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The Impact of China's Policies on Global Biopharmaceutical Industry Innovation

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China is striving to become the global leader in biopharmaceuticals, but many of its policy steps are "innovation mercantilist" in nature. This not only is expected to threaten U.S. leadership, but also slow global life sciences innovation, with negative consequences for cures and treatments.

KEY TAKEAWAYS

- America leads in drug discovery and production, ranking first in most innovation measures, whereas China's biopharma industry is still relatively small. But the government's "Made in China 2025" plan targets it as a key sector for global growth.
- Some Chinese policies help global innovation, such as (modest) funding of early stage biomedical research. But many others are harmful—such as weak IP protection, draconian price controls, pressured tech transfers, and discriminatory procurement.
- When Chinese firms sell drugs with unfair support from the Chinese government, they reduce the pace of global drug innovation by taking market share and revenue from more innovative non-Chinese firms operating without such support.
- 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.
- In the trade arena, the administration should limit Chinese acquisitions and investments in U.S. drug designers and producers; ensure trade negotiations include biopharma issues; and fund the FDA to effectively inspect Chinese exports.
- Domestically, Congress should increase NIH funding, expand R&D tax subsidies, support the Bayh-Dole Act, streamline drug approvals, enable data-driven life-science innovation—and, perhaps most importantly, reject draconian drug price controls.

INTRODUCTION

The production of biopharmaceuticals—large-molecule biotech drugs and small-molecule chemical drugs—is one of the most innovation-intensive industries in the world. Worldwide, the industry invests a greater share of sales into research and development (R&D) than any other industry in order to continue to develop and bring to market new drugs and other treatments.

Unlike industries wherein China has already gained significant global market share, including high-speed rail, solar panels, and telecom equipment, China's global market share and competitiveness in biopharmaceuticals is still quite low, with the global leaders largely in the United States, with Japan and Europe following.

Competition can drive innovation, but it needs to be market-based competition.

It is for this reason that China has targeted the industry for global competitive advantage, as detailed in a number of government plans, including "Made in China 2025." China is taking a range of steps to propel itself to become a major global biopharma competitor—starting with developing a world-class generics industry. However, while some of these policy actions are fair and legitimate, many are not, and are "innovation mercantilist" in nature, seeking to unfairly benefit Chinse firms at the expense of more innovative foreign firms.

Competition can drive innovation, but it needs to be market-based competition. When Apple came out with the iPhone and helped drive Blackberry from the market, this advanced innovation, because it was based on consumer demand for a better product, drove the change. In contrast, a Chinese biopharma firm selling a drug largely because it was supported unfairly by the Chinese government likely reduces the pace of global drug innovation by taking market share and revenue away from more innovative non-Chinese firms.

INNOVATION IN THE BIOPHARMA INDUSTRY

The biopharmaceutical sector includes research, discovery, testing, and manufacturing of medicines and therapeutics that cure disease and improve patient health. The development of new drugs requires years of painstaking, risky, and expensive research that for a new pharmaceutical compound takes on average between 11.5 and 14 years of research, development, and clinical trials at a cost of $1.5 billion to $2.6 billion.[1]

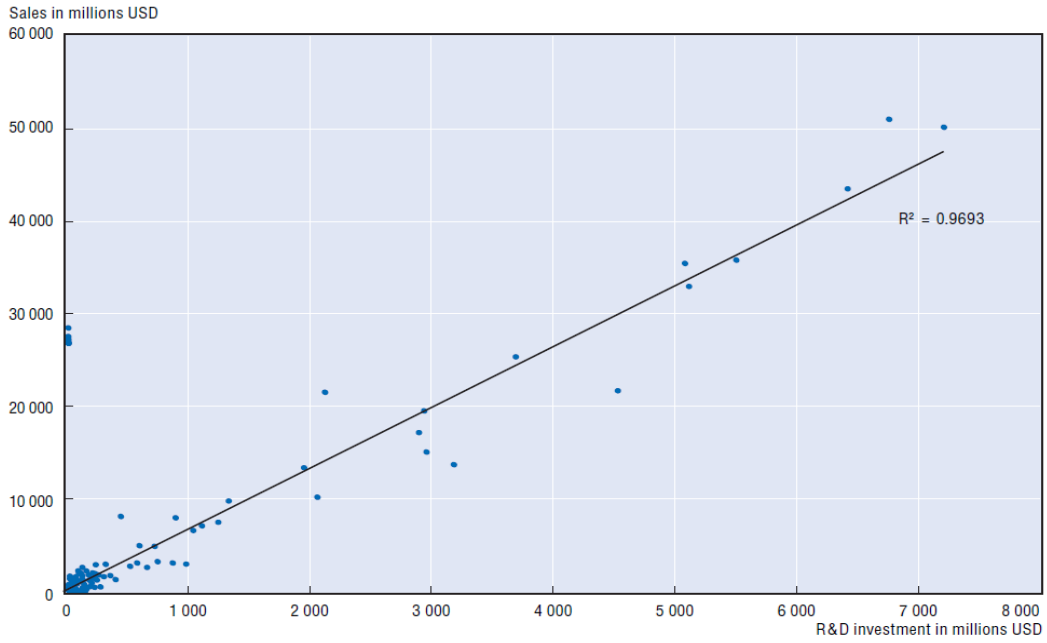
The industry is extremely innovative and far from mature: Maturity would mean either all human diseases have effective treatments or further technological progress is not possible. Neither is true. Many diseases, including cancer and Alzheimer's to name just two, are unfortunately still all-too prevalent. And new technologies and discoveries, including personalized medicine, gene editing, organ printing, and immunotherapy, show enormous promise. In other words, this is an innovative industry, not a mature one.

We see this in R&D investment. Large biopharma firms invest considerable resources in R&D, with the top 30 companies globally (ranked by revenue) being responsible for 77 percent of global pharmaceutical R&D funding. The U.S. life-sciences sector, for example, is extremely research intensive, investing over 21 percent of its sales in R&D, while accounting for 23 percent of domestic R&D funded by U.S. businesses—more than any other sector.[2] Measuring R&D

expenditures, the U.S. biopharmaceutical sector leads all other U.S. manufacturing sectors, investing more than 10 times the amount of R&D per employee.[3] And in the United States, companies' share of R&D classified as basic (14.3 percent) instead of later-stage applied and development is higher than any other U.S. industry—and more than twice as high as the U.S. industry average (6.4 percent).[4]

As companies earn more revenues, they invest more in R&D. As the Organization for Economic Cooperation and Development (OECD) explained, "There is a high degree of correlation between sales revenues and R&D expenditures."[5] (See figure 1.) This relationship is tight because pharmaceutical sales are the main source of revenue pharmaceutical companies use to generate the funding needed to finance research into, and development of, future generations of innovative medicines.

Figure 1: R&D expenditures and sales in the pharmaceutical industry, 2006[6]



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

Source: DIUS (2007).

Advanced Economies Lead

Most innovative biopharma companies are headquartered in advanced economies. The 2017 Biopharmaceutical Competitiveness and Investment Survey ranks 27 nations on a variety of measures the biopharma innovation. Singapore led, with the United States second, followed by Switzerland, Germany, the United Kingdom, and Israel.[7] China ranked 20th. One study ranking the 20 most innovative biopharma companies finds that the top 10 were outside of China, with companies in Japan, Switzerland, the United Kingdom, and the United States; and of the top 20, only 1, Jiangsu Hengrui Medicine, was headquartered in China.[8]

The United States remains the leader in discovery and production, ranking first in nearly all measures of innovation.[9] Of the top 25 pharmaceutical companies, 11 were headquartered in the United States, accounting for 48 percent of total sales from this group. And in 2015, the United

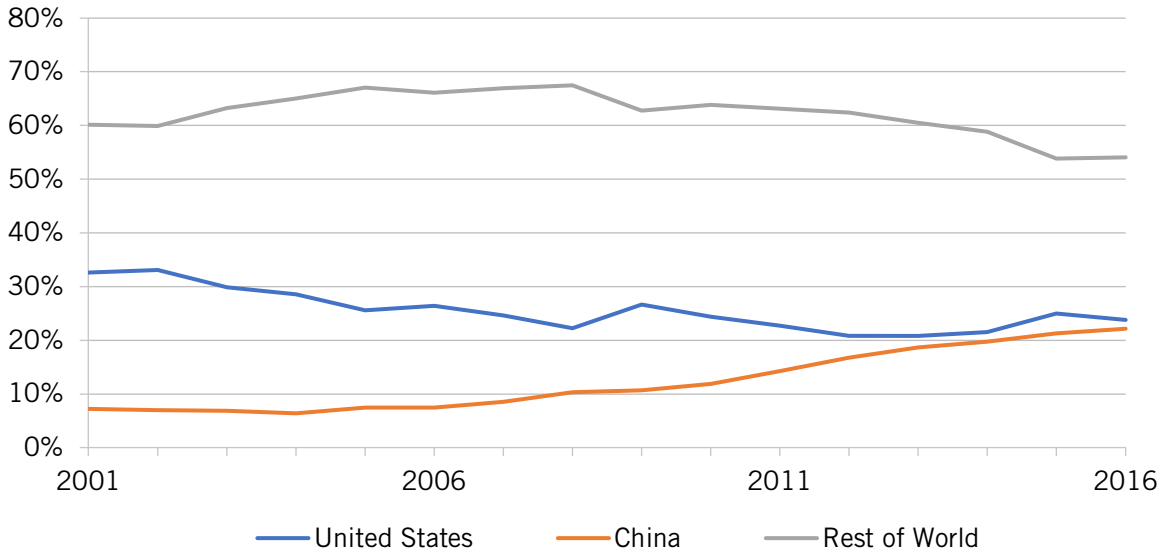
States attracted 74 percent of all worldwide venture-capital investments in the industry.[10] Moreover, the United States increased its share of pharmaceutical R&D expenditures among developed countries between 1995 and 2010 from 43 percent to 57 percent.[11] In the 2000s, more new chemical entities 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.[13]

China's Competitive Position

Unlike some more-traditional manufacturing or electronics industries wherein China has dominated global production, China's biopharmaceutical industry is an emerging industry that is still relatively small, but targeted by the Chinese government.

One reason the industry is relatively nascent is that as a still emerging economy, China's health care expenditures, including on drugs, are significantly lower than in higher-income nations. Nonetheless, Chinese biopharma industry output has grown rapidly over the past decade as Chinese incomes have grown and as China has dramatically expanded the share of its citizens that are eligible for health insurance.[14] Chinese sales increased from $26.2 billion in 2007 to $122.6 billion in 2017 (U.S. sales were $466.6 billion).[15] 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 2.) 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 a key generics producer.[16] APIs and generics are less innovation based, with simpler production processes and less need for original innovation. China more than doubled its biopharmaceutical production capacity, including APIs, from 2010 to 2014.[17] 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."[18]

Figure 2: Global shares of value added of the pharmaceutical industry[19]



However, China is moving toward becoming a developer and producer of innovative new drugs. As 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."[20] It 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."[21] 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).[22] 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.[23] As of mid-2018, 25 Chinese companies had applied for approvals for advanced anticancer drugs based on biotechnology (PD-1/PD-L1 inhibitors).[24] 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.[25] Of just over 400 CAR-T clinical trials conducted in March of 2019, 166 were in China, and 165 in the United States.[26] 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.[27] And in 2016, China had filed 410 clustered regularly interspaced short palindromic repeats (CRISPR gene-editing) patents, with the United States filing 447.[28] In 2015, there were 173 publicly traded pharmaceutical companies in China.[29]

China more than doubled its biopharmaceutical production capacity from 2010 to 2014.

Much of this has been based on the practice of simply copying from the leading Western companies.[30] In 2015, Chinese companies still produced less than 1 percent of new molecular entities (e.g., drugs) globally.[31]

However, many global biopharmaceutical firms have expanded 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 have manufacturing facilities in China—and many have also established R&D centers there.[32] China is an important market for foreign life-sciences companies, with the top-10 mature drugs from foreign companies adding $2.8 billion additional revenue to China from 2014 to 2018.[33] From 2010 to 2014, annualized growth in Chinese sales revenue among biopharma manufacturers was 23 percent.[34]

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 that have shown considerable willingness to invest in U.S. R&D and production facilities.[35]

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 and 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."[36]

Copying can certainly work if China wants to develop a globally competitive generics and biosimilar industry, but it will not be enough to achieve significant market share in innovative drugs.

Moreover, 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.[37] 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.[38] 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 had less than 3 percent of global market sales in 2015.[39]

China's relatively low per capita income is also a factor because it makes it harder for China to pay for innovative new drugs, thus limiting the development of Chinese firms. This is why just 8 percent of new drugs approved globally between 2011 and 2017 are available in China.[40]

CHINESE BIOPHARMA INDUSTRY GOALS

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 16 "megaprojects," including pharmaceutical innovation and development, and control and treatment of AIDS, hepatitis, and other major diseases.[41] 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."[42] 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.[43]

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.[44] 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.

The State Council has called on all levels of government to target the industry for support.

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, up from less than 2.5 percent a few years prior.[4546]

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."[47] 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.[48] 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."[49] 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.[50]

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, and 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 percent 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, and 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 (FDA) or EU authentication and enter the international market; construct, improve, and support the national drug innovation system for external services; form a high-level innovation team with an international perspective; and promote China's drug internationalization development strategy.[51]

In addition to the national Made in China 2025 plan, at least 19 of China's 23 provinces have their own plans.[52] 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 states:

> 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.[53]

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.[54]

China also appears to be "skating where the puck will be" in the sense that the government is focusing more on biotechnology and biology 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."[55] 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."[56] 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).[57]

CHINESE BIOPHARMA POLICIES

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 World Trade Organization (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 intellectual property (IP). (While 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—Trade-Related Aspects of Intellectual Property Rights—regime does respect IP.)

It is important to distinguish between innovation policies that are fair and legitimate and those that are unfair and illegitimate.

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. (See table 1.)

For Chinese industrial policies, while some are legitimate and non-distorting innovation policies, a much higher share are mercantilist and distorting policies.

Legitimate Chinese Biopharma Policies

China deploys an array of legitimate policies to spur biopharma growth and innovation.

Two key policy areas relate to talent and research funding. Chinese universities produce around 150,000 life-sciences graduates annually, compared with America's 137,000.[58] This supports global biopharma innovation as long as more-innovative foreign firms have equal access to this talent in China, which they do not.

When it comes to biomedical research funding, the Chinese government invests much less than the United States. In 2015, the Chinese government invested around $600 million to support R&D in biotechnology, compared with over $40 billion in the United States.[59] However, funding levels are increasing, particularly in targeted emerging areas. For example, in 2016, China launched its precision medicine initiative with the equivalent of $9.2 billion over 15 years, compared with the U.S. National Institutes of Health (NIH) effort of $1.5 billion over 10 years.[60] The Chinese government also provided $295 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.[61] China has also established five new National Centers for Translational Medicine.[62]

The Chinese government also provides an array of incentives and supports, including research grants, for biopharma firms. One study finds 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.[63] Local Chinese governments are also providing financial incentives to help grow the industry. One key incentive is large-scale biomedicine science parks. Zhaofeng Zhang, 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.[64] 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.[65] For example, Shanghai's "Pharma Valley" is a 10-square-kilometer life-sciences park that houses more than 500 biotech companies. Other local governments are also targeting the industry, in part by building research parks and providing tax incentives and direct subsidies.[66] Often, these provincial parks provide discounted or free office, 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).[67]

In contrast to EU and U.S. rules that make the collection and use of patient data for research difficult, there are no similar laws restricting the use of health data in China.

The central government is also investing in a nationwide network of manufacturing innovation centers modeled on the Manufacturing USA Centers but funded at significantly higher levels, plans to have almost 40 centers by 2025, and will presumably have some of them be 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.[68]

Data will be increasingly important to biopharma innovation, especially in the next wave of personalized medicine. In contrast to EU and U.S. rules that make the collection and use of patient data for research difficult, there are no similar laws restricting the use of health data in China.[69] 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.[70] 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.[71] 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.[72] The Chinese government uses access to this massive database to attract foreign genetic research companies to China.[73]

China has improved its biopharma regulatory system. China joined 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 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.[74]

China is improving its process of conducting clinical trials of new drugs, including establishing more clinical trial centers.[75] It has also announced it will put in place an expedited orphan drug review process and create a new medical reimbursement agency. 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.[76] Also added to the NRDL through direct listing were 128 Western drugs.[77] 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.[78] 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.

Finally, one could argue that China's large and growing market for drugs is likely to spur global biopharma innovation. Drug consumption, particularly of non-generics (original innovative drugs) in China is significantly lower than in richer nations. However, as per capita incomes continue to grow, that gap will lessen. Moreover, China's population of 1.4 billion is more than 4 times larger than that of the United States. In part because of a growing economy and an aging pollution, the Chinese drug market grew six times larger from 2005 to 2017.[79] It is set to become the second largest in the world, behind the United States, by 2020.[80] Tragically, China now has a third of the world's cases of colorectal cancer, 40 percent of lung cancer, and half of gastric cancer cases—all factors that will lead to the growth of drug sales in China.[81] 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.[82] But this growing market will only support global life-sciences innovation if foreign firms have a fair shot at selling into the Chinese market, which is not the case.

Chinese Innovation Mercantilist Biopharma Policies

Notwithstanding the "good" non-mercantilist Chinese innovation policies for this industry, China's "bad" mercantilist policies significantly outweigh the former. There a number of different types of mercantilist policies: some relate to discriminatory market access for foreign firms, some relate to unfair subsidies, and others relate to IP theft. (See table 1.)

Table 1: Assessing China's biopharma industry policies on global innovation

Type of Policy	Impact on Global Innovation
Pressured joint ventures and technology transfer	Harmful
Draconian drug price controls	Harmful
Intellectual property theft	Harmful
Undervalued currency	Harmful
Protected domestic market	Harmful
Limits of cross-border health data transfers	Harmful
State-owned enterprises	Harmful
Weak intellectual property protection	Harmful
Discriminatory procurement	Harmful
Government-backed venture capital investing	Neutral
R&D subsidies favorable to Chinese firms	Neutral
Supporting STEM education	Helpful
Funding early stage biomedical research	Helpful
Enabling use of personal health data for biomedical research	Helpful

Pressured Joint Ventures

The Chinese three-stage playbook is quite similar for all advanced industries. Phase 1 starts with allowing foreign imports. Phase 2 transitions to requiring and incenting foreign production in China tied to forced technology transfer. And as a final stage, it switches to supporting China's

domestic firms. China is actively in phases 2 and 3. Chinese government policies are supportive of inbound foreign direct investment (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."[83] In other words, in contrast to the developed, rule-of-law nations wherein 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 a WHO report notes, most foreign biopharma firms do not enter into joint ventures in other nations, but do in China.[84] In fact, virtually all major foreign biopharma firms have manufacturing facilities in China—and some have R&D facilities.[85] According to a comprehensive study of Chinse joint ventures, out of 29 industries, biopharma had the 5th-highest rate of joint ventures.[86] 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."[87] 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."[88] 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.

One key way to pressure firms into establishing joint ventures is through the drug approval process. 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.[89] 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."[90] Similarly, in exchange for investing in China, provincial governments tout their willingness and ability to help firms gain regulatory and market approval.[91]

Undervalued Currency

China's biopharma industry has benefited from a deeply undervalued Chinese currency, which at least for many years, provided it with a 25 to 35 percent price subsidy.[92] One key benefit of this was it made it easier to attract foreign biopharma companies to invest in China, as it reduced their costs and lowered the costs of their exports. In 2007, it was estimated that companies could achieve cost savings of up to 80 percent by conducting biomedical research in China.[93] A study in 2008 estimates 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.[94] A study from 2013 estimates 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.[95] One website estimated that by 2019, the median salary for a research scientist

in China would have been $39,000, compared with $78,000 in the United States.[96] This artificial price reduction likely distorted the global patterns of research, thereby reducing research in more innovative nations than would otherwise be the case.

Draconian Drug Price Controls

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. This is particularly true because so many drugs never make it to market, and even of the ones that do, the marginal cost of production is much lower than the average cost because of high levels of R&D needed.[97]

China is working aggressively to develop domestically produced generic alternatives to foreign drugs, in part by dramatically cutting reimbursements for drugs, prior to which many were foreign. China's State Council has said it will adopt international cost-containment practices as reference pricing for drugs, including new drugs. As the McKinsey Global Institute noted, "Most imported drugs in the 2018 NRDL negotiation came out with a price significantly lower than neighboring countries, 36 percent lower on average."[98] 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.[99] 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.[100] 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).[101] 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.

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.

One goal of this is to centralize procurement of generics so as to generate a consolidation in the industry in order 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 more innovative, foreign drug companies.[102] 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.[103] 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.

Overall, Chinese drug price controls limit innovation for two reasons. First, they reduce revenues going into the global drug discovery system. Overly restrictive price controls levied against pharmaceuticals, by definition, mean less revenue for biopharma companies to invest in R&D. For example, Golec and Vernon found that because of EU drug-price regulations, "European Union pharmaceutical firms are less profitable, spend less on R&D, and earn smaller stock returns than U.S. firms."[104] By using data from 1986 through 2004, they showed that the economic trade-off for the EU, by maintaining real pharmaceutical prices constant over 19 years, was forgoing about 46 new medicine compounds. They took this one step further by presenting a counterfactual scenario wherein, if the United States had adopted EU-type price controls over the same time period, then the result would have been 117 fewer new medicine compounds.[105] Price controls also delay the launch of drugs in markets with controls.[106] In other words, the debate about price controls is not really one about whether society wants lower prices in exchange for lower drug company profits; it is about whether society wants lower drug prices in exchange for less and slower drug innovation—that is, cheaper prices today, and less effective drugs when our children become adults.

Second, significantly limiting drug pricing harms foreign firms more than Chinese firms that have a lower cost structure. This is made worse by the Chinese government's recently mandated significant price cuts on many drugs.[107] By imposing very strict price controls and favoring Chinese firms in national drug selection, China is seeking 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.

Protected Domestic Market

China supports domestic biopharma firms by limiting foreign market access. The large and growing Chinese market plays a key role in enabling these firms to gain scale and boost innovation so they can then take on foreign firms in foreign markets. As noted, China limits the market in part by favoring Chinese-company-produced drugs in competitions to be purchased by hospital systems. China also protects the market by requiring drug import licenses, which can be difficult to obtain, and issuing them for only for five years—and renewals are not guaranteed.[108]

China also uses its regulatory system as a protectionist, industrial policy tool. For example, only 4 of the 42 cancer drugs approved globally in the past 5 years are available in China.[109] In addition, some of the proposed regulatory changes are designed to benefit domestic companies over foreign ones. For example, NMPA has given priority review to innovative medicines produced in China over those produced outside China.[110] 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.[111]

The Chinese government also imposes import tariffs. 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 are still subject to a 5 to 6 percent import tariff.[112] In comparison, U.S. tariffs are zero.[113]

Protecting the Chinese market enables Chinese generics firms, which make up the lion's share of Chinese biopharmaceutical firms, to make 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."[114] 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. These increased profits allow these firms to reinvest more in R&D to become original drug innovators and ultimately challenge foreign leaders.

Discriminatory Procurement

The Chinese government also uses discriminatory procurement practices to favor Chinese-owned firms. The 2016 State Council document on the industry states, "In principle, government procurement projects must purchase domestically produced products and gradually improve the level of domestic equipment configuration of public medical institutions."[115] 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. Many believe this was in order to give a Chinese domestic pneumococcal vaccine more time to be developed free from competition.[116]

Limits on Exports of Data

Chinese policy regarding genetic data is mercantilist in nature. In particular, Chinese law makes it extremely difficult for genomics data or material to leave the nation, including by being published in scientific journals, and has prosecuted a number of companies for doing so.[117] Moreover, foreign companies using genetic data from Chinese persons must enter into cooperative agreements with Chinese organizations.[118] At the same time, Chinese have invested in U.S. operations so they can use and export genomic data of Americans.[119] The Chinese National Congress has proposed a Biosecurity Law, which would restrict all data resulting from cross-border scientific collaborations from leaving China without government approval and without the Chinese entity retaining some sort of rights over any technologies eventually developed, even if normally they would not receive these rights.

Weak Intellectual Property Protection

Strong IP protection is key to innovation in the biopharmaceutical industry. Compared with the United States and Europe, China's IP environment for drug development has been decidedly weaker. For example, both the United States and the European Union provide a period of marketing exclusivity (aka "regulatory data protection") for a drug independent of patent protection, as well as patent-term extension to compensate for the loss of the patent term during the approval process. China does not, effectively reducing 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 that of the United States.[120] China also uses patent procedures to invalidate patents based on heightened "enablement" and nonobviousness requirements. It also makes it more difficult than the other IP5s (U.S., 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. China also provides only a 6-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.[121] This government strategy is key to enabling Chinese firms to "legally" copy the drug discoveries of more innovative foreign companies.

Despite few other nations having such a discriminatory policy, 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. 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.[122]

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.[123] 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."[124] 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.[125]

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. But to date it has not acted on this. 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.[126] A linkage regime would be critical in addressing the problem 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.[127] 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.[128]

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 finds that 44 percent of the challenged pharmaceutical patents had been invalidated in whole, while 32 percent were declared partially invalid.[129] Another study estimates 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.[130] The speed by which patents are invalidated has purportedly increased, and is much higher than invalidation rates in the United States and Europe.[131] Invalidating foreign patents appears to be a key way for China to enable its generics industry to gain market share.

Many of these patenting 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 (USPTO) issued a patent for the drug that will expire later this year.[132] 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."[133] 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.

Some have argued that the Chinese patent office imposes overly strict requirements for sufficiency of disclosure for enablement and inventive steps 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 and then sharing the data with domestic firms.[134] 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.[135]

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 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.

Also, 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.[136] 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.[137]

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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.[138] 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.

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.

IP Theft

Another important policy tool for China to advance its biopharmaceutical industry is IP theft. 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.[139] 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 foreign IP.[140] For example, recently the U.S. Justice Department charged Harvard University's Charles Lieber with "one count of making a materially false, fictitious and fraudulent statement" regarding his work with Chinese-based organizations, including the 1000 Talents Plan, while he applied and received NIH funding.[141] The U.S. Justice Department investigated an individual who was "[k]nowingly and willfully working in the United States on behalf of government-controlled and government-directed entities … for the purpose of recruiting high-level molecular geneticists and stem cell researchers to work at state-controlled universities and laboratories in [China], and for the purpose of acquiring and transferring to those state-controlled universities and laboratories, cutting-edge molecular genetics and stem-cell research and technology developed at leading academic and private sector research platforms in the United States."[142]

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).[143] And, as in most technology fields, Chinese state-sponsored actors also target biopharma firms for theft of IP, including through cybertheft and rogue employees.[144] 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.[145] 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.[146] 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.[147] And last year a second scientist pled guilty as well.[148] In 2019, MD Anderson and Emory University both dismissed Chinese-born scientists for theft of IP.[149] 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."[150] This information was 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.[151] 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.[152]

China is also a major source of fraudulent medicines imported to the United States, allowing its producers to earn revenues for poor-quality or patent-infringed drug products.[153] 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.

Government-Backed 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 venture capital (VC) investment. Much of this money is provided by provincial governments.

At the end of 2017, there were a recorded 1,166 government-led venture funds, up from 214 funds in 2013, with 5.3 trillion yuan ($780 billion) in targeted capital.[154] 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.[155] These government-backed VC funds are targeted to industries deemed strategic by the Chinese government, including the biopharmaceutical 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.[156]

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.[157]

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.[158] Of the 20 largest Chinese government guidance VC funds today, most set up in Chinese provinces and cities, and 7 identify health care (which includes biopharmaceuticals) as a key sector of focus.[159] It is not clear how much of this money comes from government 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 sent 70 questions to WTO about Chinese subsidies, including in biotechnology.[160] 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.[161]

State-Owned and Backed Enterprises

Chinese governments also influence the industry structure 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.[162] There are several very-large-scale state-owned pharmaceutical companies, including Sinopharm, China Resources Pharmaceuticals, and Shanghai Pharmaceutical Group.[163] State-owned enterprises benefit from a number of advantages, including more-generous financing from Chinese state-owned banks, and reduced profit pressures.

In addition, unlike most governments, Chinese governments provide subsidies beyond early-stage investments in research. For example, the Beijing Genome Institute, the world's largest gene-sequencing organization, was funded in part by local government incentives and, in 2010, a $1.5 billion line of credit from the China Development Bank.[164]

How to Think About China's Biopharmaceutical Innovation

Views of Chinese innovation policy tend toward the Manichean: China is either helping global innovation or hurting it. 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 also good for the rest of the world. If China were to employ fair and legitimate policies to grow its domestic life-sciences industry, it would create direct competition for non-Chinese workers, as Chinese employment in the industry would grow while non-Chinese industry employment would shrink—at least its global share. (See table 2.) The impact on foreign firms is indeterminate, as it is possible they would lose market share from fair Chinese policies. But foreign firms could move R&D and production to China and continue to thrive. In both cases, overall, foreign workers would be hurt, although foreign firms would retain or even grow their global market share. Foreign consumers would 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.

Table 2: Framework for understanding the impact of Chinese life-science policies

	Fair Policies	Unfair Policies
Foreign biopharma workers	Harmful	Harmful
Foreign biopharma firms	Indeterminate	Harmful
Foreign consumers	Beneficial	Indeterminate
Global drug innovation	Beneficial	Harmful

However, if China continues to employ unfair, mercantilist practices, the results are likely to be harmful along all aspects. Because Chinese firms would gain global market share, foreign 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 other countries—for example, through government subsidies to its producers—foreign consumers could be better off. However, foreign consumers would be hurt because Chinese mercantilist policies would reduce the pace of global drug innovation. This is akin to drug price controls in domestic markets: Consumers are better off from lower drug prices but worse off from less biopharma innovation and fewer new and more-effective drugs.[165]

Innovation mercantilist policies would likely be detrimental to global innovation in large part because foreign firms are more innovative. For example, Chinese 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 sales and R&D, leading to a slower rate of innovation. Chinese government-backed venture investments can harm global innovation when their investments crowd out more innovative start-ups. For example, these firms may invest in foreign biopharma companies with more-generous terms than foreign 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 foreign—especially U.S.—innovation ecosystems, leading to less innovation. To be sure, these kinds of firm-specific government intervention are very different from 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.

COMPARATIVE INNOVATION PERFORMANCE

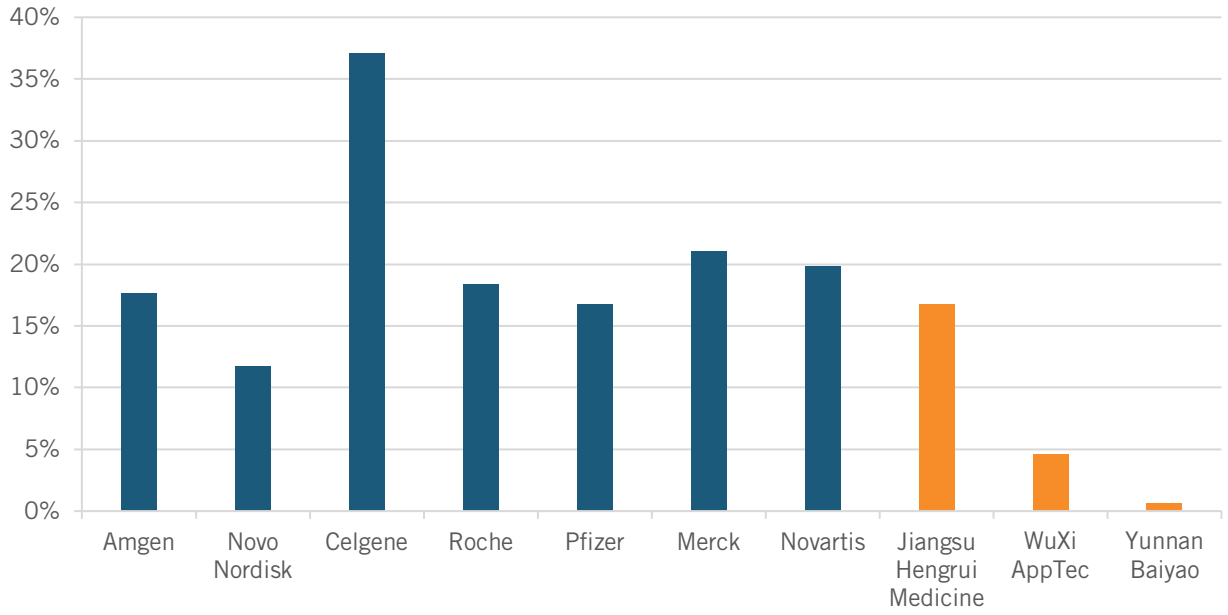
Overall, Chinese biopharma firms are significantly less innovative than the leading firms around the world. One measure is scientific publications. From 2011 to 2015, China ranked second in the world behind the United States in international biomedical publications.[166] And it quadrupled its global share of biomedical articles between 2006 (2.4 percent) and 2015 (10.8 percent).[167] In 2016, it was responsible for almost as many biotechnology and applied microbiology publications as the United States.[168]

However, it also has a population 4.4 times larger than the United States, so on a per capita basis, China lags significantly behind the United States. In addition, its share of documents in the top 1 percent of citations is lower than its overall share of articles.[169] 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.[170] On a per capita basis, this is just 4.3 percent and 2.2 percent of U.S. levels, respectively. Moreover, there is evidence that at least some of the papers published by Chinese scholars are fraudulent and produced by "paper mills."[171]

Corporate R&D

Chinese pharmaceutical business R&D investment increased at a very rapid rate, by 254 percent, from 2008 to 2015, compared with 7.3-percent growth for the United States.[172] In 2016, Chinese biopharma R&D stood at an estimated $7.2 billion, up from just $163 million in 2000.[173] But 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.[174] For example, figure 3 compares R&D to sales ratios for 7 leading non-Chinese companies and 3 major Chinese companies.[175] Only Jiangsu Hungrui Medicine comes close to the leaders with an R&D-to-sales ratio of 16.7 percent. The other two companies, WuXi App Tec and Yunan Baiyo, invest significantly less.[176]

Figure 3: Biopharma firm R&D-to-sales ratio—Chinese (in red) and Non-Chinese (in blue) firms, 2019[177]



Patenting

Patenting is a measure of innovation. However, because so many patents issued by the Chinese Patent Office are of relatively poor quality, patent counts from China cannot be compared against patents issued by USPTO. As a result, this section includes USPTO patents as well as patents filed internationally.

Only 688 life-sciences patents (in medical technology, biotechnology, and pharmaceuticals) were granted by USPTO to Chinese inventors in 2018. Biotechnology and pharmaceuticals patents issued to Chinese companies were only 5.2 and 6.3 percent respectively of the patents granted to U.S. companies.[178]

Moreover, according to OECD, in 2016, 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.[179] While triadic patents filed by inventors in China grew between 1995 and 2015 (the latest year available), the number remains quite small. (See figure 4.) And as share of GDP, China lags significantly behind the EU, Japan, and the United States, with just 18 percent of the patent intensity of these three nations combined. (See figure 5.)

Figure 4: Number of triadic biotechnology and pharmaceuticals patent applications by priority date[180]

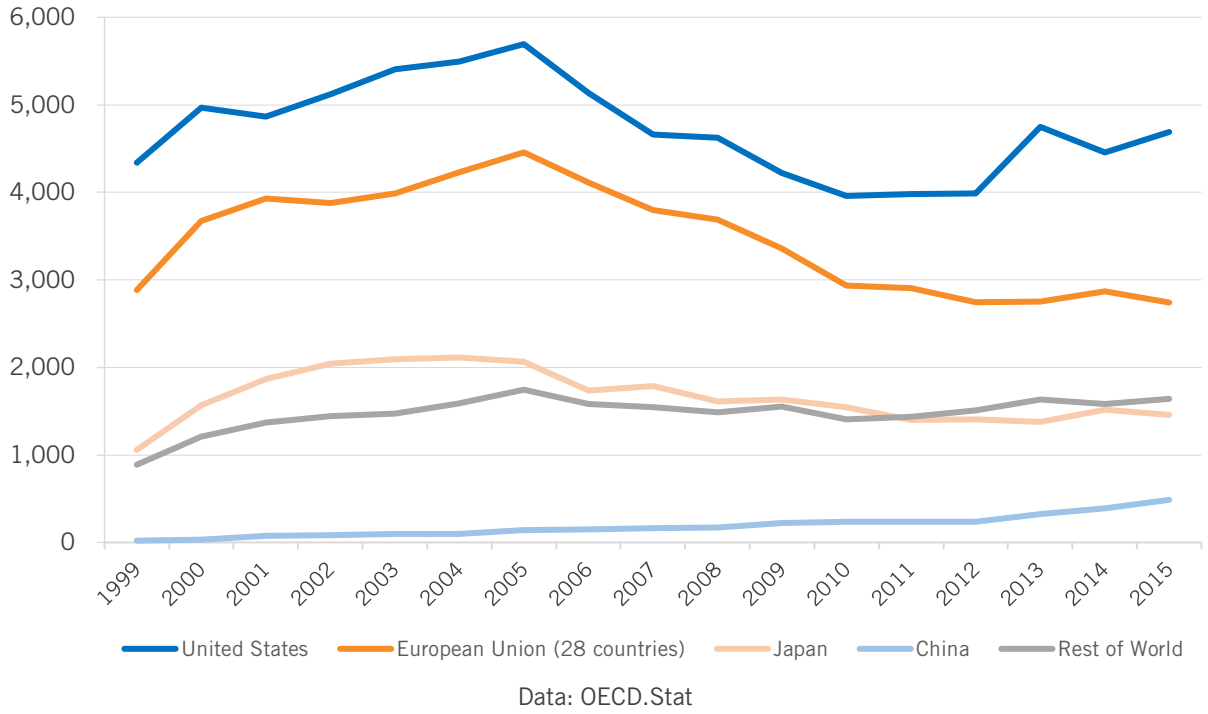
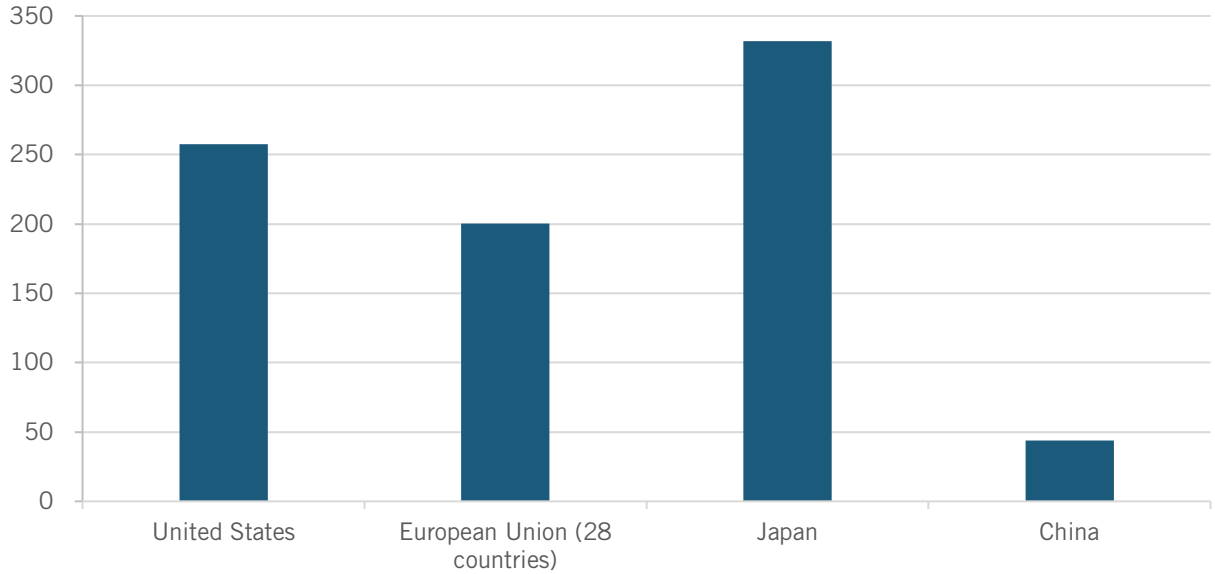


Figure 5: Number of triadic biotechnology and pharmaceuticals patent applications by priority date per trillion USD of GDP in 2015[181]



RECOMMENDATIONS

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 of the Committee on Foreign Investment in the United States (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.

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.

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 wherein the Chinese could develop a commercial advantage.[182] 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 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.[183] Moreover, according to 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."[184] 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.[185] 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.[186] 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 processes for large-molecule biotech drugs. This will be important if the federal government wants to increase domestic drug production, especially of generics and APIs, and reduce dependency on China.[187]

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 do more to better enable data-driven biopharma innovation in the United States. The ability of life-science innovators in China to access data is much greater than those in the United States. The Information Technology and Information Foundation's (ITIF) 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.[188] 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.

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.[189] However, it does suggest there is more room for risk-taking in China, even if it comes at the expense 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."[190]

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."[191] 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 the Paris Climate Accord to take steps to lower greenhouse gas emissions. (The United States also did sign on to the Mission Innovation agreement.) Even though they would be better off economically not paying the higher costs for clean energy, small and mid-sized nations are participating in this accord because there is a global expectation that everyone needs to cooperate in order to address a global challenge. Smog might be a local problem, but carbon dioxide 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).[192] 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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Robert D. Atkinson is the founder and president of ITIF. Atkinson's books include: *Big Is Beautiful: Debunking the Myth of Small Business* (MIT, 2018), *Innovation Economics: The Race for Global Advantage* (Yale, 2012), and *The Past and Future of America's Economy: Long Waves of Innovation That Power Cycles of Growth* (Edward Elgar, 2005). Atkinson holds a Ph.D. in city and regional planning from the University of North Carolina, Chapel Hill, and a master's degree in urban and regional planning from the University of Oregon.

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