intensive. In fact, according to the OECD, U.S. pharmaceutical companies devoted 43.8 percent of their value-added to research and development. This was higher than any other industry in any other country. The U.S. life-sciences sector accounts for 23 percent of domestic R&D funded by U.S. businesses—more than any other sector.³ America’s life-sciences industries performed \$96.5 billion of R&D in 2013 (the most recent year for which public data are available), of which \$74.5 billion was self-funded.⁴ Eighty-four percent of this R&D activity occurred in the United States.⁵ Measured by R&D expenditure per employee, the U.S. biopharmaceutical sector leads all other U.S. manufacturing sectors, investing more than 10 times the amount of R&D per employee than the average U.S. manufacturing sector.⁶ This robust investment has made the United States the world’s largest global funder of biomedical R&D investment over the past two decades, a share that some analyses suggested reached as high as 70 to 80 percent over that time period.⁷

America’s robust investment in life-sciences R&D has translated into global leadership in new drug development. In the last decade, biopharmaceutical companies have invested over half a trillion dollars in R&D, and more than 350 new medicines have been approved by the U.S. Food and Drug Administration (FDA).⁸ In the 2000s, more new chemical entities were developed in the United States than in the next five nations—Switzerland, Japan, the United Kingdom, Germany, and France—combined.⁹ However, it wasn’t always that way; in fact, in the latter half of the 1970s, European-headquartered enterprises introduced more than twice as many new drugs to the world as did the United States (149 to 66).¹⁰ But, as noted, a combination of conscientious and intentional public policy decisions—including increasing R&D investments, providing robust tax credits for research and innovation (e.g., introducing the research and experimentation tax credit and the orphan drug tax credit), and strengthening IP, technology transfer, and commercialization policies (e.g., the Bayh-Dole tax credit), among many others—enabled the United States, starting in the 1980s, and growing in the decades since, to become the world’s life-sciences innovation leader.¹¹ Indeed, in every five-year period since 1997, the United States has produced more new chemical or biological entities than any other country or region. And from 1997 to 2016, U.S.-headquartered enterprises

accounted for 42 percent of new chemical or biological entities introduced around the world, far outpacing relative contributions from European Union member countries, Japan, China, or other nations.¹²

Since 2000, the FDA has approved more than more than 500 new medicines. And today, U.S. biopharmaceutical companies have more than 3,400 drugs under clinical development.¹³ This accounts for almost half of the estimated 7,000 medicines under development globally. And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is that many drugs currently under development are trying to tackle some of the world’s most intractable diseases, including cancer and Alzheimer’s. Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first-of-their-kind. For instance, in 2014, the FDA approved 41 new medicines (the most since 1996 at that point) many of which were first-in-class medicines, meaning they represent a possible new pharmacological class for treating a medical condition.¹⁴ In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.¹⁵ As of 2018, 74 percent of medicines in clinical development are potentially first-in-class medicines.¹⁶ The following sections will elaborate further on the key factors that have made the U.S. life-sciences innovation system the world’s most successful—specifically robust public and private sector investment in life-sciences R&D, robust intellectual property rights that facilitate effective technology transfer and commercialization from universities and federal laboratories to the private sector, and a drug pricing system that enables companies to earn sufficient returns from their investments in one generation of life-sciences innovation to enable their investment in the next.

PUBLIC AND PRIVATE CONTRIBUTIONS TO LIFE-SCIENCES INNOVATION

Public and private R&D investments and activities are highly complementary—and indispensable—to America’s successful life-sciences innovation system.¹⁷ Public sector researchers perform the upstream, earlier-stage research elucidating the underlying mechanisms of disease and identifying promising points of intervention, whereas corporate researchers more perform the downstream, applied research resulting in the discovery of drugs for the treatment of diseases and carry out the development activities necessary to bring them to market.¹⁸

The federal government, principally through the National Institutes of Health (NIH), funds basic research in the life sciences that sets the stage for the industry-led applied research and development activity that leads to the commercialization of new medicines and treatments.¹⁹ Congress provided \$37.3 billion in 2018 for NIH—which is comprised of 27 institutes and centers, each with a specific research agenda, often focusing on particular diseases or body systems—and approved legislation raising NIH’s funding to \$39.1 billion in 2019.²⁰ While the private sector does invest in basic scientific research, private-sector life-sciences enterprises primarily undertake the difficult, risky, and expensive process of conducting the applied research and development activities required to turn basic life-sciences discoveries into innovative medicines, therapies, or devices and bring them to market—everything from synthesizing molecular compounds to conducting clinical trials proving the safety and efficacy of new medicines.

A number of studies have elucidated this complementary dynamic. For instance, a 2000 study by the U.S. Senate Joint Economic Committee found that: “Federal research and private research in medicine are complementary. As medical knowledge grows, federal research and private research are becoming more intertwined, building the networks of knowledge that are important for generating new discoveries and applications.”²¹

Government funding of early stage research is critical. As America’s National Academy of Sciences writes, “Fewer investments in basic research [by NIH] can result in fewer new drug therapy candidates, which in turn can result in fewer investments by private industry to advance promising candidates.”²² Likewise, the Tufts Center for Drug Development concludes, “Scientific and development histories demonstrate the rich interconnectivity of all sectors in the drug-discovery and drug-development ecosystem.”²³ This explains why a 2015 Battelle Memorial Institute study found that, “NIH funded research produced an average of 5.9 patents per \$100 million in R&D expenditures from 2000-2013—or at a rate of one patent per every \$16.9 million in NIH funding.”²⁴ Those findings are similar to ones from a 2017 National Bureau of Economic Report study which found that, “An additional \$10 million in NIH funding for a research area generates 2.3 additional private-sector patents in that area, or roughly 1 patent for every 2 to 3 NIH grants.”²⁵ Similarly, the 2015 Battelle report went on to find that, “NIH patents also averaged 5.14 forward citations, meaning the NIH is an integral part of the knowledge chain for \$105.9 million in downstream R&D for every \$100 million in taxpayer funded awards. These downstream connections represent other research organizations, in both the private and public sector, leveraging NIH discoveries into follow-on R&D spending.”²⁶

While public sector investment in life-sciences research builds a vital base of biomedical knowledge, the private sector undertakes the risky, expensive, and uncertain process of bringing innovative medicines to market.

Biopharmaceutical companies conduct laboratory screening for as many as 5,000 to 10,000 chemical compounds for each new drug approved for use in humans. On average, of the 5,000 to 10,000 compounds that are screened, approximately 250 enter preclinical testing, and 5 enter clinical testing.²⁷ Moreover, less than 12 percent of candidate medicines that even make it into Phase I clinical trials are ultimately approved by the FDA.²⁸ This process is lengthy and expensive, explaining why developing a new pharmaceutical compound takes an average of 11.5 to 15 years of research, development, and clinical trials at a cost ranging from \$1.7 to \$3.2 billion.²⁹ For instance, as noted, one in-depth study conducted by the Tufts University Center for the Study of Drug Discovery, *Cost of Developing a New Drug*, estimated that the average cost of developing a new drug in 2014 was \$2.56 billion.

Demonstrating the complementary nature of public and private investment in the life-sciences innovation process, in 2016, DiMasi, Milne, Cotter, and Chakravarthy examined the roles of the private and public sectors in drug development by examining an array of evidentiary materials on the history of 19 individual drugs, 6 drug classes, and 1 drug combination identified as the most transformative drugs in health care over the past 25 years by a survey of over 200 physicians.³⁰ The authors found that only four of the drugs appear to have been almost completely researched and developed by one sector, although one sector or the other did dominate particular phases of the R&D continuum. Specifically, they found that 54 percent of basic science milestones were achieved by the public sector and 27 percent by the private sector. The private sector contributed 58 percent of discovery-oriented milestones, while 15 percent were contributed by the public sector. The private sector proved the dominant player in achieving major milestones related to the production and drug development phases (81 percent and 73 percent of the drugs reviewed, respectively).³¹ As the authors conclude, “Industry’s contributions to the R&D of innovative drugs go beyond development and marketing and include basic and applied science, discovery technologies, and manufacturing protocols, and that without private investment in the applied sciences there would be no return on public investment in basic science.”³²

TAXPAYERS AREN'T “PAYING TWICE” FOR INNOVATIVE MEDICINES

In 1980, on a bipartisan basis, Congress enacted the Bayh-Dole Act, legislation which gave universities, small businesses, and non-profit institutions rights to the intellectual property (IP) stemming from federally funded research undertaken in contracting organizations. The legislation was hailed by *The Economist* as:

Possibly the most inspired piece of legislation to be enacted in America over the past half-century. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.³³

In 1968, President Johnson asked then-Comptroller General of the United States Elmer Staats to analyze how many drugs had been developed from NIH-funded research. His finding that “not a single drug had been developed when patents were taken from universities [by the federal government]” was pivotal toward Congress's subsequent decision to create the Bayh-Dole legislation, recognizing that market forces would do a better job of commercializing government-funded technology than federal agencies could. Since its enactment, the Bayh-Dole Act has played a catalytic role in getting the results of federally funded scientific research off of shelves and into marketplaces where they can benefit citizens and society. The legislation also has led to a dramatic rise in innovation activity U.S. universities. For instance, while only 55 U.S. universities had been granted a patent in 1976, 240 universities had been issued at least one patent by 2006.³⁴ Similarly, in 1980, only 390 patents were awarded to universities; but, by 2009, that number had increased almost 10-fold to 3,088.

As ITIF writes in “The Bayh-Dole Act's Vital Importance to the U.S. Life-sciences Innovation System,” the law has stimulated many life-science innovations resulting from federally funded research conducted at U.S. universities, which generated new knowledge into biomedical processes, therapies, or molecular compounds that the university took IP ownership of and subsequently licensed the IP to the private sector to further develop into a commercializable product. ITIF's report provides four in-depth case studies—of Yervoy, CardioMEMS, Gleevec, and Luxturna—showing the Bayh-Dole Act in action, helping to turn federally funded, university-conducted research into new knowledge subsequently licensed to and brought to market as an innovative drug or device by private-sector actors. Those are just four examples of the almost 300 new drugs, vaccines, and devices that have been developed through public-private partnerships facilitated in part by the Bayh-Dole Act since its enactment in 1980.³⁵

However, some contend that taxpayers are “paying twice” for innovative drugs: from their contribution to federally funded basic research and then again when they consume a given medicine, if the lineage of the development of that drug can trace back to research activities in part funded by the federal research. But this misrepresents the role of federal investment in basic life-sciences research. Its intent is to contribute to a stock of knowledge—for instance into understanding the fundamental processes by which diseases develop and are transmitted, or identifying novel biomarkers signaling the presence of a disease—that creates a platform for innovation potentially leading to the discovery of new medicines, new tests (e.g., blood tests for substances), new procedures (e.g., improved cardiac stents that substitute for surgery), or new equipment (e.g., gene sequencers).³⁶ The taxpayer's interest (i.e., society's) is served and the taxpayer benefits by that expansion of biomedical knowledge, irrespective of whether those investments ever lead to the development of a specific drug, test, or procedure that a specific patient may benefit from. (And, indeed, just like not all companies' investments will succeed in bringing new drugs to market through a

grueling series of clinical trials, not all NIH-funded research will bear fruit or generate meaningful results, but that does not invalidate the value of the basic life-sciences research enterprise.)

Most importantly, it's critical to remember that significant investment is required to bring a drug to market even after a degree of basic research has been conducted. In fact, one study finds that biotechnology companies invest \$100 in development for every \$1 the government invests in research leading to an innovation.³⁷ As a specific example, consider the anti-prostate cancer drug Xtandi. Less than \$2 million in federal money was invested in related early work at UCLA compared to the over \$900 million invested by companies like Astellas that developed the drug through clinical trials and brought it to market.³⁸ While Xtandi may not be an inexpensive drug, it is a breakthrough treatment that improves survival in metastatic and non-metastatic prostate cancer with rising PSA.³⁹ Moreover, with the average federal grant to an NIH-funded university researcher totaling approximately \$520,000, taxpayers incur only a small fraction of the hundreds of millions of dollars, if not billions, it takes to shepherd an innovative drug to market.⁴⁰

Nevertheless, some civil society organizations, and members of Congress, have called for the use of “march-in rights”—a provision within the Bayh-Dole Act that permits the government, in specified circumstances, to require patent holders to grant a “nonexclusive, partially exclusive, or exclusive license”—to “control” allegedly unreasonably high drug prices. For instance, Representative Lloyd Doggett (D-TX) has led a group of some 50 members of Congress who have called on NIH to cancel exclusivity when patented drugs are not available on reasonable terms.⁴¹

The first problem with this approach is that, as the architects of the legislation, Senators Birch Bayh and Bob Dole, have themselves noted, the Bayh-Dole Act's march-in rights were never intended to control or ensure “reasonable prices”—indeed, the Bayh-Dole Act contains no definition thereof.⁴² Rather, Bayh-Dole's march-in provision was designed as a fail-safe for limited instances in which a licensee might not be making good-faith efforts to bring an invention to market or when national emergencies require that more product is needed than a licensee is capable of producing.⁴³

But the more serious problem with proposals to use march-in rights to control drug prices—or those that would seek to revoke patents or issue compulsorily licenses to force the disclosure of IP rights in cases in which drug prices are alleged to be too high—is that it undermines private intellectual property rights that innovators depend upon to be secure in their knowledge that they have a potential to earn a return on the capital they must invest to bring risky, innovative new therapies to market. If a government ever had the capacity to march in decades later and compulsorily license the intellectual property underpinning a novel pharmaceutical or biologic drug on the grounds that some of it may have in part been contributed by federally funded scientific research—and now the government deems the price for that drug “unreasonable”—it would seriously undermine the mechanics of America's life-sciences innovation system, giving enterprises considerable pause about investing the enormous sums required to bring innovative drugs to the marketplace. Compromising the intellectual property rights that have contributed substantially to making the United States the world's leading location for breakthrough biomedical innovation is not the right approach to addressing drug price issues.

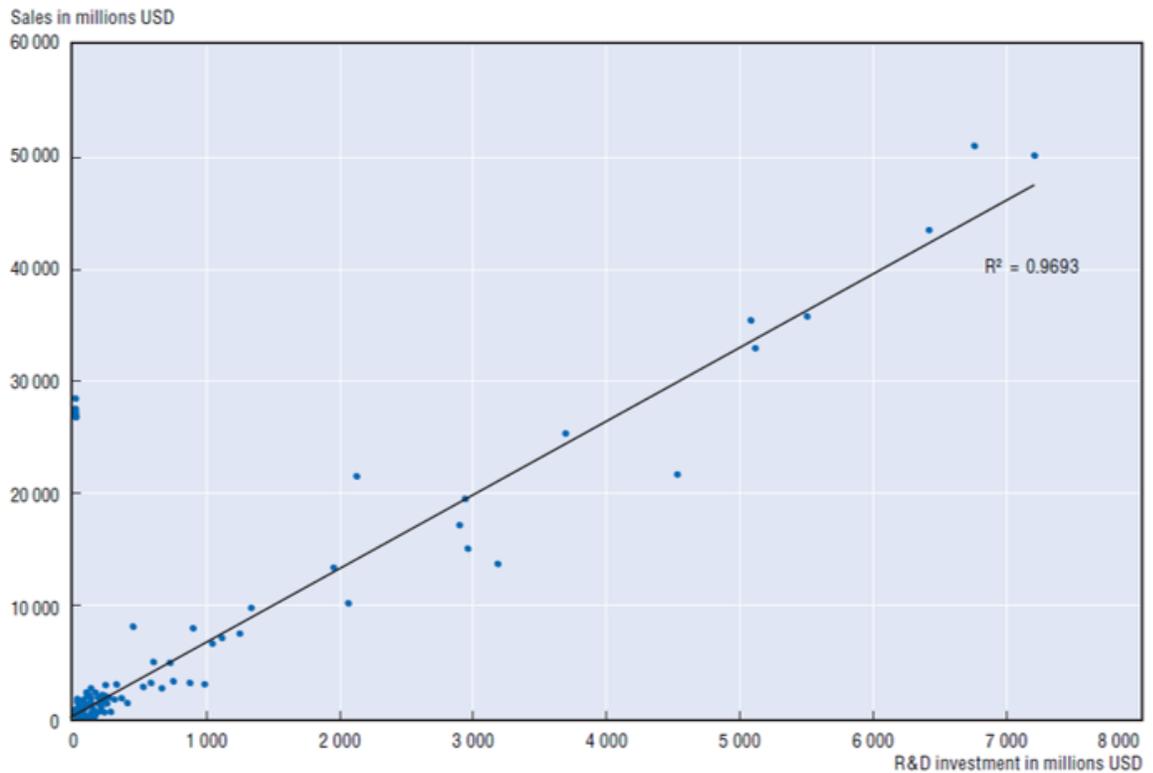
LIFE-SCIENCES INNOVATION DEPENDS ON THE ABILITY TO GENERATE REVENUES

As ITIF writes in “Why Life-Sciences Innovation Is Politically ‘Purple’—and How Partisans Get It Wrong,” while some claim that industry R&D and industry revenues are not related, the fact is they are intimately and causally linked.⁴⁴ The reality is that limiting industry revenues through drug price controls would reduce investment in R&D, and thus inhibit drug discovery. As industrial organization economist F.M. Scherer writes:

Governmental bodies that regulate prices and profits characteristically have a myopic bias. They are inclined toward what might be called ‘Willie Sutton’ regulation, emphasizing recapture of ‘excess’ profits on the relatively few highly profitable products without taking into account failures or limping successes experienced on the much larger number of other entries. If profits were held to ‘reasonable’ levels on blockbuster drugs, aggregate profits would almost surely be insufficient to sustain a high rate of technological progress. Assuming that important new drugs yield substantial consumers’ surplus untapped by their developers, consumers would lose along with the drug companies. Should a tradeoff be required between modestly excessive prices and profits versus retarded technical progress, it would be better to err on the side of excessive profits.⁴⁵

A number of studies find this causal relationship. For instance, as the Organization for Economic Cooperation and Development (OECD) writes plainly, “There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures.”⁴⁶ Indeed, as figure 1 illustrates, there exists an almost one-to-one correlation (0.97) between R&D expenditures and sales. Moreover, data from the United Kingdom’s Department of Innovation, Universities, and Skills R&D Scoreboard show a very strong relationship between R&D and sales for the largest 151 pharmaceutical firms worldwide.⁴⁷ Similarly, Henderson and Cockburn have identified scale effects for R&D in the pharmaceutical industry, finding that R&D expenditures are directly proportional to the sales revenues available to undertake R&D investment.⁴⁸ This explains why academic research shows a statistically significant relationship between a biopharma enterprise’s profits from the previous year and its R&D expenditures in the current year.⁴⁹ Moreover, the pharmaceutical firms with the greatest sales are also the ones with the largest R&D investments, which may in part explain why most global R&D investments are undertaken by the largest multinational firms.⁵⁰ Symeonidis notes that this is in part because large firms are better able to spread the risks of R&D uncertainty, since they can undertake several projects simultaneously.⁵¹ Likewise, Gambardella determined sales revenue from previous periods have a significant, positive impact on current-period biopharma R&D.⁵²

Figure 1: R&D expenditures and sales in the pharmaceutical industry, 2006⁵³



Note: The data were prepared on the basis of annual reports and consolidated accounts received up to and including 31 July 2006. Annual reports with a year-end older than 30 months from the cut-off date or a publication date older than 24 months from cut-off date are excluded.

Source: DIUS (2007).

The price that buyers pay for medicines—whether they are consumers, hospitals, pharmacy benefit managers, or government programs like Medicare—is a complex topic, and subject of intense debate. But while the list prices of prescription medicines are often referenced, the net price paid is often considerably lower. In fact, as the *Wall Street Journal* notes, “average U.S. list prices for prescription medicines rose in the past decade, but net prices—after rebates and discounts—rose less sharply and have recently declined.”⁵⁴ As the *Journal* notes, “During the third quarter of 2018, list prices for U.S. branded drugs increased 4.1 percent compared with 5.3 percent a year earlier. Net prices, meanwhile, fell 5.1 percent, compared with a 0.4 percent gain a year before (see figure 2).”⁵⁵ One study found that more than one-third of drug list prices were rebated back to pharmacy benefit managers and other entities in the supply chain.⁵⁶ As that report describes, “Pharmaceutical spending estimates that omit rebates and discounts do not fully reflect the underlying competitive dynamics of the pharmaceutical sector and provide a misleading impression of drug spending.”⁵⁷

Figure 2: Change from a year earlier in U.S. prescription brand prices⁵⁸



Put simply, America’s (and the world’s) research-based life-sciences industry creates new-to-the-world medicines and treatments that improve the lives of the world’s citizens, not an industry engaged in price gouging consumers and making wildly excessive profits. It’s true that one study found the rate of profits of the U.S. drug industry from 2010 to 2012 was 14 percent, while profits for U.S. industry overall were 8 percent over that period.⁵⁹ However, there are a number of studies that show that these figures overstate true profits. As industrial organization economist F.M. Scherer writes:

A more compelling objection is that accounting data on profits yield biased implications, given the special circumstances faced by the pharmaceutical industry. Under standard accounting practice, R&D and new product marketing outlays, both of which are atypically high in pharmaceuticals, are written off as current expenses. Since both, and especially R&D, affect revenues for many years to come, it would be more accurate in principle to capitalize the outlays and then depreciate them over appropriate time periods. Otherwise, the rate of return on “investment” is calculated using an asset base that improperly excludes accumulated intangible R&D and marketing capital. Accounting figures tend to *overstate* the true rate of return on investment under these conditions. Most studies attempting to correct for this accounting bias have reached the same conclusion: reported drug company returns on stockholders’ equity are overstated.⁶⁰

The former Congressional Office of Technology Assessment (OTA) came to a similar conclusion, finding that, “Over a longer span of time, economic returns to the pharmaceutical industry as [a] whole exceeded returns to corporations in other industries by about 2 to 3 percentage points per year from 1976 to 1987, after adjusting for differences in risk among industries. A risk-adjusted difference of this magnitude is sufficient to induce substantial new investment in the pharmaceutical industry.”⁶¹ Even these modestly higher returns should not be cause for significant concern. As the OTA study points out, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary to induce companies to invest in researching new chemical entities.”⁶² Scherer writes, “Had the returns to

pharmaceutical R&D investment not been attractive, it seems implausible that drug-makers would have expanded their R&D so much more rapidly than their industrial peers.”⁶³

Furthermore, while only a tiny fraction of drugs that enter clinical trial testing are ultimately approved by the FDA, an even smaller fraction of drugs approved ever become economically profitable. A study released in 2010 by Vernon, Golec, and DiMasi found that 80 percent of new drugs made less than their capitalized R&D costs. Entities in the second-most-profitable decile barely broke even; those in the first decile had discounted profits more than twice their discounted R&D costs.⁶⁴ Other studies have found that of the most successful 10 percent of approved drugs, only 1 percent of those that entered clinical trials—maybe three new drugs each year—generate half of the profits of the entire drug industry.⁶⁵

That’s why, in 2018, the Congressional Budget Office (CBO) estimated that because of the high failure rates, biopharmaceutical companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investments (i.e., a risk-free rate they could readily attain in public markets).⁶⁶ The 61.8 percent figure was predicted on the CBO finding that new drug research and development had a 14-year development period and a 90 percent failure rate. Concentrating only on the rate of return to successful projects therefore gives a misleading picture of the overall profitability of biopharmaceutical companies.

Finally, in their quest for lower prices and a more socialized drug industry, advocates hold out optimistic promises for massive price declines. Yet as the OTA study found, “excess returns over R&D costs would be eliminated if the annual revenue per compound was reduced by 4.3 percent over the product’s life.”⁶⁷ This is similar to the OTA’s finding that U.S. drug firms had an average profit rate just 2 to 3 percentage points higher per year than the internal rate of return in control-group industries.⁶⁸ In other words, efforts to drive down profits would yield only very small price declines, but as noted, would reduce R&D.

DRUG PRICE CONTROLS LEAD TO LESS LIFE-SCIENCES INNOVATION

Because of this essential link between drug prices, industry revenues, and industry R&D, drug price controls contribute to decreased levels of life-sciences innovation. In fact, one reason why Europe has produced fewer biopharmaceutical innovations than the United States is that European Union (EU) price controls make its biopharmaceutical firms generate less profit that can be reinvested into R&D than U.S. firms. For example, Golec and Vernon demonstrate that, because of price regulations, “European Union pharmaceutical firms are less profitable, spend less on R&D, and earn smaller stock returns than U.S. firms.”⁶⁹ By using data from 1986 through 2004, the authors go on to show that the economic tradeoff for the EU, by maintaining real pharmaceutical prices constant over 19 years, was forgoing about 46 new medicine compounds. They took this one step further by presenting a counterfactual scenario of the United States adopting EU-level price controls over the same time period and estimate that similar price controls would have resulted in a decline in firms’ R&D expenditures in the range of 23 to 33 percent and the development of 117 fewer new medicine compounds.⁷⁰ Likewise, a study by Maloney and Civan estimates that a 50 percent drop in U.S. drug prices would result in the number of drugs in the development pipeline decreasing by up to 24 percent.⁷¹

U.S. government research has also documented these effects. A 2005 Department of Commerce report, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*, found that international reference pricing and other price controls in foreign countries already suppress worldwide private R&D investment by 11 to 16 percent annually.⁷² A 2006 analysis of the possible impact of requiring federal negotiation of prescription drug prices for Medicare Part D found that, while prices might be driven down by over 35 percent by 2025, the cumulative decline in drug R&D from 2007 to 2025 would be approximately \$196 billion in 2005 dollars, or \$10.3 billion per year, potentially leading to the loss of about 196 new drugs.⁷³ The paper estimated that an annual R&D decline of \$10 billion would result in an expected loss of 5 million life-years annually, suggesting the economic cost of this effect would be about \$500 billion per year, far in excess of total U.S. spending on pharmaceuticals. Likewise, a February 2018 report by the President’s Council of Economic Advisors finds that while lowering reimbursement prices in the United States would reduce the prices Americans pay now for biopharmaceutical products, it would “make better health costlier in the future by curtailing innovation,” thus failing to meet the administration’s goal of reducing the price of health care by reducing the incentives for innovative products in the future.⁷⁴

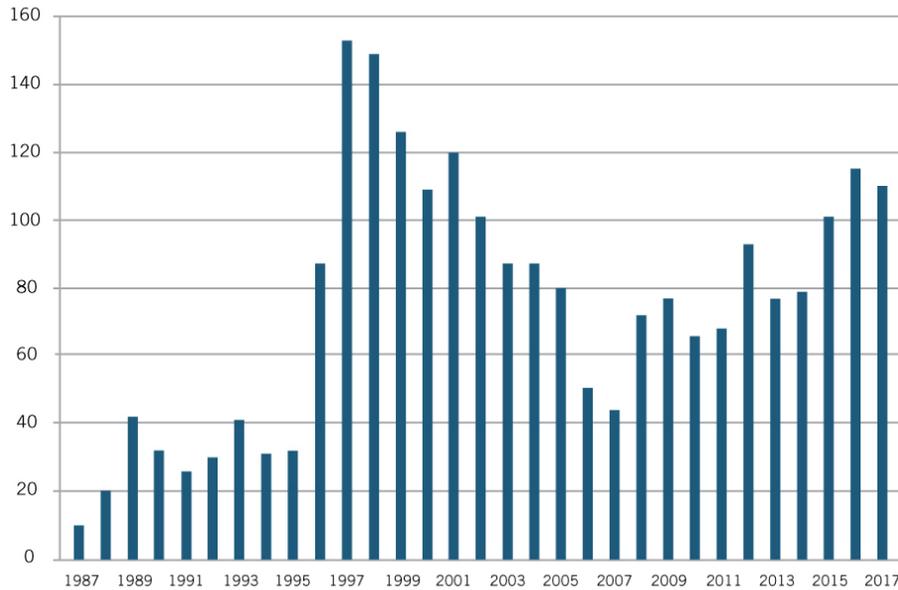
Conversely, relaxing price controls can bolster levels of life-sciences innovation. For instance, research from Precision Health Economics finds that if government price controls in non-U.S. OECD countries were lifted, the number of new treatments available would increase by 9 to 12 percent by 2030, equivalent to 8 to 13 new drugs in that year.⁷⁵ Greater rates of innovation would further contribute to increased expected longevity. Indeed, the Precision Health Economics study finds that the new treatments that would be available if drug prices were lifted would potentially increase the life expectancy of someone who is 15-years-old today by 0.6 to 1.6 years on average.⁷⁶

There’s also strong historical evidence that drug price controls stifle life-sciences innovation. In 1989, the NIH’s Patent Policy Board adopted a policy statement and three model provisions addressing the pricing of products licensed by public health service (PHS) research agencies on an exclusive basis to industry or jointly developed with industry through Cooperative Research and Development Agreements (CRADAs). In doing so, the Department of Health and Human Services (HHS) became the only federal agency at the time (other than the Bureau of Mines) to include a “reasonable pricing” clause in its CRADAs and exclusive licenses.⁷⁷ The 1989 PHS CRADA Policy Statement asserted that:

[HHS] has a concern that there be a reasonable relationship between pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for the NIH/ADAMHA [Alcohol, Drug Abuse, and Mental Health Administration] intellectual property rights may require that this relationship be supported by reasonable evidence.

As Joseph P. Allen notes, such “attempts to impose artificial ‘reasonable pricing’ requirements on developers of government supported inventions did not result in cheaper drugs. Rather, companies simply walked away from partnerships.”⁷⁸ As figure 3 shows, use of CRADAs began in 1987 and rapidly increased until the reasonable pricing requirement was introduced in 1989.

Figure 3: Private sector Cooperative Research and Development Agreements with NIH, 1987-2017⁷⁹



Recognizing that the only impact of the reasonable pricing requirement was undermining scientific cooperation without generating any public benefits, the NIH eliminated the reasonable pricing requirement in 1995. In eliminating the reasonable price requirement on NIH CRADAs in 1995, then-NIH Director Dr. Harold Varmus explained that, “An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public. Eliminating the clause will promote research that can enhance the health of the American people.”⁸⁰ As figure 3 shows, after NIH eliminated the requirement in 1995, the number of CRADAs immediately rebounded in 1996 and grew considerably in following years.⁸¹ The case represents a natural experiment showing the harm pricing requirements can inflict.

DRUG PRICE CONTROLS LIMIT ACCESS TO DRUGS

Countries that impose overly strict regulations on the prices of pharmaceutical drugs also disincentivize international companies from entering markets to provide more innovative health-care solutions. A study that examined the 28 largest pharmaceutical markets between 1980 and 2000 found that countries with strict price controls hurt not only domestic innovation in the life sciences but also the interests of domestic consumers.⁸² Not only are drug launches delayed in these price-controlled countries compared to other less-regulated countries; companies are also less likely to introduce their products in additional markets once they’re available where there are heavy price regulations. Domestically produced pharmaceutical products from countries with stronger price controls also reach a smaller market internationally.⁸³

Other studies yield similar findings in the international market for pharmaceuticals. In one, the probability of pharmaceutical launch is positively correlated to the expected price and volume of sales for a given market.⁸⁴ This follows the logic that pharmaceutical companies will launch their products in markets where they can better capture

the value of their innovations. Another study confirms the finding that consumers in countries that have stricter price controls, compared with countries that do not, have to wait longer for drug launches by international firms.⁸⁵ Similarly, Cockburn, Lanjouw, and Schankerman, in their paper “Patents and The Global Diffusion of New Drugs,” find that countries that adopt strong price controls experience “significantly longer lags” in new drug launches and that in these countries “introducing price controls increases drug launch lags by 25-80 percent.”⁸⁶ These studies highlight the interconnected nature of global life-sciences innovation, where government-mandated price controls do a disservice to consumers, domestic pharmaceutical firms, foreign pharmaceutical firms, and overall drug innovation.

The Department of Health and Human Services’ October 2018 report “Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures” analyzed price and availability of 27 drugs across 16 comparator countries.⁸⁷ Only 11 of the 27 drugs examined were widely available in all the comparator countries, indicating that patients in these countries were experiencing delays in access to innovative treatments. For instance, while 95 percent of new cancer drugs are available to patients in the United States, on average this compared to just 55 percent in the 16 reference countries. Further, for the cancer drugs available in the reference countries, there appears to be a 17-month average lag between the time they are available in the United States and their availability elsewhere.⁸⁸ To be sure, anti-cancer drugs tend to be available to American patients before Europeans not just because of European drug price controls—it’s also in part a result of faster approvals by the FDA than by the European Medicines Agency—but it is one reason.⁸⁹

THERE ARE BETTER WAYS TO CONTROL HEALTH-CARE SYSTEM COSTS

Drug prices are not the major driver of increased U.S. health-care system costs. In fact, drug prices in nations that belong to the Organization for Economic Cooperation and Development grew more slowly than total health care costs from 2005 to 2013.⁹⁰ Moreover, far from being the leading cause of rising U.S. healthcare system costs, greater levels of life-sciences innovation over the long term will actually be key to limiting the growth of healthcare system costs—while improving health care outcomes. Indeed, significant economic benefits could be achieved if innovative medicines could make progress toward addressing some of the most intractable diseases.⁹¹ For instance, a 1 percent reduction in mortality from cancer would deliver roughly \$500 billion in net present benefits, while a cure could deliver \$50 trillion in present and future benefits.⁹² Likewise, the financial impact of Alzheimer’s disease is expected to soar to \$1 trillion per year by 2050, with much of the cost borne by the federal government, according to the Alzheimer’s Association report “Changing the Trajectory of Alzheimer’s Disease.”⁹³ However, the United States could save \$220 billion within the first five years if a cure or effective treatment to Alzheimer’s disease were found. Similarly, ITIF estimates that the potential economic opportunity associated with curing brain diseases and disorders could be more than \$1.5 trillion per year—or 8.8 percent of gross domestic product.⁹⁴

But even short of breakthrough cures, the economic benefits of pharmaceutical innovation are manifold. Indeed, pharmaceutical innovation is often not just cost-effective, it’s cost saving. For instance, in his article “The Impact of Pharmaceutical Innovation on Disability Days and the Use of Medical Services in the United States, 1997-2010,” Lichtenberg finds that “the value of reductions in work loss days and hospital admissions attributable to pharmaceutical innovation was three times larger than the cost of new drugs consumed.”⁹⁵ Lichtenberg further finds that the mean number of lost work days, lost school days, and hospital admissions declined more rapidly among medical conditions with larger increases in the mean number of new (post-1990) prescription drugs consumed. Indeed, when medicines help Americans live longer, healthier lives, the economic benefits are considerable. For

instance, improvement in U.S. life expectancy from 1970 to 1990 added \$2.8 trillion to U.S. productivity, which equaled \$12,000 per U.S. citizen, per added year of life expectancy.⁹⁶ Prescription medicines, including retail pharmacy sales and provider-administered drugs, represent only approximately 14 percent of overall U.S. healthcare spending.⁹⁷ In 2016, Part B medicines accounted for 8 percent of total Medicare fee-for-service Part B spending and 3 percent of total Medicare spending.⁹⁸ Put simply, innovative medicines deliver tremendous value for the economy and society, and there are better ways to tackle burgeoning healthcare system costs than importing foreign drug price controls, including by focusing on the cost of chronic disease, focusing on high-value care, or making better use of value-based contracts for medicines.

One of the most important ways to better manage drug prices would be to enhance R&D efficiency in drug research, in other words, to find collaborative ways to work together to make the cost of innovating new drugs less expensive. Most expensive for companies are candidate drugs which reach Phase III clinical trials and then fail; better success at weeding out those types of drugs earlier in the R&D process would make the entire drug discovery process more efficient and less expensive. One important step in this regard has actually been the Prescription Drug User Fee Act (PDUFA). By putting in place mechanisms that allow drug developers to have frank conversations with regulators about the technical and scientific expectations for a drug to clear certain clinical trial hurdles, it has streamlined the drug review process to some degree and helped drug developers make better decisions about the likelihood of candidate drugs passing the clinical trial gauntlet. Congress's 2017 reauthorization of PDUFA (PDUFA VI) also placed greater focus on supporting rare diseases and breakthrough therapies, including continued application-fee waivers and advanced reviews for medicines that can treat rare diseases, as well as prioritizing the development of breakthrough medicines for patients with life-threatening diseases. Further, the advent of new technologies such as artificial intelligence and big data are likely to facilitate the drug-discovery process, helping to better identify biomarkers or to apply high-performance computing to analyze chemical and structural of proteins and molecular compounds that may lead to cures. Ensuring U.S. leadership in these advanced technologies, including through a highly educated STEM workforce, effective national strategies for AI implementation, and robust federal funding of scientific research broadly will also play an important role over the long term in facilitating the more cost-effective new drugs.

CONCLUSION

The U.S. system encourages life-sciences innovation in the private sector by providing strong intellectual property protections and a drug reimbursement system that together allow companies to earn sufficient revenues to reinvest in highly risky research and development.⁹⁹ But it has also implemented a system that facilitates generic competition to help manage drug prices. As Jack Scannell, a senior fellow at Oxford University's Center for the Advancement of Sustainable Medical Innovation (CASMI), explains, "I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995."¹⁰⁰ He continues, "Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good."¹⁰¹ It's the dynamic that enables us to envision a future where drugs are available at generic prices in 2040 for a set of innovative drugs that that have greater medical utility than the entire set available to anyone, anywhere, at any price in 2020. But if that's going to be the case, policymakers will need to affirm the role of intellectual property in underpinning America's life-sciences innovation system and resist calls from those who would

advocate for the government marching in years after the fact to seize or to compulsorily license intellectual property under the guise of trying to control drug prices.

The broader debate about price controls is not really one about whether society wants lower prices in exchange for lower drug company profits; it is about whether society wants lower drug prices in exchange for less and slower drug innovation—that is, cheaper prices today, and less effective drugs when our children become adults.¹⁰² Managing burgeoning U.S. healthcare system costs is a laudable objective, but there are mechanisms to pursue that goal without endangering an American life-sciences innovation system that has come to be the envy of the world. It's important that the objective of lowering health care costs now not come at the expense of less and slower drug innovation for future generations.¹⁰³

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