ITIF | INFORMATION TECHNOLOGY & INNOVATION FOUNDATION

Going, Going, Gone? To Stay Competitive in Biopharmaceuticals, America Must Learn From Its Semiconductor Mistakes

STEPHEN J. EZELL | NOVEMBER 2021

America has lost 70 percent of its semiconductor manufacturing capacity over the last three decades. That serves as a harsh lesson for policymakers: Failing to maintain a supportive policy environment could set up other high-tech industries to falter, too.

KEY TAKEAWAYS

- The United States has a long history of being the first to develop innovative industries, but then losing production to other nations. Process and product innovations are joined at the hip, so the result is industries become innovation laggards.
- The underlying erosion of U.S. manufacturing in industries like semiconductors, solar panels, and telecom equipment has often resulted from foreign governments "buying industry share" with subsidies, and U.S. policymakers have failed to respond.
- Some contend it's acceptable to lose leadership in innovation industries, because we'll just create new ones. But intensifying global competition, notably from China, makes such indifference untenable.
- America created the semiconductor industry, lost global leadership in the 1970s, then regained it with effective policies in the 1980s. But inattentiveness in recent decades has led once again to erosion, requiring a new, $50 billion CHIPS package.
- Similarly, America was once a global "also-ran" in biopharmaceutical innovation, but it became the leader with policies like robust R&D investments, IP protections, and drug-pricing systems that enabled innovators to earn profits to reinvest.
- Now the U.S. policy environment for biopharma innovation and production is in danger of eroding with calls to impose drug price controls, weaken IP protections, and roll back supportive tax credits. Policymakers should avoid making those mistakes.

INTRODUCTION

The United States has a long history of being the first to develop innovative industries, but then losing production to other nations with more effective policies, and eventually, because of that loss, becoming an industry laggard. We have seen this in sectors such as consumer electronics, machine tools and robotics, nuclear reactors, telecommunications equipment, solar panels, and now potentially in semiconductors and biopharmaceuticals.[1] In every case, these losses were eminently preventable had there been effective federal policy.

The damage to the United States from this dynamic had been somewhat tolerable because the United States continued to develop new industries as it shed others. But given intense global competition, especially with China growing as a global adversary, the United States can no longer afford to take a hands-off posture. Too many other nations are now focused intensely on the innovation phase in foundational and emerging technologies, effectively limiting U.S. global market share. Many are subsidizing innovation-industry production, which in turn weakens both U.S. innovation and production.

This dynamic, coupled with an increasingly "asset-lite" and short-term orientation of many U.S. advanced-industry companies, along with diminishing U.S. government support for innovation industries and increased U.S. government attacks on them (e.g., aggressive antitrust policies, tax increases, regulations, and price controls), will invariably mean the "UKization" of the United States economy—following the United Kingdom path where that economy first lost production and then innovation capabilities in most industries, and as a result the country struggles to compete globally on anything more than tourism and finance.[2]

The United States now faces two choices. Policymakers can continue to turn a blind eye to this increasingly damaging dynamic and be indifferent to U.S. industrial structure, believing "potato chips, computer chips—what's the difference?" With a fundamentally weak U.S. industrial structure, each political camp has fallen back on shortcuts, hoping to artificially prop up stagnant living standards with tax cuts (if you are a Republican) or spending increases (if you are a Democrat). Failure to address the underlying problem of diminished U.S. competitiveness in key industries will mean lower real income and gross domestic product (GDP) growth, an even larger trade deficit (or a significant decline in the value of the dollar and an increase in the cost of imports), more foreign supply chain dependency, and a deterioration of the national defense technology base.

While it is too late to restore many advanced technology industries America has already lost, it's by no means too late to retain U.S. biopharma innovation leadership and restore domestic production.

Or policymakers can realize that U.S. leadership (including in both innovation and production) is by no means assured and that the United States has no natural "right" to these industries and the jobs they support because of some inherent U.S. advantages. Recognizing this means not only putting in place policies to ensure U.S. leadership in foundational and emerging technology industries, but at minimum, avoiding "shooting ourselves in the foot" and handing key industries to other nations by enacting harmful U.S. regulatory or tax policies.

The former scenario is increasingly confronting America's biopharmaceutical industry today, where the United States still has enormous strengths, but could very well lose much of the industry in the next two decades if U.S. policy does not work to shore up America's global competitiveness.

The good news is that it is now possible for policymakers to see the likely path if they don't act; they just have to look at many U.S. advanced-technology industries in the past, like telecom equipment, where U.S. leadership has eroded or vanished. While it is too late to restore many advanced technology industries America has already lost, it's by no means too late to retain U.S. biopharmaceutical innovation leadership and restore domestic production.

The bad news is that many policymakers pay almost no attention to the competitive position of the biopharmaceutical industry, focusing instead on policies that would accelerate that decline, such as weaker intellectual property (IP) protections, reduced tax incentives, and stringent price control measures. We have seen this scenario play out before: Europe followed this playbook in the 1980s and early 1990s, putting in place strict drug price controls and regulatory barriers to innovation, and the result was ceding half-century-long leadership to the United States. Suppose the United States follows the EU's path, as many in Congress appear to want to do. In that case, these measures will increase the odds of other nations, especially China, capturing market share in this critical innovation-based industry. The result will be fewer good jobs, a larger trade deficit, less drug innovation, higher overall health costs, and more foreign supply-chain dependency.[3]

This report starts by articulating why U.S. leadership in advanced-technology industries matters and why the U.S. position in such industries isn't guaranteed. It then examines the factors that have contributed to the erosion of the U.S. semiconductor manufacturing base as a possible scenario for the future of the U.S. biopharmaceutical industry. It then explores how similar trends have emerged in the latter sector. It contends that policymakers must be committed to maintaining a supportive policy environment for America's innovation-based industries, closing with a set of recommendations for policymakers to maintain U.S. biopharmaceutical innovation and production leadership.

U.S. ADVANCED-TECHNOLOGY INDUSTRY LOSSES

The United States emerged from World War II (WWII) as the world's leading industrial economy. This was not, despite the popular view, principally due to the destruction of foreign nations' production capabilities during the war, which were largely "built back better" by the late 1950s. Rather, the United Sates had built up core technology strengths from the Civil War to WWII, and during the Cold War, with massive federal investments accelerating those capabilities.

It's easy to forget that in virtually every advanced industry, the United States dominated through the 1960s. But there are a litany of industries where the United States once held dominant market share in the post-WWII period, only to see those leads significantly erode, and in some cases evaporate entirely. Consider machine tools. In 1965, American machine tool manufacturers held 28 percent of the world market, a share that has cratered to less than 5 percent, as machine tools transformed from a U.S. export to an import industry, and one that imported more than twice as many goods ($8.6 billion) than it exported ($4.2 billion) in 2018.[4]

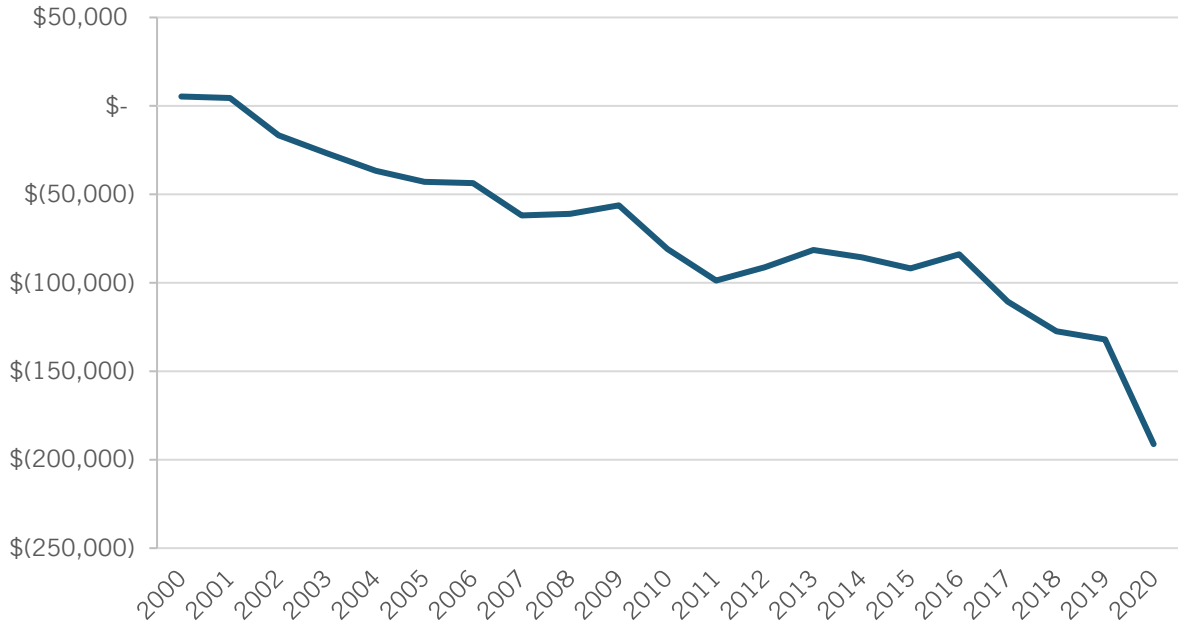
Similarly, Western Electric (which became Lucent) once commanded 59 percent of the global market for telecommunications equipment, but America had lost the industry entirely by the first decade of this century, in significant part because of a long legacy of policy failures.[5] In 1996 four of the top five global personal computer (PC) makers were headquartered in the United States.[6] Today, only three of the top six PC producers are U.S. headquartered, with the largest (China's Lenovo, formerly IBM) now headquartered in China. The United States once led in consumer electronics, but other nations, especially Japan and South Korea, now dominate, with China potentially taking that position going forward.

There are a litany of industries where the United States once held dominant market share in the post-World War II period, only to see those leads significantly erode, and in some cases evaporate entirely.

Elsewhere, the United States went from accounting for over 70 percent of commercial jet aircraft exports in 1991 to just 39 percent by 2009.[7] And the United States is losing share even in many new technologies. For instance, from 2006 to 2013, the United States' share of the global solar photovoltaics cell market fell by nearly 75 percent.[8]

Evidence of faltering U.S. advanced manufacturing competitiveness shows up clearly in the trade statistics, where the United States went from consistently holding a positive trade balance in advanced technology products (ATP) in the 1980s and 1990s until terms of trade turned negative in the 2000s, with America's annual ATP deficit now nearing $200 billion. (See figure 1.) Using a broader definition, the National Science Foundation (NSF) estimated a U.S. trade deficit in advanced technology products of over $300 billion in 2020.[9]

Figure 1: U.S. trade balance in advanced technology products, 2000–2020 ($ millions)[10]



WHY DID THE FEDERAL GOVERNMENT LET THIS HAPPEN?

To be sure, the loss of U.S. leadership in various American advanced-technology industries has many causes, including miscalculations made by businesses. But all too often the underlying causes have been foreign governments "buying industry share" with U.S. policymakers standing on the sidelines, ignoring the damage and believing that any result was simply a result of the workings of the free market.

There are a number of reasons for this somnambulism. One is economic pundits who contend that America does not need an advanced industrial base. For instance, when asked how much manufacturing the United States could really lose and still be economically healthy, the head of one Washington, D.C.–based international economics think tank replied: "Really? Really we could lose it all and be fine."[11] Likewise, former Obama economic policy head Larry Summers stated: "America's role is to feed a global economy that's increasingly based on knowledge and services rather than on making stuff." It's hard to blame policymakers for being inattentive to the state of U.S. advanced industry manufacturing with so many economists and think tanks telling them it doesn't matter.

In other cases, the dominant narrative of "we're America so we're always destined to lead" has meant that policy can focus on other matters, such as regulating drug prices. After all, in this view innovation takes care of itself. Related to this is an unwillingness to believe, or accept, that many nations are "buying" global market share with subsidies and, in China's case, pursuing innovation-mercantilist, "power trade"-based economic and trade strategies specifically designed to wrest control of advanced industries from the United States and other nations.[12] As Larry Summers purportedly said, if the Chinese are dumb enough to subsidize key industries, we should thank them for cheaper imports. This, of course, ignores that most consumers are also workers, and that the United States cannot be dependent on China for many advanced products if it wants to maintain its own autonomy.

Related to this is the widespread view that it doesn't matter if the United States loses global production and market share in advanced-technology industries—America will simply invent new ones, as it did with biotechnology or the Internet economy (where by 2015 U.S.-headquartered digital platform companies held an estimated two-thirds of global market capitalization).[13] If America loses leadership in these, the narrative goes, it'll just build new ones in areas like artificial intelligence (AI), quantum computing, nanotechnology, hypersonic technologies, etc. Some even go as far as to say that is it good that the United States sheds these advanced industries, as it's proof of some natural evolution to even more advanced technologies.

But that process of shedding somewhat mature advanced-technology industries and growing the next generation of new ones is no longer as straightforward as it once was. As recently as two decades ago, few nations outside of East Asia (i.e., Japan, Singapore, South Korea, and Taiwan) had robust advanced industry and technology strategies designed to capture market share in emerging, next wave industries and technologies. Today, all advanced countries, and many emerging ones, do. And of course, China is the most aggressive and is gaining in emerging technologies like quantum computing, AI, hypersonics, and biotechnology, backed by aggressive government support policies.[14] For example, at least two dozen nations have national AI competitiveness strategies, and while a 2019 Center for Data Innovation report found the United States remains in the lead overall across six categories of AI metrics—talent, research,

development, adoption, data, and hardware—it found China rapidly catching up with the United States.[15]

Moreover, in 2019 the Information Technology and Innovation Foundation (ITIF) examined 36 indicators of China's scientific and technological progress vis-à-vis the United States a decade ago versus today, to get a sense of where China is making the most progress, and to what extent it is closing the innovation gap with the United States. This analysis found that China has made progress on all indicators, and in some areas it now leads the United States. In fact, averaging all the indicators, China has cut the gap with the United States by a factor of 1.5 from the base year to the most recent year.[16] In other words, in the span of about a decade, China has made dramatic progress in innovation relative to the United States. In short, there's no guarantee the United States and its enterprises will lead the industries of the future.

Retaining and recapturing jobs in manufacturing and other advanced-technology industries must represent a central focus of any worker-centered U.S. trade and economic strategy.

Still others argue that if the United States for some reason needs to regain lost advanced-technology production it should be able to do so relatively easily, especially if the dollar were to significantly decline in value, making U.S. exports more price competitive. But the reality is that advanced industries are not simple ones like call centers. Once leadership in advanced-technology industries is lost, it's incredibly difficult and expensive to reconstitute and regain, if that's even possible. As one *Industry Week* article notes, "Some of the industries [the U.S. is losing competitiveness in], such as textiles, apparel, furniture, hardware, magnetic media, computers, cutlery, hand tools, and electrical equipment, have been declining for many decades and are probably beyond recovery."[17] For instance, if Boeing were ever to go out of business the United States could not rely on market forces, including a steep drop in the value of the dollar, to later re-create a domestic civil aviation industry. To do so would require not only creating a new aircraft firm from scratch but also the complex web of suppliers, professional associations, university programs in aviation engineering, and other knowledge-sharing organizations. With fewer aviation jobs, fewer students would become aeronautical engineers, making it difficult to rebuild capacity. If a country loses the intangible knowledge about how to build an airplane, it cannot reconstitute it without massive government subsidies and almost complete domestic purchase requirements.[18]

Finally, some argue that advanced industries don't employ large numbers of jobs and that other industries, especially low-paid service industries, are our future. But the U.S. challenge is not the number of jobs, but the quality. And manufacturing and other advanced-technology industries represent a source of high-skill, high-value-added, high-paying jobs. That's why U.S. manufacturing jobs paid 19.2 percent more than the average U.S. job in 2020, and why advanced-technology industries paid 75 percent more.[19] Similar research has found that the earnings premium for jobs in export-intensive U.S. manufacturing industries averages 16.3 percent.[20] Retaining and recapturing jobs in advanced-technology industries must represent a central focus of any worker-centered U.S. trade and economic strategy.

U.S. SEMICONDUCTOR DECLINE

Semiconductors, sometimes referred to as integrated circuits (ICs) or microchips, consist of transistors that amplify or switch electronic signals and electrical power and thus constitute an essential component of electronic devices, powering everything from automobiles and airplanes to medical devices and home appliances.[21] Leading-edge semiconductors contain circuits measured at the nanoscale ("nm," a unit of length equal to one millionth of a meter), with the newest fabrication facilities producing semiconductors at 5 nm and 3 nm scales.[22] The global semiconductor industry, itself valued at $551 billion in 2021, helps create $7 trillion in global economic activity and is directly responsible for $2.7 trillion in total annual global GDP.[23]

The Rise of U.S. Semiconductor Leadership

As America's experience with the semiconductor industry, just like any other advanced-technology industry, shows, leadership is never assured: indeed, the United States has created and led, lost, and regained global leadership in semiconductor innovation and production, only to see it, in some dimensions, increasingly slip away again.

The invention of the semiconductor was a uniquely American phenomenon.[24] In 1947, Bell Labs' John Bardeen, Walter Brattain, and William Shockley invented the transistor, a semiconductor device capable of amplifying or switching electronic signals and electrical power, and for which they would win a Nobel Prize in 1965. Bell Labs could support this fundamental, yet groundbreaking research because it was part of the AT&T monopoly and had the luxury and resources to focus on long-term, technical challenges.[25]

The United States created and led the semiconductor industry, then lost leadership and regained it, only to see it, in some dimensions, increasingly slip away again.

Because of his dissatisfaction at Bell Labs, Shockley moved to what is now Silicon Valley to start Shockley Semiconductors, which soon spun off talent that started other firms, including Fairchild Semiconductor. In the mid-1950s, Jack Kilby at Texas Instruments and Robert Noyce and a team of researchers at Fairchild each independently pioneered the integrated circuit, placing multiple transistors on a single flat piece of semiconductor material, giving rise to the modern visage of a "semiconductor chip."[26] In 1968, Robert Noyce and Gordon Moore—who in leaving Shockley Semiconductor had been among the founders of Fairchild Semiconductors in 1957—founded Intel, with the help of venture capital (VC) provided by Arthur Rock, a seminal moment that helped give rise both to Silicon Valley and the modern VC firm and its capitalization model.[27] But without the presence of a key buyer—in this case, the United States Air Force—the picture would have been much different. The U.S. Air Force needed high-performance semiconductors for missiles, jets, and early-detection systems like radar and was able to pay the higher prices that were involved. This core customer enabled firms like Fairchild to get enough learning and scale to keep the technology progressing until prices and performance fit the commercial market. No other nation could match that combination of risk-taking (individuals leaving good jobs to start their own companies), venture capital, and lead customer (the Defense Department).

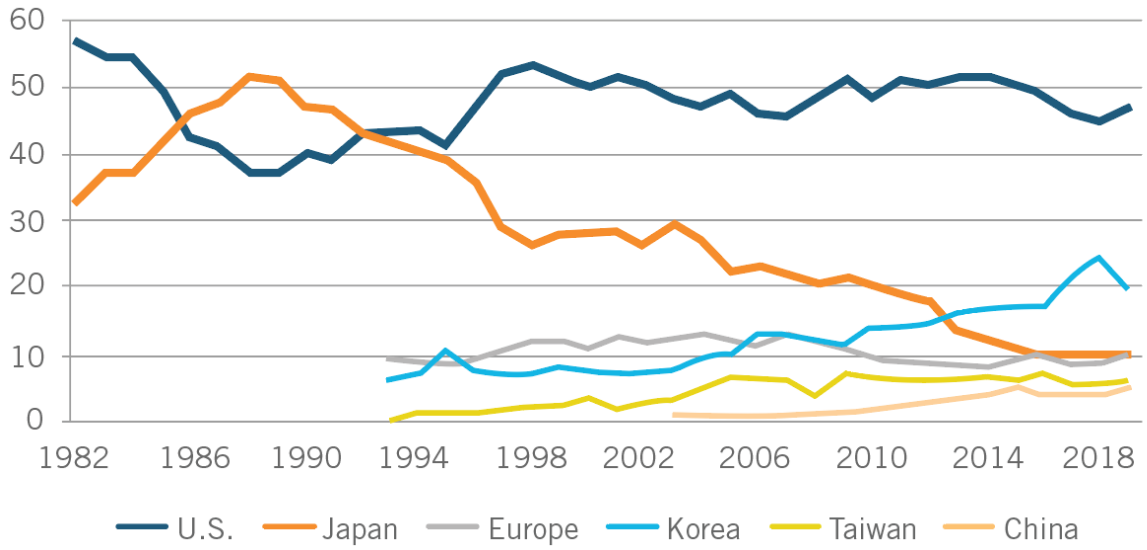
Throughout the 1960s and 1970s, U.S. semiconductor enterprises, led by Texas Instruments, Fairchild Semiconductor, National Semiconductor, and Intel, among others, "dominated worldwide production of semiconductors."[28] By 1972, the United States accounted for 60 percent of global semiconductor production (and 57 percent of consumption).[29] The industry was very much one in which innovation and scale provided important leads that would be difficult for foreign firms to match.

The Japan Challenge

However, beginning in the latter half of the 1970s and into the 1980s, U.S. semiconductor industry competitiveness began to wane, particularly in the face of withering competition from Japanese players—notably Fujitsu, NEC, Hitachi, Mitsubishi Electric, and Toshiba—and especially in the dynamic random access memory (DRAM) chip sector. By the mid-1980s, Japanese players had captured the majority of the global DRAM market. By the late-1980s, across all memory, logic, and analog chips in the global semiconductor market, Japan's global market share in terms of sales eclipsed 50 percent while the United States' fell to less than 40 percent. (See figure 2.) Japan's burgeoning competitiveness was the result both of astute technical engineering and intense government support. The latter included robust research and development (R&D) investment in the sector, subsidized borrowing, and tax incentives for investment.[30] Japan also benefited from protectionist trade policies including shielding Japanese competitors with market-access restrictions on U.S. and other foreign DRAM competitors so Japanese players could reach scale at home and then export into global markets, abetted by below-cost pricing in foreign markets, a playbook aggressively copied by China today across a range of high-tech industries.[31]

Had Japan been a traditional free-market economy with firms focused on profit maximization, it is likely that it would not have been able to make inroads into the U.S. market share. The reason is simple: catching up to U.S. producers in scale and innovation was only possible through a combination of protection from competition, government subsidies (including keeping the value of the yen lower than it otherwise would have been), and a willingness by companies to suffer losses for a long time. As Charles Kaufman writes, "The Japanese chip makers could withstand continuing losses because all were units of keiretsu trading groups with deep pockets. They shared a determination to use their excess capacity to gain prized semiconductor market share no matter what the cost. It has been estimated that the Japanese semiconductor industry lost over $4 billion through memory chip dumping during the 1980s."[32] In contrast, by the 1980s, the role of the U.S. government in the industry was minimal, the United States had no trade protection, and U.S. semiconductor companies were keenly focused on short-term profits. It was this divergence in practices that led the Japanese competitors to gain market share so quickly.

Figure 2: Global semiconductor market share, by revenues, 1982–2019[33]



However, while Japan's innovation mercantilist practices were real, so too was the reality that U.S. semiconductor manufacturing practices had faltered and Japanese players were producing more-reliable, more-defect free chips at a lower price point than their U.S. competitors.[34] By 1987, the Defense Science Board's Task Force on Semiconductor Dependency found U.S. leadership in semiconductor manufacturing to be rapidly eroding and that not only was "the manufacturing capacity of the U.S. semiconductor industry … being lost to foreign competitors, principally Japan … but of even greater long-term concern, that technological leadership is also being lost."[35]

In response, in 1987 the U.S. industry and government collaborated to establish SEMATECH, a public-private research consortium that sought to help improve U.S. industry's technological position by developing advanced manufacturing technology, with a particular focus on increasing the speed and quality of chip production systems.[36] Congress provided approximately $870 million, principally channeled through the Defense Advanced Research Projects Agency (DARPA) from FY 1986 to 1996, with those contributions matched by contributions from 14 industry participants.[37] SEMATECH focused on applied R&D and its only product was generic manufacturing technology, not the development of semiconductors themselves. Notable SEMATECH achievements included that by 1993 U.S. device makers could manufacture chips at 0.35 microns using all-American-made tools and by 1994 the United States had recaptured semiconductor device market share leadership over Japan (48 percent to 36 percent).[38] SEMATECH also set a goal of reducing generational advantages in chip miniaturization from three years to two, a goal the industry has achieved consistently since the mid-1990s.[39] According to the National Academy of Sciences, "SEMATECH was widely perceived by industry to have had a significant impact on U.S. semiconductor manufacturing performance in the 1990s."[40]

Even before SEMATECH, in 1982, the Semiconductor Research Corporation (SRC) formed as a cooperative for implementation of research activities responding to the generic needs of the integrated circuit industry.[41] As SRC CEO Ken Hansen explains, "SRC launched in 1982 with a mission to fund university research in the pre-competitive stage to leapfrog the technology

disadvantage we felt at the time and to develop a workforce pipeline of well-educated Ph.D. students working on industry-relevant topics."[42] SRC's experience has shown that university research can provide substantial contributions to the advancement of semiconductor technology as well as provide additional workforce to enhance the industry, university, and government technical infrastructure of the United States.[43] SRC continues today, now running the Joint University Microelectronics Program (JUMP), which focuses on high-performance, energy-efficient microelectronics in partnership with DARPA and also the nano-electronic Computing Research program in partnership with NSF and the National Institute of Standards and Technology (NIST).[44]

The United States has lost over 70 percent of its share of global semiconductor manufacturing capacity over the past three decades.

The government took additional steps to bolster the competitiveness of the U.S. semiconductor industry, including the 1984 Cooperative Research and Development Act, the Federal Technology Transfer Act of 1986, the Technology Transfer Improvements and Advancement Act, the Technology Transfer Commercialization Act, and the Omnibus Trade and Competitiveness Act in 1988.[45] On the trade front, in 1986 the U.S. government negotiated the U.S.-Japan Semiconductor Agreement, which called for an end to Japanese dumping and (at least partial) opening of the Japanese market to foreign producers.[46]

At the same time, U.S. firms took needed action to restore their competitiveness. Perhaps the most important was Intel's decision to specialize in logic chips to power the emerging PC revolution in the 1990s.

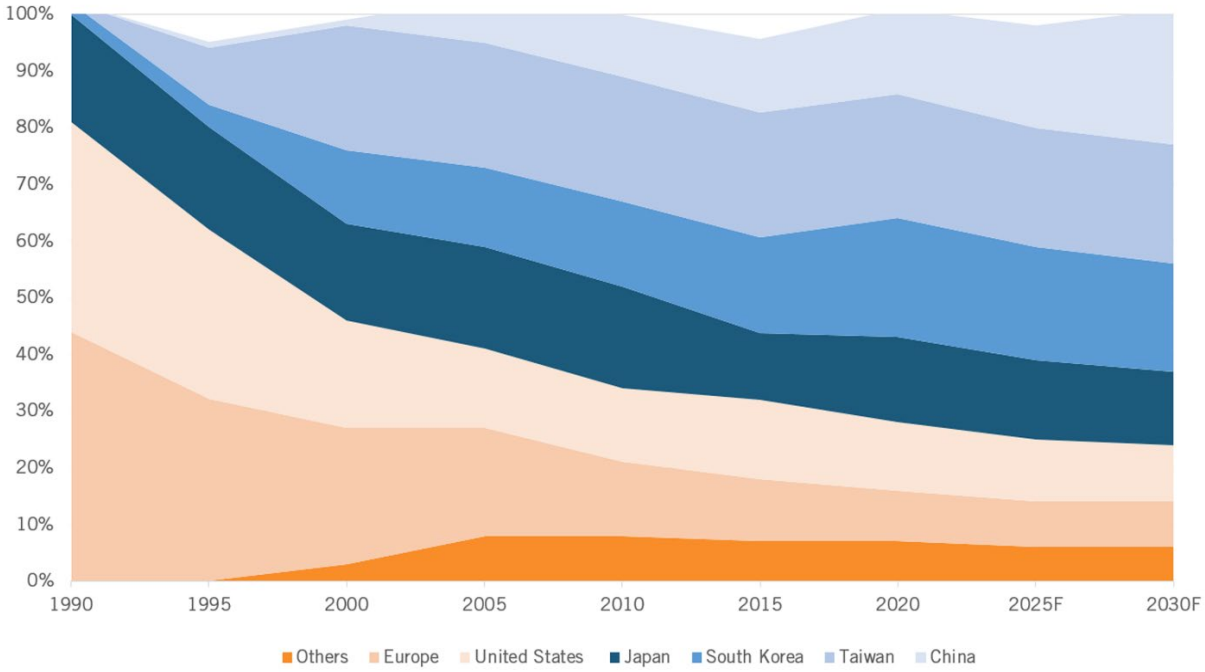
In short, the recovery of the U.S. semiconductor industry in the 1990s—which played a pivotal role in laying the groundwork for the Internet era and the advent of the modern digital economy—was the result of intentional and concerted public policies, effective public-private partnerships, and industry executives' willingness to make long-term investments to restore the sector's competitiveness.

The U.S. Semiconductor Industry Today

While the United States retains many strengths in the semiconductor industry, especially on the R&D and innovation side of the ledger, it has faltered considerably with regard to domestic semiconductor production.

Over the last four decades, U.S.-headquartered semiconductor firms have built many more fabs outside the United States than inside, in large part due to generous production subsidies offered by foreign governments seeking a share of this critical industry. No U.S. semiconductor Chief Executive Officer could keep the job if he or she had not taken advantage of these subsidies. By 2021, the U.S. share of global semiconductor production had fallen from 37 percent in 1990 to 12 percent. (See figure 3.)

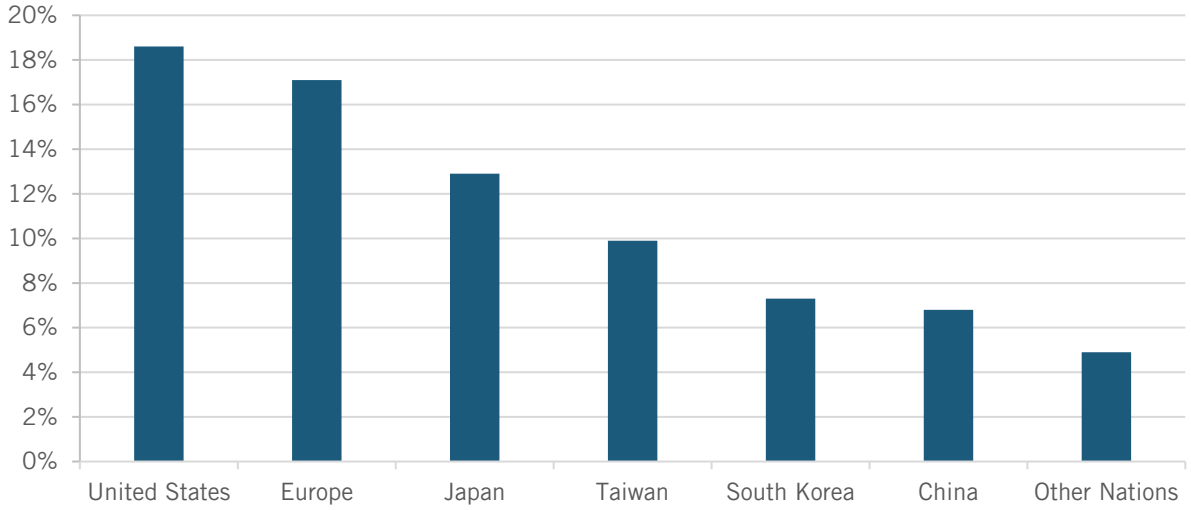
Figure 3: Global manufacturing capacity by location[47]



At current trends, with just 6 percent of new global semiconductor capacity development expected to be located in the United States over this decade, absent effective policy intervention, the U.S. share of global semiconductor manufacturing capacity is expected to fall to 10 percent by 2030. In summary, the United States has lost over 70 percent of its share of global semiconductor manufacturing capacity over the past three decades. Conversely, whereas China held barely 1 percent of global semiconductor manufacturing capacity in 2000, by 2010 this share had grown to 11 percent, and to 15 percent by year-end 2020, with that share forecast to increase to 24 percent by 2030.

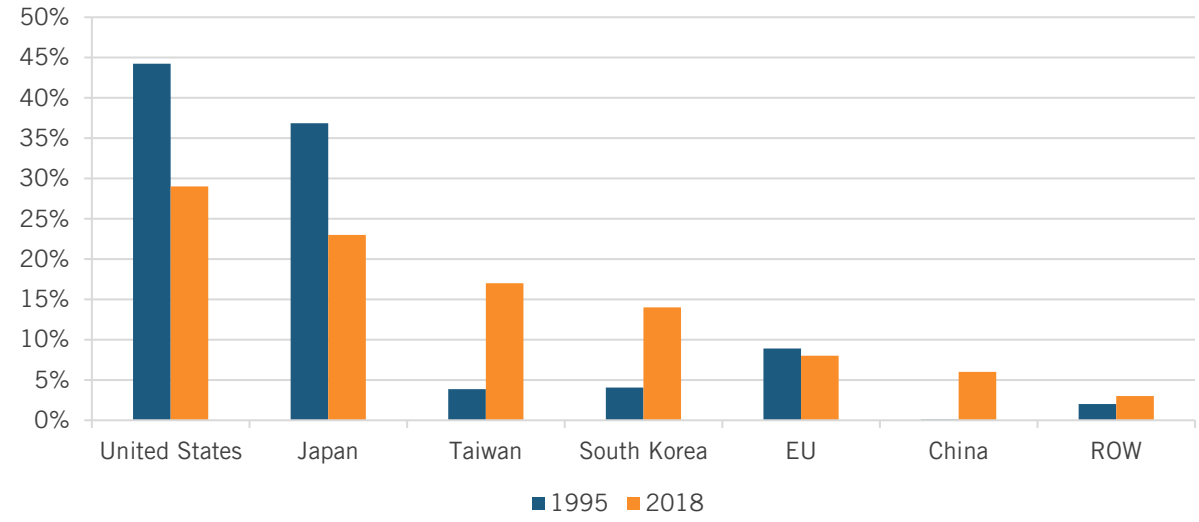
While global production has grown offshore and declined in the United States, U.S. firms were still able to lead in innovation, at least until recently. U.S. semiconductor enterprises' R&D intensity, at 18.6 percent, outpaces that of global peers: with European-headquartered ones at 17.1 percent; Japan's at 12.9 percent; South Korea's 9.9 percent; and China's 6.8 percent.[48] (See figure 4.)

Figure 4: Global investment by firms on semiconductor R&D as a share of sales, by country/region, 2020[49]



When it comes to patenting the picture is less robust. While U.S.-headquartered enterprises (or other entities) received 44 percent of the semiconductor patents awarded by the U.S. Patent and Trademark Office (USPTO) in 1995, by 2018 this share had fallen to 29 percent. In contrast, over that period, Taiwanese-based applicants saw their share increase from 4 to 17 percent, South Korean ones from 4 to 14 percent, and Chinese ones from less than 1 to 6 percent. (See figure 5.)

Figure 5: Share of USPTO semiconductor patents granted by country/region, 1995 and 2018[50]

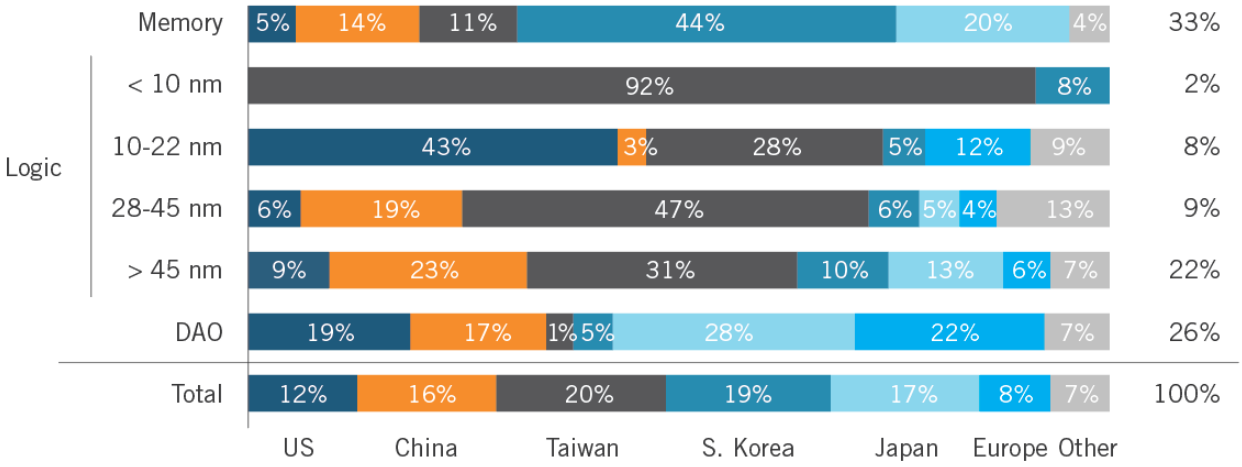


The erosion of U.S. innovation capabilities has been particularly apparent with regard to advanced chip production capabilities. While Intel remains the world's leader in logic chip market share and America's leading logic chip maker, is has slipped off the leading pace. TSMC is now producing 5 nm chips and expects to enter the volume production phase for 3 nm chips by the second half of 2022.[51] In contrast, in July 2020, Intel announced that it had fallen at least one year behind schedule in developing its next major advance in chip-manufacturing technology.[52] (That is, in moving from 10 nm to 7 nm technology; although, effectively Intel's 7

nm architecture in performance will be roughly equivalent's to TSMC's 5 nm, and it's important to remember that while process node size is indicative, it's not necessarily reflective of the actual performance features of a given chipset.) Nevertheless, Intel has vowed to catch up, and in August 2021 it released an aggressive technology roadmap that promises significant improvements in technology performance, efficiency, and architecture in the upcoming Intel chipsets through 2025. The company plans to ship Intel 4, its first 7 nm chipset, starting in early 2023 and to follow on with Intel 3, which it expects to deliver an 18 percent performance increase over the Intel 4, in the latter half of 2023. By 2024, Intel plans to release Intel 20A, with the "A" referring to an angstrom, a unit of length equal to 0.1 nanometers, based on significantly new chip architectures.[53]

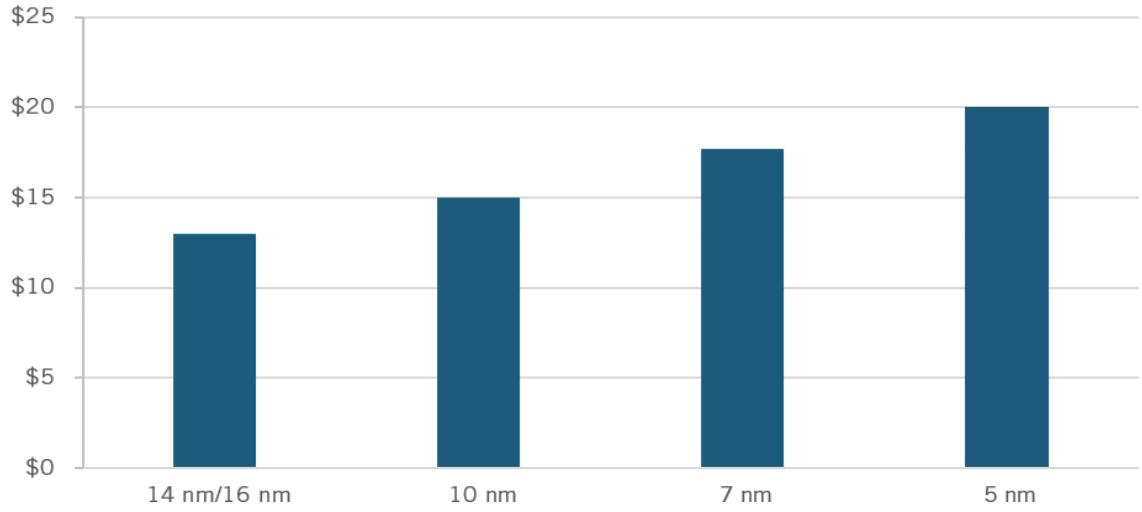
But the reality is that the vast majority of the world's most sophisticated semiconductor logic chips, those at the sub 10 nm process node level or below, are manufactured in Asia, where Taiwan (largely due to TSMC) held a 92 percent share in 2019 and South Korea the remaining 8 percent. (See figure 6.) In other words, for an industry it invented, the United States had clearly fallen off the leading edge in domestic semiconductor manufacturing.

Figure 6: Share of global semiconductor wafer manufacturing capacity by region (2019, %)[54]



One reason for this falloff is that the costs of advanced fab development are so great—it costs $20 billion or more to build the latest 5 or 3 nm fabs—that it's hard for American semiconductor makers to justify these expenses, especially as U.S. financial markets value asset-light companies that shed hard capital assets. (See figure 7.) That's a large part of the reason why whereas almost 30 companies manufactured integrated circuits at the leading edge of technology 20 years ago, only 5 do so today (Intel, Samsung, TSMC, Micron, and SK Hynix). But another reason is that the erosion of production capabilities overseas has hurt innovation capabilities.

Figure 7: Average cost to build a new foundry/logic fab (US$, billions)[55]



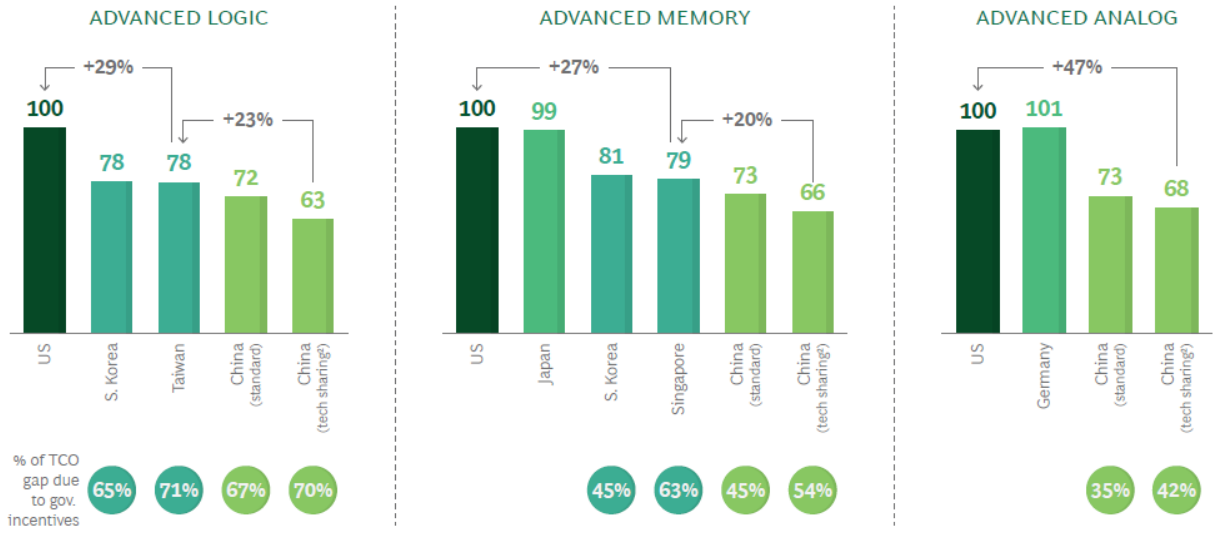
Explaining the Decline in Leading-Edge U.S. Semiconductor Production

A number of factors explain faltering U.S. leadership on the leading-edge of semiconductor production. To be sure, a great degree of it stems from ever-intensifying foreign competition, which has in many cases enjoyed considerable government support and investment, although it's also stemmed from disruptive innovators like Taiwan's TSMC, which pioneered the innovative fabless business model. However, faltering U.S. leadership has also resulted from failures, or at least errors or miscalculations, on both the public and private side of the U.S. ledger.

Foreign Investment Incentives

Frankly, other countries are willing to subsize the building of semiconductor fabs, whereas the United States is largely not. That explains much of the U.S. decline. Many countries help companies defray the high costs of building a fab, with incentives that reduce up-front capital expenditures on land, construction, and equipment and that can also extend to recurrent operating expenses such as utilities and labor. Foreign government incentives may offset from 15 to 40 percent of the gross total cost of ownership (pre-incentives) of a new fab, depending on the country.[56] The 10-year total cost of ownership (TCO) of U.S.-based semiconductor fabs is 25 to 50 percent higher than in other locations, with government incentives accounting for 40 to 70 percent of the U.S. TCO gap.[57] (See figure 8.)

Figure 8: Estimated 10-year TCO of reference fabs by location (U.S. indexed to 100)[58]



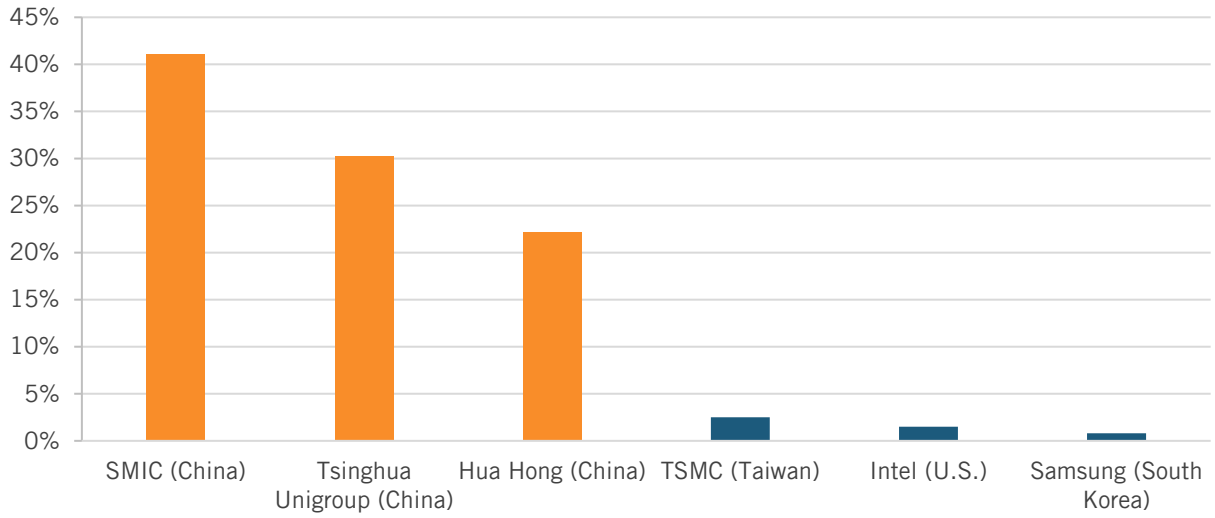
China's semiconductor industry has received over $170 billion worth of government subsidies, which China has used both to stand up entirely new companies from scratch and to finance the acquisition of foreign competitors.

Other countries are willing to subsize the building of semiconductor fabs, whereas the United States largely is not. That explains much of the U.S. decline.

In many of these countries, such as Japan, South Korea, and Singapore, such incentive packages are offered at the national Ministry of Economy level to attract globally mobile semiconductor investment (in China such packages are offered at the national, provincial, and regional levels). For example, Korea recently announced a program of 40 to 50 percent tax credits for chip R&D and 10 to 20 percent tax credits for facility investments, as well as low-cost loans therefore.[59]

China is even more generous. Its semiconductor industry has been the recipient of over $170 billion worth of government subsidies, which China has used both to stand up entirely new companies from scratch and to finance the acquisition of foreign competitors.[60] An Organization for Economic Cooperation and Development (OECD) study of 21 international semiconductor companies from 2014 to 2018 found that Chinese companies received 86 percent of the below-market equity provided by their nations' governments.[61] Considering state subsidies at the firm level—that is, as a percentage of revenue for semiconductor manufacturers (from 2014 to 2018)—Chinese enterprises clearly led their foreign competitors by an order of magnitude. State subsidies accounted for slightly over 40 percent of Semiconductor Manufacturing International Corporation's (SMIC) revenues over this period, 30 percent for Tsinghua Unigroup, and 22 percent for Hua Hong. (See figure 9.) In contrast, this figure was minimal for TSMC, Intel, and Samsung, each for whom revenues identifiable as state subsidies accounted for, at most, 3 percent or less of their revenues over this period. Of particular import, the OECD study found that there "notably appears to be a direct connection between equity injections by China's government funds and the construction of new semiconductor fabs in the country."[62]

Figure 9: State subsidies as a percentage of revenue for chip fabs, 2014–2018[63]



Another example pertains to China's efforts to build leadership in memory technologies such as DRAM and NAND. For instance, Yangtze Memory Technologies (owned by the state-backed Tsinghua Unigroup) announced that by year-end 2020 it had tripled its production to 60,000 wafers per month (wpm), equivalent to 5 percent of global output, at its new, $24 billion plant in Wuhan.[64] Similarly, ChangXin Memory Technologies, also a state-funded company, announced that in 2020 it would quadruple production of DRAM chips to 40,000 wpm (or 3 percent of world DRAM output) at its $8 billion facility in Hefei.[65]

The 10-year TCO of U.S.-based semiconductor fabs is 25 to 50 percent higher in the United States than in most other countries, with government incentives directly account for 40 to 70 percent of the U.S. TCO gap.

The bottom line: because of this intense competition, if a nation wants to maintain or expand its semiconductor production it must pay for it. To date, the United States has not been willing to do that, and it has paid the price. To be sure, some U.S. states have put together elements of incentive packages, but because of state fiscal constraints they are quite modest in size. The historical inability to offer attractive incentive packages explains why two of the most-significant elements in the CHIPS package are a $10 billion federal program that matches state and local incentives offered to a company for the purpose of building a semiconductor foundry with advanced manufacturing capabilities as well as a 40 percent investment tax credit for semiconductor equipment and facility expenditures.

Foreign Innovation Mercantilism

Some nations, especially China, complement subsidies with unfair trade and economic policies. These include policies such as forced technology or IP transfer or domestic production as a condition of market access, IP theft, and demands to produce locally as a condition of market access. Japan practiced some of these measures (e.g., closed markets, product dumping, etc.) in the 1980s. But China's actions make Japan's look like child's play, as ITIF writes in "Moore's Law Under Attack: The Impact of China's Policies on Global Semiconductor Innovation."[66]

For instance, the acquisition of foreign semiconductor technology through IP theft has been a key pillar of Chinese strategy. One assessment found that China's SMIC alone has accounted for billions in semiconductor IP theft from Taiwan.[67] Chia also regularly coerces technology transfer in the semiconductor industry. As the OECD observed, "[T]here is also unease in the [semiconductor] industry regarding practices that may amount to forced technology transfers, whereby government interventions create the conditions where foreign firms may be required to transfer technology to local partners or to share information that can be accessed by competitors."[68] A 2017 survey conducted within the semiconductor industry by the U.S. Department of Commerce's Bureau of Industry and Security found that 25 U.S. companies—which accounted for more than $25 billion in annual sales—had been required to form joint ventures and transfer technology, or both, as a condition of Chinese market access.[69]

U.S. Innovation System and R&D Weaknesses

Part of the reason the United States has fallen off the leading edge in semiconductor manufacturing and performance stems from its own missteps, including with regard to R&D and innovation policy. Here, perhaps the most fundamental lacunae has been faltering federal R&D investments. In 1978, U.S. federal investment into semiconductor R&D totaled 0.02 percent of GDP. While 40 years ago, this investment was on par with private levels, federal R&D investment for semiconductors in 2018 rose only one-hundredth of a percentage-point, to about 0.03 percent of GDP. Meanwhile, U.S. private investment in semiconductor R&D has steadily grown over the last 40 years, totaling about 0.19 percent of GDP in 2018.[70]

In industries like biotechnology and semiconductors, product and process innovations are increasingly joined at the hip, and if production leaves U.S. shores, it hampers both process and product innovation, leading to a "make there, innovate there" paradigm.

Alex Williams and Hassan Khan point to deeper structural problems in the organization of the U.S. science and innovation policy system. They contend that in the 1990s the United States essentially tried to conduct "science policy" on the cheap, where "policy privileged research, design, and ideas over implementation, production, and investment."[71] Ultimately, Williams and Khan's critique is quite similar to those of Bill Bonvillian and Suzanne Berge at MIT (and others like Greg Tassey, former NIST senior economist), contending that over time innovations in process and product innovations in industries like semiconductors or biotechnology become joined at the hip and inseparable from one another, and as the manufacturing (i.e., process innovation) part of the equation increasingly left American shores then America fell further behind on product innovation as well.[72]

THE BIOPHARMACEUTICAL INDUSTRY

The U.S. biopharmaceutical industry increasingly looks like it is on the same path that the U.S. semiconductor industry has been on: It is a laggard in production, and it faces growing threats to innovation leadership. Just as U.S. semiconductor leadership can no longer be taken for granted, neither can continued U.S. leadership in the life-sciences, especially if U.S. policymakers fail to respond to foreign policies to promote the industry within their borders, weaken positive programs in the United States, and enact harmful policies (e.g., weaker IP protections and strong drug price controls).

As this section will show, the United States turned itself from a global biopharmaceutical laggard into the leader, helped considerably by harmful European policies, which U.S. policymakers now appear to want to copy. Taking the industry for granted and believing that government can impose regulations with no harmful effect—common policy views in Washington—will almost certainly mean passing the torch of global leadership to other nations, especially China, within a decade or two. This section begins by examining how a series of poor policy choices from the 1980s through the early 2000s cost Europe its leadership in the global pharmaceuticals industry.

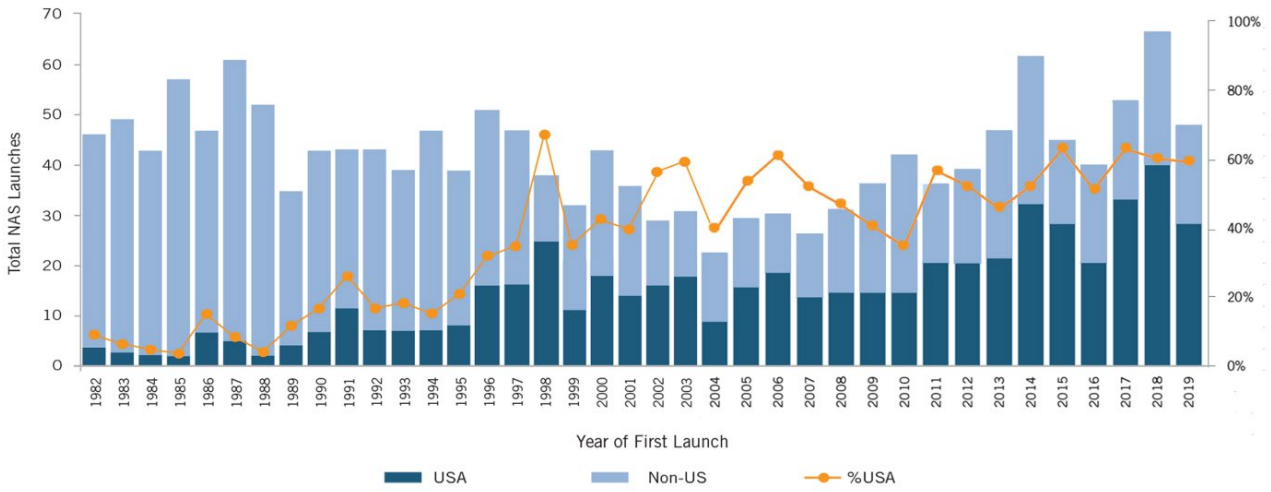
The United States turned itself from a global biopharmaceutical laggard into the innovation leader, helped considerably by harmful European policies, which U.S. policymakers now appear to want to copy.

Learning From Europe's Loss of Pharmaceuticals Industry Leadership

Beyond the U.S. semiconductor industry, U.S. policymakers also can look to Europe's experience to see what happens to an industry when a supportive policy environment for innovation isn't maintained and harmful policies are put in place. Europe's introduction of intensive drug price controls, heavy-handed drug price negotiation tactics, regulations limiting biotechnology research, and limitations on mergers all played roles in undermining the competitiveness of Europe's biopharmaceuticals sector and helping set the table for the United States to wrest global leadership.

Europe was once the world's pharmaceuticals industry leader. Between 1960 and 1965, European companies invented 65 percent of the world's new drugs, and in the latter half of the 1970s, European-headquartered enterprises introduced more than twice as many new drugs to the world as did U.S.-headquartered enterprises (149 to 66).[73] In fact, throughout the 1980s, fewer than 10 percent of new drugs were introduced first in the United States.[74] (See figure 10.)

Figure 10: U.S. share of new active substances launched on the world market, 1982–2019[75]



And, as recently as 1990, the industry invested 50 percent more in Europe than in the United States.[76] As Shanker Singham of the Institute of Economic Affairs notes, "Europe was the unquestioned center of biopharmaceutical research and development for centuries, challenged only by Japan in the post-war period."[77] As of 1990, European and U.S. companies each held about a one-third share of the global drug market.

But leadership began to shift in the 1990s. By 2004, Europe's share would fall to 18 percent, while the U.S. share jumped to an astounding 62 percent.[78] From 1990 to 2017, pharmaceutical R&D investment in the United States increased almost twice as fast as in Europe.[79] In fact, from the early 1970s to the mid-1990s, biopharma R&D from America's top firms went from about one-half of European firm levels to over three times more.[80] As Nathalie Moll of the European Federation of Pharmaceutical Industries and Associations (EFPIA) wrote in January 2020:

> The sobering reality is that Europe has lost its place as the world's leading driver of medical innovation. Today, 47 percent of global new treatments are of U.S. origin compared to just 25 percent emanating from Europe (2014–2018). It represents a complete reversal of the situation just 25 years ago."[81]

By 2014, nearly 60 percent of new drugs launched in the world were first introduced in the United States, an indication both that more were being invented in the United States and that drug companies from Europe and elsewhere were introducing new drugs in America first because that's where they could recoup their investments.

This dramatic shift away from Europe serving as the "world's medicine cabinet" did not happen principally due to deficient corporate strategy or management. Instead, poor public policy in Europe and superior policy in the United States made the difference. This was particularly the case when it came to drug price controls. As one report explained in 2002, "the heart of pharma's problem in Europe is the market's inability to 'liberate the value' from its products."[82] This was a reference to the "complex maze of government-enforced pricing and reimbursement controls" that "depressed pharma prices to the point where some companies now believe it is just not economical to launch new products in certain European countries."[83] Starting in the 1980s, many European nations began to introduce drug price controls, including a combination of international (and even regional) reference-pricing regimes, global prescribing budgets (under which provider organizations are at risk of medical spending above a predetermined budget), profit controls (which set an upper limit on the amount an insurer could pay for groups of identical or equivalent drugs), and restrictions on the use of more-expensive drugs to their use only at hospitals, among many other types.[84] Today there are: "fixed reimbursement prices in France; set reference prices in Germany; and profit limits in the United Kingdom."[85] As one 2006 article noted, policymakers in many European countries supported such drug price controls to meet: "stated pharmaceutical policy goals to keep pharmaceutical price increases at or below the general rate of consumer price inflation" (despite the fact that "economic efficiency could easily justify real pharmaceutical price increases because pharmaceutical demand rises more than proportionately with income").[86]

European countries' extensive use of drug price controls really began in earnest in the early 1980s and accelerated in the 1990s. For instance, as one 2003 report explained, "For the aim of fiscal consolidation, price-freeze and price-cut measures have been frequently used [in

European nations] in the 1980s and 1990s."[87] As that report elaborated, "in the 1970s, most European countries financed medicines indiscriminately," but "starting in the 1980s, positive or negative lists were introduced" (these being lists defining the drugs eligible for reimbursement).[88] By the late 1980s, manufacturers were free to set prices in only three European countries: Germany, Denmark, and the Netherlands.[89] By the 1990s, virtually all European countries would have various drug price controls schemes in place.[90] As Arthur Daemmrich wrote for the Harvard Business School, "Whereas [U.S] safety and efficacy regulation were seen as causes for the industry's decline in the 1970s, its subsequent turnaround has been attributed largely to price control policies in Europe and their absence in the United States."[91]

This dramatic shift away from Europe serving as the "world's medicine cabinet" did not happen principally due to deficient corporate strategy or management. Instead, poor public policy in Europe and superior policy in the United States made the difference.

By imposing such draconian drug price controls, European regulators severely disrupted the economics of innovation in the European life-sciences industry. As EFPIA explained in a 2000 report, "Many European countries have driven prices so low that many new drugs can no longer recoup their development costs before patents expire."[92] As the report continues, "These policies, most of which seek only short-run gains, seriously disrupt the functioning of the market and sap the industry's ability to compete in the long-run."

Some European policymakers were aware that this could harm innovation and attempted to put in place provisions to limit the damage. At least one country, Germany, established its drug price control system in a way that was intended to avoid limiting the development and use of innovative drugs. But in reality, it did not work that way. As a 2006 commentary in *Nature Biotechnology* noted, "In theory, innovative drugs should be excluded from the mechanism, but in the past, more and more patent-protected drugs were included as they were dubbed 'pseudo-innovative' by the system's oversight bodies."[93]

As industry analyst Neil Turner wrote in 1999, those policies set "in motion a cycle of under-investment and loss of competitiveness that's very difficult to break out of."[94] As Turner observed, of the new European pharmaceutical products with a significant rollout in 2001, relatively few achieved consistent price premiums across Europe, and that disrupted the innovation process, because "leading industry contenders need between two and four major new product launches a year to deliver the stock market's historic expectations of 10 percent annual sales growth."[95] However, it's important to note that Europe's price controls weren't applied just on the innovative blockbuster drugs but also to follow-on drugs that provided subsequent improvements. As one European firm's senior pricing and reimbursement executive explained in 2002:

> Pharmaceutical innovation is an organic process. Progress doesn't come in big leaps; it comes from incremental improvements. As long as the authorities refuse to accept that an incremental improvement deserves some price advantage, Europe will not be at the forefront of promoting progress in the pharmaceutical business.[96]

European regulators also surreptitiously delayed the introduction of new drugs (as a way to control costs) through protracted price negotiations. One analyst suggested:

> now that marketing authorization is largely harmonized across Europe, such negotiations are the new preferred delay tactic of national authorities" and "a reflection of reimbursement authorities' growing confidence in using their strong negotiating positions to drive prices down even further.[97]

It certainly wouldn't be surprising to see such tactics used in the United States after the introduction of drug price controls as envisioned in pending Build Back Better legislation.

While Europe's drug price controls led to lower drug prices and charges that Europe "free rides" off U.S. biopharmaceutical innovation, one 2004 report noted "Europe's free ride is not free" and showed that Europe's drug price controls lead to considerable "social and economic costs in Europe, in the form of delayed access to drugs, poorer health outcomes, decreased investment in research capabilities, and a drain placed on high-value pharmaceutical jobs."[98]

Indeed, European drug price controls had a very significant impact on reducing pharmaceutical companies' R&D investments and, therefore, innovation. This explains why the health economists Joseph Golec and John Vernon found that European drug price controls contributed to EU pharmaceutical firms investing less on R&D.[99] While European-headquartered drug companies out-invested U.S.-headquartered ones by about 24 percent in 1986, by 2004, the U.S. companies were outinvesting the European ones by about 15 percent. Overall, Golec and Vernon estimated that EU price controls from 1986 to 2004 shaved about 20 percent off European-headquartered pharmaceutical firms' R&D levels, resulting in 46 fewer new medicines (and 32,000 fewer R&D jobs) than would otherwise have been the case over that period, and that, if European drug price control policies continued going forward (beyond 2004), this would result in European companies inventing 526 fewer new medicines.[100]

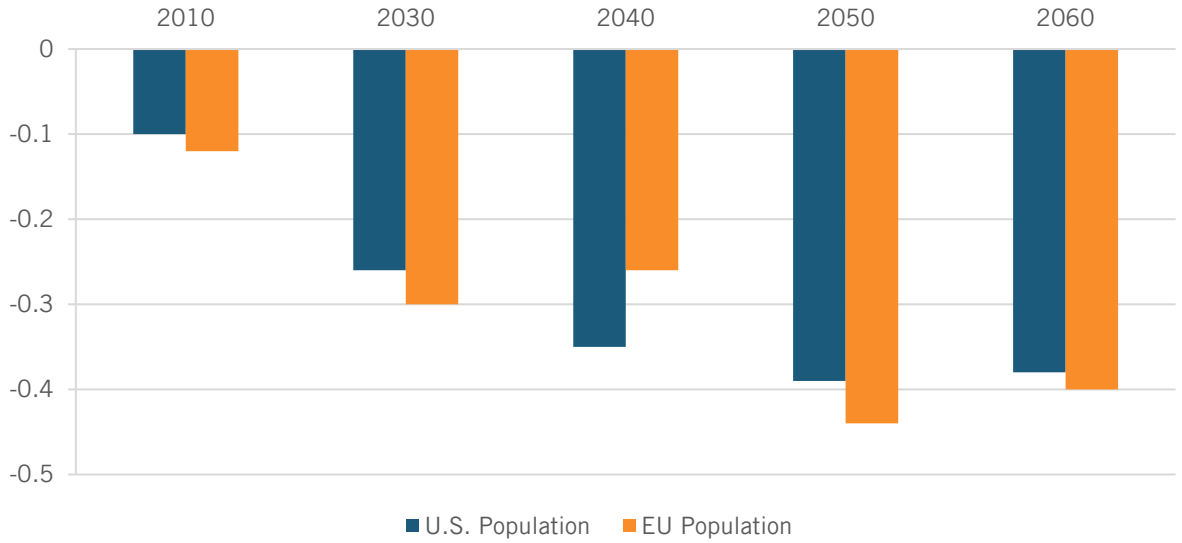
A similar study by Brouwers et al. found that drug price levels within OECD countries would have been 35 to 45 percent higher in the absence of price regulation, and that these higher prices would have triggered additional annual R&D investments of $17 to $22 billion, which in turn would have resulted in 10 to 13 new drug introductions per year.[101]

Moreover, beyond forestalling the innovation of new drugs, drug price controls also contributed to delayed or limited introduction of innovative new drugs in European markets, which has considerable health consequences. As Darius Lakdawalla et al. have elaborated, "if lower spending leads to less innovation for future Europeans, there may be downstream costs borne by Europeans themselves."[102] Research his team conducted in 2008 found that:

> European policies that impose further price-tightening, by lowering manufacturer prices by 20%, would cost about $30,000 in per capita value to American near-elderly cohorts alive in 2060, and $25,000 to similarly aged Europeans in that year.[103]

Their research found that "reductions in EU prices would lower life expectancy in the 55-59 year-old EU and U.S. cohort by about one-tenth of a year" and that since "per revenues have cumulative effects on forgone innovations, the effects on longevity accumulate in a similar fashion," such that "for the 2050 and 2060 cohorts, the reduction in longevity more than triples from the original effect, to range between 0.3 and 0.4 years of life."[104] (See figure 11.)

Figure 11: Effect of EU price regulation on longevity among 55- to 59-year-olds in the United States and Europe, by years of life[105]



Moreover, the loss of industry was real. As Golec and Vernon noted, "The growing gap between EU and U.S. pharmaceutical R&D, and the movement of R&D facilities to the U.S. by EU firms, should be a signal to EU policymakers that low pharmaceutical prices through regulation has costs."[106] Indeed, Europe's excessive price controls contributed to some European firms, such as Novartis, moving their entire R&D headquarters to the United States. Elsewhere, in 2003, after German President Angela Merkel introduced new drug controls, Merck cancelled plans to open a research center in Munich, while Pfizer moved much of its European research base to the United Kingdom. As Bain notes, this process accretes, as once R&D starts to leave a region the entire ecosystem departs, including "R&D suppliers and the equipment and technology suppliers that provide pharmaceutical companies with basic chemistry, diagnostic equipment, and tools."[107] Explaining industry's move out of Germany, Nikolaus Schwikert, CEO of the specialty chemical and pharmaceutical firm Altana, said: "Our system, which considers the pharmaceuticals industry and its innovations solely as a cost factor and not as a use factor … is the basic problem."[108] As the United States has found with the semiconductor (and many other manufacturing industries) once the industrial commons supporting the industry leaves U.S. shores, it's very difficult to reconstitute it.

Europe's loss of pharmaceutical leadership should serve as a cautionary tale for U.S. policymakers who are running headlong to adopt the very same policies that felled the European industry.

However, drug price controls weren't the only factor contributing to Europe's loss of biopharmaceuticals leadership. Another was restrictions on direct-to-consumer advertising (common in the United States), which diminished European pharmaceutical firms' efforts to demonstrate the cost-effectiveness of their medicines to patients and regulators alike.[109]

The United States' "innovation-principle"-focused regulation, compared to Europe's "precautionary principle" regulation, also played a role. As Turner argued, in the United States in the 1990s:

> the industry benefitted from a climate in which government and industry were pulling in the same direction" with "unnecessary regulation being kept out of new drug discovery programs and, where it existed, legislation being designed to facilitate—rather than impede—technological progress.[110]

In contrast, in Europe, "pharmaceutical companies are directly affected by the constraints that EU biotechnology legislation has imposed on the already highly regulated industry."[111]

In addition, restrictive merger policies in Europe also played a role in deterring needed industry consolidation, which especially mattered as the costs involved in new drugs continued to increase and made innovation more difficult for mid-sized firms that lacked scale. That's ironic because, as ITIF's Aurelien Portuese has noted, "the first modern pharmaceutical companies were European because they reached a sufficient size," a lesson that European regulators appeared to forget.[112] For instance, even the 2006 merger of Schering and Bayer "was greeted with skepticism" by regulators, though analysts noted that the two mid-size German pharmaceutical firms merging would only create the world's 12th-largest drug company.[113]

Finally, Daemmrich argued that "how countries resolve tensions between protecting patients and empowering consumers impacts the international competitive standing of their domestic pharmaceutical industries."[114] In other words, he argues that differences in regulatory cultures—notably, responses to a new disease, boundaries to compassionate use, and attention to biomarkers and other aspects of consumer-oriented drug development—provide an important explanatory dimension to nations' relative levels of life-sciences competitiveness. He suggests that U.S. regulatory and clinical trial approaches, especially establishing strict boundaries between testing and marketing has "allowed for greater access to new medicines" than in European countries such as Germany, where "the medical profession exercised a near-monopoly over constructions of 'the patient' and drug laws codified existing power-sharing arrangements." In essence, he contended that "the predictability of centralized regulation based on a tight regime of quantified clinical trials in the United States coupled to the emergence of a focus on consumers and their access to drugs ultimately benefited firms operating in that country over their German counterparts."[115]

A forthcoming ITIF report will delve more comprehensively into the inferior policy choices both Europe and Japan made from the 1980s to 2000s to undermine the competitiveness of their pharmaceutical industries and set the table for U.S. biopharmaceutical leadership through the introduction of a much more-effective suite of supportive policies. But even this brief overview of Europe's loss of pharmaceutical leadership should serve as a cautionary tale for U.S. policymakers who are running headlong to adopt the very same policies that felled the European industry.

The Competitive State of the U.S. Biopharmaceutical Industry

One reason we know U.S. leadership in biopharmaceutical innovation is no sure thing is because, as the previous section explained, at least until the late 1980s the United States was at best a global "also ran" in biopharmaceutical innovation behind Europe. But as Europe introduced a variety of policies that hamstrung its industry, it set the table for the United States, to wrest leadership. The United States would do so with robust and complementary public and private investment in biomedical R&D; supportive incentives, including tax policies, to encourage biomedical investment; robust IP rights and effective policies to support biomedical technology

transfer, development, and commercialization; an effective regulatory and drug-approval system that was also responsive to patients' rights groups and focused more on patients than doctors; and finally, a drug-pricing system that allows innovators to earn sufficient revenues for continued investment into future generations of biomedical innovation.

Those policies, and the demise of the European sector, set the stage for the United States to become the global leader on several measures of biopharmaceutical innovation, particularly with regard to biopharmaceutical R&D funding and performance and the introduction of new-to-the-world medicines. But as the following sections will show, the now-deteriorating U.S. policy environment for biopharmaceuticals innovation is evincing increasing signals of concern in the sector.

Biopharmaceutical R&D Funding and Performance

The United States has become the world's largest global funder of biomedical R&D investment, its share of global R&D as high as 70 to 80 percent over the past two decades.[116] In 2019, the U.S. pharmaceutical industry invested $83 billion dollars in R&D; adjusted for inflation, that amount is about 10 times what the industry invested per year in the 1980s. As the Congressional Budget Office (CBO) writes, "[U.S.] pharmaceutical companies have devoted a growing share of their net revenues to R&D activities, averaging about 19 percent over the past two decades," with the industry's R&D intensity exceeding 25 percent in 2018 and 2019.[117] And not only does the U.S. biopharmaceutical industry invest more than double the average OECD nation's biopharmaceutical industry does (12 percent), it invests about eight to ten times the level of the average U.S. industry, "with R&D intensity across all [U.S.] industries typically ranging between 2 percent and 3 percent."[118] The sector accounts for almost 17 percent of U.S. business R&D performance and nearly one-quarter of the industry's workforce labors at the R&D bench.[119] Moreover, almost one-third of global biopharmaceutical R&D activity occurs within the United States.

New Drugs

While biopharmaceutical R&D, scientific publications, and patents represent staring points, the acid test of nations' and enterprises' investments is whether they translate into new-to-the-world drugs. On this score, the United States excels, and its lead over Europe and Japan is growing. From 2004 to 2018, U.S.-headquartered enterprises produced almost twice as many new chemical or biological entities (NCEs and NBEs) as did European ones, and three to four times as many as Japan. (See Table 1.) However, at least in percentage terms, new drugs from other nations, such as China, have been growing even faster (albeit from a smaller base).

Table 1: Number of new chemical or biological entities[120]

Region	1999–2003	2004–2008	2009–2013	2014–2018	Total: 2009–2018
Europe	62	47	66	67	133
U.S.	73	67	64	125	189
Japan	28	16	26	34	50
Other	8	14	23	41	64

Moreover, the pace of U.S. biomedical innovation has grown over the past two decades. The FDA's Center for Drug Evaluation and Research (CDER's) 5-year rolling approval average stands at 45 new drugs per year, double the lowest 5-year rolling average, of 22 drugs approved in 2009. And the majority of these drugs are being produced by U.S.-headquartered biopharmaceutical companies. For instance, of the 101 new NMEs and BLAs approved by the FDA in 2019 and 2020 combined, 58 percent came from U.S.-headquartered companies, 32 percent came from EU-headquartered companies, and 10 percent came from companies headquartered elsewhere.[121]

U.S. Biopharmaceutical Production

However, despite its strengths at drug innovation, at least for now, the U.S. biopharmaceutical industry is increasingly evincing a number of weaknesses, especially with regard to domestic production, just as is the case with the U.S. semiconductor industry.

The U.S. pharmaceutical industry produced $182 billion of value added in 2018, up 107 percent from the $88 billion it produced in 2002. However, global value added increased much more, at 170 percent. Some of that increase globally reflected the growth of domestic markets and resultant local production in developing nations. For example, Chinese output grew by more than 10 times, while Indian value added grew by 7 times. (See figure 12.) As a result of this increased international competition, the United States' share of the world total of global pharmaceutical industry value added fell from 34 to 26 percent from 2002 to 2018, while China's share grew four-fold. (See figure 13.)

Figure 12: Global value added of pharmaceutical industry (millions), 2002–2018[122]

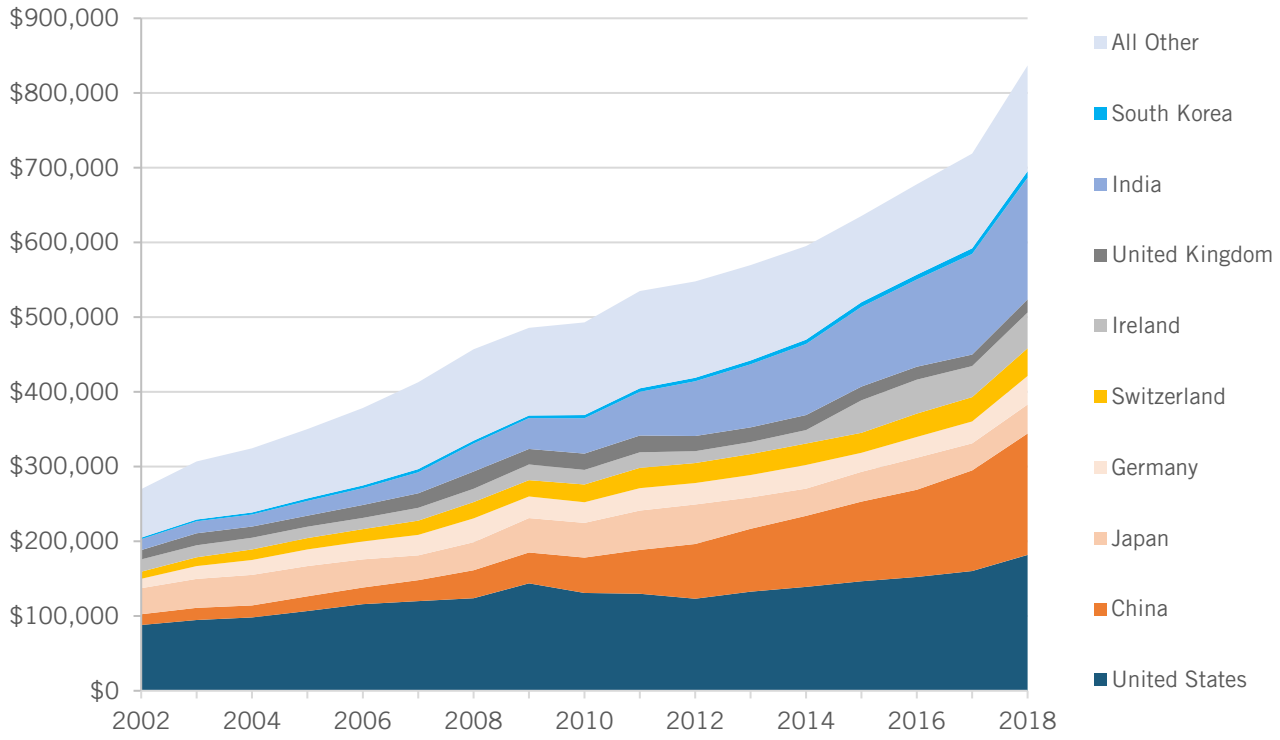
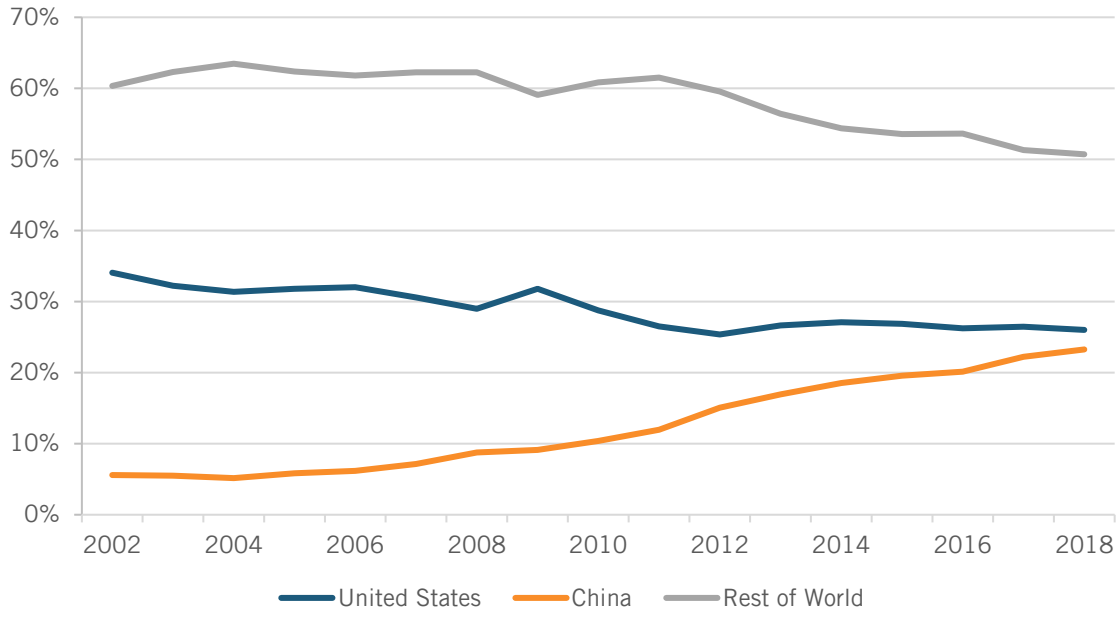
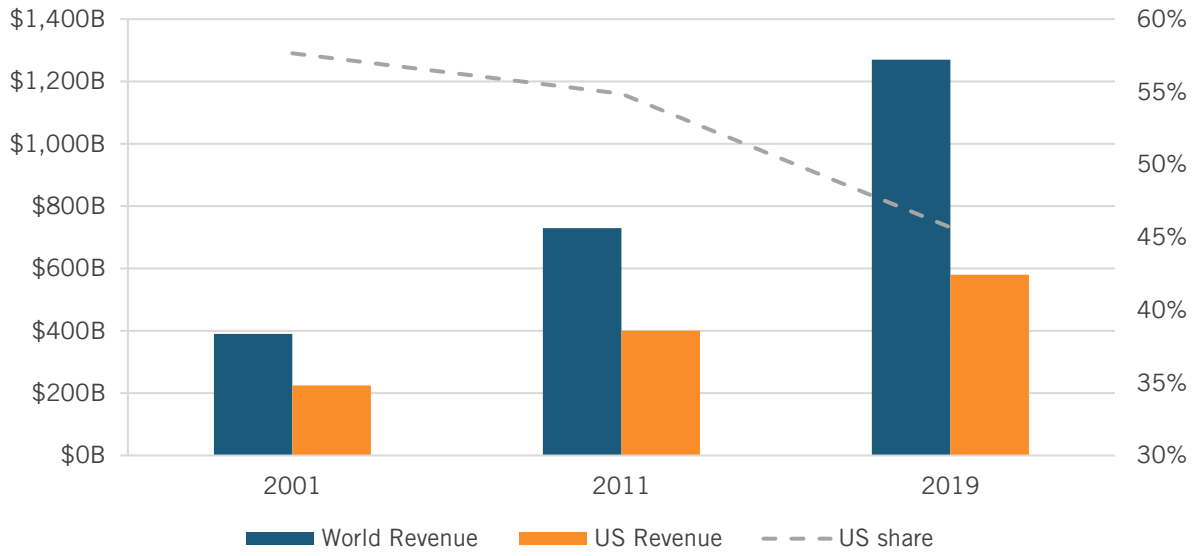


Figure 13: Shares of value added in global pharmaceutical industry, by select country, 2002–2018[123]



Another way to visualize this decline is through the decrease in U.S.-headquartered pharmaceutical companies' share of world revenues in the global pharmaceutical industry, which declined from 58 percent in 2001 to 46 percent in 2019. (See figure 14.)

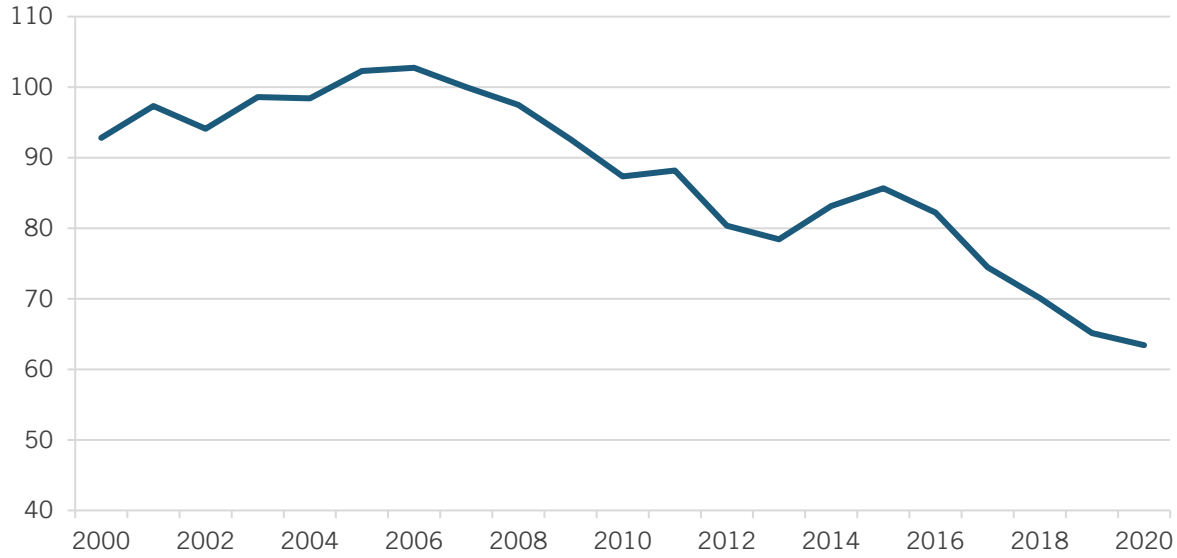
Figure 14: Revenue of U.S.-headquartered companies in the global pharmaceuticals industry, 2001-2019[124]



But while international competition certainly intensified over this period, another part of the equation was that U.S. pharmaceuticals and medicines (just like semiconductor) manufacturing was faltering. For starters, productivity growth in the U.S. pharmaceuticals and medicines industry has significantly lagged over the past several decades. According to the U.S. Bureau of Labor and Statistics (BLS), from 1987 to 2019 labor productivity in the pharmaceuticals and medicines sector actually fell by 0.8 percent annually, the worst performance by any U.S.

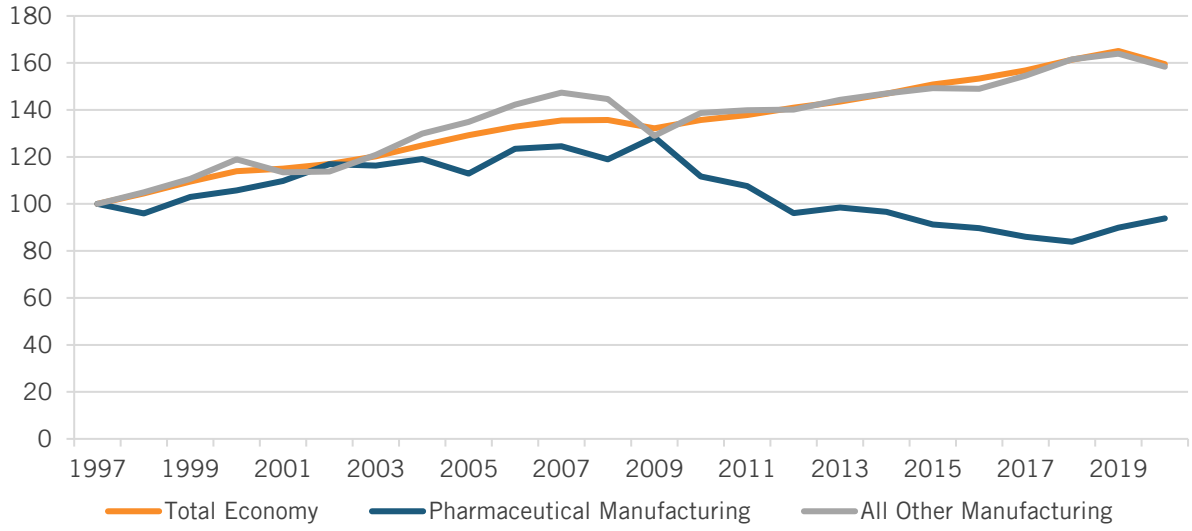
manufacturing industry.[125] In fact, the labor productivity of America's pharmaceutical and medicines manufacturing sector was about 40 percent lower in 2020 than it was in 2006.

Figure 15: U.S. labor productivity of pharmaceutical and medicine manufacturing (2007 = 100)[126]



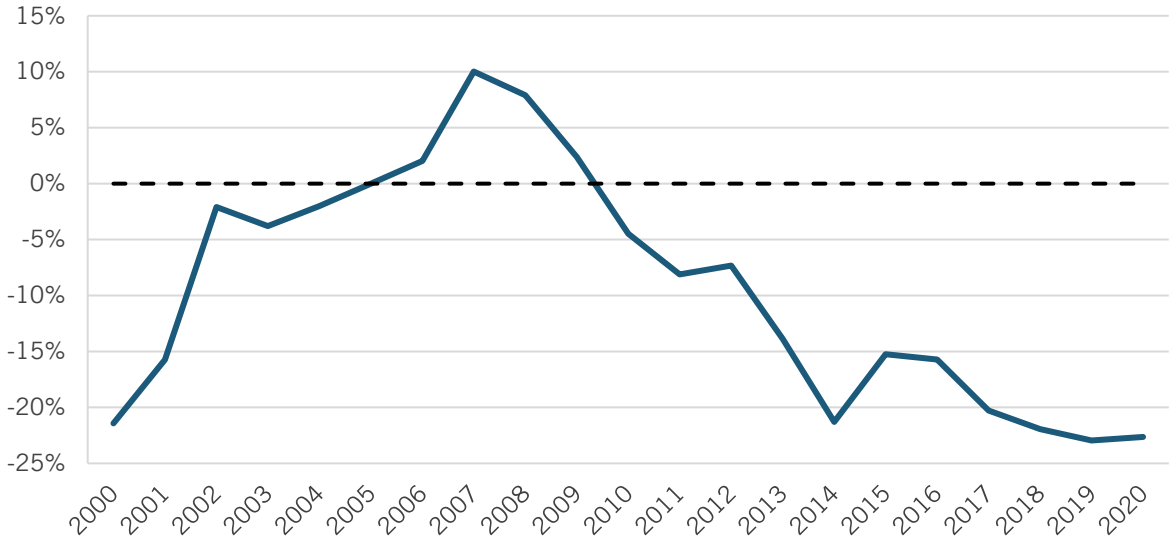
U.S. pharmaceuticals and medicines manufacturing real (i.e., inflation-adjusted) value added—defined as the value of final sales minus inputs, such as raw materials, energy, etc.—has also begun to falter. From 1997 to 2009, U.S. pharmaceutical and medicines manufacturing value added lagged but ultimately grew in line over that period with real value added growth across all other U.S. manufacturing industries. But, starting in 2009, the picture reversed. Between 2009 and 2020, pharmaceutical and medicines manufacturing real value added fell by 27 percent, whereas for all other U.S. manufacturing industries it increased it by 23 percent. (See figure 16.)

Figure 16: Indexed growth of real value added in pharmaceutical and medicine manufacturing, 1997–2020 (1997 = 100)[127]



In fact, U.S. production of pharmaceuticals and medicines peaked in 2006, with 2020 output about 20 percent below the 2006 level. (See figure 17.)

Figure 17: Change in domestic production of pharmaceuticals & medicines, indexed to 2005 output[128]



One reason the year 2006 represented an inflection point for declining domestic production of pharmaceuticals and medicines is because that was the year Congress began phasing out the Section 936 tax provision, which released pharmaceutical manufacturers from taxes on profits made in Puerto Rico and other U.S. territories. Some further contend that the Homeland Investment Act of 2005, which provided a window to repatriate tax-deferred offshore profits at a special lower rate, encouraged firms to shift manufacturing, and thus production, abroad in anticipation of a tax holiday.[129] High U.S. corporate tax rates, especially before the Tax Cuts and Jobs Act (TCJA) of 2017, may also have contributed to a spate of inversions, especially in the mid-2010s, where U.S. biopharmaceutical companies merged with a foreign competitor and moved the combined headquarters overseas.[130] As one 2017 report noted, "While global bio/pharma companies have spent more than $50 billion in just the past five years on new plant and equipment, much of that new capacity has been built in tax-favored locations such as Ireland and Singapore, and in emerging markets. Only about a quarter of the projects have been in the US."[131]

One area in which the United States has especially lost production capacity is in manufacture of active pharmaceutical ingredients (APIs). For instance, the last major API facility constructed in the United States was built almost 30 years ago.[132] And in recent decades, more than 70 percent of API production facilitators supplying the United States have moved offshore.[133] Overall, one study found that "between 2013 and 2017 the United States lost about 22 percent of its drug manufacturing, while the number of foreign facilities selling to the United States declined by 10 percent for API production and 3 percent for final drug production."[134]

In August 2019, Janet Woodcock, director of the FDA's CDER, testified before Congress that only 28 percent of the manufacturing facilities making APIs to supply the U.S. market were located in the United States, with 72 percent of the manufacturers supplying the U.S. market located overseas, including 13 percent in China.[135] Woodcock further reported that the number

of registered facilities making APIs in China more than doubled between 2010 and 2019. She also noted that at least three World Health Organization-identified essential medicines—capreomycin and streptomycin for treatment of Mycobacterium tuberculosis and sulfadiazine, used to treat chancroid and trachoma—rely on API manufacturers based solely in China.[136]

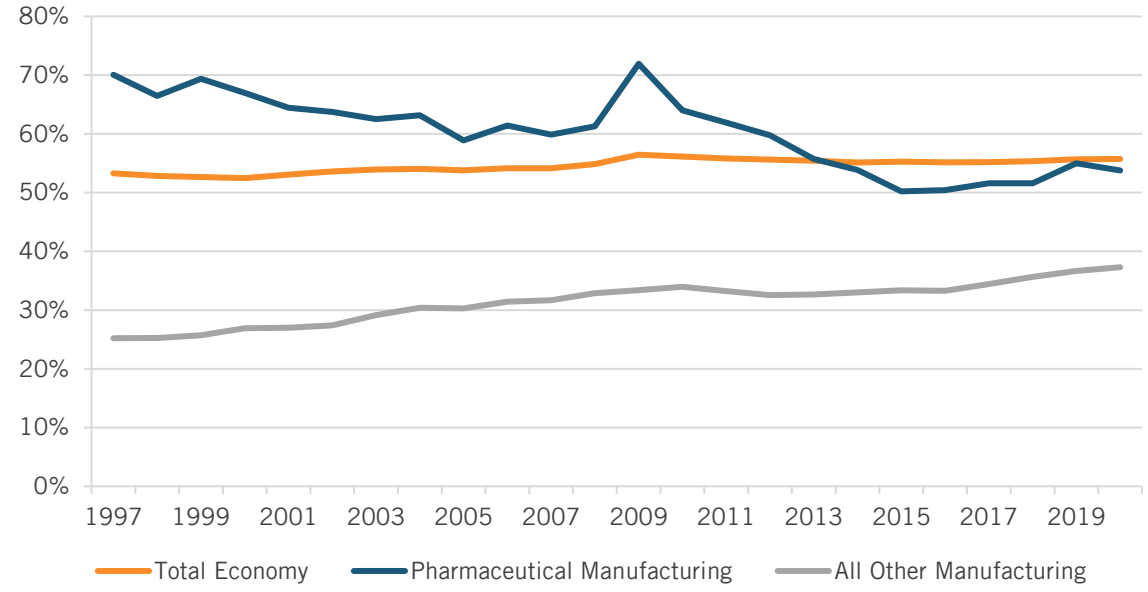
From 1987 to 2019 labor productivity in the pharmaceuticals and medicines sector actually fell by 0.8 percent annually, the worst performance by any U.S. manufacturing industry.

Beyond tax-driven considerations, other factors drove the offshoring of API and generic drug manufacturing. For instance, a December 2019 National Bureau of Economic Research (NBER) study examined levels and trends in the manufacturing locations of the most commonly used prescription pharmaceuticals—off-patent generic drugs—and found "that the base ingredients required for the manufacturing of these prescription drugs are overwhelmingly and increasingly manufactured in non-domestic locations, specifically India and China."[137] So being closer to sources of key chemical ingredients—and thus realizing greater economies of scale in—for the manufacture of APIs was a factor. That NBER report further found manufacturing of finished prescription drugs for the American market was equally split between U.S. and foreign suppliers and that the share of foreign suppliers had been growing.[138]

Anthony Sardella and Paolo De Bona, of the Washington University Olin School of Business and School of Medicine respectively, assert that, "In part to reduce costs, pharmaceutical companies sought to achieve economies of scale and arbitrages by aggregating and outsourcing operations, including manufacturing, often in nations with lower labor costs and looser environmental regulations such as India and China, often with an estimated cost saving of about 30 to 40 percent."[139] In addition to lower-cost production environments, many countries have offered more-appealing incentive and tax strategies to attract pharmaceuticals manufacturing investment than the United States, as the following section of this report will further elaborate.

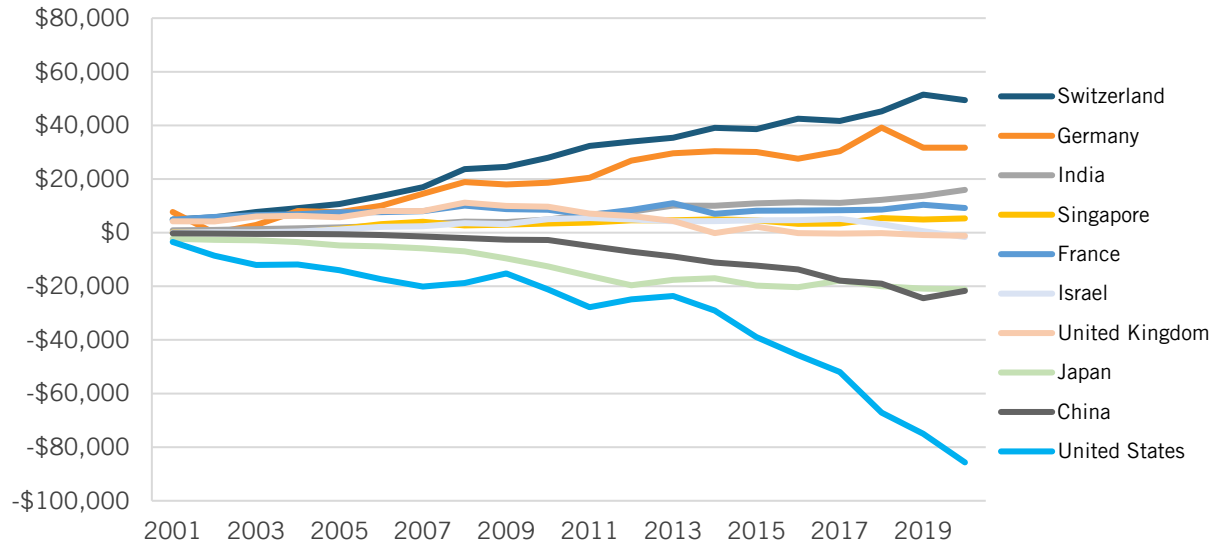
This offshoring of pharmaceuticals and medicines manufacturing is also reflected in the relatively lower value-added to gross output ratio for the U.S. industry. From1997 to 2009, the value added to gross output ratio of pharmaceutical and medicine manufacturing held relatively consistent (69.4 percent in 1999 to 71.9 percent in 2009), however, from 2009 through 2020, that ratio has fallen by one-quarter (down to 53.8 percent in 2020). (See figure 18.) In contrast, since 2009, the value-added to gross output ratio for all other U.S. manufacturing grew by 9 percent. The falling value added to gross input ratio is consistent with the interpretation that drug companies have been relying more on foreign inputs for their final production of drugs.

Figure 18: Value added to gross output ratio of pharmaceutical and medicine manufacturing, 1997–2020[140]



Faltering U.S. biopharmaceutical production shows up in the trade statistics. To be sure, the nominal value of U.S. biopharmaceutical exports increased 35 percent from 2010 ($49.4 billion) to 2019 ($66.7 billion). However, U.S. GDP increased by 48 percent over this time. To have kept pace with the growth of GDP, exports would have had to increase to $73 billion. Over the same period, imports grew from $87 billion to $152 billion, a 75 percent increase.[141] This is one reason why the U.S. trade deficit in the sector has significantly worsened over the past decade, more than quadrupling from a deficit of $21 billion in 2010 to $85.7 billion in 2020, whereas in 2000, the trade deficit in the sector was just $3.4 billion. (See figure 19.) America's negative trade balance in pharmaceutical products and preparations is significantly worse than that for any other comparable nation.

Figure 19: Nations' trade balances in pharmaceutical products and preparations, 2001–2020[142]



Explaining Faltering U.S. Biopharmaceutical Competitiveness: International Factors

The U.S. biopharmaceutical industry appears to be following the same path as multiple other U.S. advanced-technology industries: progressive loss of domestic production, followed by a slow erosion of innovation capabilities. The end stage of this process—although clearly not here yet for biopharmaceuticals—is the significant decline or complete loss of the industry. As John McShane, a managing partner at the health care product consulting firm Validant argues, "To even get to 50% of our drugs being made in the U.S., it would take one to two decades and billions of dollars."[143] In other words, just as with semiconductors and the need for a $50 billion package to reinvigorate domestic production, the offshoring of so much biopharmaceutical manufacturing capacity would likewise require billions in investment to recapture that share. Adding on top of that significantly reduced industry revenues from strict drug price controls would only exacerbate the challenge.

This section examines international factors explaining faltering U.S. biopharmaceutical competitiveness, including foreign investment and R&D incentives and unfair foreign trade practices. The following section will consider explanatory domestic factors.

Foreign Investment and R&D Incentives

Many foreign nations recognize the value of growing their biopharmaceutical industry. That is why many countries have implemented aggressive and holistic incentives to attract biopharmaceutical industry investment.

For instance, the Chinese government has provided an array of incentives and supports, including research grants, for biopharma firms. The Beijing Genome Institute (BGI), the world's largest gene-sequencing organization, was funded in part by local government incentives and, in 2010, a $1.5 billion line of credit from the China Development Bank.[144] One study found that one-third of Chinese firms engaged in agricultural biotechnology research received government grants for R&D that play a key role in increasing firms' R&D spending.[145] Local Chinese governments are also providing financial incentives to help grow the industry, with one key incentive being large-scale biomedicine science parks. Zhang Zhaofeng, director of the Chinese Ministry of Science and Technology's Science and Technology for Social Development program, reported that by 2020, China will invest about $1.45 billion to support 20 biomedicine science parks.[146] This is in addition to the already over 100 national-level high-tech and economic industrial parks involving biotechnology, and more than 400 provincial-level parks.[147] For example, Shanghai's "Pharma Valley" is a 10-square-kilometer biopharmaceutical park that houses more than 500 biotech companies. Other local governments are also targeting the industry, in part by building research parks and providing tax incentives and direct subsidies.[148] Often, these provincial parks provide discounted or free office space, laboratory and small-scale production space for up to six months, and after that, free manufacturing space—for as long as five years. For example, the Shanghai government provides any company that obtains new drug approvals in China and intends to manufacture and sell the medicines in Shanghai with an annual subsidy equal to 10 percent of its initial research budget, up to a cap of 10 million RMB ($1.4 million).[149] Box A below expands on the challenge posed by China's burgeoning biopharmaceutical industry.

Singapore has offered a wide variety of incentives to attract biopharmaceutical investment, including development and expansion incentives (firms engaging in new projects or expanded or upgraded operations in Singapore are eligible for a concessionary tax rate of 13 percent for 10

years), accelerated depreciation allowances (instead of the normal 20 percent, companies can claim 33.3 percent over three years for all plants and machinery), and exemptions from withholding taxes on foreign loans. Some companies even benefit from "Pioneer Status" which is conferred upon new manufacturing investments which can qualify for complete exemption from the 25.5 percent corporate tax on profits for 5–10 years.[150] The biopharmaceutical industry leads foreign direct investment into Singapore, and these aggressive incentives, combined with other government support, contributed to Singapore's biopharmaceutical industry growing over three-fold from 2000 to 2010 alone.

Many nations recognize the value of growing their biopharmaceutical industries. That is why many have implemented aggressive and holistic incentives to attract biopharmaceutical investment.

Elsewhere, in May 2019, Korea introduced its "Innovative Strategy on the Bio-health Industry," a holistic strategy seeking to create a comprehensive, innovative ecosystem ranging from technology development, approval, production, and export.[151] The strategy increased the government's annual R&D investment in the sector to KRW 4 trillion ($3.3 billion), up from KRW 2.6 trillion ($2.15 billion) annually; increased financing for the industry from state banks by KRW 2 trillion ($1.7 billion) over five years; and established a big data strategy to support the sector's development, including the introduction of five new big data platforms.[152] To attract biopharmaceutical investment in particular, Korea has established seven government-assigned Free Economic Zones and provides financial aid to offset the cost of foreign manufacturers moving biopharmaceutical production to Korea.[153]

Many other countries have introduced incentives to attract R&D-intensive sectors such as biopharmaceuticals.[154] In terms of general tax incentives, Ireland offers a 25 percent tax credit—in addition to any available industrial allowances—for costs related to the construction or refurbishment of buildings used for R&D.[155] Belarus, Colombia, Russia, and Turkey all offer various forms of tax exemptions, including value added taxes (VAT), real estate, and land tax reductions or exemptions. Argentina provides VAT reimbursement and exceptions specifically for biotech companies, and Indonesia provides a tax allowance incentive for priority sectors, including the pharmaceutical and medical equipment sectors.

Box A: The China Challenge

For over a decade, the Chinese government has targeted biopharma as a key industry for development, developing a concerted national strategy to enable China to catch up to the United States in biopharmaceutical innovation.[156] The sector has been targeted in China's 13th and 14th Five-Year Plans, in the Made in China 2025 strategy, and through its Bio-Industry Development Plan. Moreover, at least 19 of China's 23 provinces have created their own biotechnology industry development strategies.

There is evidence these strategies are beginning to have an impact: from 2002 to 2018, China's share of global value added in the pharmaceutical industry grew over four-fold, from 5.6 to 23 percent, increasing from $14.4 billion to $162.5 billion.[157] Some of this is due to China being the leading producer of APIs in drugs, accounting for between 20 and 40 percent of global output, and being the world's largest API exporter, as well as a key generics producer.[158] China more than doubled its biopharmaceutical production capacity, including APIs, from 2010 to 2014.[159] Per a KPMG report on China's biopharmaceutical industry, "Thanks to substantial state support, the biopharmaceutical industry has enjoyed concentrated, high-speed growth over the past several years."[160]

China has also made rapid progress in biomedical knowledge creation. From 2011 to 2015, China ranked second in the world behind the United States in international biomedical publications.[161] And it quadrupled its global share of biomedical articles between 2006 (2.4 percent) and 2015 (10.8 percent).[162] In 2016, it was responsible for almost as many biotechnology and applied microbiology publications as the United States.[163] China also increased its pharmaceutical business R&D investment at a very rapid rate, by 254 percent from 2008 to 2015, compared with 7.3 percent growth for the United States.[164]

Finally, China is moving toward becoming a producer of innovative new drugs. As Fangning Zhang and Josie Zhou of the McKinsey Global Institute wrote, "[S]ome leading Chinese pharma companies that historically focused on generics have started building capabilities and making investments in innovative drugs."[165] They added, "[T]he number of applications of local innovative drugs entering clinical trials in China has grown from 21 in 2011 to 88 in 2016."[166] In 2017, 800 innovative molecules were under development in China, ranging from preclinical to phase III stages in the pipeline, of which 10 percent were at clinical stage III (the stage at which medicines are definitively tested for effectiveness or cure).[167] China is also making considerable progress regarding advanced anti-cancer drugs: in 2017, China had 139 clinical trials with chimeric antigen receptor treatment (CAR-T) cell therapy, compared with around 118 in the United States.[168]

Several countries have also instituted patent box regimes to attract biopharmaceutical industry investment, including Ireland, Italy, Portugal, the Slovak Republic, Spain, Switzerland, the United Kingdom, two Canadian provinces, and—most-recently introduced—Australia.[169] Beginning on July 1, 2022, the Australian patent box regime "will provide a 17 percent concessional tax rate for corporate income derived directly from medical and biotechnology patents" applied "in proportion to the percentage of the patents' underlying R&D activities conducted in Australia." Similarly, other countries have instituted various forms of IP-related incentives.

Foreign Unfair Trade Practices

As with semiconductors, the U.S. biopharmaceutical industry is often the target of unfair foreign trade practices, in areas such as IP theft, discriminatory procurement, or failing to pay their fair share for innovative medicines.

As in most technology fields, Chinese state-sponsored actors also target biopharma firms for theft of IP, including through cybertheft and rogue employees.[170] For instance, Chinese agents have hacked into systems at U.S. biopharma companies, including Abbott Laboratories and Wyeth (now part of Pfizer).[171] In 2018, Yu Xue, a leading biochemist working at a GlaxoSmithKline research facility in Philadelphia admitted to stealing company secrets and funneling them to Renopharma, a rival Chinese biotech firm funded in part by the Chinese government.[172] In 2019, MD Anderson and Emory University both dismissed Chinese-born scientists for theft of IP.[173] A report to the U.S. China Economic and Security Review Commission notes Ventria Bioscience, Genentech, GlaxoSmithKline, Dow AgroSciences LLC, Cargill Inc, Roche Diagnostics, and Amgen have all experienced theft of trade secrets or biological materials perpetrated by a current or former employee(s) with the intent to sell them to a Chinese competitor.[174] As the 2019 report of the U.S. China Economic and Security Review Commission to Congress concludes, IP theft has been a key reason for the emergence of China's biotech sector, which is becoming the world's leading producer of APIs.[175]

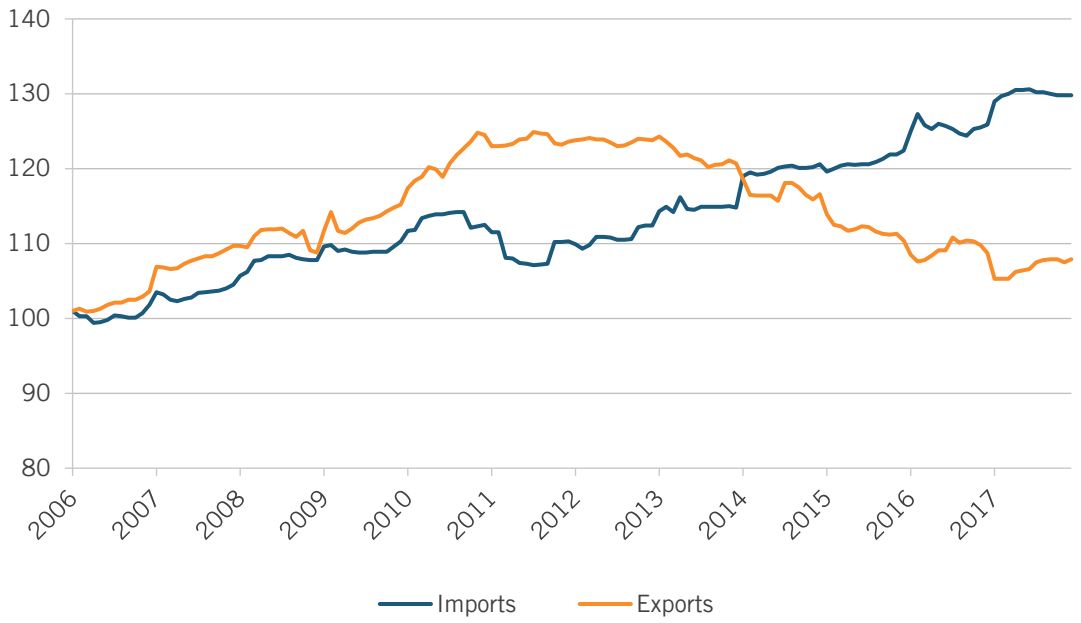
U.S. policymakers must be well-attuned to how foreign trade practices such as IP theft, discriminatory procurement, and failure to pay their fair share for innovative medicines affects the U.S. biopharmaceutical industry.

Likewise, some countries try to advantage domestic biopharmaceutical producers through discriminatory procurement practices. China is one. For instance, the 2016 State Council Document on the industry stated, "In principle, government procurement projects must purchase domestically produced products and gradually improve the level of domestic equipment configuration of public medical institutions."[176] Some argue that China uses the drug import license as an industrial policy tool, limiting imports in order to give domestic firms a respite from foreign competition. For example, the government did not approve the 2015 renewal of Pfizer's license for the importation of its Prevnar 7 drug, a pneumococcal vaccine. Some have argued this was in order to give a domestic pneumococcal vaccine more time to be developed free from competition.[177] Likewise, Japan's Pharmaceutical PMP, the program responsible for ascertaining reimbursement levels the government pays for innovative medicines, includes preferences when companies conduct more clinical trials and launch new products early in Japan. And countries such as Brazil and Russia offer significant price preferences in government procurement for locally manufactured biopharmaceutical goods.[178]

Another trade-related issue pertains to foreign nations not paying their fair share for America's innovative medicines. A significant cause of the United States' large trade deficits in pharmaceuticals and medicines manufacturing is that most other nations impose significant price controls on pharmaceuticals, artificially reducing the value—but not the quantity—of exports, making the trade deficit look worse than it actually is. A foreign country imposing price controls on drugs 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. The divergent prices helped explain roughly 40 percent of the U.S. pharmaceutical trade deficit in 2016 and 2017. (See figure 20.) 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.

Figure 20: BEA import/export price indexes for pharmaceutical and medicine manufacturing (Dec. 2005 = 100)[179]



Explaining Faltering U.S. Biopharmaceutical Competitiveness: Domestic Factors

As noted, foremost among the policies underpinning America's biopharmaceutical leadership have been: robust and complementary public and private investment in biomedical R&D; aggressive incentives, including tax policies, to encourage biomedical investment; robust IP rights and effective policies to support biomedical technology transfer, development, and commercialization; a drug pricing system allowing innovators to earn sufficient revenues for continued investment into future generations of biomedical innovation; and an effective regulatory/drug approval system. Unfortunately, the policy environment supporting biopharmaceutical innovation is weakening across many of these dimensions.

Undermining the Complementary Public-Private Biopharmaceutical R&D Investment Dynamic

A signature strength of America's biopharmaceutical innovation system has been the complementarity between public and private-sector investment in biopharmaceutical R&D. The federal government, principally through the National Institutes of Health (NIH), funds basic biopharmaceutical research that sets the stage for industry-led applied R&D activity. That activity leads to the commercialization of new medicines and treatments.[180] NIH-funded basic biopharmaceutical research—for instance, into understanding the fundamental processes by which diseases develop and are transmitted, or identifying novel biomarkers that signal the presence of a disease—creates a platform for innovation that has led not only to the discovery of

new medicines, but to new tests (e.g., blood tests for substances), new procedures (e.g., improved cardiac stents that substitute for surgery), and new equipment (e.g., gene sequencers).[181]

Whereas early-stage public-sector research elucidates the underlying mechanisms of disease and identifies promising points of intervention, the over $90 billion in U.S. business-funded research (while some is basic) focuses more on the downstream, applied research resulting in the discovery of drugs for the treatment of diseases, in addition to carrying out the development activities necessary to bring new drugs to market.[182] In other words, private-sector companies perform much of the applied R&D, including the completion of clinical trials required to transform basic scientific research into commercial products.

Moreover, public-private R&D investments are highly complementary and stimulative. Dr. Everett Ehrlich found that a dollar of NIH support for research leads to an increase of private medical research of roughly 32 cents.[183] Similar findings were reported in a 2012 Milken Institute study, which found that $1 of NIH funding boosted the size of the bioscience industry by $1.70, and that the long-term impact may be as high as $3.20 for every dollar invested.[184]

One study found that biotechnology companies invest approximately $100 in development for every $1 the government invests in research that leads to an innovation.

As a 2000 U.S. Senate Joint Economic Committee summarized the dynamic, "Federal research and private research in medicine are complementary. As medical knowledge grows, federal research and private research are becoming more intertwined, building the networks of knowledge that are important for generating new discoveries and applications."[185] Similarly, as DiMasi, Milne, Cotter, and Chakravarthy concluded from a 2016 study of the roles of the private and public sectors in drug development, "Industry's contributions to the R&D of innovative drugs go beyond development and marketing and include basic and applied science, discovery technologies, and manufacturing protocols," and that "without private investment in the applied sciences there would be no return on public investment in basic science."[186] In fact, one study found that biopharmaceutical companies invest as much as $100 in development for every $1 the government invests in research that leads to an innovation.[187] This highlights a critical point: it's private companies, not the government or universities, that assume the risk of failure in trying to bring often-billion dollar projects over the finish line of Phase III clinical trials.

However, this effective U.S. biopharmaceutical research a system is under threat from two dimensions. First, as ITIF wrote in "Why Biopharmaceutical Innovation Is Politically "Purple"—and How Partisans Get It Wrong," it's under threat from drug populists on the left and drug libertarians on the right who believe that biomedical research and innovation should be undertaken predominantly by the public sector, or private sector, respectively.[188]

Drug populists believe biopharma companies charge too much for drugs and that the government should impose price controls, weaken patent and other IP protections, and some even believe the government should take over drug innovation and production entirely. As Dean Baker writes, "We could expand the public funding going to NIH or other public institutions and extend their charge beyond basic research to include developing and testing drugs and medical equipment."[189] To that end, 2020 presidential candidate Senator Bernie Sanders (D-VT) has called for creation of a

Medical Innovation Prize Fund that would equal 0.55 percent of U.S. GDP, an amount greater than $80 billion per year, with the federal government funding half and private health insurance companies the other half.[190] Such advocates wish to delink the cost of R&D from the final price paid for a medicine, and make governments the planners and funders of drug development, although the truth is this would almost surely lead to less new drug development and slower progress in improving human health.[191]

While the position of drug populists is untenable, so is that of "drug libertarians" who argue that the private sector can and should do most, if not all, of the work involved in driving biomedical innovation. Just like drug populists, who seek to shrink the role of corporations, drug libertarians seek to shrink the role of government, arguing that a great deal of federal funding of biopharmaceutical research is wasted by bureaucracy and moreover that federal funding represents state confiscation of individuals' hard-earned money for a collective enterprise.[192] But such views fail to acknowledge the very real power of federally funded R&D in stimulating American innovation in general, and, as aforementioned, the biopharmaceutical sector in particular.[193]

Federal investment in biopharmaceutical R&D is indeed vital, but just as for semiconductors (and federal R&D funding broadly across all sectors), federal investment in biopharmaceutical R&D has been faltering. In fact, just to restore NIH funding to 2003 levels as a share of GDP, Congress would need to boost NIH funding by $11.6 billion per year. One effect of this relatively declining level of NIH funding is that the success rate of applications for investigator-initiated basic research grants at NIH—the "R01" grants—has fallen from nearly 60 percent in 1963 to just 20.2 percent in 2018.[194] To be sure, the Biden administration has called for increasing NIH's current funding level of $42 billion by $9 billion to $51 billion in its FY 2022 NIH budget request and similar increases are contemplated in the Senate-passed United States Innovation and Competitiveness Act (USICA).[195] Congress and the Biden administration need to collaborate to ensure these increases are indeed realized.

Faltering Incentives, Including Tax Policies

Throughout the 1970s and 1980s, the United States introduced a number of incentives into the tax code to stimulate biomedical investment. In 1976, Section 936 released pharmaceutical manufacturers from taxes on profits made in Puerto Rico and other U.S. territories. The United States was the first country in the world to introduce, in 1981, an R&D tax credit. It introduced the Orphan Drug Tax Credit in 1983. Each of these tax incentives played an important role in stimulating biomedical innovation and production in the United States, but the effectiveness of all these measures have waned considerably over time.

Section 936 contributed to making Puerto Rico a pharmaceutical manufacturing powerhouse, turning the island into America's so-called "medicine cabinet." But while biopharmaceutical manufacturing still does account for more than half of Puerto Rican manufacturing activity and contribute 30 percent of Puerto Rico's GSP (gross state product), the phase out of the provision from 2006 to 2016 contributed to a shrinking of the sector, not to mention a 40 percent reduction in the territory's manufacturing jobs base.[196] This is why the territory's economy has shrunk nearly every year since phase out of the provision began in 2006.[197] Restoring Section 936 could return Puerto Rico to a biopharmaceutical manufacturing powerhouse, while providing both a solid foundation for the island's economic growth and providing a platform to expand API

manufacturing in the United States, reducing dependence on countries such as China and India for key pharmaceutical ingredients.[198]

In 1983, Congress introduced the Orphan Drug Tax Credit (ODTC), a federal tax credit available to pharmaceutical companies working to find cures for certain rare diseases that affect patient populations of fewer than 200,000 individuals.[199] There are approximately 7,000 rare diseases, the majority of which are genetic in nature and which affect between 25 and 30 million Americans, although approximately 95 percent have no effective treatment.[200] To incent research and development of drugs for such diseases, Congress set the ODTC equal to 50 percent of qualified clinical trial costs (and also offered a seven-year period of orphan drug exclusivity). Since the law's enactment, over 500 orphan products have been approved by the U.S. FDA, whereas prior to the law's introduction fewer than 40 drugs were approved in the United States to treat rare diseases and on average only two new orphan drugs were produced each year.[201] A 2015 study by the National Organization for Rare Disorders found that at least one-third fewer new orphan drugs would have been developed to treat rare diseases over the preceding 30 years had the act not been implemented.[202] Unfortunately, the TCJA halved the ODTC to just 25 percent.[203]

Throughout the 1970s and 1980s, the United States introduced a number of incentives into the tax code to stimulate biomedical investment, but the power and effect of these incentives have waned in the ensuing decades.

When the United States introduced the R&D tax credit in 1981 it was revolutionary and for well into the 1990s the United States maintained the world's most generous R&D tax credit. But by 2020, the United States had slipped to 24th out of 34 nations in a comparison group consisting of OECD member countries plus Brazil, Russia, India, and China. China's R&D tax subsidy, for example, is 2.7 times more generous than the United States'.[204]

Weakening Intellectual Property Protections

Robust IP rights have been essential to stimulating U.S. biopharmaceutical innovation. Unfortunately, across several dimensions, the robust IP protections the United States has effectively introduced to stimulate biopharmaceutical innovation are faltering.

The 1980 Bayh-Dole Act, which affords universities rights to the IP generated from federal funding, was hailed by *The Economist* in 2002 as "possibly the most inspired piece of legislation to be enacted in America over the past half-century" and identified in *The Hill* as one of the 15 highest-quality acts of legislation Congress has ever introduced.[205] As late as 1978, the federal government had licensed less than 5 percent of the as many as 30,000 patents it owned, while a 1979 study by then-comptroller general Elmer Staats found that "not a single drug had been developed when patents were taken from universities [by the federal government]."[206] The Bayh-Dole Act reversed this, turning American universities into engines of innovation and unlocking the latent potential of federally funded R&D that was otherwise sitting on shelves. Academic technology transfer, largely enabled by Bayh-Dole, has supported the launch of over 13,000 start-ups while well over 250 new drugs and vaccines have been developed through public-private partnerships since the Bayh-Dole Act was enacted in 1980.[207]

But now some wish to misapply an arcane provision in the Bayh-Dole Act, march-in rights, to enable the government to retroactively apply price controls on drugs whose provenance could in any way be traced to federally funded research that played a part in the drug's discovery or development. As ITIF writes in "The Bayh-Dole Act's Vital Importance to the U.S. Biopharmaceutical Innovation System," such proposals are misguided for a multitude of reasons, but most importantly because the act prescribed only four very specific instances in which the government would be permitted to exercise march-in rights, and lowering drug prices is not one of them.[208] Even the bipartisan architects of the law, Birch Bayh and Bob Dole, have said explicitly that the Bayh-Dole Act's march-in rights were never intended to control or ensure "reasonable prices" and that "The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research."[209]

The Bayh-Dole Act helped turn American universities into engines of innovation while unlocking the latent potential of federally funded R&D that was otherwise sitting on shelves.

Nevertheless, some lawmakers—including Senators Elizabeth Warren (D-MA) and Amy Klobuchar (D-MN) and Representative Lloyd Doggett (D-TX) in a July 2021 letter to Health and Human Services Secretary Xavier Becerra—have asked the Biden administration to misuse Bayh-Dole march-in rights provisions to control drug prices.[210] But as Joe Allen writes, "While making health care more affordable is a laudable goal, it can't be done on the back of Bayh-Dole…The system of public-private collaboration established by the Bayh-Dole Act is the most successful in the world. Making the commercialization process even riskier will create fewer critically needed drugs without doing anything to control costs."[211]

The aforementioned legislators, along with other civil society advocates, have also misguidedly called for the government to use 28 U.S.C. § 1498 of U.S. law, an authority which permits the government to "manufacture, import, and use" products protected by active patents, as long as it provides patent holders with "reasonable and entire compensation for such use and manufacture" to compulsorily license the IP (to others, so that they may manufacture them) for innovative drugs whose price the government might deem to be too high. But as Sean Conner of the Center for the Protection of Intellectual Property Rights writes, "while Section 1498 is often mischaracterized as a compulsory license, it is in some ways the complete opposite." As he elaborates:

> Due to sovereign immunity, patent owners could not sue the government for infringement into the early 20th century. However, Congress can enact statutory exceptions to this general principle. Section 1498 does just that by giving patentees an express right to sue the government for full and fair compensation in the Court of Federal Claims. Thus to call this a compulsory license turns the statute on its head. The government is no more "authorized" to infringe patents than are private individuals.[212]

In other words, just as with Bayh-Dole march-in rights, advocates are asserting new interpretations of laws that simply aren't there and even trying to turn the original intention of

laws entirely around. It should go without saying that weakening the certainty of access to IP rights, whether through 28 U.S.C. § 1498 or Bayh-Dole march-in rights to address drug pricing issues—especially if it meant a government entity could walk in and retroactively commandeer innovations that private-sector enterprises invested hundreds of millions, if not billions, to create—would significantly diminish private businesses' incentives to commercialize products supported by federally funded research.[213]

Yet there's another area where advocates are trying. In October 2015, India and South Africa petitioned the WTO's Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) asking for a waiver to suspend all IP rights associated with COVID-19 technologies and innovations. As the petition itself acknowledged, "To date, there is no vaccine or medicine to effectively prevent or treat COVID-19."[214] In other words, even though the knowhow and IP that would be needed to combat COVID-19 with effective vaccines and therapeutics hadn't even been invented yet, the petitioners already felt the need to abrogate IP rights on drugs that didn't even yet exist. As ITIF has written, on the contrary, IP rights have actually played a catalytic role in both the innovation behind COVID-19 vaccines and therapeutics and in facilitating scores of voluntary licensing agreements to bolster global COVID-19 vaccine and therapeutic production.[215] Indeed, there's simply no evidence that invalidating IP rights would achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries such as Brazil, Egypt, and India.[216] In part through those voluntary licensing arrangements, the global biopharmaceutical industry will produce over 12 billion COVID-19 vaccines in 2021.[217]

If government entities could walk in and retroactively commandeer the IP behind innovations that private-sector enterprises invested hundreds of millions, if not billions, to create it would substantially chill incentives to invest in biopharmaceutical innovation.

Lamentably, in May 2021, the Biden administration announced its support for the COVID-19 TRIPS IP Waiver, although the status of the waiver remains uncertain as it is still being negotiated at the WTO and won't be taken up again until the next WTO Ministerial meeting at the end of November 2021.[218] While the status of the waiver remains in abeyance, a positive development occurred on October 25, 2021, when the Biden administration concluded, after a months-long legal review, that it lacks the legal authority to divulge details of COVID-19 vaccine-maker Moderna's vaccine production process.[219] That should be a lesson and a decision that policymakers in all countries, including not just the United States, heed. The reality is that innovating new to the world drugs takes years and usually billions of dollars. Robust IP rights protect those investments and allow biopharmaceutical innovators to earn a return on them that they can reinvest into future generations of biomedical innovation; imperiling IP rights puts that effective and productive system at risk.

Drug Price Controls Risk U.S. Biopharma Competitiveness

In addition to robust IP rights, another key feature of the U.S. biopharmaceutical innovation system has been a drug pricing and reimbursement system that allows innovators to earn sufficient revenues. The complexity, risk, and expense of biopharmaceutical innovation explains why the CBO estimates pharmaceutical companies need to earn a margin of 62.2 percent on

their successful products in order just to average a 4.8 percent rate of return on all of their assets.[220]

Capitol Hill has been awash in proposed legislation to stem allegedly out of control drug prices, and on November 2, 2021 Senate Democrats, backed by the White House, reached agreement on reconciliation bill provisions that would empower Medicare to negotiate the price of some drugs and penalize drug companies for raising prices faster than the rate of inflation.[221] Government price negotiations would begin with 10 drugs in 2023, starting with some of the most innovative drugs, including treatments for cancer and arthritis as well as some anticoagulants. And while Senate leaders assert that the drugs will be subject to "price negotiations," it's more likely they'll be subject to arbitrary government price setting.

Academic studies consistently demonstrate that a reduction in current drug revenues leads to a decrease in future research and the number of new drug discoveries.

Unfortunately, in this zealousness to rein in drug prices, policymakers risk imperiling future generations of biomedical innovation, to the detriment of both patients and the broader economy. That's because the link between revenues and R&D investment is intrinsic to the biopharmaceutical industry. It's why the OECD has found that "there exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures" and why there's a statistically significant relationship between a biopharma enterprise's revenues in the previous year and its R&D expenditures in the current year.[222] Indeed, every $2.5 billion of additional biopharmaceutical revenue leads to one new drug approval.[223]

And this explains why academic studies consistently demonstrate that a reduction in current drug revenues leads to a decrease in future research and the number of new drug discoveries.[224] For instance, one study found that a real 10 percent decrease in the growth of drug prices would be associated with an approximately 6 percent decrease in pharmaceutical R&D spending as a share of net revenues.[225] Similarly, Columbia University's Frank Lichtenberg found a 10-percent decrease in cancer drug prices would likely cause a 5- to 6-percent decline in both cancer regimens and research articles.[226] Likewise, Golec and Vernon show that if the United States had used an EU-like drug pricing system from 1986-2004, this would have resulted in a decline in firms' R&D expenditures of up to 33 percent and the development of 117 fewer new medicines.[227]

The CBO examined the potential impact of the proposed House legislation H.R. 3, which among other provisions would require drug companies to negotiate lower prices with the government. CBO's preliminary conclusion was that reducing manufacturers' revenues by between $500 billion and $1 trillion over the next decade could result in 8 to 15 fewer new drugs coming to market over that time (out of about 300 that would otherwise be expected), reducing the number of new drugs by 3 to 5 percent over the ensuing decade.[228]

Put simply, drug price controls decrease future biomedical innovation. Fortunately, the converse is true, which is why one study found that if government price controls in non-U.S. OECD countries were lifted—that is, if other countries paid their fair share for innovative medicines—the number of new treatments available would increase 9 to 12 percent by 2030, equivalent to 8 to 13 new drugs in that year, with this dynamic increasing the life expectancy of a 15-year-old

OECD citizen today by 0.6 to 1.6 years on average.[229] All this explains why the U.S. Council of Economic Advisors has written that while lowering reimbursement prices in the United States would reduce the prices Americans pay today for biopharmaceutical products, it would "make better health costlier in the future by curtailing innovation," thus failing to achieve the goal of reducing the health care prices, by reducing incentives for innovative products in the future.[230]

Moreover, policymakers seeking to impose strict price controls on drugs have a natural experiment to learn from: When many European nations went down the same road in the 1980s, the result was dramatic—a transfer of global competitive advantage and jobs to the United States. There is no reason to believe that if U.S. policymakers follow Europe's lead by price controls the result would not be a weakening of U.S. competitive advantage, and likely a shift over the next two decades of biopharma leadership to China.

There is no reason to believe that if U.S. policymakers follow Europe's lead by imposing price controls the result would not be a weakening of U.S. competitive advantage, and likely a shift over the next two decades of biopharma leadership to China.

Instead of trying to slash prices on the dubious theory drug companies can make do with lower revenues, lawmakers should turn their attention to the other side of the industry's ledger—the staggering cost of R&D—by spurring the kinds of innovations that can radically improve R&D productivity. A new slate of biomedical technologies including AI, CRISPR gene editing, and biologics manufacturing is transforming how new drugs are discovered, developed, and clinically tested.[231] Capitalizing on these trends to lower the cost of drug innovation is the only viable way to achieve what everyone wants—a long-term trend toward producing more cures (and more ancillary economic benefits) at less cost.

Investing More in Advanced Biopharmaceutical Manufacturing Process Innovations

Lastly, as the Biden administration's 100-Day Supply Chain review observed, "To build diversification and redundancy into the supply chain for pharmaceuticals and APIs, and to support national economic growth, a greater proportion of manufacturing of pharmaceuticals and APIs will need to occur in countries other than those with the lowest labor costs and least robust environmental frameworks."[232] As the report elaborates:

> Advanced manufacturing technologies could enable United States-based pharmaceutical manufacturing to bolster its competitiveness with those of foreign countries and potentially ensure a stable supply of drugs critical to the health of U.S. patients, as well as increase good-paying American jobs. [But] in spite of the benefits provided, the cost of adoption for advanced manufacturing processes remains a limiting factor, especially for generic manufacturers.[233]

This is why ITIF has called for substantially increased investments in biopharmaceutical process innovation that can make it more attractive and cost effective to manufacture drugs and APIs in the United States. Indeed, higher U.S. labor costs can be offset by using and investing in more and better machinery, which in turn would lead to a virtuous cycle of production: higher wages, leading to better machinery and organization of work, and higher skills. As Drew Endy, a member

of the bioengineering faculty at Stanford University, explained, "America could disrupt the currently dominant batch manufacturing processes used to make APIs with a less capital-intensive continuous-manufacturing process based on flow chemistry."[234]

The opportunity here is significant. One study contends that pharmaceutical manufacturing is expensive, inefficient, and non-innovative, with firms using outdated production techniques and old plants.[235] The study estimates modern biomanufacturing techniques could eliminate as much as $50 billion in annual production costs. The following section includes policy recommendations to stimulate U.S. biopharmaceutical process innovations.

POLICY RECOMMENDATIONS

In addition to threading policy proposals throughout this report, ITIF has comprehensively documented its full suite of policy recommendations to restore U.S. semiconductor competitiveness in its report "An Allied Approach to Semiconductor Manufacturing" and to sustain biopharmaceutical competitiveness in its report "Ensuring U.S. Biopharmaceutical Competitiveness Act."[236] The following provides a summary of the recommendations related to America's biopharmaceutical industry.

Maintain U.S. Strengths

- The Biden and future administrations should not introduce drug price control schemes, such as HHS' proposed International Pricing Index Model for Medicare Part B Drugs.
- NIST should affirm that price is not an adequate basis for the exercise of march-in rights under the Bayh-Dole Act.
- Congress should reauthorize the Prescription Drug User Fee Act (PDUFA) when renewal comes up in 2022, and continue to incorporate innovation-enhancing elements to it.
- The U.S. Treasury should apportion any withheld user fees to the USPTO with alacrity, in order to fund continued, uninterrupted USPTO operations.

Expand and Adopt New Policies to Spur Greater Domestic Innovation

R&D Funding

- Congress should at least restore NIH funding to 2003 levels as a share of gross domestic product (GDP), which would entail boosting NIH funding by $11.6 billion annually.

Investment Incentives

- Congress should at least double the Alternative Simplified R&D tax credit.
- Congress should amend the existing collaborative R&D tax credit to allow companies to take a flat 20 percent tax credit when they invest in university R&D activity.
- Congress should stimulate further investment in rare-disease R&D and innovation by restoring the orphan drug tax credit to 50 percent.
- Federal support for joint industry-university research efforts in biopharma R&D efficiency and effectiveness should be expanded.

Support Policies to Spur Increased Domestic Production

Support R&D for Biopharma Process Innovation

- Congress should significantly expand funding for biomedical Manufacturing USA centers, including for the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), as well as establish other centers that address related manufacturing technology challenges.
- Federal funding for NIIMBL and the other Institutes of Manufacturing Innovation that constitute the Manufacturing USA network should be ongoing and not sunset.
- Congress should fund NSF to both expand support to university-industry research centers working on biopharmaceutical production technology and establish new centers.
- Congress should increase funding for NSF's Division of Engineering, and target much of the increase to the Chemical Process Systems Cluster and Engineering Biology and Health Cluster.
- The administration should encourage the creation of the biopharma equivalent of the Semiconductor Research Corporation, a public-private consortium dedicated to developing long-term industry R&D and technology development roadmaps.
- The industry should collaborate on a production technology innovation roadmap, and the federal government should match industry funding to research institutes and universities on a dollar-for-dollar basis.
- Congress should establish an investment tax credit for new manufacturing facilities and equipment in the United States.

Create Incentives for Domestic Production

- Congress should task the administration with developing a national medical products strategy that would identify key vulnerabilities in biopharmaceutical and medical-product supply chains and develop solutions, where appropriate, to encourage reshoring or promote greater levels of domestic manufacturing at home.
- Congress should create the equivalent of the CHIPS (Creating Helpful Incentives to Produce Semiconductors) Act, legislation supporting the expansion of U.S. semiconductor production, for the biopharmaceutical industry. This would include allocating at least $5 billion per year to states (matched at least with 50 cents in state funding for every $1 in federal funding) to provide incentives for the establishment of new biomedical production facilities in the United States.
- Congress should restore the tax credit for biopharma production in Puerto Rico and other U.S. territories.

Improve Regulations of Biomedical Production

- Congress and the administration should continue to work with the FDA to streamline and accelerate the agency's capacity to evaluate and approve innovative new pharmaceutical manufacturing processes.

More Aggressively Contest Foreign Biopharmaceutical Mercantilism

- A key objective of U.S. trade policy should be to prevail on America's trade partners to appropriately value innovative medicines.

- Congress should use the opportunity of Trade Promotion Authority (TPA) renewal to affirm that a key priority of U.S. trade policy should be that America's trade partners pay their fair share for innovative drugs.
- U.S. trade policy needs to resist the mistaken view that IP is not a trade policy issue. At a minimum, U.S. administrations should continue to seek at least 10 years of data exclusivity in free trade agreements (FTAs), including the FTA currently being negotiated with the United Kingdom and also the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP), which the Biden administration should have the United States join.
- The United States Trade Representative's Office should continue to contest countries' data localization practices and restrictions on genomic data movement as well as promoting rules, such as those in the United States-Mexico-Canada (USMCA) free trade agreement,, that promote open data flows and proscribe data localization measures.

CONCLUSION

For over half a century, the United States' role in the global innovation ecosystem was to be the seedbed for innovation, generating the discoveries, and moving them into the market, but all too often seeing the production performed offshore, either by U.S. or foreign companies. Once this dynamic matured, and foreign producers had increased their learning, and U.S. producers had seen theirs erode, industry leadership was lost.

Over the last decade, the process has become even more untenable. Too many countries, especially China, have put in place sophisticated and effective advanced-technology strategies to ensure that the United States is no longer the principal early-stage innovator. And they continue to expand their programs, including direct and indirect subsidies, to attract global production, weakening the U.S. innovation and production system.

On top of that, the U.S. business and finance system has exacerbated this dynamic, with most publicly traded companies pressured by equities markets into an "asset-lite" model where they are rewarded for shedding production (in the case of semiconductors becoming fabless; in the case of biopharmaceuticals, buying most of their ingredients from others).

Finally, U.S. policymakers have largely been indifferent to the need to ensure continued U.S. leadership in advanced-technology innovation and production. While policymakers are aware of this risk in semiconductors, most appear oblivious to the risk in the biopharma industry, or they simply don't care.

U.S. leadership in advanced-technology industries is neither guaranteed or assured, it requires constant curation and tending to the policy environment that supports advanced-technology industry innovation, and at minimum, avoiding policies that lead to outright harm. In large part through policy inattentiveness, the United States ceded its position as the world's leading semiconductor manufacturer, a situation which policymakers are now trying to redress through a $50 billion package to stimulate U.S.-based semiconductor innovation and production. Likewise, the United States has witnessed substantial decline of its domestic pharmaceuticals manufacturing capacity, and if similar trends continue and the policy environment continues to degrade, in the not-too-distant future policymakers may be having to look at a similar package to restore U.S. biopharmaceutical competitiveness and domestic manufacturing capacity.

Acknowledgments

The author would like to thank Robert Atkinson, Luke Dascoli, Jaci McDole, and Alex Key for their assistance with this report.

About the Author

ITIF Vice President, Global Innovation Policy Stephen J. Ezell focuses on science, technology, and innovation policy as well as international competitiveness and trade policy issues. He is the coauthor of *Innovating in a Service Driven Economy: Insights Application, and Practice* (Palgrave McMillan, 2015) and *Innovation Economics: The Race for Global Advantage* (Yale 2012).

About ITIF

The Information Technology and Innovation Foundation (ITIF) is an independent, nonprofit, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized by its peers in the think tank community as the global center of excellence for science and technology policy, ITIF's mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress.

For more information, visit us at www.itif.org.

ENDNOTES

1. Robert D. Atkinson, "Who Lost Lucent?: The Decline of America's Telecom Equipment Industry," *American Affairs Journal* Vol. IV, No. 3 (Fall 2020), https://americanaffairsjournal.org/2020/08/who-lost-lucent-the-decline-of-americas-telecom-equipment-industry/.
2. Giri Varadarajan, Jeff Scholsser, and Abhi Ahuja, "How asset-light strategies and models can boost business growth" (Ernst and Young, April 28, 2021), https://www.ey.com/en_us/strategy-transactions/how-asset-light-strategies-and-models-can-boost-business-growth; Nick Crafts, "Reversing Relative Economic Decline? The 1980s in Historical Perspective," *Oxford Review of Economic Policy* 7, No. 3 (1991): 81, https://www.jstor.org/stable/23606188.
3. Joe Kennedy, "How to Ensure That America's Life-sciences Sector Remains Globally Competitive" (ITIF, March 2018), https://itif.org/publications/2018/03/26/how-ensure-americas-life-sciences-sector-remains-globally-competitive.
4. Michael Collins, "Is US Manufacturing Losing Its Toolbox," *Industry Week*, August 16, 2019, https://www.industryweek.com/supply-chain/article/22028096/is-us-manufacturing-losing-its-toolbox.
5. Atkinson, "Who Lost Lucent?"
6. Wikipedia, "Market share of personal computer vendors," https://en.wikipedia.org/wiki/Market_share_of_personal_computer_vendors.
7. Author's calculations using UN Comtrade data on 2017 HS6 codes 880220, 880230, and 880240. Accessed via https://comtrade.un.org/data.
8. Although the U.S. share of the global solar photovoltaics cell market was just 7.22 percent in 2006, falling to 1.95 percent by 2013. Here, Germany lost the most share in the face of China's innovation mercantilist policies, its share falling from 19.1 to 2.4 percent, while China's rose from 13.9 to 60.4 percent over that time period. David M. Hart, "The Impact of China's Production Surge on Innovation in the Global Solar Photovoltaics Industry" (ITIF, October 2020), https://itif.org/publications/2020/10/05/impact-chinas-production-surge-innovation-global-solar-photovoltaics. Earth Policy Institute Data Center, "Climate, Energy, and Transportation," accessed July 23, 2020, http://www.earth-policy.org/data_center/C23.
9. National Science Board, "Science and Engineering Indicators, 2020: Production and Trade of Knowledge- and Technology-Intensive Industries," https://ncses.nsf.gov/pubs/nsb20205/introduction.
10. United States Census Bureau, "Trade in Goods with Advanced Technology Products," https://www.census.gov/foreign-trade/balance/c0007.html.
11. Robert D. Atkinson and Stephen J. Ezell, "Innovation Economics: The Race for Global Advantage," (New Haven, Connecticut; Yale University Press, 2012): 116.
12. Robert D. Atkinson, "The Global Third Way," *The International Economy* (Winter 2021), https://www2.itif.org/2021-winter-TIE-global-third-way.pdf.
13. Dr. Holger Schmidt, "Die Unwucht der Plattform-Ökonomie," https://www.platformeconomy.com/.
14. A July 2021 *Scientific American* article contended that "China is pulling ahead in [the] global quantum race," citing a report introducing a new Chinese superconducting quantum processor comprised of 66 superconducting qubits with performance characteristics rivaling Google's Sycamore quantum computer. Daniel Garisto, "China Is Pulling Ahead in Global Quantum Race, New Studies Suggest," *Scientific American*, July 15, 2021, https://www.scientificamerican.com/article/china-is-pulling-ahead-in-global-quantum-race-new-studies-suggest/.

15. Daniel Castro, Michael McLaughlin, and Eline Chivot, "Who Is Winning the AI Race: China, the EU or the United States?" (Center for Data Innovation, August 2019), https://datainnovation.org/2019/08/who-is-winning-the-ai-race-china-the-eu-or-the-united-states/.
16. Robert D. Atkinson and Caleb Foote, "Is China Catching Up to the United States in Innovation?" (ITIF, April 2019), https://itif.org/publications/2019/04/08/china-catching-united-states-innovation.
17. Collins, "Is US Manufacturing Losing Its Toolbox."
18. Atkinson and Ezell, "Innovation Economics: The Race for Global Advantage," 96-97.
19. National Association of Manufacturers, "Facts About Manufacturing," https://www.nam.org/facts-about-manufacturing/.
20. David Riker, "Export-Intensive Industries Pay More on Average: An Update," (Office of Economics Research, U.S. International Trade Commission, April 2015), https://www.usitc.gov/publications/332/ec201504a.pdf.
21. Semiconductor Industry Association (SIA), "What Is a Semiconductor?" https://www.semiconductors.org/semiconductors-101/what-is-a-semiconductor/.
22. Stephen Ezell, "An Allied Approach to Semiconductor Leadership" (ITIF, September 2020), 5, https://itif.org/publications/2020/09/17/allied-approach-semiconductor-leadership.
23. World Semiconductor Trade Statistics, "WSTS has published the Q2 2021 market figures," news release, August 16, 2021, https://www.wsts.org/76/Recent-News-Release; SemisMatter, "Powering the Economy," http://www.semismatter.com/why/.
24. For an in-depth and fantastic explication of the history of the America semiconductor industries, see the movie *The Real Revolutionaries*. IMDB, "The Real Revolutionaries," https://www.imdb.com/title/tt1531937/.
25. Atkinson, "Who Lost Lucent?"
26. PBS, "Integrated Circuits," https://www.pbs.org/transistor/background1/events/icinv.html.
27. Intel, "Intel's Founding," https://www.intel.com/content/www/us/en/history/virtual-vault/articles/intels-founding.html.
28. Congressional Research Service (CRS), "U.S. Semiconductor Manufacturing: Industry Trends, Global Competition, Federal Policy" (CRS, June 27, 2016), https://www.everycrsreport.com/files/20160627_R44544_77fdee097eaaac05bcf7bd6041d5bdf44b24c7b9.pdf; National Defense University, *Industry Study: Electronics* (Spring 2015): 1, https://es.ndu.edu/Portals/75/Documents/industry-study/reports/2015/es-is-report-electronics-2015.pdf.
29. Consumption as measured in value. Congressional Research Service, "Semiconductors: U.S. Industry, Global Competition, and Federal Policy" (CRS, October 2020), 47-48, https://fas.org/sgp/crs/misc/R46581.pdf; William F. Finan, "The International Transfer of Semiconductor Technology Through U.S.-Based Firms" National Bureau of Economic Research, Working Paper No. 118, (December 1975), http://www.nber.org/papers/w0118.pdf; Peter R. Morris, *A History of the World Semiconductor Industry*, (The Institution of Engineering and Technology, 1989): 141.
30. William C. Rempel and Donna K.H. Walters, "The Fairchild Deal : Trade War: When Chips Were Down," *The Los Angeles Times*, November 30, 1987, https://www.latimes.com/archives/la-xpm-1987-11-30-mn-16900-story.html.
31. Robert D. Atkinson, "Industry by Industry: More Chinese Mercantilism, Less Global Innovation" (ITIF, May 2021), https://itif.org/sites/default/files/2021-industry-chinese-mercantilism.pdf.
32. Charles S. Kaufman, "The U.S.-Japan Semiconductor Agreement: Chipping Away at Free Trade" *UCLA Pacific Basin Law Journal* Vol. 12, No. 2 (1994), https://escholarship.org/uc/item/6nm902k9.

33. Dylan Gerstel and Matthew P. Goodman, "From Industrial Policy to Innovation Strategy: Lessons From Japan, Europe, and the United States" (Center for Strategic and International Studies, September 2020), 30, https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/200901_Gerstel_InnovationStrategy_FullReport_FINAL_0.pdf. Information provided by the Semiconductor Industry Association.
34. Remarks of Tom Howell, Senior Counsel, DentonsUS at CSIS Roundtable on Industrial Policy: "Lessons From Sematech: U.S. Style Industrial Policy," January 28, 2020.
35. CRS, "Semiconductors: U.S. Industry, Global Competition, and Federal Policy," 48; Department of Defense, Defense Science Board, Task Force on Semiconductor Dependency, *Report of Defense Science Board Task Force on Semiconductor Dependency*, February 1987, at http://www.dtic.mil/cgi-bin/GetTRDoc?Location=U2&doc=GetTRDoc.pdf&AD=ADA178284.
36. Bill Bonvillian, "Emerging Industrial Policy Approaches in the United States" (ITIF, October 2021), 10, https://itif.org/publications/2021/10/04/emerging-industrial-policy-approaches-united-states.
37. CRS, "Semiconductors: U.S. Industry, Global Competition, and Federal Policy," 48-49.
38. Howell, "Lessons From Sematech: U.S. Style Industrial Policy."
39. Gerstel and Goodman, "From Industrial Policy to Innovation Strategy," 30.
40. CRS, "Semiconductors: U.S. Industry, Global Competition, and Federal Policy," 48-49; National Research Council, Policy and Global Affairs, Board on Science, Technology, and Economic Policy, Committee on Comparative Innovation Policy: Best Practice for the 21st Century, *21st Century Innovation Systems for Japan and the United States: Lessons from a Decade of Change: Report of a Symposium* (2009): 8, http://www.nap.edu/download/12194.
41. R.K. Cavin, L.W. Sumney, and R.M. Burger, "The Semiconductor Research Corporation: Cooperative research" *Proceedings of the IEEE* Vol. 7, Issue 9 (1989): 1327-1344, https://ieeexplore.ieee.org/document/35239/authors#authors.
42. Phone conversation between Stephen Ezell and Ken Hansen, July 13, 2020.
43. Cavin, Sumney, and Burger, "The Semiconductor Research Corporation: Cooperative research."
44. SRC, "SRC 2018 Annual Report" (SRC, 2018), 1, https://www.src.org/about/corporate-annual/2018.pdf.
45. Robert D. Atkinson, "Understanding the U.S. National Innovation System, 2020" (ITIF, November 2020), https://itif.org/publications/2020/11/02/understanding-us-national-innovation-system-2020.
46. Gerstel and Goodman, "From Industrial Policy to Innovation Strategy," 30.
47. Antonio Varas et al., "Government Incentives and U.S. Competitiveness in Semiconductor Manufacturing" (SIA and Boston Consulting Group), 7, https://www.bcg.com/en-us/publications/2020/incentives-and-competitiveness-in-semiconductor-manufacturing.
48. Semiconductor Industry Association, "2021 State of the U.S. Semiconductor Industry" (SIA, 2021), 18, https://www.semiconductors.org/state-of-the-u-s-semiconductor-industry/.
49. As of 2020, or the latest year available for country/region. SIA, "2021 State of the U.S. Semiconductor Industry," 18; Peter Cowhey, "Expanding the analysis of subsidies and semiconductors" (Power Point Presentation, World Semiconductor Congress, Honolulu, Hawaii, 2019).
50. National Center for Science and Engineering Statistics, "USPTO patents and patent families granted in semiconductors, by region, country, or economy: 1998–2018," accessed at https://ncses.nsf.gov/pubs/nsb20204/data and https://wayback.archive-it.org/5902/20160210221011/http:/www.nsf.gov/statistics/seind10/appendix.htm.

51. Paul Lilly, "TSMC 3nm Chip Production On Track For Late 2022 With Huge Power Efficiency Gains," *HotHardware*, June 7, 2021, https://hothardware.com/news/tsmc-3nm-chip-production-late-2022-power-efficiency-gains.
52. Aaron Pressman, "Intel has fallen behind again on its next big chip manufacturing improvement," *Fortune,* July 23, 2020, https://fortune.com/2020/07/23/intel-chip-manufacturing-delay-7-nanometer/.
53. Sukesh Mudrakola, "Intel's Next-Generation Chipmaking Roadmap: Where Does It Lead?" *TechGenix*, August 12, 2021, https://techgenix.com/ntels-next-generation-chipmaking-roadmap/.
54. Antonio Varas et al., "Strengthening the Global Semiconductor Supply Chain in an Uncertain Era" (Boston Consulting Group and Semiconductor Industry Association, April 2021), 35, https://www.semiconductors.org/wp-content/uploads/2021/05/BCG-x-SIA-Strengthening-the-Global-Semiconductor-Value-Chain-April-2021_1.pdf.
55. SIA, "2020 State of the U.S. Semiconductor Industry," 13.
56. Varas et al., "Strengthening the Global Semiconductor Supply Chain in an Uncertain Era," 17.
57. Ibid.
58. Ibid.
59. Lim Sung-hyun, Lee Jong-hyuk, and Minu Kim, "Korea vows to build world's largest semiconductor supply chain by 2030," *Pulse*, May 14, 2021, https://pulsenews.co.kr/view.php?year=2021&no=465248.
60. Stephen Ezell, "Moore's Law Under Attack: The Impact of China's Policies on Global Semiconductor Innovation" (ITIF, February 2021), https://itif.org/publications/2021/02/18/moores-law-under-attack-impact-chinas-policies-global-semiconductor.
61. Organization for Economic Cooperation and Development (OECD), "Measuring distortions in international markets: The semiconductor value chain" (OECD, November 2019), 77, https://www.oecd-ilibrary.org/docserver/8fe4491d-en.pdf.
62. Ibid., 9.
63. Saif M. Khan and Carrick Flynn, "Maintaining China's Dependence on Democracies for Advanced Computer Chips" (Brookings Global China in Partnership With the Center for Security and Emerging Technology, April 2020), 7, https://www.brookings.edu/research/maintaining-chinas-dependence-on-democracies-for-advanced-computer-chips/. Citing: OECD, "Measuring distortions in international markets: The semiconductor value chain," 84.
64. Alex Capri, "Semiconductors at the Heart of the US-China Tech War" (The Hinrich Foundation, January 2020), 29, https://www.hinrichfoundation.com/research/white-paper/trade-and-technology/semiconductors-at-the-heart-of-the-us-china-tech-war/.
65. David Manners, "China to run 4% of world's memory wafers in 2020," *Electronics Weekly,* November 21, 2019, https://www.electronicsweekly.com/blogs/mannerisms/memory-mannerisms/china-aiming-4-world-memory-market-2020-2019-11/.
66. Ezell, "Moore's Law Under Attack."
67. Douglas B. Fuller, Paper Tigers, Hidden Dragons: Firms and the Political Economy of China's Technological Development (Oxford, UK: Oxford University Press, July 2016), 137.
68. OECD, "Measuring distortions in international markets: The semiconductor value chain," 48.
69. United States Trade Representative's Office, "Findings of the Investigation into China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation Under Section 301 of the Trade Act of 1974" (USTR, March 2018), https://ustr.gov/sites/default/files/Section%20301%20FINAL.PDF.

70. SIA, "Sparking Innovation: How Federal Investment in Semiconductor R&D Spurs U.S. Economic Growth and Job Creation" (June 2020), 2, https://www.semiconductors.org/wp-content/uploads/2020/06/SIA_Sparking-Innovation2020.pdf. Author's calculations.
71. Alex Williams and Hassan Khan, "A Brief History of Semiconductors: How the U.S. Cut Costs and Lost the Leading Edge" (Employ America, March 2021), https://employamerica.medium.com/a-brief-history-of-semiconductors-how-the-us-cut-costs-and-lost-the-leading-edge-c21b96707cd2.
72. Gregory Tassey, "Rationales and Mechanisms for Revitalizing US Manufacturing R&D Strategies," *Journal of Technology Transfer* 35, no. 3 (2010): 283-333, http://www.nist.gov/director/planning/upload/manufacturing_strategy_paper.pdf.
73. Neil Turner, "What's gone wrong with the European pharmaceutical industry," *Thepharmaletter*, April 29, 1999, https://www.thepharmaletter.com/article/what-s-gone-wrong-with-the-european-pharmaceutical-industry-by-neil-turner; David Michels and Aimison Jonnard, "Review of Global Competitiveness in the Pharmaceutical Industry" (U.S. International Trade Commission, 1999), 2-3, https://www.usitc.gov/publications/332/pub3172.pdf.
74. John K. Jenkins, M.D., "CDER New Drug Review: 2015 Update" (PowerPoint presentation, U.S. Food and Drug Administration/CMS Summit, Washington, D.C., December 14, 2015), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM477020.pdf.
75. Jenkins, "CDER New Drug Review," 23; Ian Lloyd, "Pharma R&D Annual Review 2020 NAS Supplement," (PharmaIntelligence, April 2020), 3. https://pharmaintelligence.informa.com/~/media/informa-shop-window/pharma/2020/files/whitepapers/rd-review-2020-nas-supplement-whitepaper.pdf
76. European Federation of Pharmaceutical Industries and Associations, "The Research Based Pharmaceutical Industry: A Key Actor for a Healthy Europe" (EFPIA, 2006).
77. Shanker Singham, "Improving U.S. Competitiveness—Eliminating Anti-Market Distortions" (working paper, International Roundtable on Trade and Competition Policy, 2012).
78. Kimberly Cleaves, "Imbalanced Innovation," *Modern Drug Discovery* (July 2004): 23-24, http://pubsapp.acs.org/subscribe/archive/mdd/v07/i07/pdf/704business3.pdf.
79. Nathalie Moll, "Would the last pharmaceutical investor in Europe please turn the lights out," European Federation of Pharmaceutical Industries and Associations blog, January 3, 2020, https://www.efpia.eu/news-events/the-efpia-view/blog-articles/would-the-last-pharmaceutical-investor-in-europe-please-turn-the-lights-out/.
80. Arthur Daemmrich, "Where is the Pharmacy to the World? International Regulatory Variation and Pharmaceutical Industry Location," Harvard Business School, Working Paper 09-11, 2009, www.hbs.edu/ris/Publication%20Files/09-118.pdf.
81. Moll, op. cit.
82. Neil Turner, "European Pricing Squeeze," *PharmaExec.com,* October 1, 2002, https://www.pharmexec.com/view/european-pricing-squeeze.
83. Ibid.
84. Lakdawalla et al., "Policy Options for European Pharmaceutical Markets" (January 2008), https://healthpolicy.usc.edu/wp-content/uploads/2018/01/Lakdawalla20et20al.20200820Policy20Options20for20European20Pharmaceutical20Markets.pdf; Turner, "European Pricing Squeeze"; David J. Gross, "International Pharmaceutical Spending Controls: France, Germany, Sweden, and the United Kingdom," *Health Care Financing Review*, Vol. 15 (3): 27–140, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4193451/.
85. Cleaves, "Imbalanced Innovation," 23.

86. Joseph H. Golec and John A. Vernon, "European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending" National Bureau of Economic Research Working Paper 12676 (November 2006), 6-7, https://www.nber.org/system/files/working_papers/w12676/w12676.pdf.
87. Silvia M. Ess, Sebastian Schneeweiss, Thomas D. Szucs, "European Healthcare Policies for Controlling Drug Expenditure," *PharmacoEconomics* Vol. 21 (2003): 89-103, https://link.springer.com/article/10.2165%2F00019053-200321020-00002.
88. Ibid., 97.
89. Ibid., 93.
90. Gross et al., "International Pharmaceutical Spending Controls: France, Germany, Sweden, and the United Kingdom." *Thepharmaletter.com*, "Dutch Drug Pricing Plan "Will Be Disastrous," October 30, 1995, https://www.thepharmaletter.com/article/dutch-drug-pricing-plan-will-be-disastrous.
91. Daemmrich, op. cit. p. 9.
92. EFPIA, "The Pharmaceutical Industry in Figures: 2000" (EFPIA, 2000).
93. *Nature Biotechnology*, "Germany to drive down drug prices" 24 (April 2006): 377,
94. Turner, "What's gone wrong with the European pharmaceutical industry."
95. Turner, "European Pricing Squeeze."
96. Ibid.
97. Ibid.
98. Jim Gilbert and Paul Rosenberg, "Addressing the Innovation Divide: Imbalanced innovation" (Bain & Company, 2004), https://www.bain.com/insights/addressing-the-innovation-divide-imbalanced-innovation/.
99. Golec and Vernon, "European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending," 3.
100. Ibid., 28.
101. C.A. Brouwers, M.B. Silverstein, and T. Wolff, "Adverse Consequences of OECD Government Interventions in Pharmaceutical Markets on the U.S. Economy and Consumer" (The Boston Consulting Group Inc., 2004).
102. Lakdawalla et al., "Policy Options for European Pharmaceutical Markets," 3.
103. Ibid., 19.
104. Ibid., 9.
105. Gilbert and Rosenberg, ""Addressing the Innovation Divide: Imbalanced innovation."
106. Golec and Vernon, "European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending," 30.
107. Gilbert and Rosenberg, ""Addressing the Innovation Divide: Imbalanced innovation."
108. Arthur Daemmrich, "Where is the Pharmacy to the World? International Regulatory Variation and Pharmaceutical Industry Location" Harvard Business School Working Paper 09-118 (2009), 10, https://www.hbs.edu/ris/Publication%20Files/09-118.pdf.
109. Turner, "What's gone wrong with the European pharmaceutical industry."
110. Ibid.
111. Ibid.
112. Aurelien Portuese, "Pharmaceutical Consolidation & Competition: A Prescription for Innovation" (ITIF, June 2021), https://www2.itif.org/2021-pharmaceutical-task-force.pdf.
113. Daemmrich, "Where is the Pharmacy to the World?" 10.

114. Daemmrich, op. cit., 1.
115. Ibid., 10.
116. Justin Chakma et al., "Asia's Ascent—Global Trends in Biomedical R&D Expenditures" *New England Journal of Medicine* 370 No. 1 (January 2014); E.R. Dorsey et al., "Funding of US Biomedical Research, 2003-2008" *New England Journal of Medicine* 303 (2010): 137-43, http://www.ncbi.nlm.nih.gov/pubmed/20068207.
117. Congressional Budget Office (CBO), "Research and Development in the Pharmaceutical Industry" (CBO, April 2021), https://www.cbo.gov/publication/57126.
118. OECD, "Health at a Glance 2019" (OECD, 2019), 214, https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2019_4dd50c09-en; CBO, "Research and Development in the Pharmaceutical Industry."
119. NSF, "2020 Science and Engineering Indicators: Research and Development: U.S. Trends and International Comparisons," 33, https://ncses.nsf.gov/pubs/nsb20203.
120. European Federation of Pharmaceutical Industries and Associations (EFPIA), "The Pharmaceutical Industry in Figures, Key Data 2019," 8, https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf.
121. Ashley Mullard, "2020 FDA Drug Approvals" *Nature Reviews: Drug Discovery* Vol. 20 (February 2021): 85, https://media.nature.com/original/magazine-assets/d41573-021-00002-0/d41573-021-00002-0.pdf.
122. NSF, "Science and Engineering Indicators: 2020," Appendix table S6-6.
123. Ibid.
124. Author's calculations using global pharma revenue data from Statista (accessed at https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/) and firm revenues.
125. U.S. Bureau of Labor Statistics, "Productivity and Costs by Industry: Manufacturing and Mining Industries," news release, June 25, 2020, https://www.bls.gov/news.release/prin.htm.
126. Federal Reserve Bank of St. Louis, "Labor Productivity for Manufacturing: Pharmaceutical and Medicine Manufacturing (NAICS 3254) in the United States," https://fred.stlouisfed.org/series/IPUEN3254L000000000#0.
127. U.S. Bureau of Economic Analysis, "Underlying Detail, Value Added by Industry," accessed October 15, 2021 at https://apps.bea.gov/iTable/iTable.cfm?isuri=1&reqid=151&step=1.
128. Brad W. Setser, "The Irish Shock to U.S. Manufacturing," Council on Foreign Relations, May 15, 2020, https://www.cfr.org/blog/irish-shock-us-manufacturing; FRED, "Industrial Production: Manufacturing: Non-Durable Goods: Pharmaceutical and Medicine (NAICS = 3254)" accessed at https://fred.stlouisfed.org/series/IPG3254S.
129. Setser, "The Irish Shock to U.S. Manufacturing."
130. Kennedy, "How to Ensure That America's Life-sciences Sector Remains Globally Competitive."
131. Jim Miller, "Will Pharma Manufacturing Move Back to the US?" *Pharmaceutical Technology* Vol. 41, Issue 3 (March 2017), https://www.pharmtech.com/view/will-pharma-manufacturing-move-back-us-0.
132. Sydney Lupkin, "What Would It Take To Bring More Pharmaceutical Manufacturing Back To The U.S.?" *NPR,* April 24, 2020, https://www.npr.org/sections/health-shots/2020/04/24/843379899/pandemic-underscores-u-s-dependence-on-overseas-factories-for-medicines.

133. The White House, "FACT SHEET: Securing America's Critical Supply Chains," February 24, 2021, https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/24/fact-sheet-securing-americas-critical-supply-chains/.

134. Ernst R. Berndt, Rena M. Conti, and Stephen J Murphy, "The Generic Drug User Fee Amendments: An Economic Perspective," *Journal of Law and the Biosciences* Vol. 5, Issue 1 (April 2018): 103–141, https://dspace.mit.edu/bitstream/handle/1721.1/120507/lsy002.pdf?sequence=1&isAllowed=y.

135 "*Safeguarding Pharmaceutical Supply Chains in a Global Economy*," B*efore the U.S. House Committee on Energy and Commerce, Subcommittee on Health*, 116th Cong. (October 30, 2019) (statement of Janet Woodcock, Director of FDA Center for Drug Evaluation and Research), https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019.

136. Ibid.

137. Neriman Beste Kaygisiz et al., "The Geography of Prescription Pharmaceuticals Supplied to the U.S.: Levels, Trends and Implications," (National Bureau of Economic Research Working Paper No. 26524, December 2019), 44, https://www.nber.org/papers/w26524.

138. Ibid., 34.

139. Anthony Sardella and Paolo De Bona, "Safeguarding the United States pharmaceutical supply chain and policy considerations to mitigate shortages of essential medicines," 4, Washington University Olin School of Business, https://olinblog.wustl.edu/2021/06/olin-research-incentivize-domestic-drug-production-to-combat-medicine-shortages/.

140. Author's calculations using US Bureau of Economic Analysis, "Underlying Detail, Value Added by Industry" and "Underlying Detail, Gross output by Industry", accessed at https://apps.bea.gov/iTable/iTable.cfm?isuri=1&reqid=151&step=1.

141. Census Bureau, USATrade, "Exports & Imports by NAICS Commodities," accessed May 26, 2020, https://usatrade.census.gov/.

142. International Trade Center, "Trade Map Database: List of markets for the selected product," https://www.trademap.org/Country_SelProduct_TS.aspx?nvpm=1%7c%7c%7c%7c%7c30%7c%7c%7c2%7c1%7c1%7c3%7c2%7c1%7c2%7c1%7c1%7c1.

143. Lupkin, "What Would It Take To Bring More Pharmaceutical Manufacturing Back To The U.S.?"

144. "BGI Group," Wikipedia, https://en.wikipedia.org/wiki/BGI_Group.

145. H. Deng, "Impact of Government Policies on Private R&D Investment in Agricultural Biotechnology: Evidence from China" (Beijing Institute of Technology School of Management and Economics, July 2018), https://www.sciencedirect.com/science/article/pii/S004016251930188X.

146. "China's Biotech Sector to Exceed 4% of GDP by 2020: Authority," *ChinaDaily.com,* May 3, 2017, http://www.chinadaily.com.cn/business/2017-05/03/content_29181073.htm; John Carroll, "China Has a $1.45B Plan to Build Up Its Biotech Hubs – and Officials Are Moving Fast," *EndpointsNews,* May 3, 2017, https://endpts.com/china-has-a-1-45b-plan-to-build-up-its-biotech-hubs-and-officials-are-moving-fast/.

147. Gryphon Scientific, and Rhodium Group, "China's Biotechnology Development: The Role of US and Other Foreign Engagement" (report prepared for the U.S.-China Economic and Security Review Commission, February 2019), 39, https://www.uscc.gov/Research/china%E2%80%99s-biotechnology-development-role-us-and-other-foreign-engagement.

148. Yi-Ling Liu, "Pharma Valley, China's equivalent of Kendall Square, is expanding rapidly," *STAT News,* December 3, 2018, https://news.yahoo.com/shanghai-china-equivalent-kendall-square-093520932.html.

149. Maria Dahl, "What's Driving China's Impressive Level of Biotech Innovation," AstraZeneca, June 6, 2019, https://www.astrazeneca.com/what-science-can-do/labtalk-blog/oncology/whats-driving-chinas-impressive-level-of-biotech-innovation-06062019.html.
150. Hank Lim and Lim Tai Wei, "Sustainable Development Impacts of Investment Incentives: A Case Study of the Pharmaceutical Industry in Singapore" (Singapore Institute of International Affairs, 2010), https://www.iisd.org/system/files/publications/sd_impacts_singapore.pdf.
151. Korea Ministry of Health and Welfare, "Bio-health Industry to Achieve People-centered Innovative Growth," May 22, 2019, http://www.mohw.go.kr/eng/nw/nw0101vw.jsp?PAR_MENU_ID=1007&MENU_ID=100701&page=1&CONT_SEQ=349515.
152. Edward White, "S Korea boosts biotech funding as economy slows," *The Financial Times*, May 21, 2019, https://www.ft.com/content/a51d4568-7c37-11e9-81d2-f785092ab560.
153. InvestKorea, "Prestige BioPharma Korea," https://www.investkorea.org/ik-en/bbs/i-468/detail.do?ntt_sn=490760#.
154. EY, "Worldwide R&D Incentives Reference Guide," https://www.ey.com/en_gl/tax-guides/worldwide-r-and-d-incentives-reference-guide/.
155. PWC, "Corporate: Tax credits and incentives," https://taxsummaries.pwc.com/ireland/corporate/tax-credits-and-incentives.
156. Robert D. Atkinson, "China's Biopharmaceutical Strategy: Challenge or Complement to U.S. Industry Competitiveness?" (ITIF, August 2019), 16, https://itif.org/publications/2019/08/12/chinas-biopharmaceutical-strategy-challenge-or-complement-us-industry.
157. National Science Foundation, "Science and Engineering Indicators: 2020," Appendix table S6-6 (accessed June 11, 2020), https://ncses.nsf.gov/pubs/nsb20205/data.
158. European Commission and World Health Organization, "China policies to promote local production of pharmaceutical products and protect public health" (WHO, 2017), 16, https://www.who.int/phi/publications/china_policies_promote_local_production_pharm/en/; *China's Pursuit of Next Frontier Tech: Computing, Robotics, and Biotechnology, Before the US. China Economic and Security Review Commission,* 115th Cong. (2017) (Statement of Ben Shober, Founder and Managing Director, Rubicon Strategy Group and Senior Associate for International Health, National Bureau of Asian Research), 190.
159. KPMG, *The 13th Five-Year Plan-China's Transformation and Integration with the World Economy,* (October 2016), https://assets.kpmg.com/content/dam/kpmg/cn/pdf/en/2016/10/13fyp-opportunities-analysis-for-chinese-and-foreign-businesses.pdf.
160. Ibid.
161. Xiaoli Tang and Jian Du, "The performance of China's biomedical innovation: a scientometric analysis," *Science China Life Sciences*, no. 10, vol. 59 (2016): 1075, https://link.springer.com/content/pdf/10.1007/s11427-016-5078-6.pdf.
162. Ibid.
163. Task Force on American Innovation, "Second Place America: Increasing Challenges to U.S. Scientific Leadership" (April 2019), 42, http://www.researchcaucus.org/wp-content/uploads/2019/05/V3-Benchmarks-Highlights-Draft-Layout.pdf.
164. OECD, stats.oecd.org (accessed February 12, 2015). Shows R&D by main activity. The industries are defined as manufacture of basic pharmaceutical products and pharmaceutical preparations and manufacture of medical and dental instruments and supplies. Data is for 2008 and 2015 or latest year available.
165. Fangning Zhang and Josie Zhou, "What's next for pharmainnovation in China?" McKinsey & Company Pharmaceuticals & Medical Products, September 2017, 2,

https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-next-for-pharma-innovation-in-china.

166. Ibid, 3.
167. UBS, "China's Biotech Revolution," August 2, 2018, https://www.ubs.com/global/en/wealth-management/chief-investment-office/our-research/discover-more/2018/china-biotech.html.
168. With CAR-T treatment, cell-killing T-cells are removed from the body and engineered to recognize the relevant cancer target. After the edited T-cells (CAR-Ts) are reintroduced to the patient, they multiply and attack the target cancer cells. Zhang and Zhou, "What's next for pharma innovation in China?"
169. Ian Zhou, "Patent box tax regime," Parliament of Australia, https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/BudgetReview202122/PatentBoxTaxRegime (accessed November 5, 2021).
170. Office of the United States Trade Representative Executive Office of the President, *Update Concerning China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation,* (November 2018), 11, https://ustr.gov/sites/default/files/enforcement/301Investigations/301%20Report%20Update.pdf.
171. Zack Whittaker, "Justice Department Accuses Chinese Spies of Hacking Into Dozens of US Tech and Industry Giants," *TechCrunch,* January 2019, https://techcrunch.com/2018/12/20/us-indictment-tech-hacks-chinese/; Derek Lowe, "Chinese Pharma Espionage?" *Science Translational Medicine,* December 15, 2011, https://blogs.sciencemag.org/pipeline/archives/2011/12/15/chinese_pharma_espionage.
172. Jeremy Roebuck, "Chinese American scientist admits plot to steal GlaxoSmithKline's secrets for firm in China," *The Philadelphia Inquirer,* August 31, 2018, http://www.philly.com/philly/news/pennsylvania/philadelphia/chinese-american-scientist-admits-plot-to-steal-glaxosmithklines-trade-secrets-for-firm-in-china-20180831.html.
173. "Scientists Depart MD Anderson and Emory Over Undisclosed Ties to China," *ASH Clinical News,* May 2, 2019, https://www.ashclinicalnews.org/news/citing-theft-research-china-md-anderson-dismisses-three-scientists/.
174. Mark Kazmierczak et al., "China's Biotechnology Development: The Role of US and Other Foreign Engagement" (Gryphon Scientific and Rhodium Group, February 2019), 71, https://www.uscc.gov/sites/default/files/Research/US-China%20Biotech%20Report.pdf.
175. U.S.-China Economic and Security Review Commission, *2019 Report to Congress* (U.S.-China Economic and Security Review Commission, November 2019), 253, https://www.uscc.gov/annual-report/2019-annual-report.
176. Office of the State Council, National Policy on Health Industry, March 4, 2016, https://howtobehealthyforme.wordpress.com/2018/09/27/national-policy-on-health-industry/.
177. Chris Lo, "Is China the Next Great Hope For the Pharma Industry?" *Pharma Technology Focus,* https://pharma.nridigital.com/pharma_dec18/is_china_the_next_great_hope_for_the_pharma_industry.
178. United States Trade Representative, "2020 National Trade Estimate on Foreign Trade Barriers" (USTR, 2020), https://ustr.gov/sites/default/files/2020_National_Trade_Estimate_Report.pdf.
179. Bureau of Economic Analysis, Series ID EIUIY3254 and EIUIZ3254, (accessed February 13. 2018) https://www.bls.gov/mxp/.
180. Dr. Everett Ehrlich, "An Economic Engine: NIH Research, Employment, and the Future of the Medical Innovation Sector" (United for Medical Research, 2011), 3, http://www.eyeresearch.org/pdf/UMR_Economic%20Engine_042711a.pdf.
181. Ibid., 3.

182. Ashley J. Stevens et al., "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines" *The New England Journal of Medicine* Vol. 364, Issue 1 (February 2011): 1, https://www.nejm.org/doi/full/10.1056/NEJMsa1008268.

183. Ehrlich, "An Economic Engine," 5.

184. Anusuya Chatterjee and Ross C. DeVol, "Estimating Long-Term Economic Returns of NIH Funding on Output in the Biosciences" (Milken Institute, 2012, 4), http://www.milkeninstitute.org/publications/view/535.

185. U.S. Senate Joint Economic Committee, "The Benefits of Medical Research and the Role of the NIH," May 17, 2000, https://www.faseb.org/portals/2/pdfs/opa/2008/nih_research_benefits.pdf.

186. Ranjana Chakravarthy et al., "Public- and Private-Sector Contributions to the Research and Development of the Most Transformational Drugs in the Past 25 Years: From Theory to Therapy," *Therapeutic Innovation and Regulatory Science* Vol. 50, Issue 6 (July 2016), https://www.ncbi.nlm.nih.gov/pubmed/30231735.

187. Sabarni K. Chatterjee and Mark L. Rohrbaugh, "NIH Inventions Translate Into Drugs and Biologics With High Public Health Impact," *Nature Biotechnology* 32, (2014): 56, https://www.nature.com/articles/nbt.2785?message-global=remove.

188. Robert D. Atkinson, "Why Life-Sciences Innovation Is Politically "Purple"— and How Partisans Get It Wrong" (ITIF, February 2016), https://www2.itif.org/2016-life-sciences-purple.pdf.

189. Dean Baker, "Malpractice" (Center for Economic Policy Research (CEPR), May/June 2009), http://cepr.net/publications/op-eds-columns/malpractice.

190. Delinkage.org, "Sen. Sanders Introduces Medical Innovation Prize Fund Act," March 2, 2017, https://delinkage.org/sen-sanders-introduces-medical-innovation-prize-fund-act/.

191. Philip Stevens and Stephen Ezell, "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won't Work" (ITIF, February 2020), https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work.

192. Atkinson, "Why Life-Sciences Innovation Is Politically "Purple"," 4.

193. Peter Singer, "Federally Supported Innovations: 22 Examples of Major Technology Advances That Stem From Federal Research Support" (ITIF, February 2014), https://www2.itif.org/2014-federally-supported-innovations.pdf.

194. Robert D. Atkinson et al. "Leadership in Decline: Assessing U.S. International Competitiveness in Biomedical Research" (ITIF, May 2012), https://itif.org/publications/2012/05/17/leadership-decline-assessing-us-international-competitiveness-biomedical; Mike Lauer, "NIH Annual Snapshot – FY 2018 By the Numbers," NIH, March 13, 2019, https://nexus.od.nih.gov/all/2019/03/13/nih-annual-snapshot-fy-2018-by-the-numbers/.

195. American Institute of Physics, "FY22 Budget Request: National Institutes of Health," June 8, 2021, https://www.aip.org/fyi/2021/fy22-budget-request-national-institutes-health.

196. Pharmaceutical Industry Association of Puerto Rico (PIA), "The Contribution of the Biopharmaceutical Industry in Puerto Rico," (PIA, 2017), https://piapr.org/wp-content/uploads/2019/04/PIA-BROCHURE-2017.pdf.

197. John Schoen, "Here's how an obscure tax change sank Puerto Rico's economy," *CNBC*, September 26, 2017, https://www.cnbc.com/2017/09/26/heres-how-an-obscure-tax-change-sank-puerto-ricos-economy.html.

198. José A. Cabranes, "Bring the Drug Industry Back to Puerto Rico," *The Wall Street Journal*, May 20, 2020, https://www.wsj.com/articles/bring-the-drug-industry-back-to-puerto-rico-11590015910.

199. Ray Esquivel and Rich Croghan, "How Pharmaceutical Companies Can Claim the Orphan Drug Tax Credit," Moss Adams, October 18, 2019, https://www.mossadams.com/articles/2019/october/orphan-drug-pharmaceutical-credit.
200. National Organization for Rare Disorders, "Rare Disease Day: Frequently Asked Questions," https://rarediseases.org/wp-content/uploads/2019/01/RDD-FAQ-2019.pdf.
201. Jennifer Huron, "Impact of the Orphan Drug Tax Credit on Treatments for Rare Diseases" (National Organization for Rare Disorders, June 17, 2015), https://rarediseases.org/odtcwhitepaper/.
202. Ibid.
203. Zachary Brennan, "Senate, House Agree to Cut Orphan Drug Research Credit in Half in Tax Bill," Regulatory Affairs Professionals Society news release, December 18, 2017, https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2017/12/senate,-house-agree-to-cut-orphan-drug-research-credit-in-half-in-tax-bill.
204. John Lester and Jacek Warda, "Enhanced Tax Incentives for R&D Would Make Americans Richer" (ITIF, September 2020), https://www2.itif.org/2020-enhanced-tax-incentives-rd.pdf.
205. Stephen Ezell, "The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System" (ITIF, March 2019), 20, https://itif.org/sites/default/files/2019-bayh-dole-act.pdf; "Innovation's Golden Goose," *The Economist*, December 12, 2002, http://www.economist.com/node/1476653; Frank T. Manheim, "Why most federal laws are flawed — and precious few succeed," *The Hill*, April 26, 2021, https://thehill.com/opinion/energy-environment/546604-why-most-federal-laws-are-flawed-and-precious-few-succeed.
206. B. Graham, "Patent Bill Seeks Shift to Bolster Innovation," *The Washington Post*, April 8, 1978; Stevens, "The Role of Public Sector Research," 536; Statement of Elmer B. Staats, comptroller general of the United States, Before the Committee on the Judiciary United States Senate, "S. 414-The University and Small Business Patent Procedures Act," May 16, 1979, https://www.gao.gov/assets/100/99067.pdf.
207. AUTM, "Driving the Innovation Economy: Academic Technology Transfer in Numbers," https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf.
208. John R. Thomas, "March-In Rights Under the Bayh-Dole Act" (Congressional Research Service, August 2016), 10, https://fas.org/sgp/crs/misc/R44597.pdf.
209. Birch Bayh and Bob Dole, "Our Law Helps Patients Get New Drugs Sooner," *The Washington Post*, April 11, 2002, https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?utm_term=.ddbf6876a380.
210. Elizabeth Warren, Amy Klobuchar, and Llyod Doggett, "Letter to the Honorable Xavier Becerra," https://www.warren.senate.gov/imo/media/doc/2021.07.28%20Letter%20to%20Secretary%20Becerra%20re%20Drug%20Pricing%20Authorities.pdf.
211. Joseph P. Allen, "President Biden: Don't misuse Bayh-Dole march-in rights," *STAT*, September 17, 2021, https://www.statnews.com/2021/09/17/president-biden-dont-misuse-bayh-dole-march-in-rights/.
212. Sean M. O'Conner, "No, the government cannot seize, break or 'bypass' pharmaceutical patents — even for COVID-19," *The Hill*, November 25, 2020, https://thehill.com/opinion/healthcare/527231-no-the-government-cannot-seize-break-or-bypass-pharmaceutical-patents-even.
213. Stephen J. Ezell, "Why Exploiting Bayh-Dole 'March-In' Provisions Would Harm Medical Discovery," April 29, 2016, https://www.innovationfiles.org/why-exploiting-bayh-dole-march-in-provisions-would-harm-medical-discovery/.
214. World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), "Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of COVID-19: Communication From India and South Africa" (WTO, October 2,

2020),
https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True..

215. Jaci McDole and Stephen Ezell, "How IP Has Enabled Innovations Sustaining Global Society Through the Pandemic" (ITIF, April 2021), https://itif.org/sites/default/files/2021-ip-covid-case-studies.pdf.
216. Philip Stevens and Mark Schultz, "Why Intellectual Property Rights Matter for COVID-19" (Geneva Network, January 2021), https://geneva-network.com/wp-content/uploads/2021/01/Why-IP-matters-for-Covid-19.pdf.
217. International Federation of Pharmaceuticals Manufacturers and Associations, "Momentum of COVID-19 vaccine manufacturing scale up sufficient for step change in distribution," news release, September 7, 2021, https://www.ifpma.org/resource-centre/momentum-of-covid-19-vaccine-manufacturing-production-scale-up-is-now-sufficient-for-step-change-in-distribution-and-opens-way-for-urgent-political-leadership-and-country-preparedness/.
218. Marc L. Busch, "Biden's support of the TRIPs waiver gives new life to a false narrative," *The Hill*, May 15, 2021, https://thehill.com/opinion/international/553676-bidens-support-of-the-trips-waiver-gives-new-life-to-a-false-narrative.
219. Dan Diamond, "White House: We don't have 'unlimited rights' to Moderna vaccine recipe," *The Washington Post*, October 25, 2021, https://www.washingtonpost.com/nation/2021/10/25/covid-delta-variant-live-updates/#link-BRKB4URRRNFAHA5EO27QLBN6UM.
220. Congressional Budget Office, "How Taxes Affect the Incentives to Invest in New Intangible Assets" (CBO, November 2018), 22–23, https://www.cbo.gov/system/files?file=2018-11/54648-Intangible_Assets.pdf.
221. Andrew Duehren, Lindsay Wise, and Richard Rubin, "Democrats Reach Deal on Lowering Prescription Drug Prices," *The Wall Street Journal*, November 2, 2021, https://www.wsj.com/articles/democrats-reach-deal-on-prescription-drug-pricing-schumer-says-11635879481.
222. Organization for Economic Cooperation and Development, *Pharmaceutical Pricing Policies in a Global Market* (OECD, September 2008), 190, http://www.oecd.org/els/pharmaceutical-pricing-policies-in-a-global-market.htm; Destrina Grace Simanjuntak and Raymond R. Tjandrawinata, "Impact of Profitability, R&D Intensity, and Cash Flow on R&D Expenditure in Pharmaceutical Companies" (Social Science Research Network, April 29, 2011), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1824267.
223. Pierre Dubois, "Market size and pharmaceutical innovation," *The Rand Journal of Economics* Vol. 46, Issue 4 (October 2015): 844–871, https://onlinelibrary.wiley.com/doi/full/10.1111/1756-2171.12113.
224. Joe Kennedy, "The Link Between Drug Prices and Research on the Next Generation of Cures" (ITIF, September 2019), https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures.
225. Carmelo Giaccotto, Rexford E. Santerre, and John A. Vernon, "Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry," The Journal of Law & Economics, Vol. 48(1) April
2005, https://www.jstor.org/stable/10.1086/426882?seq=1#page_scan_tab_contents.
226. Frank R. Lichtenberg, "Importation and Innovation," NBER Working Paper No. 12539, September 2006, https://www.nber.org/papers/w12539.
227. Joseph H. Golec and John A. Vernon, "European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending," NBER Working Paper No. 12676 (September 2006), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=932989.

228. Congressional Budget Office (CBO), "Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare" (CBO, October 11, 2019), https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf.
229. Taylor T. Schwartz et al., "The Impact of Lifting Government Price Controls on Global Biopharmaceutical Innovation and Population Health" (Precision Health Economics, 2018), https://tools.ispor.org/research_pdfs/58/pdffiles/PHP216.pdf.
230. Executive Office of the President, Council of Economic Advisors, "Reforming Biopharmaceutical Pricing At Home and Abroad" (Executive Office of the President, February 2018), 6, https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.
231. Joshua New, "The Promise of Data Driven Drug Development" (Center for Data Innovation, September 2019), https://www2.datainnovation.org/2019-data-driven-drug-development.pdf.
232. Executive Office of the President, The White House, "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth: 100-Day Reviews under Executive Order 14017" (The White House, June 2021), 237, https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.
233. Ibid.
234. Stephen Ezell, "Faulty Prescription: Why a 'Buy American' Approach for Drugs and Medical Products Is the Wrong Solution" (ITIF, June 2020), 10, https://itif.org/sites/default/files/2020-faulty-prescription.pdf.
235. W. Nicholson Price II, "Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing," *Boston College Law Review* Vol. 55, Issue 2 (2014): 492, https://lawdigitalcommons.bc.edu/bclr/vol55/iss2/5/.
236. Ezell, "An Allied Approach to Semiconductor Leadership"; Ezell, "Ensuring U.S. Biopharmaceutical Competitiveness."