GLOBAL CHINA
ASSESSING CHINA'S GROWING ROLE IN THE WORLD

CHINA'S ROLE IN THE GLOBAL BIOTECHNOLOGY SECTOR AND IMPLICATIONS FOR U.S. POLICY

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EXECUTIVE SUMMARY

Even by the standards of emerging technologies, biotechnology has the potential to utterly transform geopolitics, economics, and society in the 21st century. Yet while the United States has long been the world leader in most segments of the global biotechnology sector, China is fast becoming a significant player. This brief assesses the implications of China's changing role in biotechnology for the United States, which span national security, data security, and economic competitiveness.

On current trends the United States is likely to remain the world leader in most biotechnology areas. However, the gap between China and the U.S. is narrowing in the biotechnology sector, and U.S. policymakers must boost public investment, liberalize immigration and foreign student visa policies, and enact regulatory reforms to ensure America remains competitive. At the same time, areas like vaccine development and regulation of emerging technologies like synthetic biology present rich opportunities for Sino-U.S. cooperation.

INTRODUCTION

Thanks to extensive government funding for biomedical research, an unparalleled ability to translate basic research into commercial products and applications, and strong intellectual property protections, the United States has been the dominant global player in developing and commercializing biotechnology for decades.[1] This dominance is reflected in the fact that United States accounted for almost half of all biotechnology patents filed worldwide from 1999 to 2013.[2] However, in the intervening years, and just as in the case of artificial intelligence and other emerging technologies, other nations, including South Korea and Singapore, have invested heavily in developing their biotechnology sectors and industries. These efforts pale, however, in comparison to those of China, and the sheer size and scale of the Chinese biotechnology industry pose a range of economic, security, and regulatory issues for American policymakers.

The determination of China's one-party state to become a leading player in biotechnology is reflected by the rapid growth in investment in the sector. Some estimates claim that collectively, China's central, local, and provincial governments have invested over $100 billion in life sciences research and development. Regardless of the true figure, official encouragement has led to a torrid place of investment. In just the two-year period from 2015 to 2017, venture capital and private equity investment in the sector totaled some $45 billion.[3] The value of commercial deals concluded in the fields of biology, medicine and medical machine technology, meanwhile increased from 25.8 billion renminbi (RMB), or $3.6 billion, in 2011 to over 75 billion RMB ($10.6 billion) in 2017.[4] Annual research and development expenditures by Chinese pharmaceutical firms, the foundation of the biotechnology sector, rose from some 39 billion RMB in 2014 ($5.5 billion) to over 53 billion RMB (US$7.5 billion) by 2017. Expenditure on new product development among these firms, an important indicator of future growth potential, increased from just over 40 billion RMB ($5.6 billion) to almost 60 billion ($8.4 billion).[5] By Western standards, some of these figures are still low. Swiss drugmaker Roche, the world leader in biotechnology research and development, spent some $11 billion in 2018 alone.[6]

As these figures suggest, the development of China's biotechnology sector paints a nuanced picture for U.S. policymakers. On one hand, the sector's rapid growth, and high-level commitment to continued investment, means that China will inevitably become an increasingly important player in the global biotechnology sector, with implications for national security, economic competitiveness, and regulation. An executive from In-Q-Tel, the U.S. government's in-house national security venture capital fund, warned Congress in a November 2019 hearing, for example, that China "intends to own the biorevolution… and they are building the infrastructure, the talent pipeline, the regulatory system, and the financial system they need to do that."[7] The CEO of European drugmaker AstraZeneca has similarly opined that "Much of [China's] innovation in the last three to four years has been 'me too,' but now on the horizon we can see first-in-class innovation."[8]

Yet on the other hand, while China's biotechnology sector will almost certainly continue to grow in scale, sophistication, and competitiveness, there is little reason to believe on current trends that the United States will lose its edge in the sector. Indeed, the biggest risk to the global competitiveness of the U.S. biotechnology industry likely comes from the prospect of declining public investment and reduced mobility for world-class researchers and industry professionals. Moreover, the COVID-19 crisis underscores both the importance of continued investment in biotechnology and the many challenges to promoting effective international cooperation on global health security.

This brief first examines the key policies and actors in China's biotechnology sector, then offers an assessment of the sector's current capabilities and future trends, and finally further explores the implications of developments in Chinese biotechnology for U.S. policy.

KEY POLICIES AND ACTORS

As with most economic sectors in China, the state plays the leading role in biotechnology. The industry has been a priority sector for state support and investment since the 1980s, when biotechnology was included as one of 12 technologies targeted for future development.[9] In 2004, the State Council, China's equivalent of the Cabinet, established a "National Leading Group on Research, Development, and Industrialization of Biotechnology" with representatives from the Ministries of Science and Technology, Education, Finance, Agriculture, and Health.[10] The Ministry of Science and Technology (MOST) has played the single most important role in supporting biotechnology industry development. In particular, MOST has taken a leading role in setting goals for the biotechnology sector, such as that it should account for 4% of China's gross domestic product (GDP) by 2020.[11] By comparison, the biotechnology industry accounted for approximately 2% of U.S. GDP in 2012.[12] MOST's leadership in biotechnology research and development was strengthened in 2018 when the China National Natural Science Foundation, the most important scientific public funding body, was placed under it.[13] Apart from MOST, the quasi-governmental Chinese Academy of Sciences, China's national academy, also plays an important role in promoting development of biotechnologies, especially in conducting basic scientific research.[14]

Provincial and municipal governments also play a key role in China's biotechnology sector. As in other sectors, state policy for biotechnology industry development relies on a "cluster" model in which certain regions and cities are designated to help develop the sector. China's biotechnology industry is clustered in three regions: the Beijing-Tianjin-Hebei area in northeastern China; the Yangtze River Delta, centered on Shanghai; and the Pearl River Delta, focused on Guangzhou and Shenzhen and proximate to Hong Kong.[15] Local governments in these regions have enthusiastically supported development of the biotech industry. The 12th China Bio-Industry Conference held in Guangzhou in June 2019, for example, was jointly sponsored by the Chinese Society of Bioengineering and the Guangdong Provincial Government.[16] At the same conference, the Guangzhou Nanshan Science and Technology Innovation Fund was launched as a public-private partnership with some 200 million RMB ($28.2 million) in financing.[17]

China's biotechnology sector is still too nascent to have produced true giants on the scale of Huawei or Alibaba. Nonetheless, it plays host to several leading global biotechnology firms. WuXi AppTec, for example, is among the largest and most prominent Contract

Research Organizations (CROs), which are often contracted by pharmaceutical companies to manage some drug development functions. Beijing-based BGI has one of the world's largest DNA sequencing capacities.[18] It is also notable that five of the 10 largest biotechnology firms offering initial public offerings (IPOs) in 2019 are based in China. One of these, the drugmaker Hansoh, whose portfolio includes treatments for diabetes and neurological diseases, raised over $980 million, making it last year's largest biotechnology offering.[19] Western companies are also important players in China's biotechnology sector. American biotech giant Amgen, for example, spent almost $3 billion in 2019 to acquire a 20% stake in a Chinese biotech firm called BeiGene, which focuses on commercializing U.S.-developed cancer drugs for the Chinese market.[20]

The policy framework for biotechnology industry development in China is set by the 13th Five-Year Plan (13th FYP), which covers the period 2016-2020. The 13th FYP divides the biotechnology industry into six categories, creating a very expansive definition of the biotechnology sector: pharmaceuticals; agricultural biotechnology, including genetically modified crops; biomass energy; environmental protection; bio-services, including fertility and reproductive services; and biomedical engineering.[21] Ambitious goals are set in each of these areas: the percentage of cropland planted with genetically-modified crops, for example, is set to reach 12%, generating over 15 billion RMB ($2.1 billion) in income by 2020.[22] As the focus on agricultural biotechnology suggests, biotechnology industry development is viewed by Chinese policymakers as important not only for future economic development, but also objectives like food security and environmental protection.[23]

China's policy framework for biotechnology increasingly prioritizes indigenous capacity-building. Whereas previous policy guidance, such as the biotechnology provisions in the 12th Five-Year Plan (2011-2015), emphasized international exchange and cooperation and support for relatively mature biotechnology sub-sectors like genetic crop modification, current policy focuses on developing globally-competitive companies and advanced biotechnology.[24] In part, this shift reflects the increasing capabilities and sophistication of China's biotechnology sector. It is also explicitly intended to nudge the sector away from producing incremental "quantity accumulation" gains toward generating "qualitative transformations."[25] China's biotechnology policy also incorporates elements of protectionism: drug approval policies, for example, provide for fast-track review of drugs developed by domestic firms, while foreign ones are subject to a considerably longer, more arduous process.[26]

Supplementary guidance to the 13th FYP issued by the State Council on development of "Strategic Emerging Industries" calls for China to "form a group of new internationally-competitive biotechnology enterprises and biotech economy clusters." The guidance proposes three key "projects" to support drug creation, especially vaccines and recombinant protein drugs; development of "beneficial biotechnology" such as biotherapeutics and biodegradable materials; and expansion of research-support infrastructure, including gene banks, high-level biosafety laboratories, and stem cell banks.[27] Though comprehensive, it appears that most of the specific targets set by this policy framework have not yet been met, and its main effect has been to signal to researchers, entrepreneurs, and investors that the state looks favorably on work in the biotechnology sector.

ASSESSMENT AND FUTURE TRENDS

As in most countries, pharmaceuticals make up the single largest segment of China's biotechnology sector. Potential growth in this industry remains high, in part because of high death rates from diseases like cancer. In 2014, China suffered some 3.8 million new cancer cases and 2.3 million deaths.[28] One estimate suggests that China's pharmaceutical market could be worth some $175 billion by 2022.[29] China now possesses the world's third-largest biopharmaceutical manufacturing capacity, accounting for some 1.6 million liters out of 18 million globally in 2016, for example.[30] However, there are some signs that China's pharmaceutical industry is less dynamic than these figures would suggest. According to official statistics, the number of drug manufacturers barely increased from 2014 to 2017, despite rapid growth in the biotechnology sector overall. In 2014, there were some 1,600 drug manufacturers in China, while by 2017 there were 1,663.[31] This seemingly anemic growth may reflect more systemic issues in China's biotechnology sector.

In particular, China's biotechnology sector possesses several shortcomings when it comes to research, development, and innovation. Chinese official sources are forthcoming about the relative weaknesses of China's biotechnology industry, especially in research and development. An official statement from MOST regarding the biotechnology provisions of the 13th FYP, for example, admitted that "China lacks original scientific discoveries and disruptive technologies, has a weak research base in areas like biological big data, and lacks independent intellectual property rights" to support advanced drug development.[32] An independent analysis from market consultancy Foresight Industry Research Institute (or Qianzhan) similarly concludes that "the lack of independent innovation capabilities of China's biotechnology sector restricts the sector's development."[33]

These frank assessments of the Chinese biotechnology sector's relatively limited research and development capabilities are moreover reflected in international scientific publication and patent data. A Chinese Academy of Sciences report concluded that while China produced nearly half the world's patent applications in the sub-sector of industrial biotechnology from 2012 to 2014, the number of overseas patent applications was very low — just 112 — suggesting a dearth of breakthrough innovations.[34] Moreover, while China's research output in biotechnology fields is increasing, the country's research base overall remains more focused on the physical than the life sciences. In 2016, the most recent year for which data is available, some 8,800 Chinese-authored scientific research articles were cited in the widely-used Science Citation Index in the field of pharmacy and 19,000 in basic medicine. By comparison, some 45,000 chemistry articles and over 29,000 physics articles were cited in international publications.[35] Finally, while the life sciences have been a significant focus of Chinese talent-recruitment schemes like the Thousand Talents (accounting for over 40% of the 2018 cohort, according to one estimate), the United States appears to remain the preferred destination for most highly-skilled biotechnology researchers.[36]

Apart from innovation capacity, China's biotechnology industry also faces investment barriers. Despite the large capital inflows into the sector, the pre-commercial state of many biotechnologies and their high-risk, capital-intensive nature restrict financing availability for small- and medium-sized biotech enterprises.[37] As a result, China's biotechnology sector remains some distance from being truly globally competitive. Even MOST concedes that the industry's international "market competitiveness is not strong."[38]

Despite these challenges, continued investment and reform of the sector points to a growing global role for China in biotechnology. There are a few areas in which Chinese biotechnology firms are globally competitive. Perhaps the most notable of these is CAR-T therapy, a cancer treatment approach that involves modifying T-cells. Use of this approach appears to be as or more advanced than in the United States thanks to a combination of lower-cost manufacturing and favorable regulations that classify CAR-T as a medical device rather than a drug, accelerating government approvals.[39] In addition, China's break-neck efforts to produce a vaccine for the COVID-19 virus have resulted in a sharp increase in resources available for its bio-pharmaceutical sub-sector, and likely portend growing global competitiveness in this segment of the biotechnology industry as well.[40]

Going forward, areas that promise technological and commercialization breakthroughs like precision medicine, synthetic biotechnology, big data, and biomimetic materials are likely to drive future industry growth and development.[41] Though not presently as advanced as that of the United States or other Western countries, China's biotechnology sector can be counted on to produce significant innovations in these and other areas in the decades ahead. The Chinese market can also be expected to increasingly shape biotechnology research, development, and commercialization. And the Chinese state itself can be counted on to become a critical player in policy and governance issues related to biotechnology.

IMPLICATIONS

The certainty that China will play an increasingly important role in the global biotechnology sector poses several issues for U.S. policymakers. The gravest of these pertain to national security. Though there is presently no sign that China's capabilities exceed those of the United States, some researchers have noted that biotechnology is a focus of increasing attention

by the People's Liberation Army.[42] U.S. policymakers and security analysts have also raised concerns that the dominant market position of Chinese firms in producing active pharmaceutical ingredients might allow Beijing to disrupt U.S. access to lifesaving drugs in the event of a conflict.[43] On the other hand, the use of tools like CRISPR, which is increasingly inexpensive and easy to use, by terrorists and non-state actors to potentially create novel bioweapons poses severe security threats to both the United States and China. It would seem to be in the interest of all states, including China, to strengthen efforts, currently led mostly by the private sector, to prevent dangerous actors from gaining access to DNA templates and other relevant materials.[44]

Though these prospects are alarming, the theft and use of biomedical data presents more immediate policy concerns. American life sciences research institutions have been subject to what U.S. officials characterize as prolific intellectual property theft and non-traditional intelligence collection by Chinese actors.[45] At home, Beijing has already incorporated biometric data on certain populations, such as the Uighur minority group, into its already-formidable social control and surveillance apparatus.[46] Chinese actors also appear to have targeted foreign citizens for covert biomedical data collection.[47] Last year, the U.S. government forced a Chinese firm to sell its majority stake in an American social network that aggregates health care data from users, primarily over worries this information could be used to persuade Americans with access to sensitive information to spy for China.[48] Such added U.S. government scrutiny has contributed to a sharp decline in Chinese investment in the U.S. biotechnology sector. Though small overall, such investment had been growing rapidly, and in 2018 the biotechnology sector constituted the single largest source of Chinese investment in the U.S. overall, surpassing real estate.[49]

As this impact suggests, access to and control over biomedical data also has profound implications for the economic competitiveness of the U.S. biotechnology sector. Many frontier areas of biotechnology, including the use of artificial intelligence for biomedical applications, depend on access to large quantities of individual patient data. Chinese biotechnology firms are likely to have access to larger quantities of such data than their competitors elsewhere thanks to the size of China's population and relatively weak rules governing data collection and sharing. An existing biomedical database of patients from China's national health care system, for example, allegedly covers some 600 million patients.[50]

The Chinese government is moreover increasingly aggressive about preventing foreign firms and organizations from accessing such data. In 2016, biomedical data was proclaimed a "national strategic resource,"[51] and the export of such data is strictly controlled. Rules specifically bar any foreign use of Chinese biomedical data that "may jeopardize national security, national interests, or public security," and in 2018 these were used to shut down several high-profile scientific collaborations including one involving Peking University and the University of Oxford.[52] It should be noted, however, that while data quantity is important, so is data quality, and a combination of poor and inconsistent record-keeping and limited population diversity may diminish the utility of biomedical data produced in China for key applications like therapeutics development.[53] In any case, the availability of biomedical datasets will be a key determinant of the relative competitiveness of the U.S. and Chinese biotechnology industries going forward.

A final, and more hopeful, policy implication of China's growing role in biotechnology is its potential to help address shared global challenges like infectious disease prevention and biodiversity protection. In the near term, the COVID-19 crisis has highlighted the need for expanded international cooperation on epidemiological data collection and analysis, vaccine development, and other areas related to biotechnology. While China's openness to such cooperation at the moment is unclear, there are likely to be future opportunities to engage China in COVID-19 tracing, vaccine development, and deployment initiatives in third countries, especially in the less-developed world. In the longer term, synthetic biology, especially the use of gene drives to rapidly spread genetic modifications throughout a population, offers great promise to eliminate insect-borne diseases like malaria, and could also help endangered species adapt to climate change effects. As the 21st century advances, advanced biotechnology will both demand new forms

of global governance and present new arenas for both competition and cooperation between researchers, business leaders, and policymakers.[54]

POLICIES AND RESPONSES

Potential U.S. policy responses to the growth of China's biotechnology industry generally fall into two categories. The first involves providing greater and more effective support to U.S. biotechnology researchers and firms. Public support for biotechnology research decreased from $33.6 billion in 2010 to $27.7 billion in 2015, for example, and funding is highly fragmented across a number of U.S. government agencies with little coordination on priority areas for high-impact investment. Beyond funding, the U.S. government should consider adopting more flexible regulatory provisions in biotechnology sub-segments like CAR-T therapy where Chinese firms are highly competitive and adopt more stringent biomedical data security regulations.[55] A second priority for policy support to the sector should be human capital enhancement. The U.S. government, ideally led by the White House Office of Science and Technology Policy, should work with scientific funding bodies and higher education institutions to strengthen science, technology, engineering, and math instruction at primary, secondary and tertiary levels; ensure openness to foreign biotechnology talent; and pilot new approaches to translational life sciences work that bridges basic research and potential commercial applications. The interface of artificial intelligence and biomedicine is an especially promising such area, and fellowships or professional development opportunities might better enable specialists in each area to explore translational applications.[56]

The second category of policy responses involves cultivating biotechnology as an area for U.S.-China bilateral cooperation. Initially, this might build on existing Track II efforts and take the form of an intergovernmental dialogue on biosafety and biosecurity. The 2018 CRISPR baby scandal highlighted China's critical role in global biosafety and biosecurity.[57] Subsequent events like the COVID-19 pandemic have further underscored the importance of establishing a regular, high-level mechanism for joint efforts toward securing the use of gene templates, exotic microbes, and other biological threats and hazards. At the same time, the growing threat of synthetic bioterrorism using genetically modified viruses or microbes presents an enormous shared security threat for the United States, China, and other major powers. Cooperation to strengthen biosafety and biosecurity protocols worldwide might open a significant new frontier for U.S.-China cooperation, similar to cooperation on nuclear security and nonproliferation in recent decades.[58] There are promising signs that China may be receptive to such cooperation. In an unusual 2019 speech to the National People's Congress, President of the Chinese Academy of Sciences Bai Chunli commented, for example, that "The United States is not only the leading country in biomedical research, but also the first country to develop biosafety regulations and legislation."[59]

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