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China's Biopharmaceutical Strategy: Challenge or Complement to U.S. Industry Competitiveness?

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China is challenging the United States for market share and jobs in one of the highest value-added, most innovation-intensive industries—and the risks extend not just to the U.S. economy, but to global biopharma innovation.

KEY TAKEAWAYS

The U.S. biopharmaceutical industry is a key driver of U.S. competitiveness and good jobs.

America's competitive position is being challenged by China, which has targeted the biopharma industry for development, in part through its "Made in China 2025" plan.

Like so many other industries in which China has gained global market share, the core component of its strategy appears to involve copying—in this case copying foreign drugs so it can develop and export generics.

While China has some positive biopharma policies, its strategy is mostly premised on "innovation mercantilism," including weak IP protection, biased drug approvals, severe price controls, subsidies, import restrictions, and substandard exports.

Rolling back China’s biopharma mercantilism is important—but the main way for the U.S. to remain competitive is to continue rapidly developing new drugs. That requires robust investments in R&D, which drug price controls would weaken.

OVERVIEW

Over the last two decades, China has successfully challenged American industrial competitiveness in many industries, but as China has gone all in on its "Made in China 2025" strategy, the challenge will increasingly be to U.S. advanced and innovation-based industries. However, America still maintains competitive advantage over many nations, including China, in the biopharmaceutical industry. In fact, since 2001, while U.S. manufacturing jobs have fallen, the number of biopharmaceutical jobs has increased over 20 percent. In short, biopharma is a U.S. manufacturing success story.

However, "Made in China 2025," as well as other plans, target life sciences for global leadership. China is taking a range of steps, including regulatory changes, funding of biomedical research and venture capital (VC), restructuring of the industry to eliminate many smaller producers, expanding medical tourism, and expediting listings on the Hong Kong exchange, to propel China to become a major global biopharma competitor—particularly by developing a world-class generics industry. However, while some of these policy actions are fair and legitimate, many are not because they are "innovation mercantilist" in nature, seeking to unfairly benefit Chinse firms at the expense of U.S. and other foreign firms. In other words, China is seeking to challenge the United States in one of the most high-value-added, innovation-intensive industries in the world—the kind of industry for which the United States has held a competitive advantage for decades.

To be sure, the Chinese market is large, growing rapidly, and represents significant market opportunities for producers in the United States, so U.S. policy should continue to push for market access. However, Chinese policies, if coupled with potential U.S. policy errors—particularly drug price controls that would slow down U.S. biopharma innovation—could mean that within the next decade or two, the U.S. biopharmaceutical industry could lose significant market share and jobs to China, hurting not only the U.S. economy and workers, but also global biopharmaceutical innovation.[1] However, unlike when the United States lost emerging technology industries such as solar panels to China, today, no one should be able to claim ignorance of China's playbook and end game. Should U.S. policymakers decide it is in the U.S. national interest to have a globally leading life-sciences industry, they will need to respond appropriately, particularly ensuring U.S. policies, including drug-pricing policies, support industry investment in research and development (R&D) and innovation.

This report first discusses the competitive position of the U.S. biopharmaceutical industry and why a competitive industry is in the U.S. national interest. It then examines the competitive position of China's biopharma industry, followed by a review of Chinese mercantilist industrial policies in other industries. The report then reviews China's strategy and policies for growing the biopharmaceutical industry. Finally, it discusses how the U.S. government should respond.

IMPORTANCE OF THE BIOPHARMACEUTICAL INDUSTRY TO THE U.S. ECONOMY

The biopharmaceutical sector includes research, discovery, testing, and manufacturing of medicines and therapeutics that cure disease and improve patient health. As life-sciences industry experts David Beier and George Baeder have written, there are at least four essential policy components nations need for a strong life-sciences innovation industry: "1) strong research and development infrastructure (including skilled researchers); 2) effective intellectual property protection; 3) integration in global standards of trade, IP [intellectual property], and drug regulation; and 4) functioning markets offering sufficient reimbursement."[2] The United States is one of the few nations with all four components, which is a major reason why it is highly competitive in life sciences, although with recent calls for drug price controls, it is at risk of seeing a weakening of the second and fourth factors.

These strengths are why employment in the biopharmaceutical industry (classified as a manufacturing industry by the U.S. government) grew 26 percent between 1998 and 2019, while total U.S. nonfarm employment increased 23 percent, and employment in manufacturing declined 27 percent.[3] Moreover, wages in the industry exceeded the average private wage by 50 percent or more in 43 states, and by more than 75 percent in 24 states.[4]

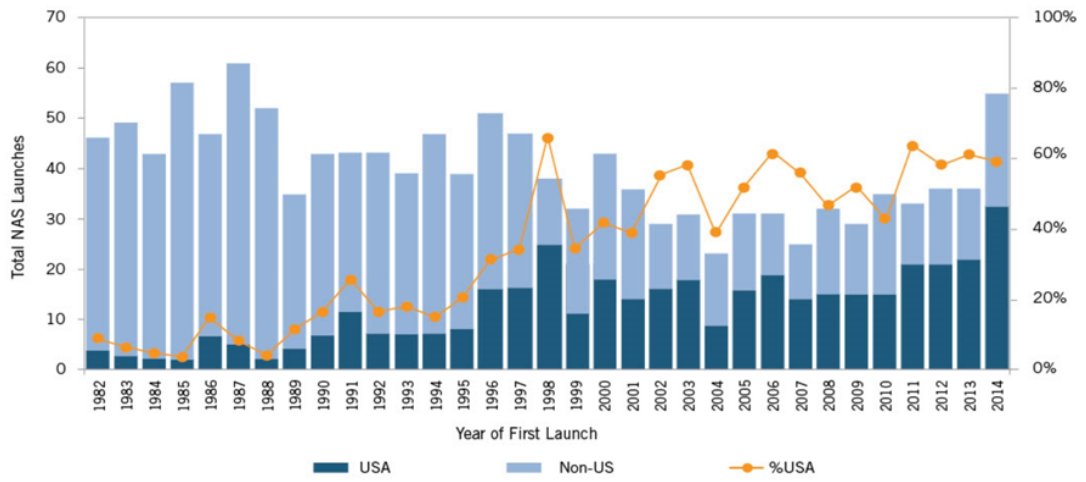
The sector, along with medical devices, performed $111.8 billion of R&D in 2016 (the most recent year for which public data is available), of which $85.9 billion was self-funded.[5] Of the total research performed, $79.4 billion was invested in the United States. Partly because 19 percent of its domestic employment was involved in research, the pharmaceutical industry accounted for 20.4 percent of all domestic R&D in the United States.[6] Moreover, the United States increased its share of pharmaceutical R&D expenditures among developed countries between 1995 and 2010 from 43 percent to 57 percent.[7] One reason is U.S. firms have kept most of their research activity at home, while European and Japanese firms have shifted some R&D to the United States.

This is why the United States remains the predominant powerhouse of drug discovery and production, ranking first in nearly all measures of innovation.[8] The Biopharmaceutical Competitiveness and Investment Survey ranked the United States first among mature markets in 2017, followed by Switzerland, Germany, and the United Kingdom.[9] The United States scored higher than the average of its top-three competitors in each of the survey's five categories, in addition to recently being ranked as the top location for life-sciences jobs in the world.[10] That same year, 11 of the top 25 pharmaceutical companies were headquartered in the United States, accounting for 48 percent of total sales from this group. Moreover, in 2015, the United States attracted 74 percent of all worldwide venture-capital investments in the biopharmaceutical industry.[11]

The United States leads the world in life-sciences innovation. In the 2000s, more new chemical entities were developed and approved by regulatory authorities in the United States than in the next five nations—Switzerland, Japan, the United Kingdom, Germany, and France—combined.[12] Broadening the lens to the years 1997 to 2016, U.S.-headquartered enterprises accounted for 42 percent of new chemical and biological entities introduced and approved around the world, far outpacing contributions from European Union member countries, Japan, China, and other nations.[13]

But this has not always been the case. In the latter half of the 1970s, European-headquartered enterprises introduced more than twice as many new drugs to the world as did those in the United States (149 to 66).[14] Throughout the 1980s, fewer than 10 percent of new active substances were introduced first in the United States, as figure 1 shows. And, as recently as 1990, the global research-based pharmaceutical industry invested 50 percent more in Europe than in the United States.[15] As Shankar Singham of the Institute of Economic Affairs noted, "Europe was the unquestioned center of biopharmaceutical research and development for centuries, challenged only by Japan in the post-war period."[16]

Figure 1: U.S. share of new active substances (NAS) launched in world market[17]



Yet, in recent decades, that picture has changed. Whereas less than 10 percent of new drugs were first introduced in the United States in the 1980s, by the 2010s, more than 60 percent of new drugs were first introduced in the United States.[18] By 2006, pharmaceutical companies invested 40 percent more in the United States than in Europe. And the United States has been the world's largest funder of biomedical R&D investment over the past two decades—a share some analysts have estimated has reached as high as 80 percent.[19] This has contributed to an unprecedented era of life-sciences innovation, and the retention and creation of good U.S. jobs. Over the last decade, biopharmaceutical companies have invested over half a trillion dollars in R&D, while more than 350 new medicines—many firsts of their kind—have been approved by the Food and Drug Administration (FDA).[20]

America's wresting of global life-sciences leadership has been no accident, but rather the result of a series of intentional policy decisions designed to make America the world's preeminent location for life-sciences research, product commercialization, and production. For instance, the United States' introduction of the world's first R&D tax credit in 1981 played a catalytic role in spurring greater levels of private-sector R&D. In the life-sciences sector, this was complemented by the 1986 introduction of the orphan drug tax credit, which allows drug manufacturers to claim a tax credit on research costs for orphan drugs (i.e., drugs for rare diseases affecting 200,000 or fewer U.S. patients). The 1992 introduction of the bipartisan Prescription Drug User Fee Act, which authorized the FDA to collect user fees associated with applications from the biopharmaceutical industry for regulatory approval of new human-drug submissions, has played a pivotal role in reducing the time it takes the FDA to make safety and efficacy determinations for new drugs—from the over 30 months it took on average in the mid-1980s to less than 10 months today.[21] America's strong IP system—including allowing 12 years of data exclusivity for biologics and providing a period of marketing exclusivity for drugs independent of exclusive patent rights, as well as providing patent linkage and patent term extension through the Hatch-Waxman Act—has helped spur investment.

Robust funding for the National Institutes of Health (NIH), especially the doubling of funding in the late 1990s and early 2000s, has helped lay the groundwork for robust biopharma innovation.[22] The United States also benefits greatly from having a drug-pricing system that permits companies to earn sufficient revenues from one generation of biomedical innovation to reinvest in the next. That matters greatly because, as the Organization for Economic Cooperation and Development (OECD) has written, "There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures."[23] Limited government price controls also make investing in the United States more attractive than in many other nations.[24]

The lesson of the U.S. gain in global competitive advantage in the biopharmaceutical industry should be clear. It was not based on absolute advantage (e.g., some nations being good in agriculture because they have a lot of arable land). Rather, it was and is based on competitive advantage (e.g., factors that are malleable by policy, such as a strong drug-approval system and reasonable drug pricing). As such, have competitive advantage in industries such as biopharmaceutical is something that has to be earned and worked at to retain. As some European nations and nations such as Japan found to their distress, competitive advantage is not a birthright; it can be lost. That should be the message for the United States: while the United States is doing well in the industry now, it could easily lose that advantage, particularly to China, which has targeted the industry for global leadership. This means that the United States needs to keep in place the right policies and make them even stronger while at the same time continuing to press China to roll back its innovation mercantilist practices in this industry.

THE COMPETITIVE POSITION OF CHINA'S BIOPHARMACEUTICAL INDUSTRY

As a recent Information Technology and Innovation Foundation (ITIF) report shows, China has made considerable progress in catching up to the United States in innovation.[25] On an average of 36 indicators, China has cut the gap with the United States by a factor of 1.5 from a decade ago to the present. (For example, had China been 80 percent behind the United States a decade ago, it would be just 50 percent behind today.) In other words, in the span of a decade, China has made dramatic progress in innovation relative to the United States. A major reason is China has put its mind, heart, and soul into not just being an innovator, but being, in the words of Chinese president Xi Jinping, "master of its own technologies." And China has backed that up with a powerful, often discriminatory, arsenal of state-directed industrial and trade policies.

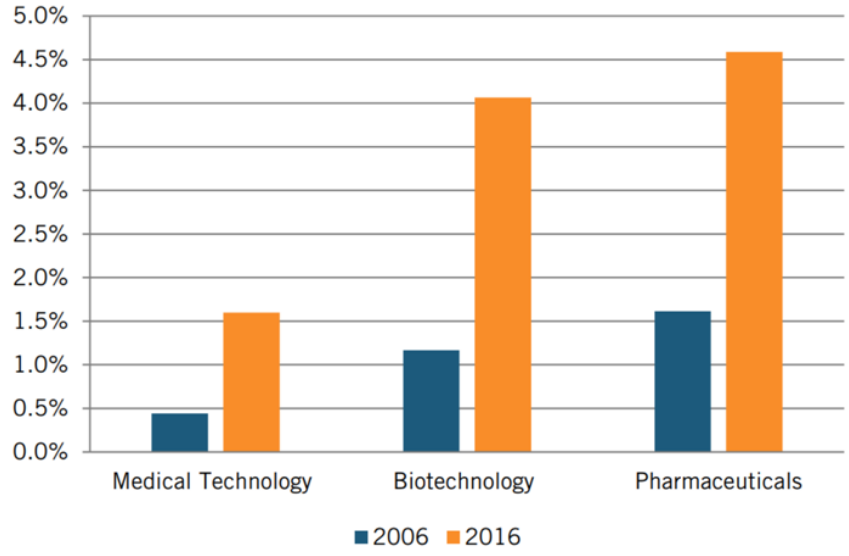
Yet, although China lags behind the United States in biopharma competitiveness, its government has targeted the industry, developing a concerted national strategy to enable China to catch up to the United States in biopharmaceutical innovation. And while China lags, it is making progress, starting with science and research. Between 2009 and 2013, Chinese government funding of medical research through the National Natural Sciences Foundation of China increased by a factor of 4, to $710 million.[26] Notwithstanding this, China accounts for just 1.8 percent of global government funding for medical research, compared with the United States' 44.2 percent.[27]

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.[28] And it quadrupled its global share of biomedical articles between 2006 (2.4 percent) and 2015 (10.8 percent).[29] In 2016, it was responsible for almost as many biotechnology and applied microbiology publications as the United States.[30] However, its share of documents in the top 1 percent of citations is lower than its overall share of articles.[31] Moreover, while the number of China's biology and medical-sciences articles relative to U.S. articles grew 161 percent and 147 percent, respectively, China still lags relatively far behind, publishing only 19 percent as many biology-sciences articles as the United States, and only 11 percent as many medical-sciences articles.[32] However, China is making faster progress in some cutting-edge areas. As the U.S.-China Economic and Security Review Commission noted, Chinese researchers increased their share of the world's genome-related scholarly papers, from 4.5 percent in 2010 to 17.3 percent by 2014.[33]

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.[34] In 2016, Chinese biopharma R&D stood at an estimated $7.2 billion, up from just $163 million in 2000.[35] However, China's biopharma firms' R&D-to-sales ratio was only around 2.7 percent, much lower than the U.S. average of 15 to 20 percent.[36]

For this reason, only 481 life-sciences patents (in medical technology, biotechnology, and pharmaceuticals) were granted to Chinese inventors in the United States in 2016. The rate of U.S. patents issued to Chinese companies for biotechnology and pharmaceuticals is only about half the overall rate of U.S. patents issued to Chinese companies. Biotechnology and pharmaceuticals patents issued to Chinese companies are only 4.1 and 4.6 percent, respectively, of the patents granted to U.S. companies. (See figure 2.) Medical technology patents increased most quickly of the three in absolute terms—more than eightfold from 2006 to 2016—but only accounted for 1.6 percent of the U.S. figure, due to significant domestic growth in U.S. patents.[37] Moreover, according to OECD, in 2106, China accounted for just 0.8 percent, 0.4 percent, and 1.5 percent, respectively, of triadic patents (patents filed in Europe, Japan, and the United States) in biotechnology, medical technology, and pharmaceuticals, compared with the U.S. share of more than approximately 40 percent in each.[38]

Figure 2: Life-sciences patents granted to Chinese inventors as a percentage of all life-sciences patents granted in the United States, 2006–2016[39]



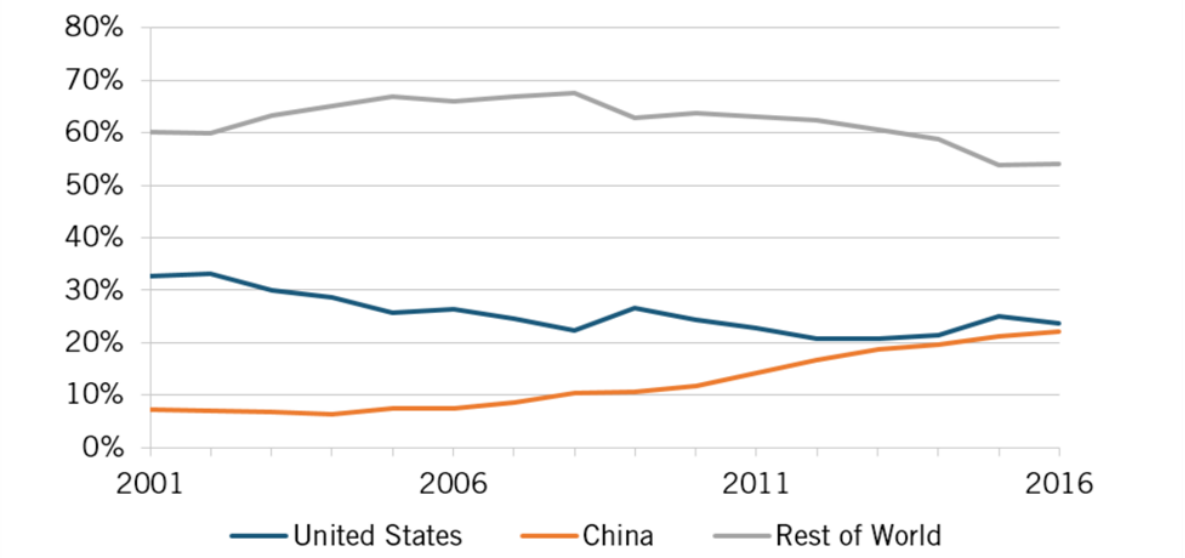
China's industrial output has grown rapidly over the past decade in part because China has dramatically expanded the share of its citizens that are eligible for health insurance.[40] Chinese sales increased from $26.2 billion in 2007 to $122.6 billion in 2017 (for comparison, U.S. sales in 2017 were $466.6 billion).[41] This is a key reason why China's share of global industry value added rose from 7.2 percent in 2001 to 22.1 percent in 2016, with over two-thirds of that growth happening after 2010 (see figure 3). Some of this is due to China being the leading producer of active pharmaceutical ingredients (APIs) in drugs, accounting for between 20 and 40 percent of global output, and is the world's largest API exporter, as well as key generics producer.[42] China more than doubled its biopharmaceutical production capacity, including APIs, from 2010 to 2014.[43] 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."[44]

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."[45] 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."[46] 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).[47] A number of Chinese biopharma companies are establishing multiregional clinical trials designed to serve global markets. For example, in 2018, Chinese biologics- and biosimilars-maker Bio-Thera Solutions Ltd. started a phase III trial of its HER2 antibody conjugate drug targeting HER2-positive metastatic cancer.[48] As of mid-2018, 25 Chinese companies had applied for approvals for advanced anticancer drugs based on biotechnology (PD-1/PD-L1 inhibitors).[49] Moreover, in 2017, China had 139 clinical trials with chimeric antigen receptor treatment (CAR-T) cell therapy, compared with around 118 in the United States.[50] Of just over 400 CAR-T clinical trials conducted in March of 2019, 166 were in China, and 165 in the United States.[51] Chinese biopharma start-ups are also broader in terms of the number of drugs they make or license to make, with the average number of drugs when filing for an initial public offering (IPO) in China being 10, versus 4 in the United States.[52] And in 2016, China had filed 410 clustered regularly interspaced short palindromic repeats (CRISPR gene-editing) patents, with the United States filing 447.[53] In 2015, there were 173 publicly traded pharmaceutical companies in China.[54]

However, much of this has been based on the practice of simply copying from the leading Western companies.[55] Moreover, Chinese companies still produce less than 1 percent of new molecular entities (e.g., drugs) globally.

Figure 3: Global shares of value added of pharmaceutical industry[56]



One reason China has made such significant progress is a number of components within its policy environment for biopharma innovation are improving. The McKinsey-Bay Helix Group China Drug Innovation Index, based on a survey of 109 industry experts, shows that China made progress on all six major indicators relative to the United States from 2015 to 2018.[57] China's regulatory-environment score increased from 3.1 to 5.5; market access, including reimbursement, increased from 3.1 to 4.0; funding for start-ups increased from 4.6 to 5.4; R&D capabilities increased from 4.8 to 5.0; local innovation systems increased from 4.1 to 4.4; and integration with the global economy, including foreign licensing and talent attraction, increased from 3.6 to 5.2. Overall, China increased from 4.0 in 2015 to 5.0 in 2018 (all U.S. scores were 8). To be sure, although still behind the United States, China's score shows it is able to make fairly rapid progress in its support system.

Moreover, these policy changes are leading many global biopharmaceutical firms to expand their investments in China. For example, the Japanese biopharma firm Takeda relocated its Asia Development Center from Singapore to Shanghai. Likewise, Sanofi is building an emerging market

business unit in China. In fact, virtually all of the world's leading 20 pharmaceutical companies now have manufacturing facilities in China—and many have also established R&D centers in the country.[58] China is an important market for foreign life-sciences companies (including those in the United States), with the top-10 mature drugs from foreign companies adding $2.8 billion additional revenue to China from 2014 to 2018.[59] From 2010 to 2014, annualized growth in Chinese sales revenue among biopharma manufacturers was 23 percent.[60]

Chinese firms are also expanding internationally, especially in world-class biopharma innovation hubs. For example, numerous Chinese biotechnology companies have started new R&D facilities in the United States, generally focused in such major biotech hubs as Boston, San Francisco, and Research Triangle Park in North Carolina. Chinese companies use this strategy to gain access to new technologies they can then bring back to the mainland—more so than firms from most other nations who have shown considerable willingness to invest in U.S. R&D and production facilities.[61]

Chinese firms overall have made such progress largely because Chinese generics firms, which make up the lion's share of Chinese biopharmaceutical firms, have for many years made above-average profits. As one article notes, "Among the top 100 generic drug makers [globally], Chinese firms had an 18 per cent profit margin in the third quarter, compared with a global average of 9.5 per cent."[62] One key reason for these higher margins is foreign firms face a significant number of barriers to selling in China, including waiting for import approval, while Chinese generics makers can more easily copy foreign drugs and avoid many of the costs foreign generics makers face.

Notwithstanding this progress, China still faces a number of challenges. Perhaps the core challenge is as a science-based industry, it is hard to close the gap with biopharma leaders simply by copying them. In other industries, such as solar panels, high-speed rail, and robotics, China caught up to leaders by copying their technology—often through theft or forced technology transfer—and then using a variety of means, including predatory pricing supported by government subsidies, to weaken foreign competitors. Copying can certainly work if China wants to develop a globally competitive generics and biosimilar industry (biosimilars are follow-on drugs to original biotech drugs), but it will not be enough to achieve significant market share in innovative drugs. To do that, China needs to develop indigenous capabilities that allow it to develop and bring to market first-to-the-world drugs. As a KPMG report notes, "The industry also faces practical constraints, including a shortage of core technology, a subpar industrial structure, weak R&D capacity, low resource efficiency, and disorderly markets."[63] In addition, given the Chinese economy grew so rapidly for so many years and generated a large number of investment opportunities with robust near-term paybacks, the appetite for investing in biopharmaceuticals—in which the payback is uncertain and long—has been relatively low.

Moreover, China suffers from having too many small and mid-sized firms competing with each other. Many of China's biopharmaceutical firms are quite small and do not have the scale to become true innovators. More than 70 percent of China's pharmaceutical manufacturers have fewer than 300 employees and revenue of less than $3 million.[64] And the vast majority produce either APIs or generic drugs. For example, in 2012, there were 1,272 applications for approval for generic drugs, with over 60 percent of them being submitted by different companies more than 20 times each.[65] This means overproduction has been an issue, with very low profits for most of these small firms making it hard for them to scale and invest in R&D. This is why China lacks world-leading major biopharmaceutical firms with the scale and technical sophistication of EU, Japanese, and U.S. firms. In branded pharmaceuticals and biotechnology drugs, Chinese companies have less than 3 percent of global market sales.[66]

China's relatively low per capita income is also a limiting factor because it makes it harder for China to pay for innovative new drugs, thus limiting the development of Chinese firms. Just 8 percent of new drugs approved globally between 2011 and 2017 are available in China.[67] This is made worse by

the Chinese government's recently mandated significant price cuts on many drugs.[68]

However, China's vast and growing market for drugs is likely to make up for that disadvantage. As a developing nation, drug consumption, particularly of nongenerics (original innovative drugs) in China is significantly lower than in developed nations. However, as per capita incomes continue to grow, that gap will lessen. Moreover, China's population of 1.4 billion is more than four times larger than that of the United States. In part because of a growing economy and an aging pollution, the Chinese drug market has grown six times larger from 2005 to 2017.[69] It is set to become the second largest in the world, behind the United States, by 2020.[70] Tragically, China now has a third of the world's cases of colorectal cancer, 40 percent for lung cancer, and half for gastric cancer—all factors that will lead to the growth of drug sales in China.[71] According to the management consulting firm L.E.K. Consulting, China's pharmaceutical market value is expected to grow from $123 billion in 2017 to $160 billion by 2022.[72]

This is important because, like many innovation-based industries, the biopharma industry is characterized by high fixed costs (e.g., R&D to develop and bring a drug to market, building a sophisticated factory, etc.) and lower marginal costs (e.g., ingredients, manufacturing processes, sales, etc.). Therefore, even if firms in China sell at a lower price than firms in the United States, Chinese biopharma companies could still earn greater revenues and profits than U.S. firms—profits they can reinvest back into the next round of innovation. This benefit will only grow as China's economy grows. Finally, as big data and artificial-intelligence analytics play a bigger role in drug development, China will also gain an advantage because of the much larger pool of medical data available to firms there.

CHINA'S INNOVATION MERCANTILIST STRATEGY IN OTHER INDUSTRIES TO DATE

While the past is never prologue, to better understand the shape of China's biopharmaceutical strategy now and going forward, it's worth understanding China's past innovation policies related to other industries. To be sure, this does not mean China will apply all such policies to the biopharma sector. International pressure, especially from the Trump administration, may constrain China's worst practices. Moreover, gaining competitive advantage in a science-based industry such as biopharmaceuticals is different than in more engineering-based industries such as machine tools, aerospace, batteries, and telecommunications equipment. It's possible this could lead China to approach the industry with innovation-supporting, rather than innovation-distorting, policies. Or it could lead China to double down on the latter policies, especially if it seeks to gain competitive advantage through low prices. As such, it's worth reviewing China's technology strategies to date.

Foreign technology acquisition has been at the center of China's industrial strategy for two decades. Chinese leadership knows that if China relies principally on market forces, foreign companies will provide Chinese firms with less technology than it wants and demands in order to grow the array of advanced industries China seeks global dominance in. As such, China has deployed a panoply of tools to unfairly—and often illegally—obtain needed foreign technology. And once Chinese firms have achieved that technology, the government then relies on an array of tools, including protected markets and massive subsidies, to help those firms scale up and gain global market share.

Based on policies in other technology sectors targeted in Made in China 2025, U.S. industry and policymakers should be alert to the deployment of a range of discriminatory Chinese practices for growing the biopharma sector in the coming decade.

Intellectual Property Theft: IP theft is an important tool in the Chinese arsenal, which China having long deployed industrial spies to obtain foreign secrets. A listing by the FBI of recent IP cases it has investigated reveals that most involve Chinese individuals attempting to steal U.S. IP.[73] For example,

as *The New York Times* has documented, a leading Chinese computer-chip maker allegedly paid employees of a Taiwanese chip company working with the U.S. company Micron to steal valuable chip designs.[74]

In 2018, one in five North American CEOs reported their companies experienced IP being stolen in China.[75] Another vector is cybertheft , which 7 percent of U.S. firms operating in China listed as a problem—a number that presumably would be higher if every firm that had faced an intrusion were aware it had done so.[76] The *IP Commission Report on the Theft of U.S. Intellectual Property* found that China accounted for nearly 80 percent of all IP thefts from U.S.-headquartered organizations in 2013, amounting to an estimated $300 billion in lost business.[77] An updated 2017 Commission report put that figure at $600 billion.[78] Former NSA Director Keith Alexander has called Chinese IP theft, calling it, "the greatest transfer of wealth in history."[79] Even though Chinese President Xi made "commitments" to end Chinese cybertheft, the Chinese government failed to follow through on his promise. As China's National Counterintelligence and Security Center stated in its "2018 Foreign Economic Espionage in Cyberspace" report:

> China has expansive efforts in place to acquire U.S. technology to include sensitive trade secrets and proprietary information. It continues to use cyber espionage to support its strategic development goals—science and technology advancement, military modernization, and economic policy objectives. China's cyberspace operations are part of a complex, multipronged technology development strategy that uses licit and illicit methods to achieve its goals.[80]

Meanwhile, China still has one of the highest rates of unlicensed software usage in the world, with 74 percent of the software in use unlicensed, and the market value of unlicensed software usage exceeding $8.7 billion in 2013.[81] Upwards of 240,000 Internet cafés in China rely on illegal copies of entertainment software.[82] Chinese firms even produce and sell technology to allow consumers around the world to circumvent encryption protection so they can pirate video games.

Another vector for purloined IP is tricking companies in the United States into believing a Chinese firm wants to invest in them. For example, a seemingly independent Chinese investment fund will approach a small or mid-sized U.S. technology company and indicate a willingness to invest needed capital in the company. But before the Chinese company can do this, they must "do their due diligence" and send over employees that actually work for a state-owned Chinese company, and are there to obtain key information about the company, including trade secrets. The firm never hears back from the investment company again.

Another path is through exchange visits and student enrollments in U.S. universities. Chinese exchange visitors to the United States have used opportunities to visit factories and other facilities to engage in industrial espionage, including measuring equipment, taking photos, and writing detailed technical notes to bring back to China. And as Daniel Golden wrote in *Spy Schools*, Chinese graduate students enrolled in U.S. universities have used their access to valuable scientific and engineering information to violate rules and provide technology and know-how to Chinese companies.[83]

Chinese trade-secret theft is a challenge that is growing in scale. A prime example is Boston-based American Superconductor (AMSC), which provides software, design, and hardware solutions for wind manufacturers and energy providers. AMSC's top customer, the Chinese-based wind-turbine manufacturer Sinovel Wind Group, faced criminal and civil actions for paying an AMSC employee to steal proprietary power-converter and control-system software, which it then used illegally in its wind turbines in order to meet electricity-grid standards.[84] The employee, an engineer at one of AMSC's subsidiaries, was recently tried and found guilty of industrial espionage in Austria. In another telling case, the global agriculture firm Monsanto decided to open production and research facilities for

advanced corn technology in China, and proceeded to develop experimental fields to grow genetically enhanced corn. It wasn't long before the advanced corn was systematically stolen—which was clearly an effort by the Chinese government to gain access to the IP embedded in Monsanto's corn.[85]

Weak IP Enforcement: Weak enforcement of IP law is another vector. Chinese firms can often copy and reengineer foreign technologies with impunity (what the Chinese government calls "introducing, digesting, absorbing and re-innovating"), even those protected by foreign—and sometimes Chinese—patents. As an *MIT Sloan Management Review* article, "Protecting Intellectual Property in China," notes, "Intellectual property protection is the No. 1 challenge for multinational corporations operating in China."[86] According to the U.S. International Trade Commission, in 2009, U.S. IP-intensive enterprises conducting business in China reported losses of approximately $48.2 billion in sales, royalties, and license fees due to Chinese IPR infringement.[87] In 2018, according to the American Chamber of Commerce in China, one-quarter of U.S. companies surveyed cited "insufficient protection offered by text of IP-related laws and regulations," while 24 percent cited "difficulty prosecuting IP infringements in court or via administrative measures" as significant challenges.[88]

China also favors domestic over foreign patent applicants when it comes to strategic industries. As the 2016 report "Technology Protectionism and the Patent System: Strategic Technologies in China," finds, "Foreign applications in technology fields that are of strategic importance to China (as defined by being listed on the MLP [Medium and Long-Term Plan for Science and Technology Development]) are 4 to 7 percentage points less likely to be approved than local applications, all else equal."[89] As the report notes, "Given the importance of industrial policy in China and the country's strong focus on indigenous innovation and intellectual property, the empirical results provide a case of technology protectionism by means of the patent system."[90]

State-Backed Purchases of Foreign Technology Companies: Until the recent reform of the Committee on Foreign Investment in the United States (CFIUS) by Congress, an increasingly important way for Chinese firms to gain access to needed technology was to simply buy U.S. technology companies or invest in high-tech start-ups. Indeed, until recently, a not-insignificant share of Chinese foreign direct investment (FDI) into the United States was in technology industries. According to the U.S. Department of Commerce's own Select USA program to encourage foreign investment into the United States, the top-four industrial categories in terms of number of Chinese FDI projects from 2003 to 2015 were electronics, industrial machinery, software and information technology services, and communications.[91]The Rhodium Group reported that over the last 16 years there has been roughly $18 billion of Chinese FDI into ICT and electronics-industry deals, with most of that in just the last few years. Of the $4.9 billion invested in electronics, $4.2 billion was invested in 2016, with 99.99 percent of that going to buy U.S. firms.[92] Of the $14.2 billion invested in ICT, 74 percent was made from 2014 to 2016, with more than 95 percent going to acquisitions.[93] These numbers would have been considerably larger if the federal government had not blocked some deals through CFIUS. Fortunately, Chinese inward FDI has dramatically fallen in the last two years, in part because of Chinese government limitations, but also as it became clear the U.S. government would take a harder look at China's attempts to buy U.S. technology.[94] In response, China has turned it sights on Europe.[95]

However, the role of Chinese government money in U.S. deals is underreported in part because of the opaque nature of this support. As Wang and Wang noted, many Chinese firms lack transparency, making it difficult for host countries to glean sufficient information about the investing firms.[96] This was evident, for example, in the attempted purchase of German semiconductor equipment firm Aixtron by a Chinese investor wherein there was "a web of relations among the customer, the buyer, and the Chinese state."[97] Moreover, the Chinese government channels funds to supposedly private investment bodies, making it look as if these deals are commercial.

The main purpose of most Chinese technology companies buying U.S. technology companies is not to make a profit, but rather to steal U.S. technology and use it to upgrade their own technology capabilities. The Rhodium Group noted about the aviation sector, "The dominant player is aviation conglomerate AVIC, which is looking to the US market to upgrade its technology and other capabilities."[98] Likewise, in the electronics and electrical equipment sector, "Chinese investors are drawn to the US electronics and electrical equipment sector for building their brands, expanding their sales and distribution channels, and upgrading their innovative capacity and technology portfolios."[99]Investments in pharmaceuticals and biotechnology are "often driven by upgrading technology (such as Wuxi's acquisition of AppTec, a laboratory services firm)."[100] As one study of Chinese FDI estimates, 30 percent of the private firm deals and 46 percent of the state-owned enterprise deals are motivated by technology acquisition.[101] The authors went on to state that Chinese acquisitions of overseas firms "has become the most widely used methods [of investing overseas] for Chinese firms, largely because it provides rapid access to proprietary technology."[102]

China has also ramped up its efforts to buy into early stage U.S. technology start-ups. A recent report from the Defense Department's Defense Innovation Unit Experimental finds that "Chinese participation in venture-backed start-ups is at a record level of 10–16% of all [U.S.] venture deals (2015–2017) and has grown quite rapidly in the past seven years."[103] Some of this investment comes from venture firms that are backed by Chinese governments (national or provincial). For example, the Zhongguancun Development Group, a state-owned enterprise headquartered in Beijing, has set up "Danhua capital" to promote the strategy of "Zhongguancun capital going global and bringing in overseas advanced technology and talents."[104] Likewise, Shenzhen Capital Group, a purportedly private VC firm that has invested in at least one advanced U.S. technology company, has actually received about 80 percent of its invested capital from the Chinese government—and its investments are focused, not surprisingly, to match the central governments key targeted industries.[105] The firm even boasts a chart that compares how the technology allocation of its investments compares to the government's priorities.[106]

FDI acquisition is not the only path to U.S. technology capabilities. For example, China is investing in U.S. universities in order to gain access to their research, often with the backing of U.S. state governments. For example, Maryland is committing nearly $600,000 over 3 years to build up the Maryland International Incubator in a bid to attract high-tech companies from China and elsewhere to collaborate with University of Maryland researchers. Of the 18 companies in the incubator, 9 are from China, most of which are biotech companies.[107] In addition, Chinese firms have become investors in early stage U.S. technology companies, including the VC arms of Chinese Internet companies such as Alibaba and Tencent. The idea is to use investments in start-ups as a way to bring technology and knowledge back to China. Indeed, at least a few Silicon Valley experts have reported seeing a significant uptick in Chinese venture investment there. In the first 3 months of 2018, Chinese-based venture-capital funds invested $1.4 billion into U.S. biotechnology companies.[108] It is possible this trend could very well increase in coming years as China sees its traditional acquisition route becoming more difficult. We see this pattern in other nations as well. For example, 40 percent of VC in Israel in 2015 reportedly came from China.[109]

Forced Technology Transfer: Dwarfing these tools is forced technology transfer. China's accession agreement with the World Trade Organization (WTO) contains rules constraining it from tying FDI or market access to requirements to transfer technology to the country.[110] However, China routinely requires firms to transfer technology in exchange for being granted the ability to invest, operate, or sell in China.[111] As Harvard Business School professors Thomas Hout and Pankaj Ghemawat documented in "China vs the World: Whose Technology Is It?" Chinese technology transfer requirements as a condition of market access have affected scores of companies in industries as diverse as aviation, automotive, chemicals, renewable energy, and high-speed rail.[112]To be sure, because such conditions usually contravene China's WTO commitments, officials are careful not to

put such requirements in writing, instead typically resorting to pressuring foreign firms to transfer technology.[113] In 2012, 23 percent of the value of all FDI projects was from joint ventures.[114] And the U.S.-China Business Council's 2014 China Business Environment Survey reports that 62 percent of companies had concerns about transferring technology to China, while 20 percent reported they had been requested to transfer technology to China within the previous three years.[115]

Forced technology transfer is not new. A 1987 Congressional Office of Technology Assessment report states, "Although most U.S. firms approach the China market with the intent to sell products, many find they must include technology transfer if they wish to gain access to the China market."[116] But what is new are two things. First, there are more foreign companies seeking to enter the Chinese market, such that the scale of forced technology transfer is much larger than it was two decades ago. In 2015, for example, 6,000 new international joint ventures, amounting to $27.8 billion of FDI inflows, were established in China.[117]

Second, the sophistication and value of the technology the Chinese government is now demanding is significantly higher than in decades past, when U.S. companies, confident in their ability to innovate faster, could afford to give their Chinese "partners" older generations of technology. Now, for many foreign advanced industry companies, doing business in China requires transferring ever-more valuable technology to Chinese joint-venture partners. In 2013, 35 percent of U.S.-business respondents in China said tech transfer requirements were a concern, while 42 percent in advanced-technology industries voiced this concern.[118]Fifty-six percent of survey respondents thought tech transfer requirements were increasing.[119] And as the Office of the United States Trade Representative (USTR) pointed out in its Section 301 report on China, it's likely these numbers have been underreported.[120]

The Chinese government has employed the weapon of forced technology transfer to gain technological know-how in a variety of industries. A well-known case in point concerns high-speed rail. Over the past 15 years, China has built the largest high-speed rail network in the world. Its massive purchase of rolling stock, signal systems, and related equipment is something no foreign rail producer can afford to ignore. As such, the Chinese government has had enormous leverage to pressure foreign producers to give the Chinese state-owned enterprise competitors key technology and IP, the Chinese term for which is "exchanging market for technology."[121]As Chen and Haynes documented, in 2004, the State Council of China adopted a new railway-development strategy that shifted from merely subsidizing domestic producers in order to help them improve their technology to "introduc[ing] advanced technology through joint design and manufacturing, [with an ultimate objective to] to build a Chinese brand."[122] After that, the state Ministry of Railways (MOR) launched three tenders for foreign high-speed electric trains in which it stipulated foreign companies had to partner with domestic firms in order to place a bid, and had to transfer key technologies to achieve localization.[16] The tender included two key conditions: To win, the bidder had to transfer technology to China, and the final products had to be marketed under the Chinese state-owned enterprise rail-car brand. This was all in support of the government's "Action Plan for the Independent Innovation of Chinese High-Speed Trains." As a result, multiple foreign train companies were pressured into transferring valuable technology to the Chinese companies (now principally one company due to the central government forcing the two main companies to merge into a powerful national champion, Chinese Railway Construction Corporation (CRCC), which is currently the largest rail producer in the world.) As Chen and Haynes wrote, "The result is a new HSR [high speed rail] industry in China has emerged which now serves the new vast HSR network and looks externally to export its new skill in HSR production and its new cutting-edge activity in HSR innovations." Not only are CRCC and related Chinese companies virtually guaranteed all Chinese rail projects, but CRCC is now aggressively exporting trains and train systems containing advanced foreign technology to other nations, backed with generous export subsidies from the central government. For example, the China Export-Import Bank (a state agency) announced in 2017 the equivalent of $30 billion in financing assistance for CRCC

exports.[123] (Surprisingly, the U.S. Department of Commerce International Trade Administration, in its document promoting U.S. rail export opportunities to China, has made no mention of the lion's share of these opportunities coming with forced technology transfer requirements.)[124]

The Chinese have employed different tactics to the same end in the biopharmaceutical industry, wherein various policies enable Chinese firms to get access to U.S. technology. For example, the relatively short six-year term for data exclusivity, coupled with the lack of a formal definition of "new chemical entity," means the Chinese government can pressure U.S. firms to turn over important data to Chinese generic drug firms. Similarly, the Chinese government requires all drugs sold in China to go through Chinese clinical trials, even if they have already been approved in the United States. This extends the time before a company can sell a drug by as much as 8 years, which means the company has only 12 years left of patent-protected sales in China before a Chinese generics company can copy the drug. Moreover, in China, unlike in the United States and Europe, there is no extension of marketing exclusivity at the back end to take into account long clinical-trial delays. Finally, China pressures foreign biopharmaceutical companies to form joint ventures if they want their drugs more easily put on the government list of drugs that qualify for reimbursement.[125]

Subsidies: Once Chinese firms gain access to needed foreign technology, the next step of the Chinese strategy is to ensure their firms have the capital needed to scale up. This involves direct and indirect subsidies, and designing markets protected from foreign competition so the Chinese firms can accumulate capital. Once firms have the technology, competencies, and scale to go global, the government often subsidizes global market expansion, such as through the China Export-Import Bank (an entity the World Bank has funded) and China's Export and Credit Insurance Corporation (Sinosure).[126] Moreover, by selling below cost, China uses its global overcapacity as a cudgel to disrupt the economics of innovation-based industries (i.e., subsidized competition prevents foreign competitors from earning reasonable profits from one generation of innovation to reinvest in future generations of innovation) and thus weaken foreign competitors, enabling Chinese firms to gain even more global market share.

The Chinese government also works to limit foreign competition to its budding national champions. For example, in the high-end equipment manufacturing sector, China maintains a program that conditions the receipt of a subsidy on an enterprise's use of at least 60-percent Chinese-made components when producing intelligent manufacturing equipment.[127] And despite China having "clarified and underscored … that it agreed that enterprises are free to base technology transfer decisions on business and market considerations," at a December 2014 meeting of the United States-China Joint Commission on Commerce and Trade, USTR noted that China had "announced two measures relating to [local procurement of] information technology equipment used in the banking services sector and in providing Internet- or telecommunications-based services more generally."[128]

China also lavishes Chinese firms that have obtained foreign technology with massive subsidies, here defined not as support for precompetitive R&D, workforce skills development, or other investments, but rather as government direct or indirect financial support designed principally to reduce firm costs. As George and Usha Haley documented in their book, *Subsidies to Chinese Industry: State Capitalism, Business Strategy, and Trade Policy*, China's gameplan has long been to "aggressively subsidize targeted industries to dominate global markets." As they documented, in the 2000s, China provided approximately $88 billion in subsidies to just 3 industries alone: $33 billion for paper, $28 billion for auto parts, and $27 billion for steel.[129] China's share of global solar-panel exports grew from just 5 percent in the mid-2000s to 67 percent today, with Chinese solar output turbocharged by at least $42 billion in subsidies from 2010 to 2012 alone.[130] China now wants to replicate this strategy in other advanced-technology industries, such as semiconductors and electric batteries.[131] For instance, China's National Integrated Circuit Strategy calls for at least $160 billion in subsidies to create a completely closed-loop semiconductor industry in China, including explicit plans to halve

Chinese imports of U.S.-manufactured semiconductors by 2025, and eliminate them entirely by 2035. The Made in China 2025 Strategy is supported by some 800 state-guided funds to the tune of more than $350 billion, including advanced-battery manufacturing, wide-body aircraft, and robotics.

Moreover, Chinese government-backed investment funds aim to spur $1.7 trillion, equal to one-third of the assets in the global private equity market.[132] Since the global financial crisis, the Chinese government has moved aggressively to stimulate capital investment that will strengthen its competitive position, both domestically and in global markets. First created in 2008, there are now more than 2,000 of these "government guidance funds," three-quarters of which were established between 2015 and 2018. Having raised $530 billion up that point, the funds already represent a massive vehicle for Chinese governments to subsidize Chinese tech companies and acquire foreign tech companies under the guise of VC.

None of this is to imply China's biopharmaceutical strategy will necessarily emulate the rampant and widespread innovation mercantilism China has employed to grow other industries. However, given Chinese government and China's business behavior over the last two decades, as well as current policies regarding the industry, there is reason for concern.

CHINA'S BIOPHARMACEUTICAL STRATEGY

For over a decade, the Chinese government has targeted biopharma as a key industry for development. Its 2006 report, "The Guidelines for the Implementation of the National Medium- and Long-term Program for Science and Technology Development (2006–2020)" called on China to master "core technologies" including "major new drugs." China's 11th Five-Year Plan listed sixteen "megaprojects," three of which addressed the industry: 1) breeding new varieties of genetically modified organisms; 2) pharmaceutical innovation and development; and 3) control and treatment of AIDS, hepatitis, and other major diseases.[133] As part of that plan, China's State Council directed provinces and municipalities to target the industry for development, which, given the ability of local Chinese Communist Party officials to move up the ranks by following the guidance of Beijing, was quite effective in driving local policy. The plan called on China to "Form an advanced industrial technology system supporting the development of biotechnology drugs, establish a batch of multi-functional, bio-technical drug production bases in line with international standards, and cultivate a group of enterprises with international competitiveness."[134] The plan went on to call for:

Key technology development: build large-scale and high-throughput genome sequencing technology and equipment, massive biological information processing and analysis technology. Construction of public technology service platform: build a large-scale biological resource pool and the core platform of the biological information center, build a networked national biological resources and biological information service facilities, strengthen the deep exploration of genetic information, and promote the development of new sequencers. Provide bioinformatics services for individualized diagnosis and treatment, biological resource discovery, animal and plant molecular breeding, and industrial microbial strain modification.[135]

China's 12th Five-Year Plan identified 7 priority strategic emerging industries, including biotechnology, aimed at increasing their contribution to China's gross domestic product (GDP) from their then-current 2-percent level (2008) to 8 percent by 2015 (which it failed to meet) and 15 percent by 2020.[136] Despite its aspirations, the plan's implementation was poor, with few important reforms actually being implemented. For example, until 2017, the Chinese Food and Drug Administration (now the National Medical Products Administration, NMPA) had a multiyear backlog of new drugs awaiting approval.

However, China appears to have gotten more serious about implementation since then. Its most recent 13th Five-Year Plan (2015–2020) maintained focus on the industry and called for biotech industry output to exceed 4 percent of GDP by 2020.[137] Given drug spending for both biotechnology and traditional pharmaceuticals is less than 2.5 percent of U.S. GDP, such a goal is extremely ambitious and would be achievable only by a massive increase in exports.[138]

Moreover, the State Council has called on all levels of government to target the industry for support, writing, "The people's governments of all provinces, autonomous regions, and municipalities directly under the Central Government, ministries and commissions under the State Council, and their respective agencies: The Bio-Industry Development Plan is hereby printed and distributed to you, please implement it carefully."[139] The Bio-industry Development Plan component set a target for biopharmaceutical sales to grow to $1.02 trillion by 2020 at an annual growth rate of 20 percent.[140] According to a set of guiding opinions from the State Council, "Innovation will be strengthened through collaboration on key R&D projects, the commercialization of pharmaceuticals, advances in medical devices, and the modernization of TCM (traditional Chinese medicine). Industry and organizational structure will be optimized through cross sectoral mergers and restructuring, trans-regional shifts, and the development of concentrated industry clusters."[141] The plan went on to note in turgid bureaucratic language that the Chinese government would:

> Establish a demand-side incentive mechanism for new biotechnology products. Break regional monopoly and support bio-innovation enterprises to open up markets. We will fully implement the price formation mechanism of biological products based on the principle of high quality and good price, same quality and competitive price, and promote the promotion and application of new products and new technologies to support the development of high-tech service industry and related industries. Expand medical insurance coverage, standardize drug procurement behavior, develop commercial health insurance, and support innovative drugs with clinical necessity, exact curative effect, high safety and reasonable price to enter the medical insurance catalog. Improve the biological breeding subsidy policy. We will steadily promote the pilot application of non-grain fuel ethanol, carry out industrialized demonstration of biodiesel in an orderly manner, and start the commercial application of aviation biofuels in a timely manner on the basis of completing aviation biofuel verification flights. Intensify efforts to promote resource tax and fee reform, speed up the elimination of outdated products, technologies and processes, and promote the promotion and application of emerging green technologies and products.[142]

Most recently, China's Made in China 2025 identified ten key industries to target, including biomedicine. It set out the following goals:

> i) Goals for 2020: Promote a large number of enterprises to achieve drug quality standards and systems that are in line with international standards, among which at least 100 pharmaceutical enterprises obtain U.S., EU, Japanese, and World Health Organization (WHO) authentication and achieve product export; according to international drug standards, develop and promote 10–20 chemical and high-end drugs, 3–5 new traditional Chinese medicines, 3–5 new biotech drugs; complete drug registration in Europe, the United States, and other developed nations; speed up the development of internationalization of domestically produced drugs; before 2020, when international patents for blockbuster drugs expire, achieve over 90% generics production; achieve breakthroughs for 10–15 important core and critical technologies; and begin to establish national drug innovation system and innovation team.
>
> ii) Goals for 2025: By 2025, basically achieve drug quality standards and systems that are in line with international standards; develop chemical drugs, traditional Chinese medicine, biotech drugs focused on 10 major diseases, achieve industrialization of 20-30 innovative new

> drugs; 5-10 drugs with indigenous property rights receive U.S. Food and Drug Administration or EU authentication, and enter the international market; construct, improve, and support the national drug innovation system for external services, form of high-level innovation team with an international perspective, promote China's drug internationalization development strategy.[143]

In addition to the national Made in China 2025 plan, at least 19 of China's 23 provinces have their own plans.[144] This should not be surprising because provincial communist-party leaders are quick to support central government strategic priorities, aware that this is key to professional advancement. Likewise, the 2016 State Council plan called for:

> All regions and relevant departments must fully understand the importance of promoting the healthy development of the pharmaceutical industry, strengthen organizational leadership, improve the working mechanism, and form a joint effort. All regions should formulate specific implementation plans based on actual conditions, carefully organize and implement them to ensure that all tasks are implemented. All relevant departments should promptly formulate supporting policies in accordance with the division of responsibilities and create a good environment.[145]

Finally, the update to China's Strategic and Emerging Industries plan, the Strategic Emerging Industry Development Key Product and Service Catalogue, first published in September 2018, also targets the life sciences.[146]

China also appears to be "skating where the puck will be" in the sense that the government is focusing more on biotechnology and biology, rather than on more traditional pharmaceuticals and chemistry. Its 13th Five-Year Plan focuses on "genomics and other biotechnologies, networked application demonstration, and the scaling up of a new generation of biotechnology products and services, including personalized treatment and innovative pharmaceuticals."[147] It focuses more on complex biotechnology drugs in part because that is where much of the industry is going globally. In addition, some genomics-based drugs may need to be tailored by ethnicity, which would give the Chinese an advantage in developing drugs for Chinese use. As one article notes, "China's leading biotech companies are already aware of the need to step up their game. The novel chemical drug space may be close to saturation, but there's still a lot to explore in the biopharmaceutical field, and that is where China has the potential to catch up with the world leaders."[148] Moreover, as one study shows, over the last two decades, nations that had strengths in biology and life sciences have done better in pharmaceutical industry competitiveness than did nations with traditional strengths in chemistry (the source of competitive advantage in small-molecule, traditional pharmaceuticals).[149]

China, however, is taking a different approach to growing the industry than many nations, including the United States. A key enabler of a robust domestic life-sciences innovation and production system is reasonable drug-pricing reimbursement so companies can earn the revenues needed to invest in the next generation of drug development. However, there are two challenges for China with enabling reasonable drug pricing. The first is China is still a low-income nation, and the government wants to limit health care expenditures, especially as the Chinese population ages. The second is a reasonable drug-pricing regime helps both domestic and foreign firms (both kinds of firms can earn reasonable returns on drug sales), although the Chinese strategy in biopharmaceuticals, as in all advanced industries, is to support Chinese firms at the expense of foreign firms. Significantly limiting drug pricing harms foreign firms more than Chinese firms that have a lower cost structure.

But without reasonable drug pricing reimbursement, it is difficult to grow a globally competitive and dynamic biopharmaceutical industry. China appears to want to address this tension in three ways.

First, by imposing very strict price controls and favoring Chinese firms in national drug selection, while at the same time supporting the development of the Chinese generics and biosimilar industry, China appears to want to build up its domestic industry capabilities initially in generics and biosimilars, just as their industrial strategies for other industries (e.g., aerospace, rail, electronics, etc.) were all about copying, rather than original innovation. Chinese regulators are focused on rationalizing and consolidating their generics drug industry and significantly improving quality because, until recently, many Chinese citizens favored foreign off-patent or generic drugs because they did not trust the quality of domestic brands. So for China to reduce imports (a goal the government seeks in all advanced industries), it needs to boost the quality and reputation of domestic drugs. The government sees this strategy as a way to reduce the imports of foreign-patented drugs, while at the same time expanding the export of generics around the world. It hopes this will build a foundation for the development of new-to-the-world drugs, with which it hopes to gain market share because of the lower cost of drug development in China. Just as China gained global market share as the world's low-cost factory workshop in the 2000s, it seeks to gain global market share as the world's low-cost "medicine cabinet" in the 2020s.

Second, China, with its new draconian price regime, hopes to compensate for its firms not being able to earn the kinds of returns needed to effectively support R&D and innovation by expanding a range of public supports, including VC, grants, free commercial space, and limited taxation.

Third, China's strategy appears to be focused on enabling its firms to sell drugs in developed-nation markets, including the United States, so foreign patients (and governments) end up paying for China's drug development. The 2016 State Council document on the industry proposed to "[a]ccelerate the development of the international emerging pharmaceutical market and adjust the export structure of products."[150] And one key means of achieving this is foreign acquisitions and investment. The Council calls for "[a]dopting various forms of cooperation to promote pharmaceutical companies to conduct overseas mergers and acquisitions, equity investment, VC, establish overseas R&D centers, production bases, sales networks and service systems, acquire new products, key technologies, production licenses and sales channels, and accelerate integration into the world."[151] This may be why 86 percent of Chinese biopharma manufacturers expect to produce for export to the United States and EU, compared with 25 percent that do so today.[152]

In summary, China's biopharma strategy appears to be focused on growing and improving its generics industry, in part by having a relatively weak IP system, and then on the basis of that growth, encouraging the generics industry to innovate more, coupled with state support to biotech start-ups. To be sure, China is more open to foreign original drugs, particular those that address key health needs, but the policy is to quickly enable Chinese generics companies to produce and sell generic copies.

To advance its goal of significant expansion of its biopharma firms and output, China has made a number of policy changes in the last few years, including changing drug regulation, drug pricing, and IP protection; spurring VC investment, pursuing FDI; and supporting expansion of core industry inputs, including skills, data and R&D. While some of these new policies are legitimate and fair, many are not; inappropriately favoring Chinese companies at the expense of fair competition.

Regulatory Changes

The Chinese government has understood that if it is to develop a globally competitive biopharma industry it must improve its drug regulatory system, including its approval system. This is important not only to hold Chinese firms to high standards so Chinese consumers will consume more of their product, but to ensure the production of high-quality Chinese-produced drugs other nations will import. Several years ago, there was a wave of optimism among China watchers that the Chinese

government was putting in place a raft of needed reforms that would improve the regulatory climate for drugs in China. While some of that optimism was justified, much of it was not, with China either walking back promised reforms or implementing some in ways that were decidedly unfair to foreign companies.

To be sure, China did join the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Both the U.S. Government and U.S. industry encouraged this move to international standards. To join the ICH, new members must implement a basic set of regulatory requirements for the manufacture of pharmaceuticals, the conduct of clinical trials, and stability testing of pharmaceutical products. In addition, the central government has either drafted or adopted other proposals. As Beier and Baeder wrote,

> Facilitate launching clinical trials after a 60-day review vs the current 12–18 month approval process; allow use of non-Chinese data in the approval process for new drugs; adopt the U.S. and Europe model to accelerated approval for breakthrough therapies; improve intellectual property protection via data exclusivity; and facilitate contract manufacturing and product licensing by severing the link between marketing authorization and manufacturing licenses.[153]

China is improving its process of conducting clinical trials of new drugs, including establishing more clinical trial centers.[154] China has also announced it will put in place an expedited orphan drug review process and create a new medical reimbursement agency. It will also shorten the time it takes to issue a drug import license. (One barrier to selling drugs in China is that China issues licenses, but only for five years, and renewals are not guaranteed.)[155] In addition, in 2017, China added 340 drugs to its National Reimbursement Drug List (NRDL), including many novel and expensive biologic drugs; replacing city and province level "experiments" developed by Western drug companies over the prior four years.[156] Also added to the NRDL through direct listing were 128 Western drugs.[157] Clearly, these regulatory changes have helped U.S. and other foreign manufacturers access the growing pharmaceutical market in China.

China has also made considerable progress in its drug approval process, significantly adding staff and reforming the approval process.[158] China also recently cracked down on fraudulent drug approval applications by holding them to fraud standards with severe penalties. This change resulted in 86 percent of drug approval applications from Chinese companies being withdrawn. Of course, the goal for China is to rationalize its industry, thereby eliminating smaller and lower-quality drug firms so Chinese consumers will accept Chinese drugs instead of foreign off-patent drugs, which many Chinese patients have come to prefer because they know they can trust the quality.

Notwithstanding this liberalization, China has a long way to go. For example, only 4 of the 42 cancer drugs approved globally in the past 5 years are available in China.[159] In addition, some of the proposed changes are designed to benefit domestic companies over foreign ones. For example, the National Medical Products Administration (NMPA) has given priority review to innovative medicines produced in China over those produced outside China.[160] China has also localized testing requirements for biologics testing and quality testing of imported ingredients, which adds to the cost and delays the release of innovative drugs.[161] Moreover, while drugs are on the approved list for FDI, Chinese governments encourage foreign biopharmaceutical companies to form joint ventures if they want their drugs more easily put on the government list of drugs to qualify for reimbursement or receive other benefits.[162] As the Shanghai American Chamber of Commerce wrote, "Adopting a minority position as an MNC (multinational company) could create increased market competitiveness and commercial opportunities and engender more favorable government treatment."[163] Similarly, in exchange for investing in China, provincial governments tout their willingness and ability to help firms gain regulatory and market approval.[164]

Moreover, China is working aggressively to develop domestically produced generic alternatives to foreign drugs, while at the same time dramatically cutting reimbursements. China's State Council has said it will adopt such international cost-containment practices as reference pricing for drugs, including new drugs. As the McKinsey Global Institute noted, "Most imported drugs in 2018 NRDL negotiation came out with a price significantly lower than neighboring countries, 36 percent lower on average."[165] In 2019, the State Medical Insurance Administration (SMIA) also launched its National Centralized Drug Purchase Trial with the goal of substituting (mostly foreign) off-patent originator drugs with locally produced and steeply discounted generics.[166] Of the 31 drugs SMIA sought generic substitutes for, 25 were selected, of which 23 went to Chinese suppliers—with price cuts as steep as 90 percent.[167] This new model is expected to spread nationally. In addition, at the end of 2018, the central government, led by the National Health Commission, issued a plan for the development of generic drugs, which is to include the issuance of a list of drugs encouraged for generic development, which will also be used to inform industrial and technology policies designed to upgrade technical development and manufacturing of these drugs (e.g., the Focused Research Program for the Development of Generic Drugs).[168] As a result, hospitals in the affected cities, where most prescribing takes place, are under pressure from the central government to ensure a minimum share of prescriptions are generics, even if patients request an original off-patent drug.

One goal of this is to centralize procurement of generics so as to generate a consolidation in the industry to improve quality and competitiveness of the remaining firms. The price cuts are so significant that few foreign drug companies can afford to make a winning bid. In short, the goal is to put out of business small, often low-quality Chinese producers while at the same time limiting market access to foreign drug companies.[169] This way, a modest number of Chinese "champions" can be cultivated.

While foreign firms are largely being shut out of the Chinese market for generics and off-patent original drugs through the new pricing policies, they still have some access to markets for on-patent innovative drugs. In these cases, despite steep price cuts, overall revenues are up because of significant increases in sales. This is due in large part to China having expanded its health insurance program nationally in 2009 such that it covers its more than 1.3 billion residents today.[170] Given new national efforts to shift to significantly discounted generics mostly produced by Chinese firms, whether revenues will continue to grow remains an open question.

Finally, China may have one advantage over the United States with its regulatory system, and that is its regulations regarding biomedical innovation are less strict. This, however, can lead to problems, such as when Chinese scientist He Jiankui modified the genes of newborn twins.[171] However, it does suggest that there is more room for risk-taking in China, even if it comes at the risk of human health. In contrast, the United States has imposed regulatory limits on innovation. For example, President Trump recently ended federal funding for medical research using fetal tissue, despite scientists insisting it is a key for innovation. As Doug Melton, a codirector of the Harvard Stem Cell Institute and president of the International Society for Stem Cell Research, stated, "With these new arbitrary restrictions on research, the United States is ceding its role as the global leader in the development of cellular therapies and regenerative medicine."[172]

Intellectual Property

Strong intellectual property protection is key to innovation in the biopharmaceutical industry. Compared to the United States and Europe, China's IP environment for drug development has been decidedly weaker. For example, independent of patent protection, the United States and European Union both provide a period of marketing exclusivity (a.k.a., "regulatory data protection") for a drug, as well as patent term extension to compensate for the loss of a patent term during the approval process. China does not, which effectively reduces the life of the patent by 40 percent, despite its

TRIPS obligations under Art. 39.3, and despite the fact that their approval process is usually longer than the U.S. process.[173] China also uses procedures to invalidate patents based on heightened "enablement" and non-obviousness requirements. It also makes it more difficult than do the other IP5s (the United States, Europe, Japan, and Korea) for applicants to file supplement data with the patent application (post-filing data supplementation), thus invalidating more patents than would be the case if the patents were filed in the other IP5s.

The Chinese government has at least made some proposals to improve its IP environment, in part to spur more biopharma development. The government has said in the most recent draft patent law amendment that it will consider patent term extension (albeit with an important limitation to drugs with simultaneous marketing applications in China and abroad).[174] China also provides only a six-year data exclusivity period for drugs that contain new chemical entities, compared with 12 years (for biologic drugs) in the United States. However, China generally does not live up to even this commitment, thereby allowing competitors to get access sooner.[175] In April 2018, the National Medical Products Administration (NMPA)—formerly the China Food and Drug Administration (CFDA)—proposed to increase that period to 12 years for new therapeutic biologics, 10 years for pediatric drugs, and 7 years for orphan drugs, but has thus far taken no action on this proposal.[176] China has also implemented its "First to China" policy whereby when a drug is launched in China at the same time or before it is launched in other nations, the foreign firm receives data protection, despite few other nations having such a discriminatory policy. But as a report for the U.S. China Economic and Security Review Commission notes:

> The CFDA's proposed rule would allow for the maximum protection period for biologics only if they are submitted with Chinese clinical trial data and submitted for approval first in China before other countries. For drugs first approved outside of China but using data from Chinese trials, the market exclusivity is only one to five years, depending on the time between foreign approval and filing in China (if the difference is more than six years, China provides no exclusivity). Drugs first approved outside of China will receive only 25 percent of the maximum data exclusivity (i.e., three years for biologics) if they use no data from Chinese trials and 50 percent (i.e., six years for biologics) if using outside data supplemented with Chinese data.[177]

China also permits follow-on applicants to rely on the data submitted by the original drug innovator to NMPA during the period of regulatory data protection, something the United States and Europe do not allow.[178] This is done in order to give a leg up to Chinese biopharma firms while at the same time reducing their costs significantly. Likewise, when firms file for marketing approval in China through NMPA, they must disclose a "new chemical entity" as part of the application. However, as Ben Shobert testified before the U.S. China Economic and Security Review Commission, "Upon approval, the submission is supposed to create six years of proprietary coverage of the product in question. Industry has brought forward several examples where domestic Chinese manufacturers have produced generic versions of the newly submitted products within the six-year period of protection of data the CFDA's filing stipulates a foreign company should enjoy."[179] Moreover, while Europe and the United States provide a 10- and 12-year exclusivity period, respectively, after the approval of a reference biologic drug before a biosimilar drug can be approved, in China, the "new drug monitoring period" only applies to Chinese-manufactured biologics.[180]

In 2017, NMPA proposed a patent linkage system that would have tied obtaining market approval for a drug to a process for identifying and litigating patent disputes relating to the product. To gain regulatory approval, generics companies would need to assert that their drug does not infringe on listed patents, and NMPA would need to independently assess this.[181] A linkage regime would be critical in addressing the problem of approval of infringing generic drugs being approved by China's regulatory authorities. Without linkage, NMPA has granted approval to Chinese generics makers to produce drugs for which foreign firms hold valid and unexpired patents. Rather than limit this

practice, NMPA asks firms to file patent-infringement lawsuits, which typically start with the filing for a preliminary injunction—but are very difficult to obtain in China. In addition, even if they are successful in their patent litigation, plaintiffs usually see only minimal awards, often making it uneconomical to even file a case.[182] In addition, there is no consolidated patent registry in China equivalent to the "Orange Book" in the United States, which lists all patented and approved drugs, so Chinese generics applicants and NMPA may not be aware they are potentially infringing on patented products.[183]

In addition, over the last few years, the rate of patent invalidation from the Chinese Patent Review Board has increased significantly, particularly for compound patents that cover all uses of a molecule. For example, since 2015, nearly 75 percent of claims filed in China for violations of pharmaceutical patents have resulted in at least 1 claim being invalidated. A study looking at 40 cases from 2018 found that 44 percent of the challenged pharmaceutical patents had been invalidated in whole, while 32 percent were declared partially invalid.[184] Another study estimated that foreign biopharmaceutical companies lost 59 percent of their patent cases brought by Chinese generics companies, with 22 percent of the cases settled, and only 19 percent won.[185] And the speed by which patents are invalidated has purportedly increased, and is much higher than invalidation rates in the United States and Europe.[186] Invalidating foreign patents appears to be a key way for China to enable its generics industry to gain market share.

Many of these challenges come from domestic Chinese generics companies. For example, in 2017, Shenzhen Salubris Pharmaceutical Co., Ltd challenged the issuance of a Chinese patent to international drug company AstraZeneca for its drug ticagrelor. Four months later, China's Patent Reexamination Board declared the patent invalid because of a lack of creativeness, even though the U.S. Patent and Trademark Office issued a patent for the drug that will expire later this year.[187] Moreover, unlike most developed nations, China places limits on post-grant submission of data demonstrating a drug is innovative.

Moreover, this high rate of invalidation has generated the creation of a "reverse patent troll" industry in China wherein individuals threaten to challenge a patent unless they are paid in cash or given a free license (which they usually sell to a Chinese generics company). As one private-practice lawyer in China stated, "It's a protection racket."[188] In addition, Chinese law requires products actually be sold in China before a patent holder can bring an infringement action. Thus, even if a Chinese company produces an infringing product and gains regulatory approval, a foreign drug company can be limited in bringing action if the company has not yet sold the drug in China.

Moreover, some have argued that the Chinese patent office imposes overly strict sufficiency of disclosure for enablement and inventive step requirements for biopharmaceutical patents that result in foreign firms having to disclose too much data, which may include trade secrets. A failure to provide this data may result in the Chinese government invalidating the patent, which it could then share with domestic firms.[189] In countries with effective patents systems, patent applicants are allowed to file additional data after the initial application is reviewed. But while China has taken some steps in this direction, it does not appear to have gone far enough in allowing additional data to be filed based on the examiner's rejection of a patent on the grounds of the application's failure to meet inventive step or disclosure requirements.[190]

The Chinese government also requires all drugs sold in China to go through Chinese clinical trials, even if they have already been approved in the United States. This extends the time for sales before a company can sell a drug by as much as 8 years, meaning that the company has only 12 years of patent-protected sales left in China, absent patent-term restoration, before a Chinese generics company can market a copy of the drug.

Moreover, in China, unlike in the United States and Europe, there is no extension of the patent term to take into account long clinical trial delays. Foreign firms also have difficulty prosecuting cases of patent infringement in Chinese courts, including in gaining injunctive relief and, if successful, receiving very small monetary damage awards.[191] In addition, China's Patent Law is more restrictive when it comes to patenting related to the human genome, which limits patent protections for biotech innovations.[192]

Finally, NMPA announced in late 2018 its Rules for Overseas Inspection of Drugs and Medical Devices, which require Chinese government inspections of R&D and manufacturing sites outside of China.[193] At one level, this is a perfectly legitimate step for the government to take; after all, the U.S. FDA has the right to inspect plants in China when the output is to be imported into the United States. However, given the long and systemic efforts by the Chinese government at industrial espionage, including using supposed competition-agency inspections for espionage purposes, this new development could in fact be used to illegally obtain valuable IP for Chinese biopharma firms.

So, the Chinese government has failed to implement many reform proposals, likely because its core strategy is to promote Chinese generics companies, and the current weak IP system helps advance that strategy. Indeed, as is true of so many Chinese economic reforms, they are designed to benefit Chinese firms in particular. For example, the new rules on data exclusivity favor companies that first launch in China, which are typically not foreign companies. At the same time, it encourages foreign companies to seek approval for their products in China first, ideally by developing drugs in China or at least doing clinical trials there.

Venture Capital Investing

In part because biopharma is such a new industry for China, with few established firms, the principal way the government is supporting it financially is through state-supported and guided VC investment. Much of this VC is provided by provincial governments.

At the end of 2017, there were a recorded 1,166 government-led venture funds, with 5.3 trillion yuan ($780 billion) in targeted capital, up from 214 funds in 2013.[194] As the China Money Network noted, this amount is equal to 32 percent of all assets managed by the global private equity and VC industry.[195] These government-backed VC funds are targeted to industries deemed strategic by the Chinese government. One of these, of course, is the biotech industry. In 2012, China's State Council Biological industry development plan targeted VC funding to:

> Through the national venture capital investment funds, promote the establishment of a number of professional bio-industry venture capital institutions engaged in different stages of investment, encourage financial institutions to provide financing support for the development of bio-industry, and guide the guarantee institutions to actively provide financing and credit enhancement services.[196]

The 2016 State Council plan repeated this, calling to:

> Innovate financial fund support methods, use incentive guidance, capital injection, and application of demonstration subsidies to support projects with strong public service nature such as application demonstration and public service platform construction; use and guide industrial investment, venture capital and other funds to support Innovative product research and development.[197]

As a result, biotech venture funding (both private and government) for firms in China increased from $0.5 billion in 2015 to $2.5 billion in 2018.[198] Of the 20 largest Chinese government guidance VC funds, most set up in Chinese provinces and cities, and seven identify health care (which includes biopharmaceuticals) as a key sector of focus.[199] It is not clear how much of this money comes from government or is really from subsidies rather than commercially guided investments. Over the last five years or so, the Chinese government has funneled government funds to supposed "private" entities in order to avoid charges of government subsidization—which is actionable under the WTO Agreement. This is why the United States Trade Representative's office recently sent 70 questions to WTO about Chinese subsidies, including in biotechnology.[200] Nonetheless, it appears at least some of these investments are much more generous in terms than they would be if the venture firms were only trying to maximize returns.[201]

These firms have also been making venture investments in U.S. biotech firms, and increased from $0.2 billion in 2015 to $2.6 billion in the first 3 quarters of 2018. At the same time a year earlier, Chinese funds invested $125.5 million, which equaled only about 7 percent of the U.S. total.[202] According to one study, in the first quarter of 2018, Chinese VC funds accounted for approximately 40 percent of the money U.S. biotech companies raised.[203] And in the first half of 2018, China-based VC funds invested $5.1 billion to private U.S. biotech firms (https://www.ft.com/content/7b045aa2-7cef-11e8-bc55-50daf11b720d).[204] As Reuters wrote, "Among the winners are Menlo Park, California's GRAIL Inc, an early-stage cancer detection company that in May raised $300 million in a Series C round led by Chinese healthcare fund Ally Bridge Group. Immuno-oncology company TCR2 Therapeutics of Cambridge, Massachusetts, received $125 million in March in a Series B round co-led by Pacific-focused investor 6 Dimensions."[205] One of China's largest health care funds, and one capitalized in part by a Chinese provincial government, 6 Dimensions Capital recently invested in the Maryland biotech Vielo Bio, which was itself spun out of AstraZeneca's biologics R&D arm.[206] A key reason for these investments is to gain access to ownership of key technologies.[207] Because Chinese firms are less restrictive in their investments (and more willing to make larger investments at earlier stages of their development), many U.S. firms are more than willing to take Chinese money. According to one article, in 2018, Chinese venture firms invested more into life-sciences and biotech firms in the United States than they did in China, providing VC funding to more than 300 companies.[208]

Moreover, between 2016 and the end of 2018, Chinese biopharma companies raised $2.3 billion through IPOs. In part, this is because it has become easier for Chinese biopharma firms to go public. The Hong Kong Stock Exchange had prohibited companies without revenue from listing. But in biotech, most companies don't have revenue, as they are still developing their products. To help foster biotech, the Exchange removed that restriction. As a result, in 2018, Chinese company BeiGene raised approximately $900 million, and Innovent raised $400 million.[209]

In addition, while Chinese investment in the United States and European Union fell significantly between 2016 and 2018, according to the Rhodium group, acquisitions of Chinse firms in the health and biotechnology sector have expanded in both places.[210] In 2018, health care and biotechnology accounted for 19 percent of Chinese FDI into the North America, second only to basic materials (38 percent, most of which was mining deals in Canada), and accounted for 11 percent in Europe.[211]

Research and Development, Technology Transfer, Skills, and Data

In addition to government support for VC funds, Chinese governments have also provided support to the industry in a variety of key ways.

One such way relates to talent. Chinese universities now produce around 150,000 life-sciences graduates annually, compared with America's 137,000.[212]It is also providing incentives for expatriates in the industry to return to China to conduct research.[213] Through its Thousand Talents Program, which encourages Chinese-born scientists and engineers who have been educated overseas to return to China, an estimated 250,000 Chinese life scientists returned between 2012 and 2018.[214] One estimate shows around 25 percent of all returnees have degrees in the life or medical sciences.[215] A reason some have returned is new regulations allowing research professors to hold positions at private companies.[216] In addition, with the rise of Chinese biotech companies, top talent from foreign firms in China is moving to Chinese firms, thereby making it more attractive for foreign talent to move home.

As a result, hundreds of thousands of high-skilled young scholars and entrepreneurs are returning to China every year, providing a significant boost to the development of the Chinese biotech industry. Many of China's biotech start-ups have founders that were educated abroad. For example, Biomics Biotechnologies was founded in 2006 by Yuanyuan Zhu, who had previously been a research director at several biopharmaceutical companies in Silicon Valley. Ge Li, a founder of WuXi AppTec, the leading Chinese medical device company, received his Ph.D. in Chemistry from Columbia University.[217]

China also builds on the advantage of this R&D talent being much cheaper than similar talent in developed nations. In 2007, it was estimated that companies could achieve cost savings of up to 80 percent by conducting biomedical research in China.[218] A study in 2008 estimated that low costs in scientific talent, clinical trials, and raw materials gave firms in China as much as a 90 percent cost advantage over firms in the United States.[219] A study from 2013 estimated that clinical trials, which can account for between 40 and 60 percent of the total costs of drug development, can be 67 to 80 percent cheaper than those in Japan or the United States.[220] One website estimated that by 2019, the median salary for a research scientist in China would be $39,000, compared with $78,000 in the United States.[221]

When it comes to biomedical research funding, the Chinese government invests much less overall than the United States. According to one study, in 2015, the Chinese government invested around $600 million to support R&D in biotechnology.[222] However, funding levels are increasing, particularly in targeted emerging areas. For example, China launched its precision medicine initiative in 2016 with the equivalent of $9.2 billion over 15 years, compared with the U.S. NIH effort of $1.5 billion over 10 years.[223] The Chinese government also provided $295.4 million for stem cell fundamental research under its 12th Five-Year Plan. Between 2016 and 2020, it is expected to allocate around $400 million for stem cell research projects, 10 percent of which will be for gene editing. In 2018 and 2019, the Ministry of Science and Technology (MOST) issued its National Key R&D Program for Stem Cell Transformational Research, funded at $60 million.[224] China has also established five new National Centers for Translational Medicine.[225]

Data will be increasingly important to biopharma innovation, especially in the next wave of personalized medicine, where China has an advantage. In contrast to U.S. laws such as the Health Insurance Portability and Accountability Act, which makes the collection and use of patient data for research difficult, there are no similar laws governing and restricting the use of health data in China.[226] Moreover, the Chinese government has made the generation and sharing of medical data a top priority. In 2016 the State Council issued a circular to promote the application and development of big data in the health and medical sectors, including the construction of national and provincial population health information platforms.[227] This means Chinese researchers are already using big data to train artificial intelligence (AI) health and biopharma algorithms. For example, Chinese researchers were able to obtain 600,000 patient records from a pediatric hospital to help train an AI algorithm to diagnose children's diseases, something that would have been extremely difficult to do in

the United States.[228] China's DNA repository of over 40 million individuals, which is targeted to reach 100 million residents by 2020, dwarfs that of any other country.[229] The Chinese government uses access to this massive database to attract foreign genetic research companies to China.[230] In addition, the Beijing Genome Institute (BGI) is the world's largest gene-sequencing organization. BGI was funded in part by local government incentives and, in 2010, a $1.5 billion line of credit from the China Development Bank.[231] Moreover, as is true with so many areas of its economy and technology, Chinese policy when it comes to genetic data is mercantilist in nature. In particular, Chinese law makes it extremely difficult for genomics data or genomics material to leave the nation (e.g., by being published in scientific journals), including prosecuting a number of companies for doing so.[232] Moreover, foreign companies using genetic data from Chinese persons must enter into cooperative agreements with Chinese organizations.[233]

Industry and Trade Policy

China goes beyond direct support for key inputs into the biomedical innovation process (research, talent, and data) by using more interventionist forms of industrial policy. One such policy is to reshape China's industrial structure. The Chinese government believes the industry is made up of too many small, uncompetitive firms, and if it is to gain competitive advantage, it needs to help restructure the industry such that there are fewer firms. There are a large number of generics producers in China. The U.S. International Trade Administration estimated that in 2015 China had about 5,000 drug manufacturers, with the largest 100 comprising only one-third of the market.[234] Another study estimated 6,000 generics producers.[235]

As a result, the 2016 State Council plan for the industry proposed to increase the adjustment of corporate organizational structure, promote cross-industry and cross-sector mergers and acquisitions of enterprises.[236] The Chinese government set a goal of having the top 20 domestic manufacturers of essential drugs control at least 80 percent of the Chinese market.[237] One way the government has done this is through its Generic Quality Consistency Evaluation, wherein China only allows the first three manufacturers of a particular drug that passes the assessment stage to be granted a license to produce the drug for the following three years.[238] In addition, NMPA's tougher manufacturing standards have had the benefit of making it harder for Chinese producers of low-quality generic drugs to meet the standards. In addition, generic drugs need to show therapeutic equivalence to original drugs. Companies that comply with the new policy benefit from a lower tax rate of 15 percent instead of 25 percent. All of this is not only leads to industrial consolidation; it improves the quality of Chinese generics, making it easier to reduce the market share of foreign drug companies. China hopes this added revenue will continue to be used to develop original drugs.

A second way the government influences the industry structure is through state ownership. Approximately 36 percent of major biopharma firms were state owned in 2006, with 35 percent privately owned and the remaining 29 percent foreign owned.[239] There are several very large-scale state-owned pharmaceutical companies, including SinoPharm, China Resources Pharmaceuticals, and Shanghai Pharmaceutical Group.[240] State-owned enterprises benefit from a number of advantages, including more-generous financing from Chinese state-owned banks, and reduced profit pressures.

The Chinese government also provides an array of incentives and supports, including research grants, for biopharma firms. 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.[241] Local Chinese governments are also providing financial incentives to help grow the industry. One key incentive is large-scale biomedicine science parks. Zhang Zhaofeng, director of MOST's Science and Technology for Social Development program, reported that by 2020, China will spend around $1.45 billion to support 20 biomedicine science parks.[242] 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.[243] For example, Shanghai's "Pharma Valley" is a 10-square-kilometer life-sciences parks 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.[244] 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).[245]

The central government is also investing in a nationwide network of manufacturing innovation centers, which are modeled on the Manufacturing USA Centers yet funded at significantly higher levels, plans to have almost 40 centers by 2025, and will presumably have some focused on biopharmaceutical technology—given it is a priority sector. In addition, tax incentives the Chinese government has developed for other high-tech sectors such as semiconductors benefit biotechnology. These include up to a 15-percent reduction in corporate income taxes, and a 150-percent pretax "super deduction" on specific types of R&D activity in China.[246]

Chinese government policies are supportive of inbound FDI, and the biotech industry is on the encouraged list of the Chinese government's Catalog of Industries for Guiding Foreign Investment. And while the sector is open to 100-percent ownership of foreign facilities, there are still incentives and pressures to form joint ventures, thus helping domestic biopharma firms. As one article on the trend to invest in China notes, "From investing in China facilities to acquisitions, licensing deals and joint ventures, the aim is to seek an edge in dealings with domestic regulators and government."[247] In other words, in contrast to the developed, rule-of-law nations where firms are largely treated the same regardless of whether they are a local producer, in China, firms know they are at a disadvantage if they are not producing locally or helping Chinese firms produce. As one WHO report notes, most foreign biopharma firms do not enter into joint ventures in other nations, but do in China.[248] In fact, virtually all major foreign biopharma firms have manufacturing facilities in China—and some have R&D facilities.[249] According to a comprehensive study of Chinse joint ventures, out of 29 industries, biopharma had the fifth-highest rate of joint ventures.[250] One reason for this, according to Asher Rubin, a partner at the law firm Hogan Lovells, is firms "need a China partner, in general, to commercialize [their] drugs in China."[251] Another reason for joint ventures is to receive better treatment by the Chinese government, including faster drug approval, preferences in purchasing drugs, and greater IP protection. As GlobalData Director of infectious diseases Christopher J. Pace noted, "[B]eing 'forced to compete against domestic firms that are given an unfair advantage by the Chinese Government' [is] one of the key concerns for foreign companies."[252] In short, many international firms are pressured by national and local officials to establish R&D centers in China for specific financial incentives, access to markets, and approvals for related business expansions.

The Chinese government also uses discriminatory procurement practices to favor Chinese-owned firms. 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."[253] 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.[254]

The Chinese government also imposes import restrictions. Under the WTO Pharmaceutical Agreement—to which China is not a party—the United States does not impose tariffs on biopharmaceutical products. In 2018, China did eliminate tariffs on 28 categories of imported cancer drugs, but remaining drug imports remain subject to a 5- to 6-percent import tariff.[255] In comparison, U.S. tariffs are zero.[256]

Another important policy tool for China to advance its biopharmaceutical industry is IP theft. For example, there have been numerous reports of Chinese biomedical researchers working at American universities, often on NIH grants, taking the IP their labs develop to China.[257] NIH Director Francis Collins, in a letter to grant institutions, wrote, "NIH is aware that some foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers and to take advantage of the long tradition of trust, fairness, and excellence of NIH-supported research activities." The Chinese 1000 Talents program also supports this effort, as one key qualification for the Chinese government offering incentives to scientists to come back to China is access to IP.[258]

Moreover, given the longstanding and widespread Chinese hacking of valuable U.S. company technology secrets, it is no surprise the Chinese have hacked into systems at U.S. biopharma companies, including Abbott Laboratories and Wyeth (now part of Pfizer).[259] And, as in most technology fields, Chinese state-sponsored actors also target biopharma firms for theft of IP, including through cybertheft and rogue employees.[260] That theft is sometimes through direct means whereby scientists working at biopharma companies in the United States engage in IP theft and the transfer of that IP to China. In 2002, a Chinese national was charged with stealing biological materials from Cornell University to bring to China.[261] In 2013, two Chinese nationals who had been employed as scientists at Eli Lilly were charged with stealing and providing trade secrets to a Chinese pharmaceutical firm.[262] In 2018, Yu Xue, a leading biochemist working at a GlaxoSmithKline research facility in Philadelphia admitted to stealing company secrets and funneling them to a rival firm, Renopharma, a Chinese biotech firm funded in part by the Chinese government.[263] In 2019, MD Anderson and Emory University both dismissed Chinese-born scientists for theft of IP.[264] A report to the U.S. China Economic and Security Review Commission notes, "Ventria Bioscience, 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 employees with the intent to sell it to a Chinese competitor. In the academic sector, researchers have stolen information or samples from their employers at Cornell University, Harvard University, and UC Davis."[265] This information is then sold to Chinese companies. In another case, a former Genentech employee was charged with trade-secret theft and passing on critical information to a Chinese competitor.[266] A former Chinese employee of a leading medical device firm was convicted of stealing IP and then traveling to China to obtain financing from the Chinese government to open a rival company using the stolen IP—even though the government knew the technology was stolen.[267]

Finally, China is also a major source of fraudulent medicines imported to the United States, allowing its producers to earn revenues for poor-quality or infringed drug products.[268] Eighty-eight percent of products seized by the U.S. Customs and Border patrol for IP violations in 2016 were from China or Hong Kong, and 8 percent involved pharmaceuticals and personal-care products.

HOW TO THINK ABOUT CHINA'S BIOPHARMACEUTICAL INNOVATION

Views of Chinese innovation policy tend toward the Manichean: either China is helping global innovation or it is hurting it and U.S. innovation. Add in the fact that the biopharma industry produces lifesaving treatments and cures for people around the world, and the question becomes even more nuanced and complicated. Resolving this issue is important because it can influence what the U.S. and global response to China's strategy and tactics should be.

First, it's important to consider this in the context of the particular industry. If, for example, China gains global and U.S. market share in the auto industry, the result might be a significant loss to U.S. jobs, but with the benefit of slightly cheaper vehicles. But drugs are different. If China gains global market share in drugs, it is possible it could significantly benefit the United States and the rest of the world through the production of better and perhaps cheaper drugs. In this regard, the biopharmaceutical industry has much in common with the clean-energy industry (e.g., solar panels, batteries, etc.). In both cases, the global need—better and cheaper medicines in the former case, and better and cheaper clean technology in the latter—may outweigh concerns about global competitiveness.

However, it is not that simple, because how China gains global market share has a major effect on whether China's biopharmaceutical innovation is good for both the United States and the rest of the world, or just China. To see why, it is important to distinguish between innovation policies that are fair and legitimate and those that are unfair and illegitimate. At one level, making such distinctions implies a value judgment, although there is considerable evidence and logic for making such distinctions. Fair and legitimate policies are those that generally abide by the letter and the spirt of the WTO, including nondiscrimination between domestic and foreign firms; not tying domestic market access to certain behaviors (e.g., technology transfer, joint ventures, etc.); generally limiting government intervention to addressing market and innovation system failures (e.g., support for research, skill development, and related infrastructure, as opposed to production or export subsidies); and ensuring a good regulatory and market environment, including robust protections for IP. (While the WTO has allowed some compulsory licensing of certain drugs for specific low-income nations or in exigent cases of national health emergency, overall, the WTO/TRIPS regime does respect IP.)

Unfair and illegitimate policies include favoring domestic over foreign firms; employing a weak IP regime, coupled with IP theft and forced technology transfer in order to obtain foreign technology without paying market rates for it; subsidies for production and export; and foreign-company acquisition not based on market prices and terms.

If China were to employ fair and legitimate policies to grow its domestic life-sciences industry, it would create direct competition for U.S. workers, as Chinese employment in the industry would grow while U.S. industry employment would shrink—at least its global share (see table 1). The impact on U.S. firms is indeterminate, as it is possible they would lose market share from fair Chinese policies. But U.S. firms could move R&D and production to China and continue to thrive. In both cases, overall, U.S. workers would be hurt, although U.S. firms would retain or even grow their global market share. U.S. consumers should benefit, both from greater competition but also from "more shots on goal" —in other words, from more researchers around the world working to develop cures and better treatments. If China employs fair policies to grow its biopharma industry, it will contribute new or cheaper drugs. For example, China is already producing anticancer PD-1 drugs, which are based on using the body's own immune system to fight tumors, at a much cheaper price than similar drugs from Western drug companies.[269]

Table 1: Framework for understanding the impact of Chinese life-science policies

Affected Interest	Fair Policies	Unfair Policies
U.S. Biopharma Workers	Harmful	Harmful
U.S. Biopharma Firms	Indeterminate	Harmful
U.S. Consumers	Beneficial	Indeterminate
U.S. National Security	Indeterminate	Indeterminate
Global Drug Innovation	Beneficial	Harmful

However, if China continues to employ unfair, mercantilist practices, the results are likely to be harmful. Because Chinese firms would gain global market share, U.S. biopharma firms and their workers would be hurt because they would lose market share to Chinese firms through unfair competition.

If China is able to produce drugs more cheaply than the United States—for example, through government subsidies to its producers—U.S. consumers could be better off. However, U.S. consumers could be hurt if Chinese policies reduce the pace of global drug innovation. This would certainly be possible because the market-distorting nature of the policies would be detrimental to global innovation leaders. For example, industrial espionage harms global innovation because it reduces the rate of return from R&D to non-Chinese companies, thus resulting in companies investing less in R&D. It also harms leading firms more than laggards, as practitioners of industrial espionage such as China generally don't spy on generics companies, but rather on companies at the leading edge. Likewise, Chinese drug price controls designed to favor Chinese generics firms reduce overall global industry R&D, leading to a slower rate of innovation. Chinese government-backed venture investments can harm global innovation when their investments distort proper market forces. For example, these firms may invest in U.S. biopharma companies with more generous terms than U.S. venture firms would do (higher levels of investment, at an earlier stage and with less ownership stake in the company). If the goal is to ensure technology and expertise are gained by China, the result is a weakening of the superior U.S. innovation ecosystem, leading to less innovation. To be sure, these kinds of firm-specific government intervention are very different than a broader form of support for the industry that does not distort individual deals (or discriminate as to whether the beneficiary is a domestic or foreign enterprise), such as an R&D tax credit start-ups and established firms can both use or support for early-stage research through entities such as NIH.

There is one final factor to consider, and that is the impact on national security. Even if U.S. consumers and global innovation were to benefit from China taking market share away from U.S. companies in industries and technologies such as lasers, AI, aviation, and high-performance computing, it would be against U.S. national interest to sit back and let that happen. However, when it comes to global goods industries such as drugs (and clean technology), the issue is not as clear cut. There are some national security issues involved with China's biopharma policy, including its significant global market share in APIs, which some argue pose a national security risk should China choose to limit U.S. access.[270] With regard to final products, if China develops a robust drug industry, as long as there is adequate production in the United States or among our allies, China's progress in this industry should not pose a serious threat to U.S. national security.

POLICY RECOMMENDATIONS

There are a number of policy changes needed in China, the United States, and globally to boost biopharmaceutical innovation.

China

The Chinese government has a unique opportunity to turn over a new leaf and show the world it can innovate while competing fair and square; in this case, with biopharmaceutical innovation. Doing so would send a powerful message to the world that China is finally committed to not just expanding its own economy, but doing it in a way, as Chinese officials like to say, that is win-win—in this case, by producing better drugs through fair means. However, turning over this new leaf would involve a number of changes, including restructuring its IP system to be neutral between drugs developed in China by Chinese firms and drugs developed by foreign firms; better protecting patents; joining the WTO Pharmaceutical Agreement and reducing its drug tariffs to zero; completely abandoning support for drug-related IP theft; significantly reducing government-backed or influenced VC investments, including in foreign firms; and holding all Chinese factories to global-standard drug quality. It is highly unlikely China will enact these reforms for the simple reason the government believes its current innovation mercantilist strategy has been a success. But should China decide it wants to approach this industry with a fresh start, one place to begin would be to establish an international panel of life-sciences policy experts to advise on policies, including providing input on which ones are fair and beneficial and which ones are unfair and harmful to global innovation.

United States

For all the focus on the U.S.-Chinese trade relationship over the last year, issues relating to the biopharma industry have received relatively little attention, especially compared with industries such as semiconductors and telecom equipment. In part, this is because these industries have important national security implications for America. But it is also because China is seen as much less of a threat to the U.S. biopharma industry than other industries. But this is a mistake. China is a significant potential threat—it's just that the actual threat, if it materializes, is at least a decade away. Nonetheless, the United States cannot afford to wait until the damage is clear (closed factories and laboratories, and unemployed U.S. workers), because by then it will likely be too late, as has already proven to be the case for a number of U.S. manufacturing companies. As such, Congress and the administration need to be thinking now about actions to help ensure U.S. biopharmaceutical leadership vis-à-vis China over the next two decades.

There are several steps the U.S. government should take internationally and domestically. Regarding China, under the extended purview (https://home.treasury.gov/system/files/206/FR-2018-22182_1786904.pdf) of CFIUS, the administration should consider blocking more Chinese acquisitions of or investments in U.S. firms involved in the design or production of drugs. This would be justified in part because the Chinese government provides large subsidies to some Chinese VC funds investing in biopharma companies, while at the same time enabling rampant IP theft.

In addition, the Trump administration and subsequent administrations should ensure trade negotiations with China include biopharma issues, such as forced technology transfer, IP theft, data-transfer restrictions, cartel and monopoly issues, and discriminatory access to the Chinese market. In addition, NIH should continue its work to better police abuse by Chinese nationals who inappropriately transfer knowledge generated by NIH grants to China. NIH should also more closely oversee any research funding or cooperation with China, particularly to limit support for areas where the Chinese could develop a commercial advantage.[271] This does not mean limiting access to U.S. universities to Chinese students, but rather increasing oversight and limiting illegal and unethical

behavior. Many in the science community will argue this goes against the global and open nature of science and scientific inquiry and exchange. But violating rules, stealing IP, and other violations are not and should not be accepted in the science community. Moreover, it's time to recognize that China is engaged in a race for competitive advantage in life sciences and seeks that advantage through unfair—as well as fair—means.

Congress should also ensure the FDA has adequate funding to effectively inspect Chinese facilities producing drugs and pharmaceutical ingredients (APIs) for U.S. consumption. According to the U.S. Government Accountability Office (GAO), of 535 of Chinese facilities subject to FDA monitoring, as many as 243 were not inspected between 2010 and 2016.[272] Moreover, according to the GAO, "FDA does not know whether or for how long these establishments have or may have supplied drugs to the U.S. market, and has little other information about them."[273] Better inspection and enforcement has several benefits. Besides improving safety, it means less production in China because many Chinese factories will likely fail inspections.

Domestically, there is also much to be done. Congress should continue its recent process of steadily increasing NIH funding, as this is an important enabler of U.S. life-sciences innovation.[274] It should expand the R&D tax credit (the Alternative Simplified Credit) from 14 percent to at least 20 percent and continue allowing first-year expensing of all capital equipment, as enacted in the recent tax reform legislation. Congress should continue to support the Bayh-Dole Act of 1980, which created a uniform patent policy that enables small businesses and nonprofit organizations, including universities, to retain title to inventions they create with the aid of federal funding.[275] Congress and the FDA should continue to improve and streamline, wherever possible, the drug approval process, keeping in place existing safety and efficacy standards. As Congress reauthorizes the Manufacturing USA program, it should add funding for at least one center focused on biopharmaceutical manufacturing process technology to complement the existing BioFabUSA center, which focuses on production process for large-molecule biotech drugs. This will important if the federal government wants to increase domestic drug production, especially of generics and APIs, and reduce dependency on China.[276]

Congress should do more to better enable data-driven biopharma innovation in the United States. ITIF's Center for Data Innovation has called for the creation of a National Health Data Research Exchange to prioritize the collection and sharing of patient medical data for research purposes.[277] In addition, the federal government should refrain from imposing arbitrary restrictions on certain kinds of research, such as stem cell, as President Trump recently did.

Perhaps most importantly, as it seeks to ensure more affordable health care, Congress should safeguard that any efforts do not inappropriately limit drug prices. The scholarly evidence is clear that limiting industry revenues through price controls results in less investment in R&D, which limits badly needed drug discovery. A number of studies have found this causal relationship. For instance, as OECD wrote, "There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures."[278] Imposing significant drug price controls would starve biopharma companies in the United States from the innovation "fuel" they need to stay at the global cutting edge, and in turn, would enable China to catch up to the United States.

Global Policy Coordination

For many areas of policy, a number of nations have an incentive to "free ride" on the rest of the world, especially if the costs of doing so are global in nature, while the benefits are local. In spite of this logic, on some issues, many nations act in a global interest. We see this when it comes to climate change, with virtually all nations—the United States excepted—signing on the Paris Climate Accord to take steps to lower greenhouse gas emissions. (The United States did sign on to the Mission

Innovation agreement.) One reason small and mid-sized nations are participating in this accord, even though they would be better off economically not participating (by not paying the higher costs for clean energy), is because there is a global expectation that everyone needs to cooperate to address a global challenge. Smog might be a local problem, but CO2 emissions are a global one. Being a free rider, in this case, comes with at least some consequences, including global opprobrium; something the United States is now facing (notwithstanding the fact that the United States is doing more to help address global warming through its significant investments in clean energy research, development, and demonstration than any other nation).[279] It is time for a similar accord for global drug development. We need the equivalent of a "Paris Drug Innovation Accord" in which nations make commitments to adopt policies that spur global drug innovation, including policies related to drug pricing, IP, and data sharing for research.

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