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How to Ensure That America's Life-Sciences Sector Remains Globally Competitive

BY JOE KENNEDY | MARCH 2018 | REVISED JULY 2020 (SEE ERRATA)

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Since the postwar period, America's life-sciences sector has been a major contributor to U.S. economic competitiveness and, in the process, has created millions of high-wage jobs. But over the last two decades, other nations have challenged that position. This report looks at several indicators of the sector's contribution to the U.S. economy. It then examines the international competitiveness of the United States in the face of concerted challenges by other countries, paying particular attention to why life sciences seem to underperform in international trade. Finally, it suggests specific policies that Congress could enact to ensure U.S. life sciences remain competitive going forward.

Life sciences—particularly the pharmaceuticals industry (defined here as the traditional pharmaceutical industry and the biotechnology industry)—is a key sector of the U.S. economy. It generates a large number of well-paying jobs, conducts an enormous amount of research and development (R&D), and is a key traded sector that supports U.S. global competitiveness. But the sector also requires a complex ecosystem that integrates research, investment, skilled labor, specific manufacturing skills, protection of intellectual property (IP), and approval of and payment for drugs and devices. During the last few decades, other nations have come to realize the importance of the sector to their economies and have therefore increasingly tried to win a larger share of global life-sciences activity. These efforts have been marginally successful, in part because U.S. policy has been less than fully adequate. The competitive threat is important because if the United States' advantage of having a strong ecosystem gets eroded beyond a certain point, it will be extremely difficult to regain. Should this come to pass, relative U.S. competitiveness, per-capita incomes, and good-paying jobs will decline. As such, U.S. policy makers will need to ensure that policies affecting the life-sciences sector are optimized to increase the nation's global market share and competitiveness.

This report details the economic contribution of the industry (including employment, value added, exports, and research and development), examining its competitive position relative to other nations. It also discusses the policy and regulatory framework needed for the U.S. life-sciences sector to retain—or even increase—its global competitiveness.

EXECUTIVE SUMMARY

The life-sciences sector, consisting of pharmaceuticals (both chemical and biological drugs) and medical equipment, as well as the research that supports them, plays a central role in both the economy and health care system of the United States. These industries are extremely research-intensive, employ a large number of skilled workers earning above-average wages, and represent a critical traded sector that helps the U.S. economy compete internationally. Because the industry is one of the most technologically complex in the world, funded predominantly by investments of large amounts of capital for long periods of time in the face of significant technological and market risk, it requires both specialized and general infrastructures, business conditions, and policy supports. In terms of general factors, success depends on an effective corporate tax system, including robust incentives for research and development, a strong patent system, and an effective rule of law. In terms of industry-specific factors, it needs a strong institutional infrastructure, including trained life-sciences workers, access to research labs, an experienced investment community, an effective regulatory approval system, a fair device and drug payment system, generous government funding of biomedical research, and a strong international trade effort to limit foreign "life-sciences mercantilism" (including weak IP protections, compulsory licenses, and deep government-forced price discounts).

Despite losing global market share over the last 20 years, the United States still has a strong life-sciences sector. America's health care system does a laudable job of compensating companies for their discoveries, while the FDA's drug-approval process remains relatively effective. While the federal government funds a healthy collection of top-tier research centers, a combination of strong life-science and related skills, a robust venture capital (VC) industry, and firm patent protection provides a climate in which companies can emerge and grow.

But America's leadership has been slipping over the past two decades. Foreign nations are aggressively competing, in both fair and unfair ways, to grow and attract more life-sciences sector investment, with many using their central government's monopsony power as a purchaser of drugs and devices to limit the prices U.S. firms are able to charge for their exports—thereby artificially inflating the United States' trade deficit in the sector.[1] These foreign pricing policies also allow many other nations to piggyback on the U.S. life-sciences innovation system in order to get the benefits of better treatments without having to pay their fair share for the costly research and development.

Meanwhile, the United States has been lukewarm in its support of the industry, cutting federal biomedical research in real terms and increasingly considering pricing policies that would hurt innovation and U.S. life-sciences competitiveness. Such policies create uncertainty regarding the willingness to pay for future treatments and the research necessary to discover and bring them to market. And, unlike other countries, the United States only recently stopped taxing the foreign income of American companies at what was considered an uncommonly high rate. It is also falling further behind in providing innovation-focused tax incentives, such as an innovation box or a competitive research and development tax credit—something the recent tax reform only made worse.[2]

Life-sciences companies located in the United States performed $96.5 billion of research and development in 2013. Of this, $74.5 billion was self-funded.

It is important for the United States to maintain a highly competitive life-sciences sector. The life sciences—especially pharmaceuticals—generate high-skilled, high-paying jobs, many of which are in research and manufacturing. And because its medications and devices are sold throughout the world, the industry makes up a key component of the U.S. traded economy. A weaker competitive position would mean a lower value for the dollar, a larger trade deficit, or both, coupled with plant closures and job losses. And as the Information Technology and Innovation Foundation (ITIF) has shown, these losses would extend to a number of states.[3]

Other nations gaining global market share at the expense of U.S. production would cause serious ramifications to the life-sciences industry—even if the value of the dollar were to fall significantly. After the devastation of World War II, the United States captured the lead from Europe in life sciences thanks to its large domestic market, strong system of university research labs, competent regulation and pricing regime, and generous federal R&D funding. Creating an industry like this was extremely difficult. Recreating the industry if it were to be lost would be even harder—if not impossible.

Major takeaways from the life-sciences sector's contribution to the U.S. economy include the following:

- In 2016, the sector employed over 1.2 million workers. The pharmaceutical subsector alone created an additional 3.5 million jobs indirectly both by creating demand for inputs and as a result of its workers spending their incomes.[4] Employment since 2001 has been growing rapidly, especially in pharmaceuticals.
- Jobs in the pharmaceutical subsector earned an average wage of $124,400 in 2016, while those in the medical-equipment subsector earned $86,200. Both were significantly higher than the real median personal income at the beginning of that year, which was $31,100—or the average annual wage for workers in all industries of $53,500.[5]
- The life sciences account for a large share of new start-ups in each of the subsectors. Start-ups tend to focus largely on research and development, and account for more than their share of job creation.
- Life-sciences companies located in the United States performed $96.5 billion of research and development in 2013. Of this, $74.5 billion was self-funded. Of the

total research, $79.4 billion was performed domestically, which was almost 25 percent of all corporate R&D performed in the United States. Private investment in pharmaceutical research equaled 10.3 percent of sales, almost three times the ratio of the average industry. The equivalent figure for the medical-equipment subsector was 4.4 percent.[6]

- Nearly 22 percent of domestic pharmaceutical employees work in research and development, making it one of the most research-intensive industries. This percentage is nearly four times that of the average U.S. industry. The ratio for medical equipment is almost 12 percent.[7]
- Private firms are not able to capture all of the benefits from the research they perform, although much of it does benefit the larger society in the form of increased productivity, lower medical costs, and less personal suffering. The total social return from biomedical research (public and private) has been estimated at 150 percent, implying that society would benefit from a significant increase in research spending—which is the opposite of what is likely to happen with widespread restrictions on drug prices.[8]
- Over the 14-year period ending in 2013, the United States accounted for roughly 40 to 45 percent of all triadic patents (patents filed in the United States, Europe, and Japan) in biotechnology, medical technology (generally medical or veterinary science), and pharmaceuticals (The United States Patent and Trade Office issues separate statistics for pharmaceuticals and biotechnology; this report generally treats biopharmaceuticals as a subset of pharmaceuticals).
- The pharmaceutical and medical-instrument subsectors' combined output was $675 billion in 2015, almost 4 percent of total GDP. This reflects steady increases in value added in both the medical equipment and electromedical manufacturing subsectors as well as research and development. However, value added in pharmaceutical manufacturing declined by 31 percent over the last seven years.
- The life-sciences industries exported almost $90 billion worth of products in 2017. Pharmaceutical exports have grown 191 percent in the last 15 years, while medical-equipment exports grew by over 185 percent. Yet imports have grown at roughly the same rate or faster. Although the medical-equipment subsector is running a rough trade balance, pharmaceuticals is experiencing a trade deficit of $56.2 billion, with imports growing faster than exports, especially since 2013.
- The trade statistics are influenced by at least two factors that artificially lower the value of exports while raising the value of imports, both of which make the trade imbalance look better than it actually is. Past tax policy encouraged international companies to shift as much of their profits abroad as legally possible, causing some domestic production to be undercounted, while widespread and often deep foreign suppression of life-sciences prices through government price controls resulted in reduced U.S. export prices, thus allowing these nations to import U.S. goods without having to remunerate an equivalent value of exports to the United States.

The United States' lead in the life sciences is being challenged. Other countries have aggressively courted life-sciences companies with lower tax rates, a range of firm-specific tax benefits, increased government research funding, improved intellectual property protections, and streamlined approval processes. In order to retain its competitive advantage, the United States needs to enact a number of important reforms.
Going forward, the United States can strengthen its life-sciences economy by:

Companies in the life-sciences sector have the freedom to conduct research and/or produce goods wherever they want and then export their products to the rest of the world. Countries that capture this activity generally experience higher incomes and better trade performance.

1. **Implementing better tax policy.** The tax reform legislation Congress passed in 2017 achieved several important things, including lowering the statutory rate and moving toward a territorial system. However, although the tax reform bill did not amend the R&D tax credit, the combination of a lower statutory tax rate and the requirement that companies begin amortizing R&D expenses starting in five years reduces the tax incentives for conducting more research. The legislation also failed to enact an innovation box, while at the same time cutting the orphan drug tax credit rate.[9]
2. **Reversing the long-term decline in federally supported basic research.** For example, to restore National Institutes of Health (NIH) funding to its 2003 share of GDP, it would have to increase by $11.6 billion per year.[10]
3. **Taking more forceful action to address unfair trade practices by other nations,** including IP theft, abuse of the compulsory license process, technology transfer as a condition for selling into a market, lack of transparent processes for obtaining government approvals, and use of government power to reduce prices and, by definition, U.S. exports, revenues, and jobs.
4. **Expanding and improving workforce training in STEM subjects.** Many life-sciences workers do not necessarily need a college degree in order to gain valuable skills. But they do need specific skills in science, engineering, and manufacturing. Overall, we need more qualified STEM workers.
5. **Passing health care reforms that restore long-term stability and provide adequate reimbursement,** including for novel therapies.
6. **Continuing to value the role robust IP rights play in underpinning life-sciences innovation.** For instance, policymakers should continue to support the Bayh-Dole Act of 1980, which creates a uniform patent policy enabling small businesses and non-profit organizations, including universities, to retain title to inventions they make with federal funding.

INTRODUCTION

Companies in the life-sciences sector have the freedom to conduct research and/or produce goods wherever they want and then export their products to the rest of the world. Countries that capture this activity generally experience higher incomes and better trade performance. Therefore, the importance of strengthening the competitiveness of U.S. life sciences by providing a strong ecosystem has never been greater—yet neither have the threats.

With the life sciences currently undergoing rapid innovation, this report looks at the growing economic importance of America's life-sciences sector and the policies needed to maintain U.S. competitiveness. The life-sciences sector consists of two major subsectors: pharmaceuticals and medical equipment. Through both chemical- and biological-based drugs, pharmaceuticals seek to address a range of illnesses, including many that currently lack any effective treatments, while the production of medical equipment and devices provides an opportunity for medical professionals to deliver higher-quality care to patients at lower prices. A methodology appendix describes the statistical definitions of each subsector and their component industries in fuller detail.

In addition to generating a continuous stream of important innovations, this sector plays a growing role in the U.S. economy, with life-sciences companies continuously hiring more workers—and paying them above-average wages because their work requires skills and training that are in high demand.

Although the United States still has a strong life-sciences industry, over the last decade or so, a number of countries have instituted policies aimed at attracting and growing more of this activity.[11] As a result, the United States is in danger of losing its competitive lead, as an ever-increasing share of this activity moves to other countries. Should this trend continue, the U.S. economy would very likely begin to suffer from an ever-worsening per-capita income rate.

This report proceeds by documenting the economic impact of the life-sciences sector on America's national economy. It then looks at the competitive threat facing the sector and explains how the United States can respond to this challenge.

AMERICA'S LIFE-SCIENCES INDUSTRIES

Briefly, the life-sciences sector is defined as containing two subsectors, which can be further broken down into 4 groups and 12 separate industries. Using the North American Industry Classification System (NAICS), the life-sciences industry consists of the following:

Pharmaceuticals and Medicines:

32541 Pharmaceutical and Medicine Manufacturing:

- 325411 Medicinal and Botanical Manufacturing
- 325412 Pharmaceutical Preparation Manufacturing
- 325413 In-Vitro Diagnostic Substance Manufacturing
- 325414 Biological Product (except Diagnostic) Manufacturing

54171 Research and Development in the Physical, Engineering, and Life Sciences:

- 541711 Research and Development in Biotechnology
- 541712 Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)

Medical Devices and Equipment:

33451 Electromedical and Electrotherapeutic Apparatus Manufacturing:

- 334510 Electromedical and Electrotherapeutic Apparatus Manufacturing
- 334516 Analytical Laboratory Instrument Manufacturing
- 334517 Irradiation Apparatus Manufacturing

33911 Medical Equipment and Supplies Manufacturing:

- 339112 Surgical and Medical Instrument Manufacturing
- 339113 Surgical Appliance and Supplies Manufacturing
- 339114 Dental Equipment and Supplies Manufacturing

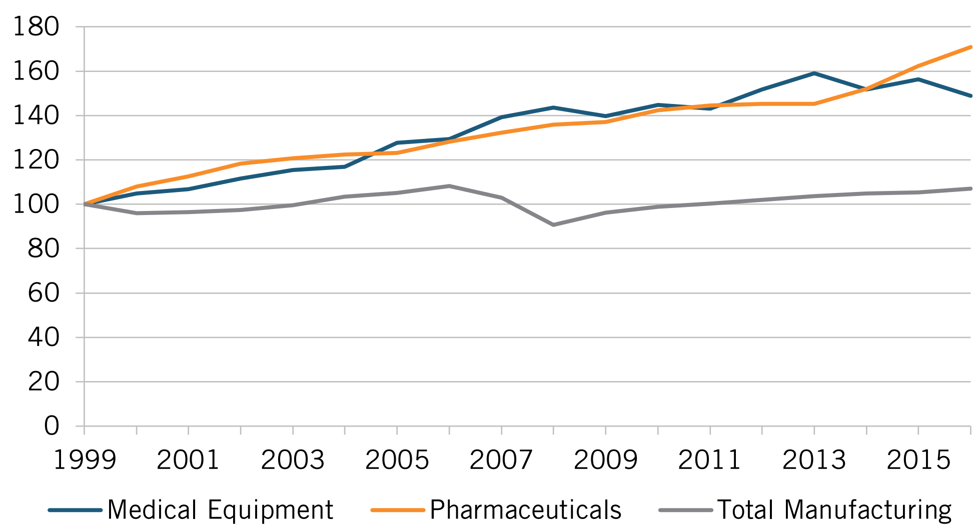
Output

While overall real U.S. manufacturing has been largely stagnant since 1999, pharmaceutical and medical equipment output has grown (see figure 1).[12] This is partly the result of these industries attracting the most direct foreign investment.

Both the pharmaceutical and medical equipment life-sciences subsectors are growing faster than the economy as a whole.

Total economic output for the pharmaceuticals subsector was $555 billion in 2016, or almost 3 percent of GDP.[13] Of the total pharmaceutical output, $286 billion came from pharmaceutical manufacturing, which has grown 144 percent since 1999. The other $269 billion was generated by firms that specialize in scientific R&D services. Although research includes a great deal of activity not related to the life sciences, the life-sciences portion is large and growing. Because the sector is so dependent on a steady stream of research ultimately leading to the creation of new drugs, research activity is just as important as pharmaceutical manufacturing. Since 1999, the total output for the research industry has increased by 132 percent, during which time nominal GDP grew by only 89 percent. Gross output for the medical equipment subsector was $140 billion in 2016, a slight decrease from the previous year, but up 107 percent since 1999. Both the pharmaceutical and medical equipment life-sciences subsectors are growing faster than the economy as a whole.

Figure 1: Change in Real Output in Pharmaceuticals, Medical Equipment, and Total Manufacturing (1999 = 100)[14]

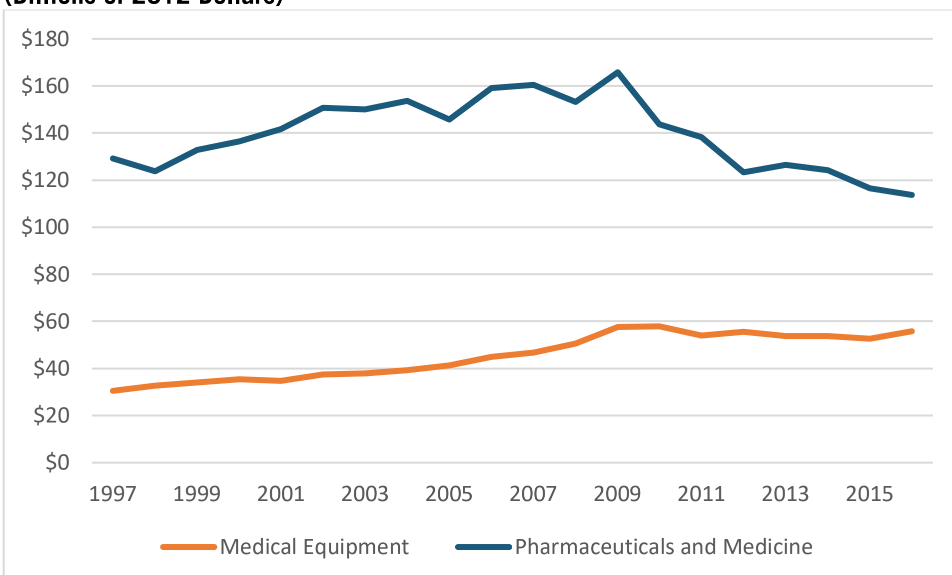


Value Added

While gross output shows the total output of an industry, it does not measure how much firms in the United States add in value. For that, we need value added. Unfortunately, the nation's value added statistics are not always broken down into 6-digit NAICS codes. Figure 2 shows value added in NAICS code 3391 (medical equipment and supplies manufacturing) and NAICS code 3254 (pharmaceutical and medicine manufacturing). We can see that real value added in medical equipment manufacturing rose steadily during the last two decades, increasing by a total of 83 percent. Manufacturing as a whole rose by only 42 percent. In contrast, pharmaceutical and medical manufacturing fell by 12 percent. From 1997-2009, the industry value added increased by 28 percent. However, in the next seven years it fell by 31 percent, a trend that has continued for the last three years. Value added in NAICS 3345 and 5417 rose steadily at 130 percent and 38 percent, respectively.

Because the life-sciences sector employs almost exclusively high-skilled labor, it pays much higher wages than average.

Figure 2: Real Value Added in Pharmaceuticals and Medical Equipment Manufacturing (Billions of 2012 Dollars)[15]

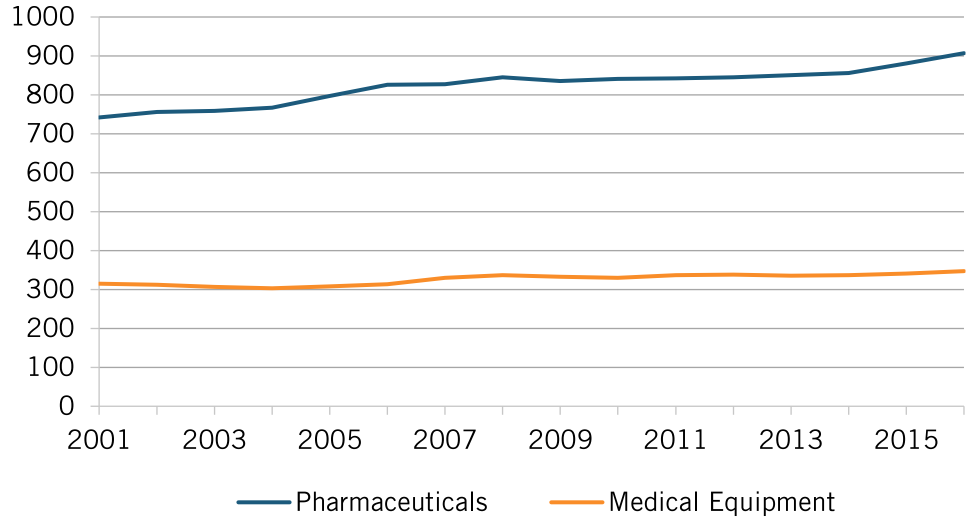


Employment

America's life-sciences sector employed a total of 1.2 million workers in 2016 (see figure 3). Most of them (907,000, or 72 percent) were in the pharmaceuticals subsector, employment in which (both production and research) increased by 22 percent between 2001 and 2016. During this same period, total U.S. nonfarm employment increased by only 9.3 percent, and employment in manufacturing actually declined by 25 percent.[16] Meanwhile, pharmaceutical employment hardly decreased at all during the recent recession, and resumed growing in 2013.

Employment in the medical equipment subsector rose by 10 percent (32,400 jobs) from 2001 to 2016, showing only a nominal decrease during the recession before leveling off for five years and resuming growth in 2012.

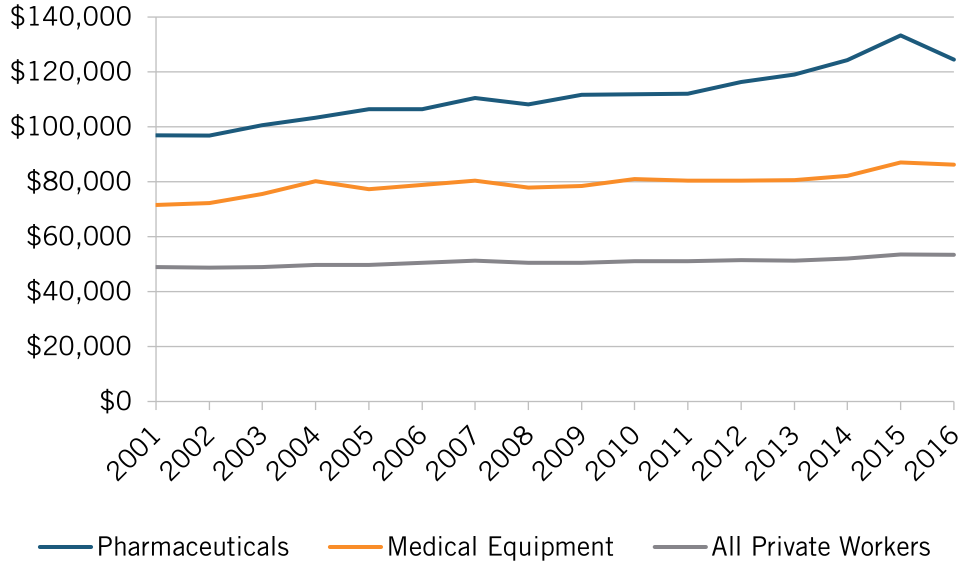
Figure 3: Employment in Pharmaceuticals and Medical Equipment (in Thousands)[17]



Wages

Because the life-sciences sector employs almost exclusively high-skilled labor, it pays much higher wages than average (see figure 4). A 2017 study found pharmaceutical wages exceeded the average private wage by 50 percent or more in 43 states—with the rate of excess being 75 percent or more in 24 states.[18] However, average wages vary by industry within the sector, and there is a gap of at least $40,000 between the highest- and lowest-paying industries in each subsector. Wages in the pharmaceutical subsector are also about $40,000 higher than those in medical equipment, with a weighted-average wage across the subsector of $124,400 in 2016. Within the pharmaceutical subsector, research and development in biotechnology pays significantly more than in any other industry, resulting in an average wage of $151,900 in 2016—compared with $86,200 for the medical equipment subsector. For that same year, the median personal income in the United States was only $31,100, and the average annual wage for workers in all industries was $53,500.[19] Since 2001, in every industry within both subsectors, wages have been rising faster than the rate of inflation.

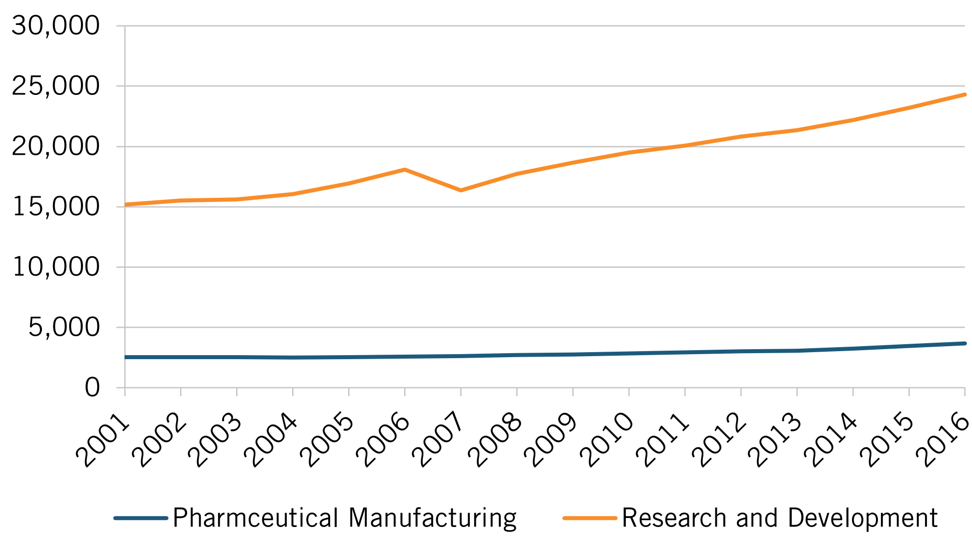
Figure 4: Real Average Wages in Pharmaceuticals and Medical Equipment, and for All Private Workers (in Thousands) [20]



Establishments

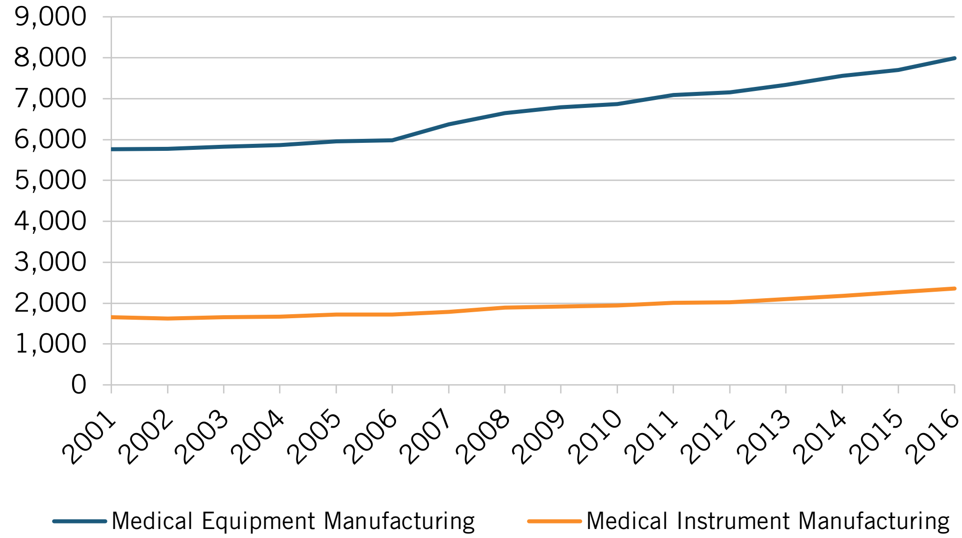
The pharmaceutical-preparation manufacturing industry dominates in its number of establishments in pharmaceuticals and medicines, accounting for 63 percent of the total (see figure 5). Both this industry and medicinal and botanical manufacturing have grown rapidly since 2001 (64 percent and 56 percent respectively). In fact, over that same time period, the total number of research and development sites—establishments that are significantly more numerous than in the other subsectors—have grown by over 9,100, or 60 percent. The number of biotechnology research sites has also increased significantly: by 71 percent since 2007.

Figure 5: Number of Establishments in the Pharmaceuticals and Research Subsector[21]



The total number of establishments in the medical equipment subsector has increased by 39 percent, or over 2,200 sites, since 2001 (see figure 6), most of which has occurred within the same three industries that experienced the most job growth.

Figure 6: Number of Establishments in the Medical Equipment Subsector[22]



A recent ITIF study of high-technology start-up companies, including those in the life sciences, shows that these firms account for a significant share of new-employment growth.

Start-Up Firms

The number and success of start-up companies are crucial to the life sciences. A recent ITIF study of high-technology start-up companies, including those in the life sciences, shows that these firms account for a significant share of new-employment growth, and a higher portion of job growth than start-ups in other industries, largely because firms in technology-based industries are better able to translate their R&D investments into jobs.[23] The study also found that start-ups in these industries tend to be more R&D-intensive than older firms. For example, in biotechnology, the average R&D intensity of all firms is 20 percent, while a survey of biotechnology start-ups found an average intensity of 62 percent.[24]

The study also found that venture capital remains critically important to the creation of high-tech start-ups, providing both the actual funds needed to sustain operations and experienced business advice to maximize their chances of success.[25]

Table 1 shows some key statistics for start-up firms in each industry. In the pharmaceutical industry, both the share of start-ups and the share of early-stage start-ups (defined as those that generate less than $8 million in sales) have increased rapidly over the last decade. Although real wages in start-ups grew by 39 percent from 2007 to 2016—compared with 26 percent for the industry as a whole—the five-year survival rate has fallen by 30 percent since 1998. This has been balanced by a rise in the number of new firms. From 2007 to 2014, the average number of new firms per year was 200. In contrast, a total of 1,200 firms entered the market in 2015 and 2016.[26]

Start-ups have decreased steadily as a share of the medical equipment industry over the last decade, as has employment within them.[27] Total employment among start-ups actually fell by 63 percent between 2007 and 2016. However, the share of early-stage start-ups has remained steady, while high-growth firms (those that increased their employment by at least 25 percent in the last year) have recently increased—as have wages, growing 33 percent from 2013 to 2016, and achieving rough parity with the industry average.

Among firms that provide R&D as a service, the number of start-ups has almost doubled since 2007, accounting for 79 percent of all R&D firms in 2016.[28] Employment has also grown rapidly in the last two years, even surpassing the employment rates of older firms. However, wages remain lower than the industry average and have mostly stagnated over the last decade. The five-year survival rate for new firms dipped dramatically in 2016 to 20 percent, from an average of about 40 percent during the prior decade.

Almost all research conducted by the pharmaceutical companies, $52.4 billion, or 84 percent, was performed here in the United States.

Table 1: Key Characteristics of Life-sciences Start-Up Companies, 2016[29]

Statistic	Pharmaceuticals	Medical Devices	R&D Services
Share of Firms in Industry	66%	34%	79%
Share of Employment in Industry	12%	12%	52%
Five-Year Survival Rate*	60%	55%	20%
Share of Start-Ups Backed by VCs	11%	31%	N/A

Investment in Research and Development

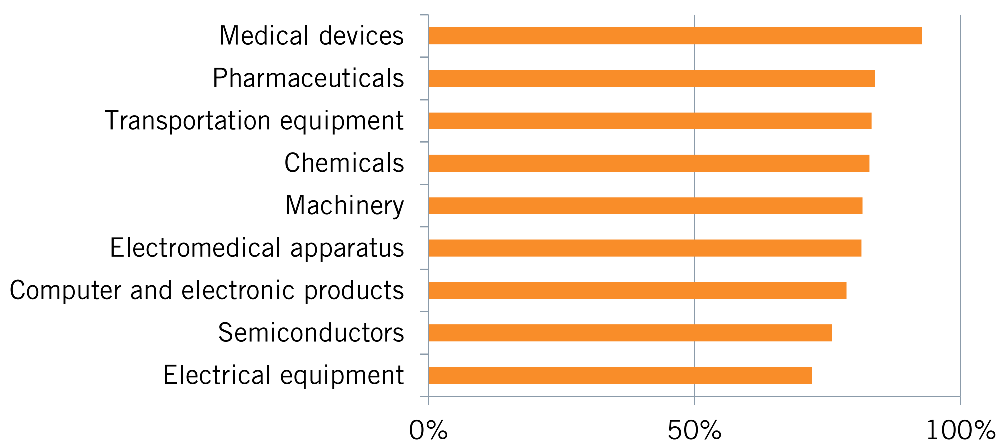
America's pharmaceutical and medical equipment sectors contribute a great deal to the nation's innovation system by conducting a significant amount of research and development. Together, these sectors performed $96.5 billion of R&D in 2013 (the most recent year for which public data are available),[30] of which $74.5 billion was self-funded. Of the total research performed, $79.4 billion was invested in the United States. Table 2 shows basic data from the National Science Foundation (NSF) for each of the four categories comprising our definition of the life-sciences sector.

Table 2: 2013 Worldwide and Domestic R&D Performed by U.S. Companies in Selected Subsectors ($ Billions)[31]

	Worldwide R&D			U.S. R&D			
Subsector	Total	2009-13 Change	Self-Funded	Total	2008-13 Change	Self-Funded	R&D Intensity
Pharmaceuticals and Medicines	$62.5	16.9%	$55.8	$52.4	8.9%	$45.9	10.3%
Scientific R&D Services	$17.7	-5.1%	$2.9	$13.4	-14.7%	$2.8	19.4%
Electromagnetic, Electro-therapeutic, and Irradiation Apparatus	$2.8	37.6%	$2.7	$2.6	-37.1%	$2.5	9.5%
Medical Equipment and Supplies	$13.5	80.4%	$13.1	$11.0	69.6%	$10.6	4.4%
Total	$96.4	14.7%	$74.5	$79.4	6.6%	$61.8	

Pharmaceutical and medicine companies located in the United States (including the U.S. affiliates of foreign companies) performed $62.5 billion of research and development worldwide in 2013, most of which ($55.8 billion) they funded themselves. The vast majority of the rest was paid for by other companies. Almost all research by these companies, $52.4 billion, or 84 percent, was performed in the United States (see figure 7). Medical device companies spent 93 percent of their R&D dollars in the United States—the highest ratio for any U.S. industry.[32]

Figure 7: Domestic Spending on R&D by Companies as a Percentage of Total Industry R&D Spending 2013[33]



Companies in the United States specializing in R&D services performed a total of $17.7 billion in worldwide research in 2013. Of this, $13.4 billion, or 75.9 percent, was performed domestically, while only 20.9 percent of domestic work was self-funded. The rest came primarily from companies outside of the industry, such as pharmaceutical firms. As might be expected, the industries have a high R&D intensity ratio of 19.4 percent. Somewhat surprisingly, total domestic R&D has fallen by 14.7 percent since 2009, due in part to the allure of growing markets overseas. But much of it is also likely due to other countries having aggressively sought to attract the pharmaceutical industry while U.S. federal research investment in life sciences has only increased by roughly the rate of inflation since 2008.[34] As this type of basic research serves as a complement to the research firms already perform, the decline in federal spending has made private research less attractive. As a result, for three of the four subsectors in table 2, worldwide R&D by U.S. companies increased at a significantly faster pace than did their domestic R&D.

The pharmaceutical subsector industry accounted for 20.4 percent of all domestic R&D in the United States, partly because it devoted 19 percent of its total domestic employment to research.

Still, the pharmaceutical subsector industry accounted for 20.4 percent of all domestic R&D in the United States in 2013, partly because it devoted 19 percent of its total domestic employment to research.[35]

The medical equipment subsector has been modestly less research-intensive. The first group, medical equipment and supplies, conducted $13.5 billion in worldwide research in 2013, of which $11.0 billion was domestic. The industry supplied the funds for 97.1 percent of its domestic research—which rose 69.6 percent between 2010 and 2013—and had an R&D intensity of 4.4 percent, slightly above the national average for all industries.

Domestic companies in the electromedical, electrotherapeutic, and irradiation apparatus group conducted a total of $2.8 billion in worldwide R&D in 2013, $2.6 billion of which was performed domestically. The industry self-funded $2.5 billion of its domestic R&D, and has an R&D intensity of 9.5 percent. Between 2009 and 2013, domestic R&D decreased by 37.1 percent, however. Again, in the absence of increased federal funding, the United States has limited powers to offset the increased relative importance of foreign markets due to both market growth and governmental inducements.

This research also has a significant effect on local institutions of higher learning. In 45 states, biomedical is the largest facet of university research, while in 28 states, it accounts for more than 50 percent of all university-based research.[36] Although bioscience research is opening up new opportunities for advancement, it requires significant investment in cutting-edge specialized laboratory facilities and research capacities.[37] In 2014, industry funding for medical-science research accounted for 41 percent of all private-sector funding to universities.[38]

ASSESSING THE COMPETITIVE POSITION OF THE U.S. LIFE-SCIENCES SECTOR

At first blush, it would appear the United States is highly competitive in the life-sciences sector. It boasts leading firms. Its share of patents is strong. It is home to many of the industry's leaders. It spends far more on research and has a competitive drug- and device-approval process. But value added in pharmaceutical manufacturing has declined rapidly, and the United States is also running a growing trade deficit with the rest of the world, an indication that on its face suggests a lack of competitiveness. How can these two factors be reconciled? One reason is that there appears to be evidence that suggests the value of real exports is being undercounted, in part by transfer pricing and foreign price controls. The following section examines the apparent evidence of the United States' competitive strength against the underlying reality of the trade deficit.

Independent Assessments of Competitive Strength

Despite the challenges previously mentioned, the United States remains the predominant powerhouse of drug discovery and production, ranking first in nearly all measures of innovation.[39] The Biopharmaceutical Competitiveness and Investment Survey ranked the United States first among mature markets in 2017—improving slightly from its 2016 score, with 86.89 out of 100—followed by Switzerland, Germany, and the United Kingdom.[40] The United States scored higher than the average of its top three competitors in each of the survey's five categories, in addition to recently being ranked as the top location for life-sciences jobs in the world.[41]

Over the last 15 years, the three-year average of New Drug Approvals (NDAs) issued per year has risen steadily from a low of 72 in 2003 to 106 in 2014.

A recent analysis of the life-sciences sector in the United Kingdom acknowledged the United States' lead and listed some of its advantages:

> The US is the global leader in the life sciences industry, is an early adopter of new classes of medicines with a large market, has good access to risk capital plus state and federal level support for research and innovation, and state or city level financial incentives for manufacturing investments. All of these have ensured the United States has a substantial level of life sciences manufacturing.[42]

Thus, despite challenges and doubts, the United States continues to enjoy several strengths in the ecosystem criteria discussed previously. These include an IP system that rewards innovation through patent and data protection, a science-based regulatory system that is considered the most rigorous in the world, the world's largest scientific research base fostered by academic institutions and decades of government research funding, and robust capital markets. In 2015, the United States attracted 74 percent of all worldwide venture-capital investments in the biopharmaceutical industry.[43] And the ability of companies in the United States to earn reasonable returns on their investments thanks to limited government price controls makes investing in the United States more attractive than investing in many other nations.[44]

In the future, the industry could also benefit from a strong world demand for pharmaceuticals, which is likely to rise significantly over the next decade. The factors behind this rise include rapidly aging populations and associated chronic diseases in developed countries and China, rising world incomes, greater government spending on health care, and demand for more effective treatments.[45]

The International Trade Administration (ITA) made similar findings for the medical device industry, noting that the industry had been designated a National Export Initiative priority.[46] The report echoed the predictions of strong growth due to aging populations and rising incomes, and noted that U.S. companies are highly regarded globally for their innovations and high-tech products, attributing much of this to the industry's heavy reliance on research and development. Although the industry does not run a large trade surplus, the ITA found that the majority of imports are for low-tech products.[47]

New Drug Development

The United States has also done well in developing new drugs. Table 3 shows the number of new chemical or biological entities developed by region since 1997. Note that this growth is part of an even longer-term trend. Between 1975 and 1979, Europe led the United States, with 149 drugs to 66.[48] The United States reversed this lead in each of the five-year periods since then, with a significant decline in the share from Japan and a rise from other nations, such as India and China.

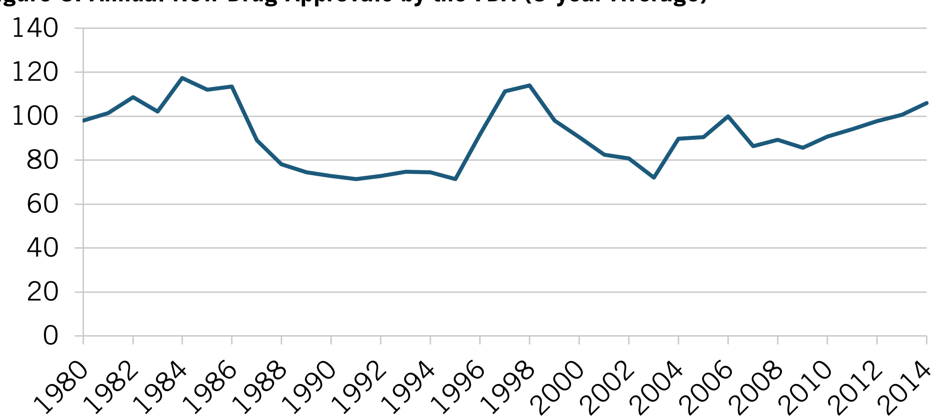
U.S. companies invest far more on research than their competitors in other countries. Moreover, this spending is increasing.

Table 3: Number of New Chemical or Biological Entities[49]

	1997-2001	2002-2006	2007-2011	2012-2016
Europe	79	46	52	75
U.S.	84	67	65	88
Japan	29	21	20	32
Other	4	14	12	38

Over the last 15 years, the three-year average of New Drug Approvals (NDAs) issued per year has risen steadily from a low of 72 in 2003 to as many as 106 in 2014 (see figure 8).[50] Although the amount of business spending on R&D per NDA has been fairly steady over the last decade, it is significantly higher than it was in the 1980s.[51] In 1980, the system was able to produce 17.3 NDAs per billion inflation-adjusted dollars of business expenditure on R&D. By 1990 this had fallen in real terms to 4.8 NDAs, and for the last decade it has averaged just fewer than two NDAs. As the industry focus has shifted to harder-to-cure diseases (e.g., cancer, Alzheimer's, etc.) and as clinical trials have become more expensive, companies are investing more money for each new approved drug.

Figure 8: Annual New Drug Approvals by the FDA (3-year Average)[52]



Dominance of U.S.-Based Companies

The United States dominates the list of the world's top life-sciences companies. Tables 4 and 5 list the top 25 companies in both the pharmaceutical and medical-equipment subsectors. In 2017, 11 of the top 25 pharmaceutical companies were headquartered in the United States, accounting for 48 percent of total sales from this group. In medical devices, 13 of the top 25 companies, accounting for 52 percent of revenues, were headquartered in the United States. These numbers would be even higher were it not for recent inversions by U.S. companies that relocated abroad, such as Medtronic and Mylan, which moved their headquarters in an attempt to lessen their tax burden.

Table 4: World's Top Pharmaceutical Companies, 2017[53]

Company	Headquarters	2016 Sales ($Billion)
Pfizer	United States	$45.9
Novartis	Switzerland	$41.6
Roche	Switzerland	$39.6
Merck & Co.	United States	$35.6
Sanofi	France	$34.2
Johnson & Johnson	United States	$31.7
Gilead Sciences	United States	$30.0
GlaxoSmithKline	United Kingdom	$27.8
AbbVie	United States	$25.3
Amgen	United States	$21.9
AstraZeneca	England	$21.0
Allergan	United States	$18.6
Teva Pharmaceutical	Israel	$18.5
Bristol-Myers Squibb	United States	$18.2
Eli Lilly	United States	$17.2
Bayer	Germany	$16.9
Novo Nordisk	Denmark	$16.6
Boehringer Ingelheim	Germany	$13.3
Takeda	Japan	$12.8
Celgene	United States	$11.1
Astellas Pharma	Japan	$11.1
Shire	Ireland	$10.9
Mylan*	United States	$10.8
Biogen	United States	$9.8
Daiichi Sankyo	Japan	$7.5

Table 5: World's Top Medical Device Companies, 2017[54]

Company	Headquarters	2016 Sales ($Billion)
Medtronic	Ireland	$28.8
Johnson & Johnson	United States	$25.1
Philips	Netherlands	$18.3
General Electric	United States	$18.3
Fresenius Medical Care	Germany	$17.9
Siemens	Germany	$14.2
Danaher	United States	$13.2
Becton Dickinson	United States	$12.5
Cardinal Health	United States	$12.4
Stryker	United States	$11.3
Roche	Switzerland	$11.3
Baxter	United States	$10.2
Boston Scientific	United States	$8.4
Abbot Laboratories	United States	$7.7
Zimmer Biomet	United States	$7.7
Essilor	France	$7.5
B. Braun	Germany	$6.8
Novartis	Switzerland	$5.8
3M	United States	$5.5
Olympus	Japan	$5.2
Carl Zeiss	Germany	$5.1
Smith & Nephew	England	$4.7
Terumo	Japan	$4.5
Dentsply Sirona	United States	$3.8
C.R. Bard	United States	$3.7

Share of World R&D

United States spending on R&D continues to surpass that of the rest of the world, although some countries, notably China, have succeeded in dramatically increasing their R&D expenditures.

Table 6: Business Enterprise R&D Spending by Industry 2015[55]

Country	Pharmaceuticals (Millions, in 2010 Dollars)	% Increase Since 2008	Medical Devices	% Increase Since 2008
Belgium	$2,211	57.5%	$18	131.4%
Canada	$326	-42.3%	$47	-8.7%
China	$11,741	253.6%	N/A	N/A
Denmark	$1,052	18.0%	$23	-47.1%
France	$917	-26.5%	$251	28.7%
Germany	$4,712	8.2%	$660	62.4%
Italy	$631	-0.8%	$74	47.7%
Japan	$13,027	15.3%	$1,040	10.9%
South Korea	$1,511	87.4%	$257	87.6%
United Kingdom	$532	1.6%	$101	155.8%
United States	$52,655	7.3%	$9,588	77.4%

High levels of R&D are important because they create the knowledge base that supports more refined research and leads to specific therapies.

Table 6 shows business investment in R&D in the United States and other countries. It is clear that U.S. companies invest far more in research than their foreign competitors. Moreover, this spending is increasing, although in many countries it has been growing at a faster rate than in the United States. Also noticeable is the rapid rise of China as a source of research in pharmaceuticals.

Table 7 shows government investment in health R&D. Once again, the United States invests far more than any other country. However, since 2000, U.S. spending has risen by far less than in many other countries. Unfortunately, the Organization for Economic Cooperation and Development (OECD) does not provide data for China.

Table 7: Government Investment in Health R&D, 2016[56]

Country	Pharmaceuticals (Millions, in 2010 Dollars)	% Increase Since 2000
Australia	$834	212%
China	N/A	N/A
Denmark	$405	272%
France	$1,087	5%
Germany	$1,616	100%
Italy	$987	19%
Japan	$1,299	30%
Mexico	$340	111%
South Korea	$1,763	367%
Norway	$498	383%
Spain	$1,194	201%
United Kingdom	$3,127	85%
United States	$32,447	40%

The ratio [of R&D spending to gross value added] for U.S. pharmaceutical companies was 43.8 percent, higher than any other nation in any other industry.

A great deal of the United States' competitive advantage is due to its emphasis on research and development. A recent report on global manufacturing noted that the United States increased its share of pharmaceutical R&D expenditures among developed countries between 1995 and 2010, going from 43 percent to 57 percent of the total.[57] It attributed this to the fact that U.S. firms have kept most of their research activity at home as European firms have shifted R&D to the United States. While there has been some movement bringing research activity to developing countries, it has mainly involved clinical trials rather than drug discovery.[58] Clinical trials represent 50 to 60 percent of the cost of developing a new drug, and companies may be able to reduce their costs per patient by 40 to 60 percent and speed recruitment as much as 20 to 30 percent by including patients from developing countries.[59]

Figure 9: Business and Government Investment in Pharmaceutical R&D (in Billions)[60]

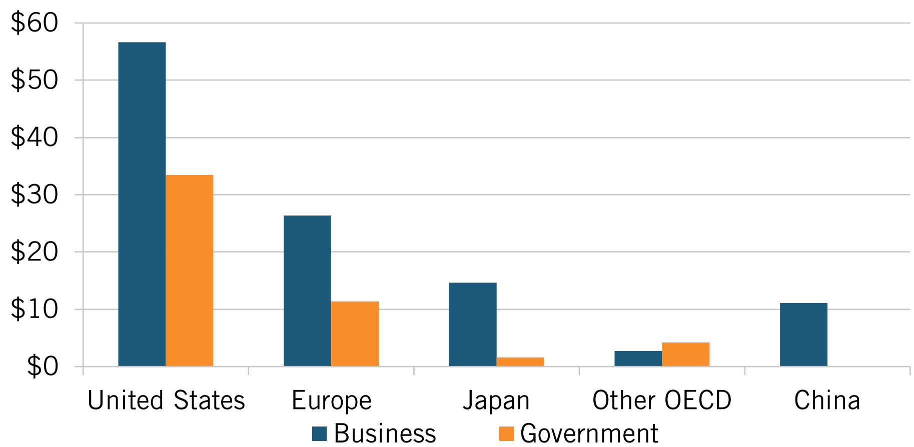


Figure 10: Business and Government Investment in Pharmaceutical R&D as a Percentage of GDP[61]

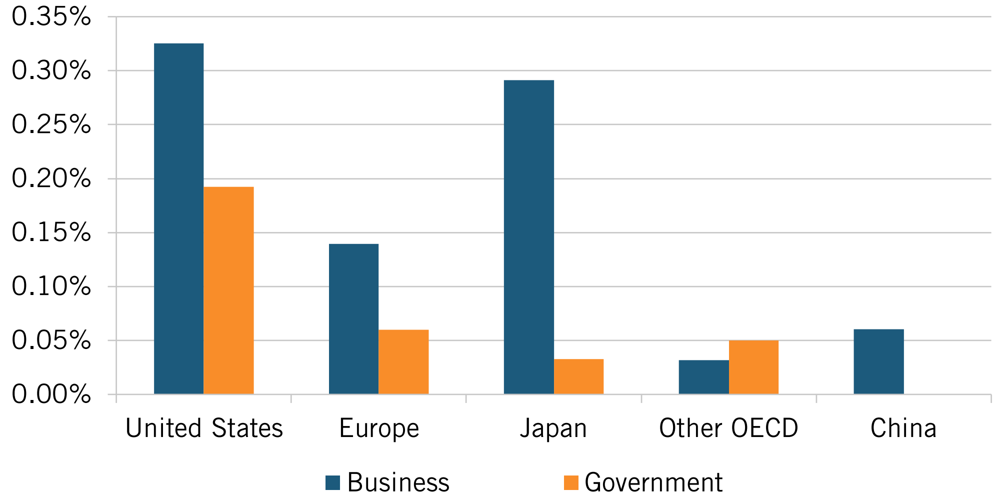
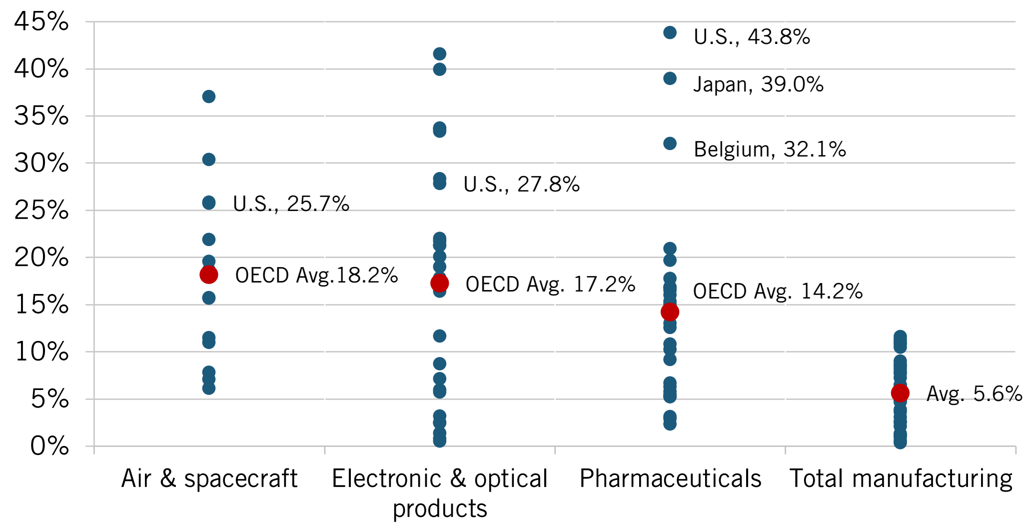


Figure 9 and figure 10 show slightly different OECD estimates for pharmaceutical investment in R&D by both industry and government (the OECD did not report government spending by China). The United States invests more than its competitors, even when measured as a percentage of GDP, with industry spending significantly outpacing that of government. U.S. firms' business expenditures on pharmaceutical R&D totaled $56.6 billion, or 0.33 percent of GDP in 2014—far ahead of Europe and Japan, which spent $26.4 billion (0.14 percent of GDP) and $14.6 billion (0.29 percent of GDP), respectively.[62] Total government spending for pharmaceutical R&D was $33.5 billion in the United States, but only $11.4 billion and $1.6 billion in Europe and Japan, respectively.

U.S. companies are also far more research-intensive than their competitors within the OECD (see figure 11). Taking all OECD countries as a group, pharmaceuticals is the third-most research–intensive industry when defined as R&D spending as a percentage of gross value added, behind air and spacecraft, and electronic and optical products.[63] In 2014, the global average ratio of business enterprise R&D to gross value added in pharmaceuticals was 14.2 percent. For air and spacecraft, it was 18.2 percent. But the ratio for U.S. pharmaceutical companies was 43.8 percent, higher than any other nation in any other industry. For pharmaceuticals, Japan and Belgium were next with 39.0 percent and 32.1 percent, respectively.

Figure 11: Business Enterprise R&D Expenditure as a Proportion of Gross Value Added[64]



When U.S. patents are measured as a global percentage, we see that each sector has basically held its own at 40 to 45 percent of the world total.

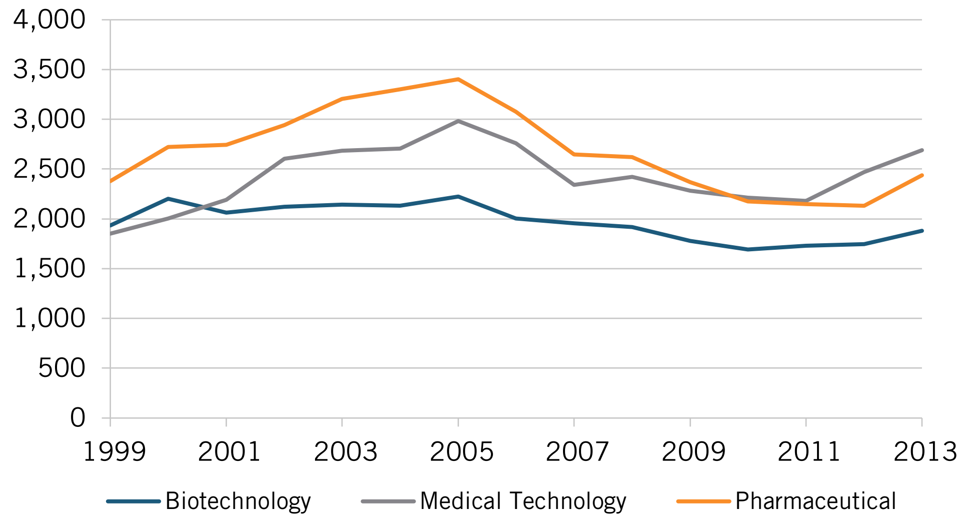
U.S. companies have increased their nominal spending on company R&D over the last two decades. A survey of members of the Pharmaceutical Research and Manufacturers of America, the industry's leading trade association, shows spending went from $15.2 billion in 1995 to an estimated $58.8 billion in 2015, for a compound annual rate of 6.7 percent.[65] However, the rate of increase since 2007 has been much slower, compounding at only 2.5 percent annually. Industry also benefits from the broader research community. The United States has 7 of the top 10 universities in the world, and 15 of the top 20.[66]

The United States is also strong in the field of biotechnology, which continues to play an increasing role in pharmaceuticals. In 2014, the OECD counted 2,653 U.S. firms that were active in biotechnology. Although Spain reportedly had 2,981 companies in 2015, no other OECD country had more than 1,000.[67] The comparison with Spain is misleading because the United States' total only includes firms specifically dedicated to R&D, and also only includes those firms that actually returned the OECD survey. U.S. biotech firms were credited with $38.6 billion worth of R&D in 2014.[68] Among OECD nations, Switzerland was second with $3.2 billion in R&D in 2015, while Spanish companies spent less than $900 million.

Share of World Patents

One indicator of the output generated by investment in life-sciences R&D is the number of innovations inventors think are worth taking the time and trouble to patent. Triadic patents are those that have been granted in the United States, the European Union, and Japan. They indicate that an innovation is both economically significant and globally relevant. The industry sectors available for the purpose of this study are biotechnology, medical technology (generally medical or veterinary science), and pharmaceuticals. The number of U.S. triadic patents granted annually in these categories fell between 2005 and 2011 but has since rebounded somewhat (see figure 12), matching a trend seen in other countries as well.

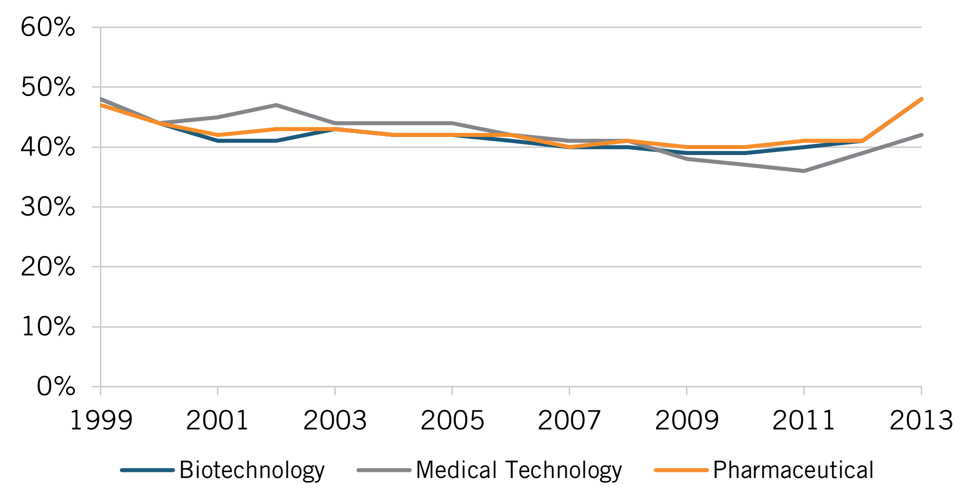
Figure 12: Number of U.S. Triadic Patents Granted[69]



A recent study of the first inventors of key patents for 3,299 drugs approved by the U.S. Food and Drug Administration over the past 25 years revealed that researchers in the United States led with 61.7 percent of those patents.

When U.S. patents are measured as a global percentage, we see that the United States has basically held its own in each sector, accounting for 40 to 45 percent of the world's total (see figure 13), with a sharp increase over the last several years. The decline in patent applications has thus been global and does not necessarily signal a decline in U.S. competitiveness. A similar picture holds when we look at patent applications to either the U.S. Patent and Trademark Office or the European Patent Office.

Figure 13: Percentage of World Triadic Patents Issued to U.S. Filers[70]



A recent study of the first inventors of key patents for 3,299 drugs approved by the U.S. Food and Drug Administration (FDA) over the past 25 years revealed that researchers in the United States led with 61.7 percent of those patents, followed by the top-five countries in the European Union (28.7 percent), and Japan (5 percent).[71] The benefit of this research was widely spread within the United States. In 2014, 21 states each had more than 500 biopharmaceutical-related patents issued to residents in their states; 13 states had more than 1,000 issued to their residents.[72]

Explaining the Poor Trade Performance

Despite the United States' strong position as a developer of new research and products, it has not been able to translate this advantage into a strong trade surplus. Trade in medical products has been roughly balanced since 2002. More worryingly, the United States has consistently run a significant trade deficit in pharmaceuticals and medicines—one that has grown rapidly since 2013 (see figure 14).

In 2017, the trade deficit in pharmaceuticals and medicines equaled $56.2 billion, or 101 percent of exports, increasing by 156 percent over the previous 15-year period even though, until recently, exports had grown at a faster rate than imports (191 percent versus 172 percent).[73] But the recovery in imports since the recession has been much stronger than in exports.

Figure 14: Exports and Imports of Pharmaceuticals and Medicines ($, in Billions)[74]

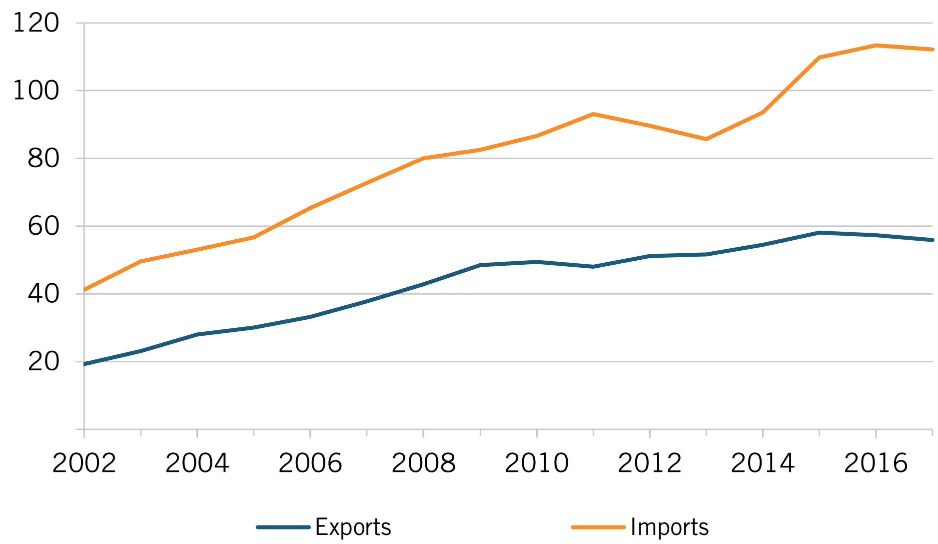
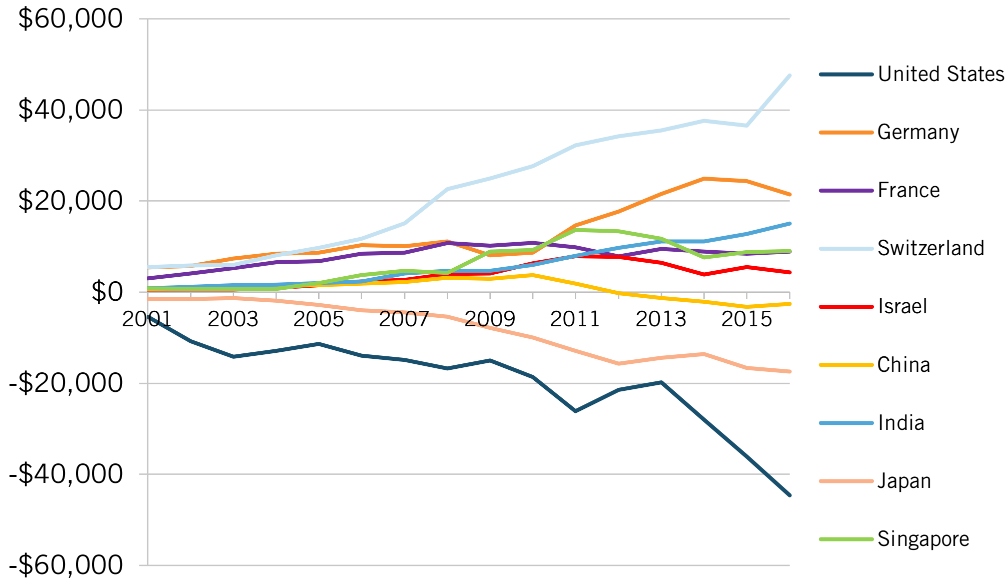


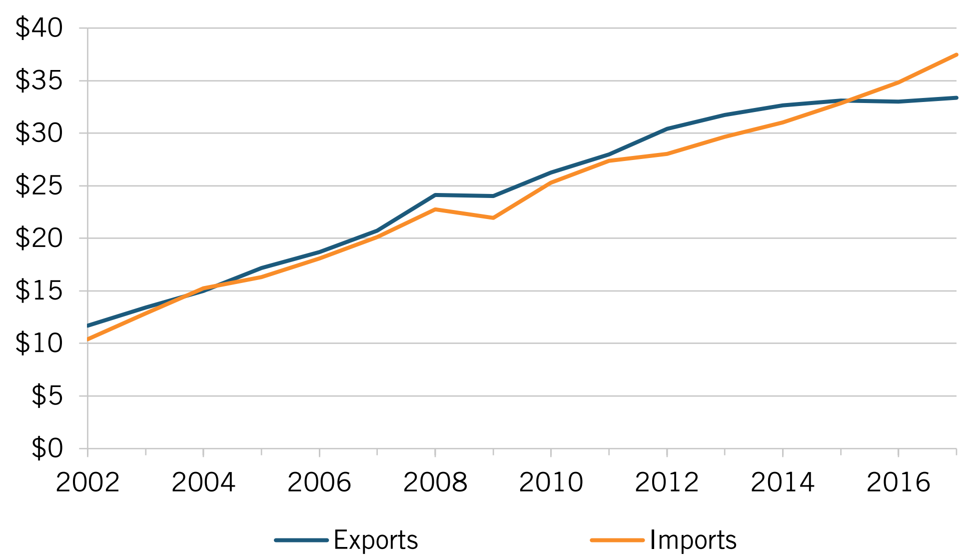
Figure 15 shows the trade balance in pharmaceutical products for several countries. It reveals that the United States and Japan have been running growing trade deficits since 2001, the beneficiaries of which were Switzerland and, to a lesser extent, Germany and India. China has run a rough trade balance over this time period, running small deficits in the last few years.

Figure 15: Trade Balance in Pharmaceutical Products, 2001-2016 (in Millions)[75]



In contrast, trade in medical equipment and supplies has been much more balanced (see figure 16). Imports and exports have basically risen in tandem since 2002. The United States ran a deficit of $4.1 billion in 2017, or 12 percent of exports, which was slightly above the 2016 deficit—prior to which the United States experienced 11 years of minor surpluses. Between 2002 and 2017, imports grew at a slightly faster rate than exports: 260 percent versus 185 percent. This difference was largely caused by exports having been relatively flat for the last three or four years.

Figure 16: Trade Balance in Medical Equipment and Supplies (in Billions)[76]



In 1999 the U.S. International Trade Commission had already noted a decline in the pharmaceutical trade balance, particularly with Western Europe. It attributed this to several factors, including intercompany shipments that crossed national borders, the greater capacity of European companies to perform production for other companies, favorable high-tech business policies, and health care policies that had reduced demand and prices in certain European countries.[77]

If the United States truly has retained its position as a leader in the production of the most advanced life sciences, as shown by its top position in each of the criteria for having a healthy industry, why is its trade balance negative? One would expect significant trade surpluses, but instead we have a rough balance in medical equipment and a growing deficit in pharmaceuticals. Table 8 shows actual trade balances in pharmaceutical products from the United Nations. A negative number means the United States is running a trade deficit with that country. The countries listed almost fully explain the deteriorating trade balance.

One would expect significant trade surpluses, but instead we have a rough balance in medical equipment and a growing deficit in pharmaceuticals.

Table 8: Trade Balance in Pharmaceuticals with the United States (in Billions) (Negative number means the United States runs a trade deficit with that country)[78]

Country	1991	1996	2001	2006	2011	2016
Canada	$0.4	$0.6	$0.9	-$0.2	$1.0	-$1.2
China	$0.0	$0	$0	-$0.1	$0.1	$0.6
France	$0	$0	-$0.8	-$2.7	-$2.3	-$2.0
Germany	$0.1	$0.1	-$1.6	-$4.8	-$6.0	-$10.6
India	$0	$0	-$0.1	-$0.4	-$3.2	-$7.2
Ireland	-$0.1	-$0.3	-$1.7	-$5.5	-$13.6	-$13.7
Israel	$0	-$0.1	-$0.5	-$2.4	-$5.5	-$4.8
Japan	$0.4	$0.3	-$0.5	$0.1	$1.3	$1.7
Netherlands	$0.1	$0.1	$0.4	$3.8	$2.4	$2.9
Singapore	$0	$0	$0	-$2.4	-$1.1	-$1.2
South Korea	$0	$0.1	$0.1	$0.2	$0.6	-$1.8
Switzerland	-$0.2	-$0.4	-$0.6	-$0.4	-$4.3	-$8.2
U.K.	-$0.3	-$0.6	-$0.2	-$1.3	$0.6	-$1.7
Rest of World	$0.7	$0.9	$1.1	-$1.2	$2.3	$1.7
United States	$1.1	$0.7	-$3.5	-$17.3	-$27.8	-$45.6

It's worth noting that there has been a significant decline in the U.S. balance of payments since 2001 and that China and Singapore were absent as major sources for the rising deficit. The balance with China has changed very little. Singapore, which has taken several steps to boost its pharmaceutical industry and hosts the Asian headquarters for a number of pharmaceutical companies, has also had a minimal effect on trade with the United States. The same is true of other countries, such as Canada, the United Kingdom and Japan, which might be thought of as competitors. Another significant factor is the concentration of countries that account for the change. Of the $45.6 billion deficit in 2016, four countries (Ireland, Germany, Switzerland, and India) accounted for $39.7 billion, or 87 percent of the deficit. A similar, though less extreme, story applies to medical devices, where Ireland has again developed a large trade surplus with the United States over the last two decades. There are a number of possible explanations for this, including discrimination against major imports from the United States. Although the trade deficit with Germany and Switzerland is reduced by significant exports to those countries, Israel and India import very little from the United States.

Figure 17 shows the distribution of value added in the pharmaceutical industry among nations between 2001 and 2016. Although value added in the United States has increased by almost 110 percent during that time period, America's share of the world total fell from 32.7 to 23.8 percent. However, 93 percent of this decline occurred before 2010. China grew the fastest during this period. Its share of value added rose from 7.2 percent to 22.1 percent. But only 31 percent of this increase occurred prior to 2010 (see figure 18).

Although "value added" in the United States increased by almost 110 percent between 2001 and 2016, America's share of the world total fell from 32.7 to 23.8 percent—although 93 percent of this decline occurred before 2010.

Figure 17: Global Value Added of Pharmaceutical Industry (in Millions) [79]

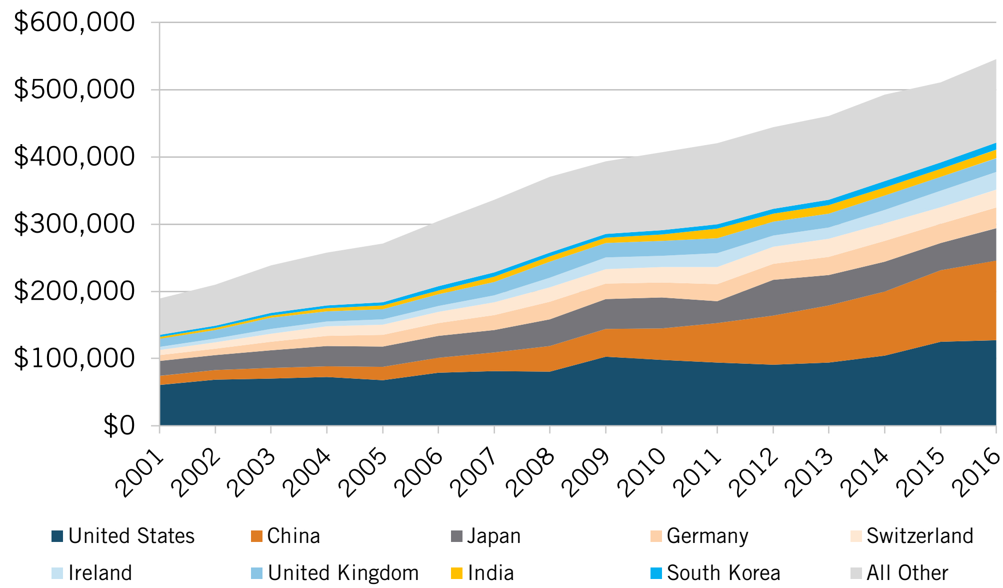
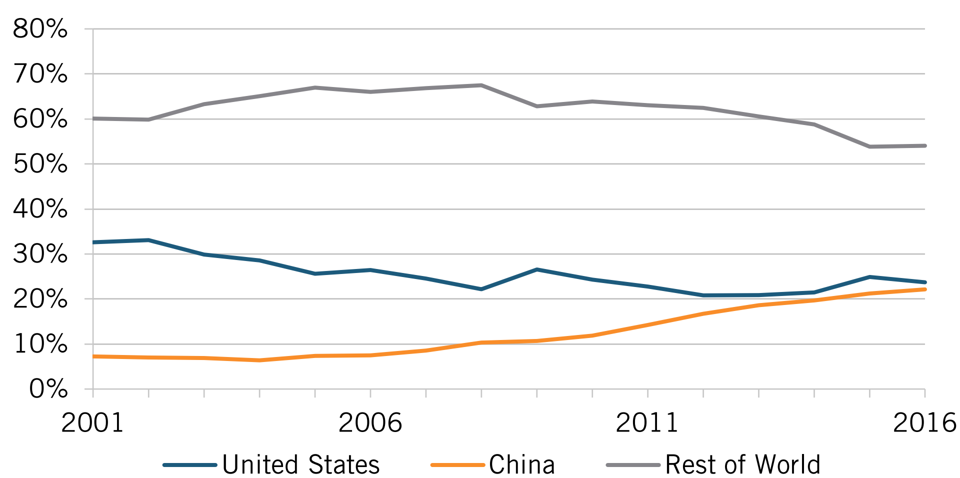


Figure 18: Shares of Value Added of Pharmaceutical Industry[80]



Tax Issues

The poorly measured trade performance may have been partially driven by tax considerations. Congress passed substantial and long overdue tax reform at the end of 2017. Prior to that, the United States suffered from one of the most complex and uncompetitive tax codes in the developed world. The problem was especially serious on the corporate side, where several provisions harmed U.S. companies competing in global markets. The first of these was a combined federal and state corporate tax of over 39 percent, the highest in the OECD.

Companies have responded in a number of ways, such as moving research and production overseas. Although foreign profits were subject to U.S. corporate tax, that tax was not due until the profits were repatriated back to the United States. Many companies delayed doing this and kept a large portion of their profits overseas. Finally, if the value of research and design is not fully reflected in the cost of the manufactured product as it crosses national borders, the United States' share of value added is likely to be underestimated, perhaps explaining some of the decline in pharmaceutical value added discussed earlier.[81]

Import prices have risen substantially above those for exports since about 2009–2011. The divergent prices help explain roughly 40 percent of the pharmaceutical trade deficit in 2016.

A number of companies have engaged in inversions, merging with a foreign company and moving the combined headquarters overseas. In 2014 and 2015, these deals were especially popular with life-sciences companies.[82] Although the Obama administration came up with rules to make inversions more difficult, the Trump administration may end up reversing them.[83] Even without inversions, companies may legally use existing transfer price agreements to shift some of their profits overseas, again escaping the immediate consequences of the United States' high corporate rate.

Were a company trying to use internal pricing agreements to shift as much profit as possible out of the United States, it would tend to underestimate the value of any research, management, or production done in the United States and inflate the value of work done in low-tax jurisdictions. This in turn would affect the trade statistics associated with those flows, reducing exports and increasing imports.

Recent tax changes will hopefully strengthen the United States' trade position. However, it is likely the combination of inversions and profit shifting worsened the trade balance in the life sciences, for which there is some evidence.[84] Ireland, with its very low statutory rate (12.5 percent), innovation box, and free trade agreements with the European Union, accounts for 30 percent of the rising trade deficit of the United States. Despite Ireland having been the destination point for a number of corporate inversions, observers have been warning of this threat since at least 2003.[85]

A similar story might explain at least some of the trade balance with Germany and Switzerland. Switzerland is home to two of the three largest pharmaceutical companies in the world (Novartis and Roche), while Germany boasts the 16th and 18th largest (Bayer and Boehringer Ingelheim). Were these companies using transfer pricing rules to realize as much income as possible at home rather than in the United States, the trade numbers would be skewed. The United Kingdom and France also have companies among the top 10 largest, yet neither has shown a large increase in their trade surplus with the United States.

Price Issues

If the value of research and design is not fully reflected in the cost of the manufactured product as it crosses national borders, the United States' share of value added is likely to be underestimated.[86] This may occur because of conscious profit shifting or because of price controls in foreign markets.

Another force behind the trade numbers may be nations imposing significant cost controls on pharmaceuticals, artificially reducing the value—but not the quantity—of exports, making the trade deficit look worse than it actually is. The Bureau of Economic Analysis generally bases its values of traded goods on the value declared by the shipper. If a foreign country imposes price controls on drugs this is likely to lead U.S. exporters to value the declared drugs at the lower, policy-constrained price. In contrast, a foreign manufacturer shipping a similar drug in the same quantities to the United States will be recorded at the higher U.S. price, resulting in an import/export imbalance.

A recent ITA report listed several foreign policies that impede U.S. pharmaceutical exports. These include opaque regulatory review procedures, a lack of IP protection, a prevalence of counterfeit medicines, burdensome reimbursement and pricing policies, and high tariffs.

Figure 19: BEA Export/Import Price Indexes for Pharmaceutical and Medicine Manufacturing (December 2005 = 100)[87]

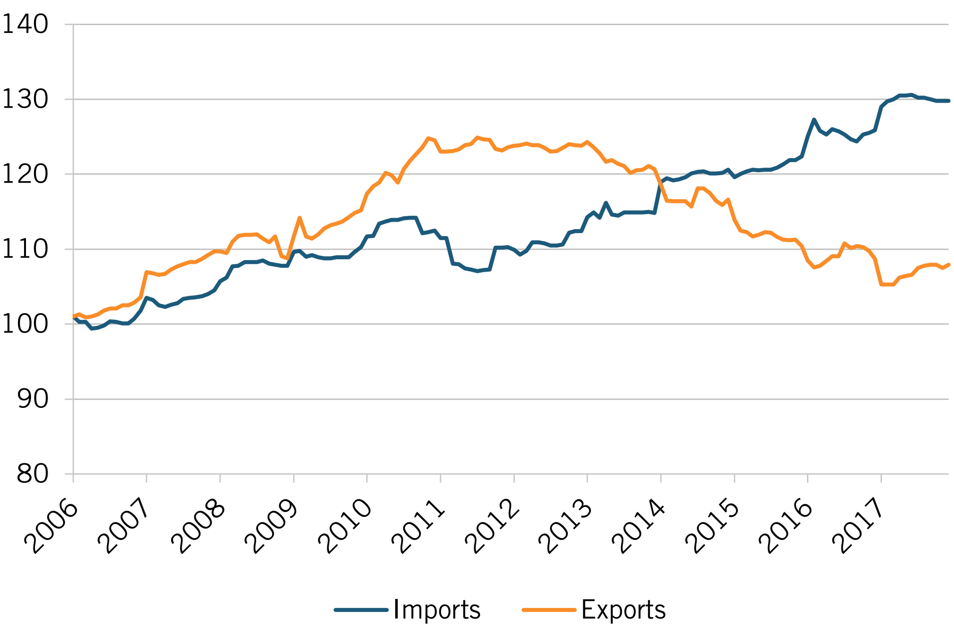
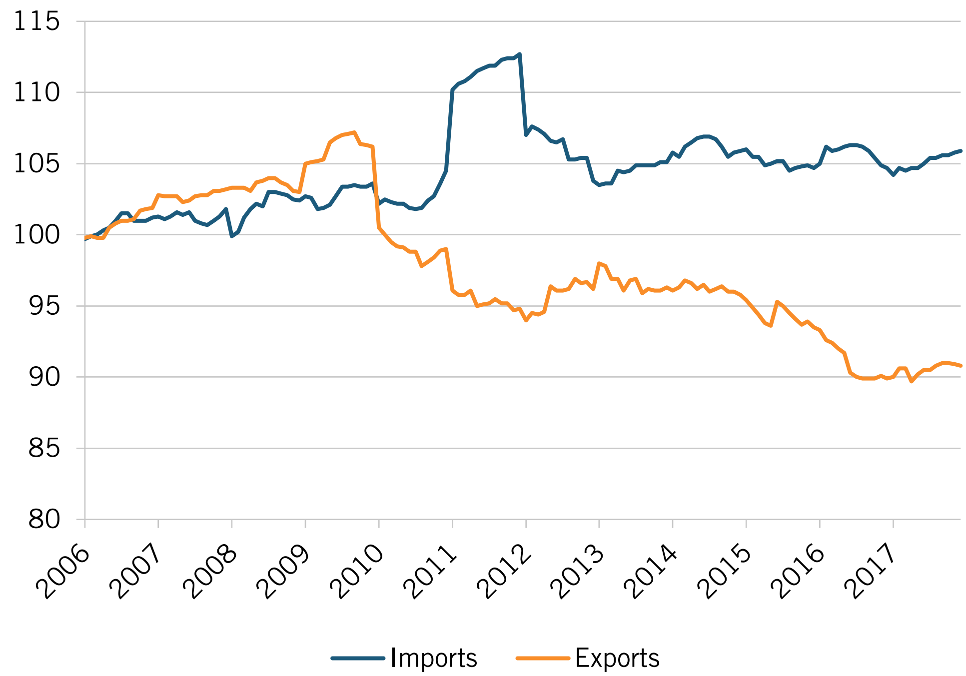


Figure 19 and figure 20 show government price indexes for both pharmaceutical and medical device manufacturing. In both cases, import prices have risen substantially above the price of exports since about 2009-2011. The divergent prices help explain roughly 40 percent of the pharmaceutical trade deficit in 2016. In other words, foreign price controls appear to inflate the actual trade deficit, making it look roughly two-thirds larger than it would be without price differences. For medical equipment, the balance switches from a 2017 deficit of $4.1 billion to a small surplus of $1.2 billion.

The U.S. government also publishes quantity data broken down into approximately 80 pharmaceutical products. From these, it is possible to see the number of kilograms exported and imported, and to calculate a value per kilogram for both. Using 2016 as an example, the data show imports of $92.0 billion and exports of $46.4 billion for a deficit of $45.6 billion. However, by weight, the United States shipped approximately 229 hundred million kilograms and imported 432 hundred million. Measured this way, the deficit improves slightly from 98 percent to 88 percent of exports. Although it appears as though the United States imports lower-value-added products than it exports, this reduction would conceivably be even greater if we controlled for value added.

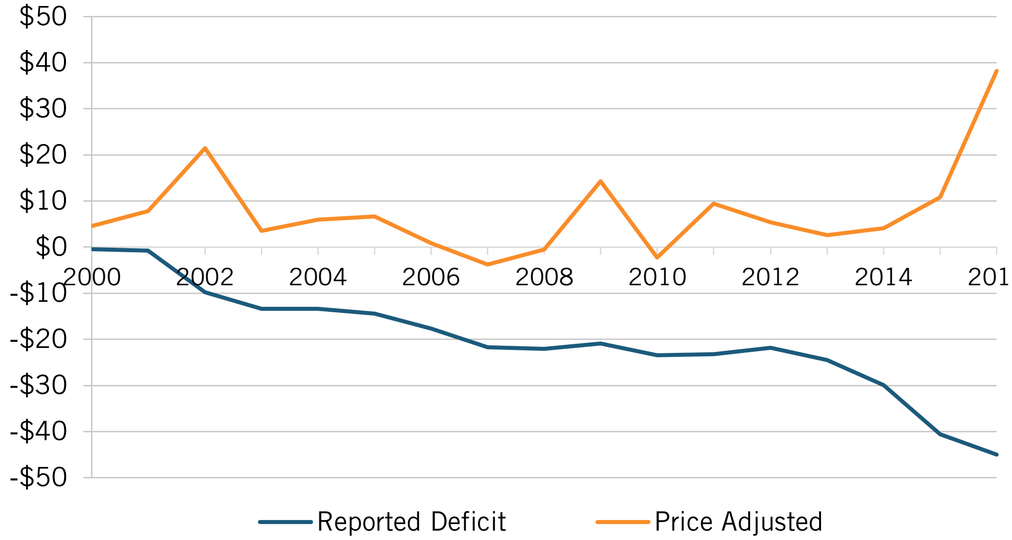
If we use the unit price of imports to value both trade flows, the trade balance is significantly altered. Every year, the trade balance is substantially improved and, in most years, turns into a significant trade surplus.

Figure 20: BEA Export/Import Price Indexes for Medical Equipment and Supplies Manufacturing (December 2005 = 100)[88]



For approximately 61 products, the United States had both exports and imports, making it possible to compare the unit prices for imports and exports. In many cases, the two prices diverged significantly, sometimes by more than 100 percent. If we then use the unit price of imports to value both trade flows, the trade balance is significantly altered (see figure 21). Every year, the trade balance is substantially improved and, in most years, turns into a significant trade surplus. It is thus clear that pricing differences play a big role in the trade flows.

Figure 21: Pharmaceutical Trade Balance, as Reported and Valuing All Shipments at Import Prices per Quantity ($ Billions)[89]



The United States faces strong competition, not only in the global market share of U.S.-based companies, but also in determining where to conduct research and manufacturing.

Several lessons seem apparent. First, the current high trade deficit in pharmaceuticals is at least partially due to mismeasurement of the value of exports and imports. Two factors seem to influence at least part of the divergence between import and export prices. The first is the repression of U.S. companies' ability to charge fair prices due to government price controls and monopsony power. Good examples of this are the recent practices of Canada's Pharmaceutical Medicines Pricing Review Board (PMPRB), which in June 2017 amended the basket of reference countries such that prices of patented medicines would be set at the OECD median, introduced various new factors to determine whether a price is "excessive," and required manufacturers to report all indirect price reductions.[90] In fact, the PMPRPB removed the United States and Switzerland as comparator countries in its reference pricing method.[91] Further, in June 2017, Health Canada released a consultation document proposing to expand the mandate of the PMPRB from ensuring "non-excessive" prices to ensuring "affordable" prices for pharmaceuticals. Korea, Japan, and Turkey are among the other nations that have used similar tactics to attempt to underprice U.S. exports of pharmaceuticals sold in their nations.

In short, U.S. exporters are unable to get a market price for pharmaceuticals sold abroad. The second lesson is that more accurate measures of trade flows would give policymakers better insight into the true nature of the industry. Outside influences, such as profit shifting, also likely play a larger role in this industry than in others. However, after the recent tax reform bill, such shifting will hopefully be considerably reduced.

Regardless of how competitive the U.S. industry currently is, there are sensible reforms that can make the country even more competitive, some of which are discussed below. Their importance is increased by other nations actively trying to attract more life-sciences value added to their shores. The suppression of U.S. exports in foreign markets constitutes a form of mercantilism that hurts both U.S. exporters and consumers. Exporters are forced to sell their products at less than full value, meaning that the United States can afford fewer imports (of all kinds of goods and services).

COMPETITIVE CHALLENGES TO THE LIFE-SCIENCES SECTOR

It should come as no surprise that the United States faces strong competition, not only in the global market share of U.S.-based companies, but also in determining where to conduct research and manufacturing. Because the life sciences are a high-value, globally traded sector, companies therein have a great deal of discretion about where they operate. As a result, jurisdictions compete in order to attract the high-skill, high-paying jobs that they create. Although many of the studies cited below focus on the pharmaceutical subsector, similar conclusions apply to the medical equipment subsector.

This section looks at the criteria needed for competitive success in the life sciences. It then reviews some of the actions other countries are taking in order to attract a greater share of this activity. Finally, it assesses how successful the United States has been in responding to this competitive threat. While the United States' lead in the life-sciences sector appears to be relatively intact, there is little room for complacency. To maintain and improve its current strength, the United States federal government should enact a number of policy reforms that would improve its competitive position.

The Importance of the Life-Sciences Ecosystem

The life sciences share the four characteristics of a classic innovation sector:[92]

1. Companies need to generate continuous innovation in order to survive.
2. Marginal costs are lower than average costs so policies that base prices on marginal cost guarantee firms will lose money.
3. Intellectual property is a large part of a company's net worth.
4. Product development depends on the unfettered movement of knowledge, information, and data across borders.

Innovation industries require the largest possible markets (to lower marginal costs as much as possible), limited nonmarket competition (to allow for the profits needed to invest in future research), and strong IP protection (to reward long-term investment).[93]

More than perhaps any other industry, the life-sciences sector requires a unique ecosystem, the presence of which provides a strong competitive advantage to the United States, in order to thrive. However, once lost, these components can be difficult to recreate. A recent report lists several traits of life sciences that demand a special environment of complementary resources:[94]

- The need for a close interface between scientific research, clinical care, and new-product development in order to maintain a steady flow of discovery from basic science, through applied research on specific drugs, and ending in testing and regulatory approval;
- Requirements for cutting-edge, specialized laboratory facilities and research capacities;

- Long development times and scientific and regulatory uncertainty that require the long-term investment of large financial resources with no guarantee of success;
- The need to raise capital for new and small companies that conduct promising research; and
- Dependence on a highly skilled workforce of scientists, technicians, and engineers with specialized knowledge in both research and manufacturing.

To grow the industry, governments need to help create a robust ecosystem capable of supporting complex supply chains delivering research, start-up capital, technology transfer, manufacturing skills, and regulatory approval.

Although the United States has weathered the challenge since 1999, its continued strength is mainly a result of its strong institutional base rather than of any recent policy actions aimed at strengthening it.

The components of this ecosystem are roughly validated by an annual survey of the biopharmaceutical industry, which evaluates each country's competitiveness in five fields:[95]

1. Scientific capabilities and infrastructure;
2. Clinical research conditions and framework;
3. The regulatory system;
4. Market access and financing; and
5. Effective intellectual property protections.

The absence of any one of these leaves the life-sciences sector weakened. The strength of the U.S. industry is reflected in its current high scores in each of these areas. The U.S. system relies on development and marketing by the private sector, accompanied by basic research and intellectual property protection by the government.[96] State and local governments can be especially helpful in providing dedicated support services and arranging early financing.[97]

Further emphasizing these points, a recent report on investment in bio-innovation highlights four key stakeholders that need to interact closely in support of the industry: academic, medical, and research sectors; biotechnology and pharmaceutical companies; investors, including venture capitalists; and local, state, and federal government institutions.[98] Each is critically important to the life-sciences sector.

Other Countries Are Moving to Capture More Value in the Life Sciences

A 1999 review of the pharmaceutical industry's global competitiveness concluded that the United States had a competitive advantage due in large part to its strong research capabilities, the availability of funds, an environment conducive to science entrepreneurs, and the relatively efficient FDA review process.[99] More recently, however, federal spending on health research has declined in real terms.

The report pointed to several new factors that might affect the United States' position in the future.[100] One was the lowering of trade barriers as a result of the North American Free Trade Agreement, which presented both an opportunity to expand exports and the threat of foreign competition at home. A related development was the enhanced property rights granted by the Uruguay Round of trade negotiations. The combination of stronger protection of intellectual property rights abroad and lower tariffs increased the potential competitiveness of other nations. The report noted even then that there was an ongoing trend toward outsourcing different stages of the development and production of individual products, resulting in a supply chain of potentially multiple countries. It also noted that, because the FDA inspected overseas facilities less often, foreign pharmaceutical manufacturers had a cost advantage in performing the highly specialized processes required for the complex chemicals used in drug production.[101]

Although the United States has weathered the challenge since 1999, its continued strength is mainly a result of its strong institutional base rather than of any recent policy actions aimed at strengthening it. Continued complacency is unwise. In 2013, ITIF studied what other nations were doing in order to attract more investment in the life sciences. It concluded, "Amidst intensifying global competition, continued U.S. life-sciences leadership is not assured, and is under clear threat from several directions."[102] A more recent review of the efforts by several countries found that, "Although the United States continues to rank first in nearly all measures of innovation, the countries profiled continue to make significant efforts to try to close the gap with the United States."[103] It continued, "The trends over the past five years continue to suggest that, in all but a few areas, the United States is not keeping pace and is actually losing ground."[104]

Fair Policies

In recent decades, several countries have enacted policies to attract an increased share of the life-sciences sector to their shores. In many cases, countries have enacted positive reforms that not only increased innovation in their own country but also created positive spillover effects for global innovation.[105] These policies included supporting research and development, investing in worker education, offering tax incentives for research, such as an innovation box or the research and development tax credit, and improving the drug-approval process.

One of the most important steps has been to make a conscious decision to focus on the sector. For instance, China has designated medicines and medical devices as one of 10 industry clusters targeted for rapid growth during the current five-year plan.[106] The results have been impressive. For example, China more than doubled its biopharmaceutical production capacity from 2010 to 2014, even surpassing the United States.[107] Both China and South Korea have also doubled their numbers of patent applications.[108]

Ireland made a similar designation for biopharmaceuticals, established a centralized office to facilitate the transfer of advanced technology from universities to firms, and set up a new Pharmaceutical Manufacturing Technology Center.[109] In 2011, the United Kingdom developed a national life-sciences strategy, undertook efforts to increase the number and quality of STEM teachers, and enhanced its research and development incentives with a patent box.[110]

The study cited a previous one showing that, "In head-to-head comparisons of the United States to seven other countries as a potential site for investments in expanded and new manufacturing, the United States trails behind other nations in its overall competitiveness, as these nations offer an increasingly higher-value operating environment."[111] As time goes on this divergence in operating environments will likely reduce U.S. competitiveness.

Unfair Policies

But the competition has not always been fair. Other countries have relied on negative policies that seek to build market share but that weaken the incentives for global innovation.[112] Many countries are primarily concerned with appropriating the benefits of foreign innovation for themselves. Because these policies reduce the benefits of performing original innovation, they lower global welfare.[113]

In order to capture its share of this emerging demand, the United States needs to be more aggressive about ensuring a level playing field by negotiating with other countries to remove many of their destructive policies.

Common unfair policies include enacting export subsidies and import barriers, forcing companies to produce domestically or share sensitive technology as a condition of market access, and failing to protect intellectual property. Restrictive price controls are also harmful. By denying producers the full benefit of their innovations, there is less incentive to develop new and better products. This in turn deprives buyers of the consumer benefit from these future products. In life-sciences markets, they artificially depress the value of U.S. exports and exacerbate the trade deficit.

A recent ITA report listed several foreign trade practices that impede U.S. pharmaceutical exports. They include opaque regulatory review procedures, a lack of IP protection, a prevalence of counterfeit medicines, burdensome reimbursements, restrictive pricing policies, and high tariffs.[114] A companion report made similar findings about the medical device industry.[115] It points to several challenges present in foreign markets, including high tariffs, regulatory approval systems that favor local producers, low reimbursement policies, and lax patent protection leading to a rise in counterfeits.[116]

The President's Council of Economic Advisors recently pointed to free-riding by other nations as a problem that needs to be addressed. It estimates that variable profit margins of patented pharmaceuticals sold in the United States are 4.1 times higher than in other developed countries. This implies that manufacturers of OECD-patented pharmaceuticals earn about 78 percent of their profits in the United States even though the country represents only 34 percent of the OECD's GDP. Part of this is due to the fact that patients in the United States tend to gain access to new drugs sooner than patients in other countries, but much is due to free-riding.[117]

THE NEED FOR BETTER POLICY

If the United States wants to thrive, it must improve its export performance. A recent McKinsey paper estimated that global prescription sales would increase by $249 billion between 2015 and 2020. But only $38 billion of this growth will occur in North America, with another $21 billion in other developed markets. The rest will happen in developing markets, with $117 billion taking place in the BRICS countries (Brazil, Russia, India, China, and South Africa) plus Mexico and Turkey.[118]

In order to capture its share of this emerging demand, the United States needs to be more aggressive about ensuring a level playing field by negotiating with other countries to remove many of their destructive, mercantilist policies. ITIF has put forward several policies that would aid this effort.[119] Countries that continue to use policies that strongly disadvantage foreign life-sciences companies should face a reduction in foreign-aid funding. Multilateral organizations such as the World Bank and the World Trade Organization need to collect better data about the nature and effect of mercantilist policies and reduce loans and trade preferences to countries that pursue them. Finally, the United States can increase the cost of mercantilist polices by fostering greater research cooperation among nations that eschew them.

If the United States wants to strengthen its role in the life sciences, it needs to actively promote each component of the life-sciences ecosystem, while Congress and the administration could take several more steps to help increase the performance of the nation's life-sciences sector.

Despite the United States' current lead in many categories such as research, venture capital, and product approvals, a number of observers have expressed concern about the future competitiveness of America's life-sciences industries. A 2015 study of medical research pointed out several worrying trends. For example, total spending on biomedical and health services research in the United States increased just 0.8 percent between 2004 and 2012, a sharp decline from the 6 percent annual growth experienced the previous decade, and significantly less than the rate of inflation.[120] For the National Institutes of Health, this translated into a decline of 13 percent in real terms. Although the United States remained the world's leading sponsor of medical research in 2011, its global share had slipped 13 percentage points.[121]

The ITA report expressed similar concerns:

> The innovative pharmaceutical industry is currently facing unprecedented challenges caused by slower sales growth, expiring patents, increasing competition for generics, shorter product life cycles, tighter regulations, adverse media coverage and reputational damage, and a decline in the number of new innovative drugs under development. Many experts are concerned that, despite enormous expenditure on R&D, the industry is producing far fewer new drugs or effective therapies than it did decades ago while sales and administration costs are rising.[122]

The ITA determined that the industry would likely suffer as a result:

> The industry is adjusting to a more competitive environment by shifting manufacturing and other operations overseas, revamping research pipelines, and reducing employment—particularly in sales but also in manufacturing and research—and organizing mergers and acquisitions (M&As)…
>
> Projecting forward, the increasing use of low-cost manufacturing bases for foreign-derived sales will inhibit the export potential of United States manufacturers, and patent expiries for high-value export products will place negative pressure on value.[123]

Although the most recent Biopharmaceutical Competitiveness and Investment Survey ranked the United States first in each of its five categories, it did note five areas in which improvement was needed:[124]

- The relatively high cost of conducting drug trials;
- Regulatory delays, although shorter than in other markets, are still long, such as in the area of biosimilars;
- Growing uncertainty about the introduction of price controls to curb the rising cost of health care;
- Suboptimal tax conditions, particularly the high corporate income tax; and
- Backtracking with regard to the ability to patent certain biopharmaceuticals and a "convoluted" patent-opposition system.

Another challenge is the shortage of skilled workers. In a recent survey, 59 percent of biopharmaceutical executives said finding and retaining the best talent is somewhat to very challenging, and higher than any other competitive factor.[125]

Some of these issues are being addressed. The recent 21st Century Cures Act gives the FDA more flexibility and resources to approve new drugs. Earlier, the Prescription Drug User Fee Act gave the FDA the ability to collect fees from drug manufacturers in exchange for a faster approval process. Similar reforms have been made with regard to medical devices.

The recent passage of corporate tax reform will make U.S. corporations more competitive. Most important, the federal statutory rate was lowered from 35 to 21 percent. Companies can also expense the full cost of capital equipment in the first year, although this provision expires in five years. The tax bill also moved the United States closer to a territorial system by largely exempting foreign profits from the United States' tax. Although some complain that this will give U.S. companies an incentive to move overseas, they were already doing so anyway. Meanwhile, the change allows those who stay in the United States to compete on a level playing field, and will hopefully encourage foreign companies to relocate here. Finally, the new law immediately taxed all foreign profits that have not been brought back to the United States, freeing large cash reserves and reducing another incentive to go abroad.

POLICIES TO IMPROVE U.S. LIFE-SCIENCES COMPETITIVENESS

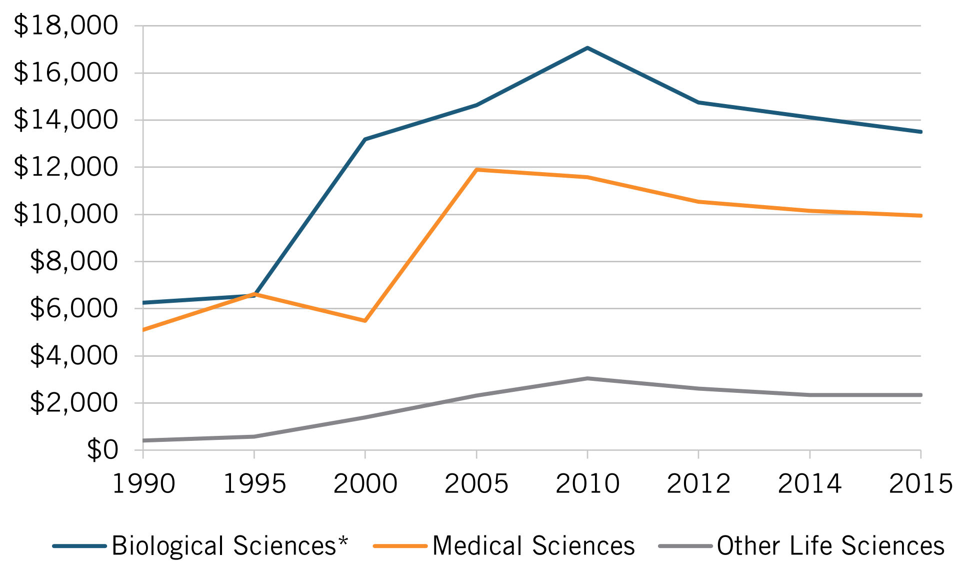
If the United States wants to strengthen its role in the life sciences, it needs to actively promote each component of the life-sciences ecosystem, while Congress and the administration could take several more steps to help increase the performance of the nation's life-sciences sector:

1. **Enact better tax policy.** Although the tax reform legislation achieved several important things, it did not enact investment incentives such as an innovation box. Unfortunately, it also cut the tax incentives for research and development and reduced the orphan drug credit rate. Congress should address this by increasing the tax credit for the Alternative Simplified Credit from 14 to 20 percent and restoring

the ability of companies to expense R&D expenditures instead of amortizing them over several years.[126] It should also enact an innovation box that taxes the profits from IP at a much lower rate when companies develop and produce the products in the United States.[127] And it should restore the orphan drug tax credit rate.

2. **Restore NIH funding to its 2003-level share of GDP.** This would require funding levels to increase by $11.6 billion per year, as federal research has not been keeping up with inflation. Figure 22 shows the decline in real federal spending on medical life-sciences research. These three fields accounted for 44.5 percent of federal research in 2015, up from 36 percent in 1990. The long-term decline in real funding has had a tangible effect on the nation's ability to develop new breakthroughs in health care.[128] High levels of government R&D are important because it creates a knowledge base that supports more refined research that leads to specific therapies. It is important for government to encourage this, both by funding basic research relevant to the life-sciences sector, and by providing tax and other inducements that reward firms for sponsoring research, especially since many of the economic benefits accrue to the general society. A review of the pharmaceutical industry in the United Kingdom concluded that every pound of additional spending on public research caused a permanent increase in private sector R&D of 20 pence.[129]

Figure 22: U.S. Federal Obligations for Research (Million, in 2009 Dollars) [130]



3. **Take more forceful action to address unfair trade practices of other nations,** including insufficient IP protection, forced technology transfer as a requirement for selling in a market, and more transparent processes for obtaining government approvals. U.S. representatives should be more forceful in negotiating cooperative arrangements that increase global innovation. At the same time, they need to

dissuade countries from pursuing mercantilist policies, whether through tariffs, IP theft, price controls, or other policies.

4. **Improve workforce training in life sciences.** Many life-sciences workers do not necessarily need a college degree in order to perform their jobs, although they do need specific skills in science, engineering, and manufacturing. These job-specific skills are rarely taught in America's colleges. In the meantime, many companies complain that they cannot find enough talented workers to fill their existing job vacancies. Congress should reward every foreign graduate with a STEM degree and green card so they may continue working in the United States. It should also take steps to increase incentives for U.S. colleges to graduate more STEM students.[131]

5. **Enacting health care reforms that restore long-term stability and provide adequate reimbursement, including for novel therapies.** Health care costs are rising faster than inflation, and large federal deficits cast doubt on the government's ability to fund Medicare and Medicaid at their current levels. At the same time, new drugs often command high prices in order to recoup the cost of developing them (and paying for drug development that did not yield a marketable product). Finally, insurance markets are facing substantial uncertainty due to the impasse over the Affordable Care Act. Capping drug prices as a means of addressing the first problem would reduce the pace of drug innovation—something that could increase health care costs in the long run–and reduce U.S. life-sciences competitiveness. Congress needs to pass bipartisan legislation—similar to the 21st Century Cures Act—that focuses less on reducing health care prices, and more on reducing health care costs. That is the only viable path to ensuring a sustainable market for public and private health care, along with adequate incentives for U.S. life-sciences innovation.[132]

6. **Continue to value the role robust IP rights play in underpinning life-sciences innovation.** For instance, the Bayh-Dole Act, which Congress enacted in 1980, created a uniform patent policy among federal agencies that fund research, enabling small businesses and non-profit organizations, including universities, to retain title to inventions made under federally funded research programs.[133] The law has played a significant role in driving impactful medical discovery and life-sciences innovation by allowing academic and other research institutions to patent inventions created by federally funded research and exclusively license them to industry for further development and commercialization.[134] As *The Economist* has written about the Bayh-Dole Act, it was "possibly the most inspired piece of legislation to be enacted in America over the past half-century…. It unlocked all the inventions and discoveries that had been made in American laboratories throughout the United States with the help of taxpayers' money."[135] Yet some have called for the U.S. government (specifically NIH) to use "march-in" rights (a privilege accorded to the government under the Bayh-Dole Act) to seize IP rights

to control prices for drugs developed under the law. But "march-in" rights have never been used in this manner, nor were they intended for this purpose. In fact, Congress intended them to only be used in instances where a licensee was not 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.[136] Moreover, weakening the certainty of access to IP rights provided under Bayh-Dole and employing march-in to address drug pricing would harm both medical discovery and the United States' robust life-sciences innovation ecosystem.[137] Accordingly, policymakers should continue to embrace Bayh-Dole and resist calls to use march-in rights to control drug pricing.

Governments play a significant role in helping to determine the environmental factors that influence high-tech sectors such as the life sciences.

CONCLUSION

America's pharmaceutical and medical equipment industries collectively play an outsized role in the U.S. economy. Although some other industries may be larger, the life sciences are especially important because of the large amount of research they conduct, the high-skilled, high-paying nature of the jobs they create, and the fact that the United States has a competitive advantage in most aspects of the sector.

But continued U.S. leadership in the life sciences cannot be taken for granted. Many countries are making concerted efforts to grow domestic firms and attract foreign ones, while the United States has merely been maintaining the status quo.

If the United States wants to remain the world's leader in life sciences, it needs to improve the health of its ecosystem by addressing the strength of each major component, including research, investment, training, and government approval. Perhaps more important, it needs to address the unfair efforts of other nations to suppress competition from the United States, such as poor IP protection, forced technology transfer, and artificial price constraints on U.S. exports.

METHODOLOGY APPENDIX

This report breaks the life-sciences sector down into two broad subsectors: biopharmaceuticals and medical equipment. The exact identification of a sector is somewhat imprecise, and different statistical agencies define industries differently, which can make a comparison of different data sources difficult. Many government agencies break down national statistics into specific industries according to the North American Industry Classification System (NAICS). A sector, such as life sciences, usually covers a number of distinct industries. Agencies tend to classify particular business establishments according to the primary work done there. Therefore, each industry or firm can include a number of different activities such as research, manufacturing, delivery, and marketing. If a plant does mostly pharmaceutical preparation manufacturing all of its employees and payroll will be counted as being in that industry, even if it also performs substantial research.

Employment, Incomes, and Establishments

Our definition of the pharmaceuticals industry is similar to the one found in a 2016 report by TEConomy, which covered a number of industries in addition to the four included in pharmaceutical and medical monitoring (NAICS 325411-14).[138] Much like this report, it includes all research and development in biotechnology (NAICS 541711). However, unlike this report, the TEConomy report only includes part of the research and development conducted in the physical, engineering, and life sciences (except biotechnology) (NAICS 541712). We include all of it.

Using detailed statistics from the U.S. Economic Census, the U.S. Bureau of Labor Statistics, and Dun & Bradstreet, a report by TEConomy concluded that NAICS 541711 and 541712 accounted for 40.2 percent of all employment under their definition of the sector.[139] Despite these industries clearly conducting research and development outside of the pharmaceutical sector, their mutual importance within the sector justifies their inclusion. This also makes sense because research plays such a key role in developing new drugs, and over time, independent research companies have been conducting more of the preliminary studies into these drugs. Although most of NAICS 541712 probably lies outside of the pharmaceutical industry, this percentage is likely to shrink over time—in addition to some shifting of activity. Although research and development companies that conduct pharmaceutical R&D appear in a different NAICS industry than the large pharmaceutical manufacturers, once this work is integrated into a large pharmaceutical firm, often through an acquisition, their activity may be shifted over to the NAICS code of their new parent.

Unlike the TEConomy study, our definition does not include drug and druggist sundries wholesale (NAICS 424210) or corporate, subsidiary, and regional offices (NAICS 551114), although both clearly include activities that are devoted to the broader pharmaceutical industry. TEConomy estimated that the former industry accounted for 21 percent of their definition of employment in pharmaceuticals. And while druggists account for a large portion of the total employment in TEConomy's definition, they deal mainly with nontraded retail services and are therefore outside of our focus on innovation in traded industries derived from research and development. Finally, pharmaceuticals are a relatively small part of the corporate office industry.

The definition of the medical equipment industry presented fewer problems and is exclusively focused on manufacturing. We chose to adopt a fairly broad definition that focused on health care equipment in general rather than medical devices per se.

The NAICS codes for each industry are listed below:

Pharmaceuticals and Medicines:

32541 Pharmaceutical and Medicine Manufacturing:

- 325411 Medicinal and Botanical Manufacturing
- 325412 Pharmaceutical Preparation Manufacturing
- 325413 In-Vitro Diagnostic Substance Manufacturing
- 325414 Biological Product (except Diagnostic) Manufacturing

54171 Research and Development in the Physical, Engineering and Life Sciences:

- 541711 Research and Development in Biotechnology
- 541712 Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)

Medical Devices and Equipment:

33451 Electromedical and Electrotherapeutic Apparatus Manufacturing:

- 334510 Electromedical and Electrotherapeutic Apparatus Manufacturing
- 334516 Analytical Laboratory Instrument Manufacturing
- 334517 Irradiation Apparatus Manufacturing

33911 Medical Equipment and Supplies Manufacturing:

- 339112 Surgical and Medical Instrument Manufacturing
- 339113 Surgical Appliance and Supplies Manufacturing
- 339114 Dental Equipment and Supplies Manufacturing

Research and Development

The National Science Foundation reports statistics using a slightly different classification. The NSF subsectors relevant for life sciences are listed below, with the NAICS industries they include provided in the footnotes:

- Pharmaceuticals and Medicines[140]
- Scientific Research and Development Services[141]
- Electromedical, Electrotherapeutic, and Irradiation Apparatus[142]
- Medical Equipment and Supplies[143]

The NSF data match up well with our definition of the pharmaceuticals sector. Pharmaceuticals and medicine covers four of our industries.[144] NSF also reports specific data for the two research industries, which we add together when presenting the data.[145] The correspondence is weaker for our definition of medical equipment. Again, the NSF data divide this into two categories. The first, medical supplies and equipment, includes two industries: ophthalmic-goods manufacturing and dental laboratories, which are not in our definition.[146] The second divergence is that NSF shows data for electromedical, electrotherapeutic, and irradiation apparatus, which includes electromedical and electrotherapeutic apparatus manufacturing and irradiation apparatus manufacturing, but not analytical laboratory instrument manufacturing.

We believe these differences will not substantially alter the results.

Patents

The OECD does not report patents by NAICS industry. Rather, its classification system includes three general categories that are relevant to life sciences: biotechnology, medical technology, and pharmaceuticals.

USPTO data does use NAICS categories, however not at the six-digit level.

Economic Output

The U.S. Bureau of Economic Analysis reports economic output by Industrial Organization (IO) codes rather than by NAICS industry, which makes it difficult to calculate exact output and value-added numbers corresponding to our definition of the industry by NAICS code. Nevertheless, we can use the description of IO codes to form separate definitions, which we expect will be close to the NAICS sectors defined previously because the numbering is almost identical. We report output numbers for our two sectors by aggregating the following IO codes:

Pharmaceuticals and Medicines:

- 325411 Medicinal and botanical manufacturing
- 325412 Pharmaceutical preparation manufacturing
- 325413 In-vitro diagnostic substance manufacturing
- 325414 Biological product (except diagnostic) manufacturing
- 541700 Scientific research and development services

Medical Equipment and Devices:

- 334510 Electromedical and electrotherapeutic apparatus manufacturing
- 334516 Analytical laboratory instrument manufacturing
- 334517 Irradiation apparatus manufacturing
- 339112 Surgical and medical instrument manufacturing
- 339113 Surgical appliance and supplies manufacturing
- 339114 Dental equipment and supplies manufacturing

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ERRATA

This report was updated on March 29, 2018 to correct the formula used in figure 4 to calculate average wages in the pharmaceutical subsector. The correction had no impact on any of the report's main conclusions.

This report was further updated on July 13, 2020 to add a new section on value added. See that discussion and figure 2 on page 8.

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