THE NATIONAL BUREAU *of* ASIAN RESEARCH

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THE RISE OF CHINESE INNOVATION IN THE LIFE SCIENCES

By Xiaoru Fei, Benjamin Shobert, and Joseph Wong

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Life Science Innovation in China

Joseph Wong and Xiaoru Fei

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EXECUTIVE SUMMARY

This essay examines China's advances in the life science sector, discussing key aspects of China's innovation ecosystem and the supportive role played by the government.

MAIN ARGUMENT

China's life science industry is rapidly catching up with those of Western countries. Although Chinese capacities still lag behind other industry leaders, recent efforts in biotechnology ensure that the country will become a key player in the global life science industry. China's main advantage is its size and scale. This is evident, for instance, in the large number of science and technology personnel in China, as well as the scale of R&D investment from both public and private sources. The government plays an important supporting role, primarily to mitigate the risks and uncertainties of life science innovation. Chinese policymakers have also strategically exploited their country's distinct advantages, notably through developing firms and organizations capable of plugging into global networks and life science value chains, recruiting overseas talent, and leveraging the promise and size of the Chinese market.

POLICY IMPLICATIONS

- Although its near-term outlook is positive, China's life science sector does not pose an immediate or even medium-term challenge to existing global biotech leaders.
- The general trajectory of Chinese reforms is not toward a more interventionist developmental state but rather toward a state that is more distant from the direct administration of the field. Reforms appear to favor market and nongovernmental institutions and to streamline the state apparatus.
- For the Chinese life science industry to become commercially viable, stakeholders in China must address the following three policy challenges: (1) develop technology transfer mechanisms that transform basic research into commercial products and processes, (2) reform the regulatory system to encourage the growth of consumer markets and the strengthening of consumer safety regulations, and (3) continue to collaborate with global innovation networks in the life science field.

China is no longer the sweatshop for the rest of the world. Beginning in the late 1970s, when the country started to open up its economy to global market forces, production networks gradually moved across the Pacific. China's economic rise benefited from both technologically advanced neighbors, such as the postwar Asian "tigers," and the large consumer markets in the region and the West. During the earlier years of its economic rise, China's development exploited the lower end of the global value chain. Chinese workers "made" the things that those in the rest of the world engineered, designed, marketed, and sold. Times are now changing, however; just as production networks turned eastward a generation before, global innovation networks are recentering in China.

This technological recentering is most evident in the development and commercialization of cutting-edge technologies, such as biotech and the life sciences more generally. In 2012 the State Council of the People's Republic of China (PRC)—the highest administrative authority in the Chinese government—released its twelfth five-year plan for strategic emerging industries. This plan explicitly stated China's goals in life science innovation, notably the entry of 30 new indigenous patent drugs into its domestic market by 2015 and at least 5 innovative drugs into global markets by 2020.[1] The "Made in China 2025" report, released also by the State Council in May 2015, reaffirmed biomedicine and advanced medical devices to be among China's ten priority industrial sectors.[2]

Indeed, the Chinese economy is becoming an R&D-intensive economy. In 2013, gross domestic expenditure on R&D in China equaled $336 billion, ranking China the second-largest R&D spender in the world, behind only the United States.[3] As a percentage of GDP, China's R&D intensity was just under 2.1%, lagging quite considerably behind the United States, Japan, and Germany (see **Figure 1**).[4] However, China's expenditure in R&D has increased at a faster rate than GDP growth (see **Figure 2**), meaning that it is only a matter of time before China will be the world's largest spender on R&D.[5] It is estimated that China will surpass the United States by 2020.[6]

Thus far, China's R&D efforts are paying off. According to the World Intellectual Property Organization, China overtook the United States in 2011 to become the world leader in the number of patent applications received.[7] In 2013, approximately one-third of the 2.6 million patent applications worldwide were filed in China, of which nearly 35% were for novel invention patents.[8] Between 2009 and 2014, the Center for Drug Evaluation (CDE), the technical review body under the China Food and Drug Administration (CFDA), received an average of 453 biologics

1 Information Office of the State Council of the People's Republic of China (PRC), "Guowuyuan guanyu yinfa shierwu guojia zhanluexing xinxing chanye fazhan guihua de tongzhi" [Notification of the State Council on the Circulation of the Twelfth Five-Year Plan for the Development of Strategic Emerging Industries], July 20, 2012, http://www.gov.cn/zwgk/2012-07/20/content_2187770.htm.

2 Information Office of the State Council (PRC), "Guowuyuan guanyu yinfa Zhongguo zhizao 2025 de tongzhi" [Notification of the State Council on the Circulation of "Made in China 2025"], May 19, 2015, http://www.gov.cn/zhengce/content/2015-05/19/content_9784.htm.

3 Organisation for Economic Co-operation and Development (OECD), "Main Science and Technology Indicators," database, http://stats.oecd.org/Index.aspx?DataSetCode=MSTI_PUB.

4 OECD, "Main Science and Technology Indicators."

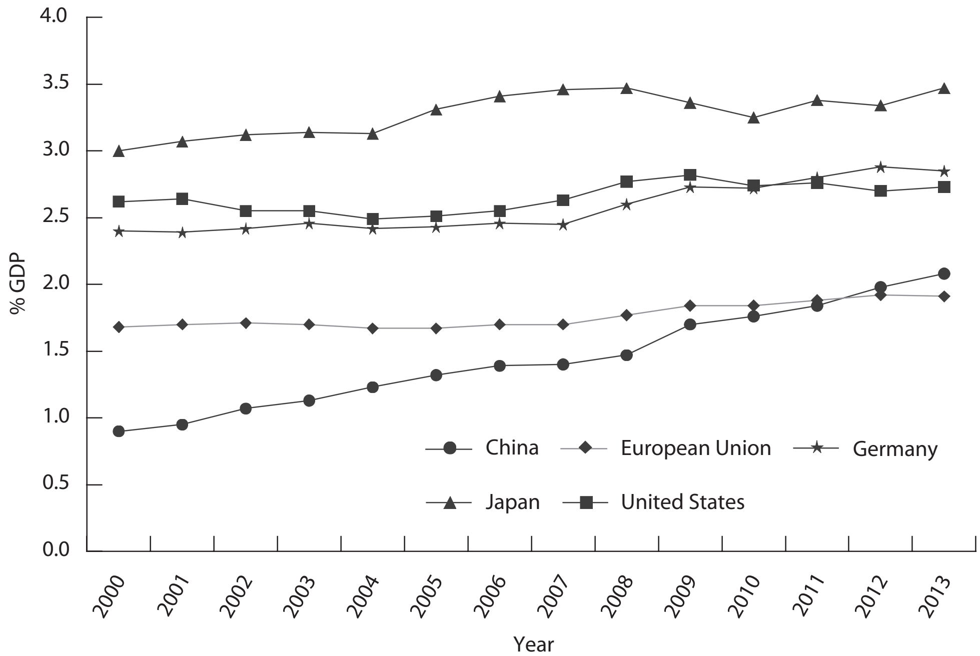
5 Ibid.

6 "2014 Global R&D Funding Forecast," *R&D Magazine*, December 2013, http://www.battelle.org/docs/tpp/2014_global_rd_funding_forecast.pdf.

7 World Intellectual Property Organization (WIPO), *World Intellectual Property Indicators* (Geneva: WIPO, 2012), http://www.wipo.int/edocs/pubdocs/en/intproperty/941/wipo_pub_941_2012.pdf.

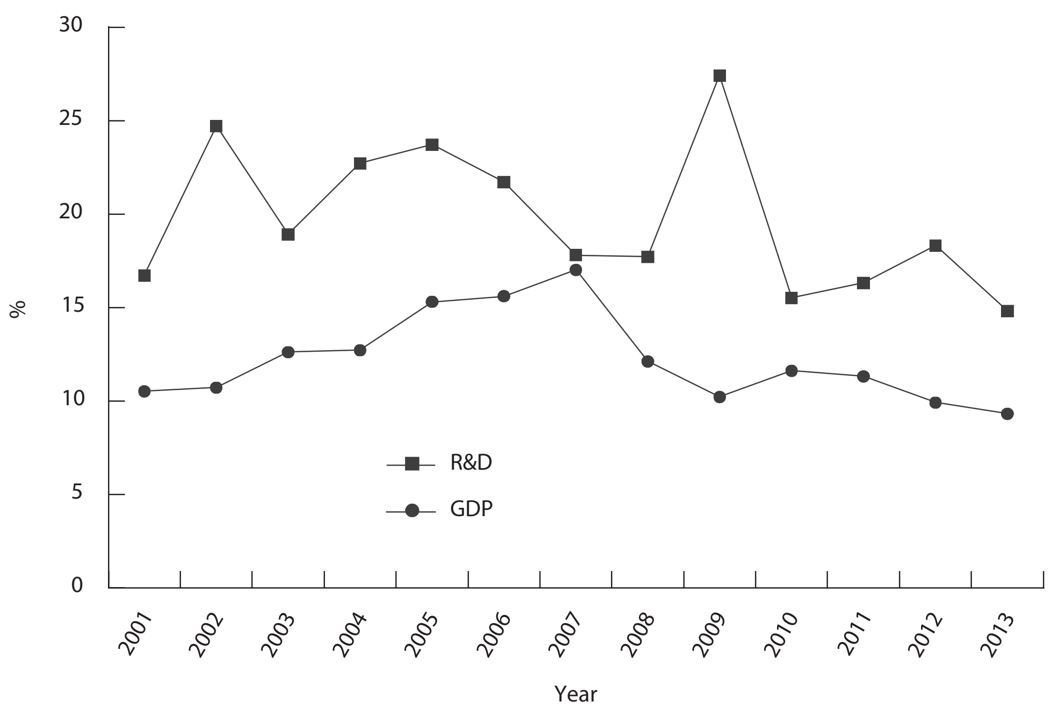
8 Ibid.

FIGURE 1 R&D investment as a percentage of GDP, 2000–2013



SOURCE: Organisation for Economic Co-operation and Development (OECD), "Main Science and Technology Indicators," database, http://stats.oecd.org/Index.aspx?DataSetCode=MSTI_PUB.

FIGURE 2 Annual growth rate of China's R&D investment and GDP, 2001–13

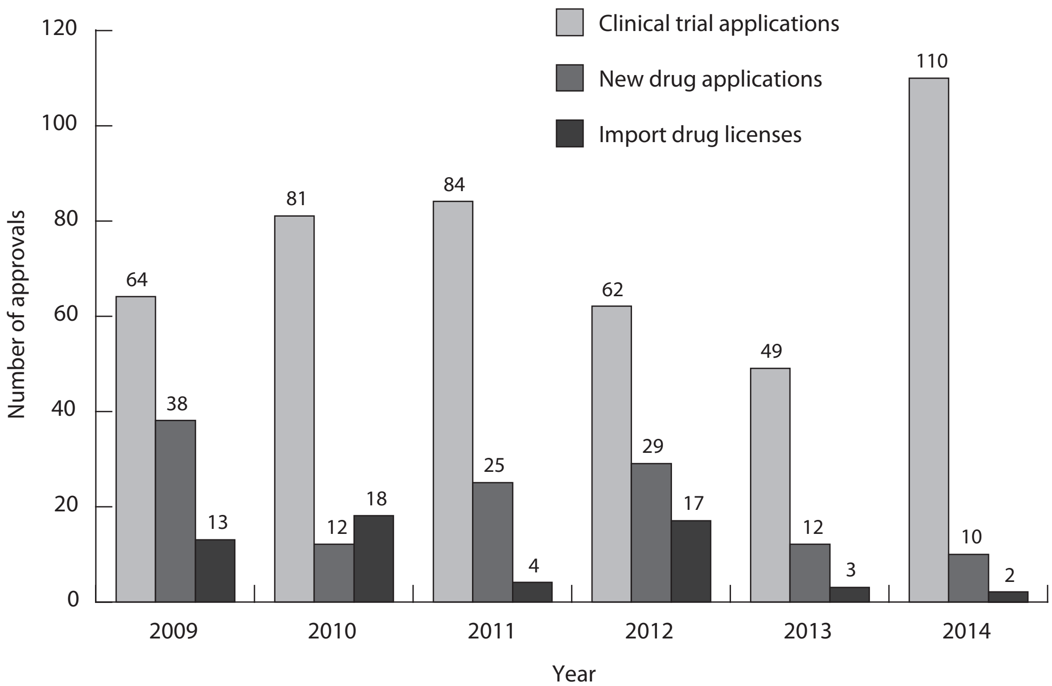


SOURCE: OECD, "Main Science and Technology Indicators."

applications each year (excluding cases of re-evaluation).[9] Although the number of approved domestic applications represents a much smaller proportion, with an average of 21 applications for new drugs approved per year during 2009–14 (see **Figure 3**), these statistics clearly suggest that Chinese labs are generating new biological leads in the life science sector, especially in Class 1 products (see **Figure 4**).

In terms of upstream research, the number of articles published by Chinese authors in high-impact journals (such as *Science* and *Nature*) is on the rise. Although U.S.-based researchers continue to dominate in scientific publications, Chinese output grew rapidly between 2004 and 2014, overtaking Japan in 2012 (see **Figure 5**). China's main competitor among developing economies—India—remains far behind.

FIGURE 3 Applications and licenses approved by the CDFA, 2009–14

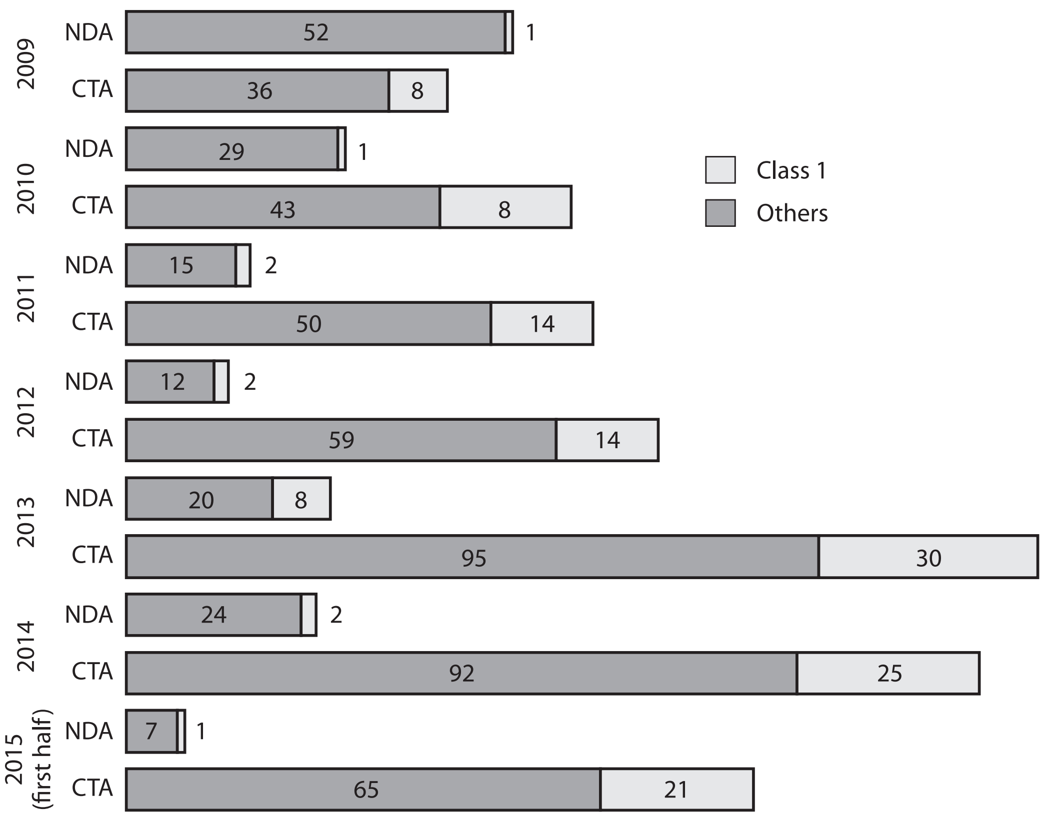


SOURCE: Compiled by the authors from the CDE's annual drug evaluation reports released between 2009 and 2014.

NOTE: Figures for 2014 are the number of applications recommended by the CDE for approval by the CDFA. The "clinical trial applications" category is similar to the U.S. Food and Drug Administration's investigational new drug application. The "new drug applications" category refers to the registration of drugs that have not been marketed within mainland China. Biosimilars are subject to the same approval processes used for innovative biologics. The "import drug licenses" category refers to the application for drugs manufactured abroad (including in Hong Kong, Macao, and Taiwan) to be marketed in mainland China.

[9] Clinical trials and new drug applications submitted to the CFDA are reviewed in several administrative units. Submissions first undergo dossier content and format checking at the CFDA's administration center. Accepted applications are then forwarded to the CDE for technical evaluation. Meanwhile, the National Institutes for Food and Drug Control under the CFDA performs tests on drug samples submitted and conveys the test results to the CDE for further review. Based on the CDE's recommendation, the CFDA's Department of Drug and Cosmetics Registration makes approval decisions and issues administrative licenses to the applicants.

FIGURE 4 Number of domestic submissions for biological new drug applications (NDA) and clinical trial applications (CTA) received by the CDE, 2009–15

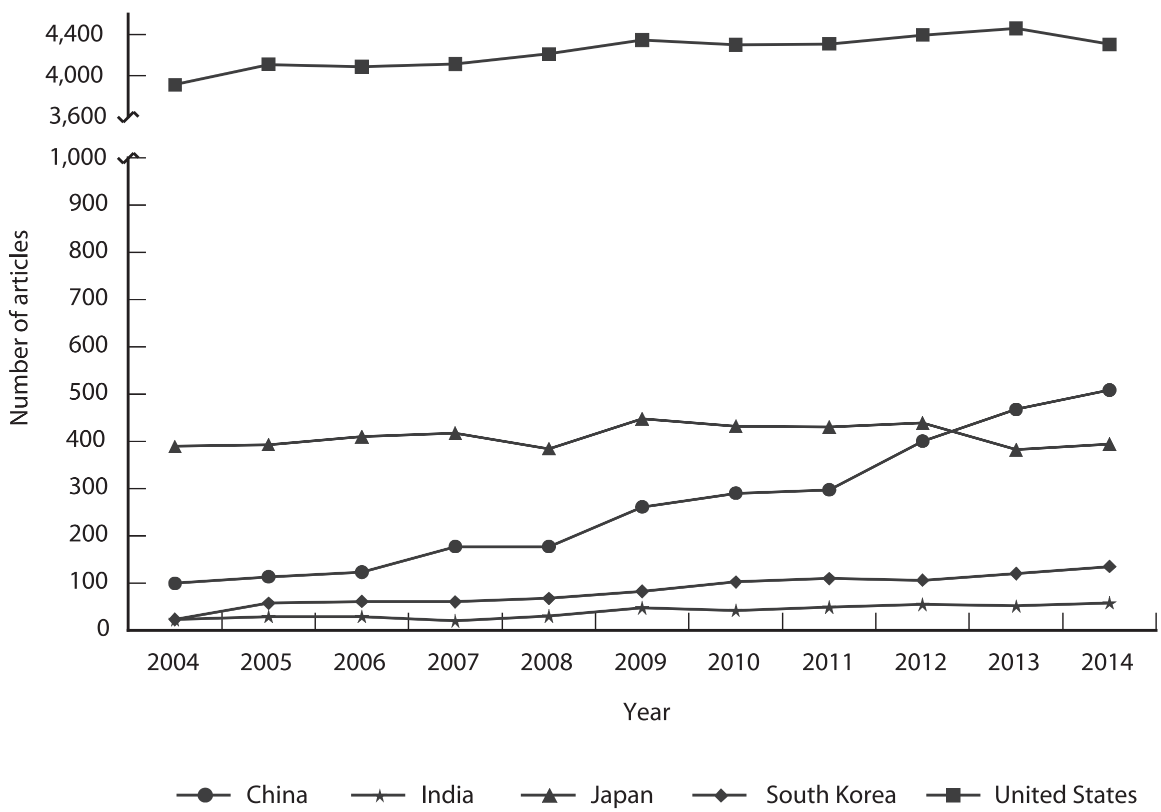


SOURCE: Compiled by the authors from the CDE's list of accepted applications.

NOTE: Class 1 biological products are products that have not yet been marketed in China or overseas.

The bottom line is that China's capacities in life science innovation—from upstream research to farther downstream commercial potential—are on the rise. In this essay, we highlight key aspects of China's life science innovation ecosystem and, in particular, the supportive role played by the government. Similar to other national economies with aspirations to become global innovation leaders, the Chinese government, through its policies, seeks to mitigate the risks and uncertainties of life science innovation by leveraging domestic resources as well as exploiting opportunities through international collaboration. We also outline some of the key reforms that China is implementing to streamline its evolving ecosystem for life science innovation and to address prevailing challenges. The upshot of this essay is that China's life science industry is rapidly catching up to the United States and other Western countries. Although Chinese capacities in this sector still lag behind industry leaders, especially the United States, China's past and present efforts in biotechnology ensure that it will become a key player in the global life science industry.

FIGURE 5 Articles published in top journals, 2004–14



SOURCE: Thompson Reuters Group, Web of Science database.

The remainder of this essay comprises five sections. The following section outlines Chinese government policies to nurture domestic capacities for life science innovation and downstream commercialization. Section two focuses specifically on Chinese strategies to engage and exploit opportunities in the global life science innovation industries. The third section describes several ongoing reform efforts as the government and stakeholders continue to develop China's ecosystem for biotech innovation. It also provides a brief discussion on the near-term outlook for the country's life science innovation system, including commercial potential. The essay then concludes by recounting the key points of this analysis.

Government Support for China's Life Science Sector

Innovation is a risky endeavor. There are multiple sources of uncertainty in the life science sector, including technological (whether it will work), market (whether people will buy it), and regulatory (whether it is acceptable) uncertainties, which together make biotechnology the epitome of a "high-risk, high-reward" industry. Although market forces play an important role in the development of the life science sector and the allocation of resources, government support is required to mitigate the inherent risks of innovation.[10] Public funding for upstream research, for example, is one way in which government policies and programs mitigate risk for otherwise risk-averse scientific researchers. Indeed, the U.S. government, through its support to the National Science Foundation and the National Institutes of Health, is the largest source of public funding for basic research in the life sciences in the world. In this respect, that governments seek to mitigate risk in knowledge-intensive innovation industries is not particularly novel or unique; but what exactly governments do to mitigate risk is quite variable across national settings. Innovation ecosystems differ among nations.

The Ministry of Science and Technology (MOST)—the central government's key ministry for setting policy on science and technology (S&T) innovation—administers China's three largest S&T programs: the 1983 National Key Technologies R&D Program, the 1986 State High-Tech Development Plan (also known as the 863 Program), and the more recent 1997 National Basic Research Program (or the 973 Program). Each of these general plans comprises specific programs for the life science sector—for example, MOST established the Major New Drugs Development Project as part of the 863 Program in 2008 and has allocated around $2 billion to it thus far.[11] The three plans focus on different aspects of the R&D value chain, from upstream basic science research to midstream technology transfer to downstream commercialization and industry development. Several other S&T programs are administered by the central government in addition to local schemes established by local administrations. The most significant R&D programs, however, are managed centrally by MOST.

Unlike other smaller national economies competing in the life science sector (such as Singapore and Taiwan), Chinese policymakers do not appear to have targeted specific technologies, applications, or firms to develop in this sector. Contrary to the more developmental state strategies of picking and making winners—common in Asia—the Chinese government has instead tended to rely on China's massive scale advantages to help absorb the risks inherent in innovation and to nurture a broad-based system of life science innovation. Put another way, because China—and hence the Chinese economy—is so large, government efforts to promote innovation industries have focused on creating multiple platforms for innovation in the life science sector.

Talent and Scale

The fact of the matter is the Chinese government has the resources to expend on R&D. On a per capita basis, or even according to standard measures of R&D intensity, China is not a global leader. But in terms of absolute (as opposed to relative) measures, China is now the world's second-largest R&D spender (see **Figure 6**).[12] Approximately three-quarters of its $336 billion expenditure in 2013 came from the private sector.[13] The Chinese government has also invested heavily in nurturing human capital development in S&T fields. MOST recently reported, for instance, that China is home to the world's largest stock of S&T personnel, with over 3.5 million full-time employees engaged in R&D activities.[14] In 2013, Chinese universities granted over 10,000 PhDs in the

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[10] Joseph Wong, *Betting on Biotech: Innovation and the Limits of Asia's Developmental State* (Ithaca: Cornell University Press, 2011).

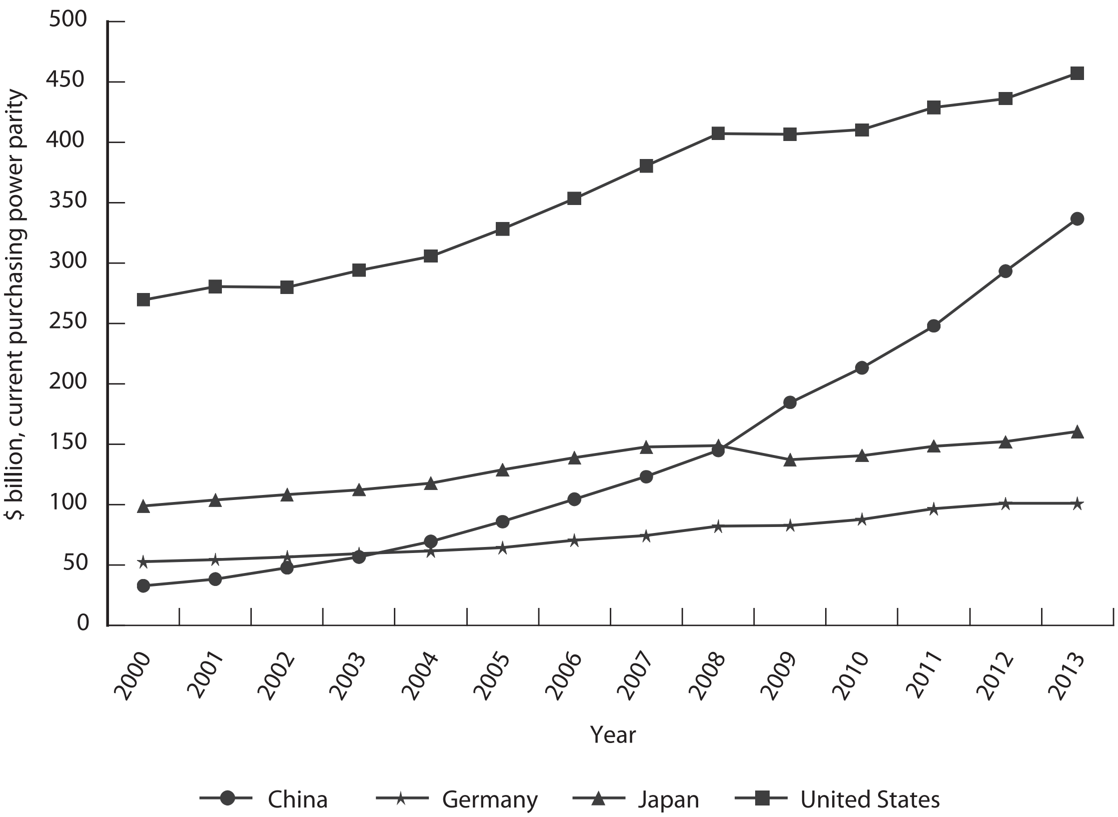
[11] Yongxiang Zhang, "Progress and Development Ideas of the National Science and Technology Major Project of 'Major New Drugs R&D'" (presentation at the 17th Shanghai International Forum on the Biotechnology and Pharmaceutical Industry, Shanghai, June 9, 2015).

[12] OECD, "Main Science and Technology Indicators."

[13] Ibid.

[14] Ministry of Science and Technology (PRC), *China Science and Technology Talent Development Report 2014* (Beijing, June, 26, 2015), http://www.most.gov.cn/kjbgz/201506/t20150626_120202.htm.

FIGURE 6 R&D investment, 2000–2013



SOURCE: OECD, "Main Science and Technology Indicators."

sciences, in addition to close to 40,000 graduate-level master's degrees in science-related fields.[15] China has also actively recruited S&T personnel from overseas, drawing from the vast Chinese diaspora. Since 1985, sixteen major national programs have been created to recruit overseas talent, with eleven of them being established after 2000. According to a Beijing-based think tank, the Center for China and Globalization, approximately 30% of all returnees are employed in high-tech fields—including in information and communications technology (ICT), general S&T, energy and materials, and biotechnology—and specifically 18.7% of returnee entrepreneurs are attracted to the biotechnology and healthcare sector.[16]

Technology Transfer

Successful innovation requires both the generation of scientific insights and applications in the lab and the transfer of such knowledge to develop downstream commercial technology. In other words, universities and other public research institutes are not only sources of S&T human capital but also the producers of new technologies and applications. Though official Chinese statistics do

[15] Ministry of Education (PRC), "Number of Postgraduate Students by Academic Field (Total)," November 29, 2014, http://old.moe.gov.cn/publicfiles/business/htmlfiles/moe/s8493/201412/181647.html.

[16] Yaohui Wang and Lu Miao, eds., "Annual Report on the Development of Chinese Returnees (2013) No. 2," Center for China and Globalization, February 25, 2014, http://www.ccg.org.cn/Research/View.aspx?Id=511.

not record rates of technology transfer, our sources in China concede that technology transfer among China's universities equals less than 10% the rate of foreign universities. In general, Chinese universities are not lacking in star scientists who publish in first-rate academic journals; however, they do lag significantly in technology transfer.

Despite the fact that 95% of scientists surveyed by MOST and the National Statistics Bureau cited intellectual property (IP) protection as the main purpose for patenting discoveries,[17] applying for patents is not the primary motivation for Chinese researchers. There are many reasons for this, according to our interviewees in China. First, the current evaluation system for researchers at both universities and public research institutes favors academic publications over patents. Second, until recently, on-duty invention and the resulting IP were considered state assets or university property, which minimized financial incentives for researchers to commercialize discoveries. Third, universities and public research institutes lack the administrative and legal infrastructures to effectively manage and transfer research from the lab bench to farther downstream. Last, upstream researchers claim that downstream industry is unable to absorb new technologies and that the absence of effective intermediaries (such as a dedicated technology patent and transfer office, which is common in most Western universities) exacerbates this gap.

The Chinese government has not been complacent, however. It recognizes that to compel upstream researchers in universities and public research institutes to transfer technologies farther downstream requires changes to the current incentive structure, in addition to minimizing the transaction costs of technology transfer for the inventor. Local governments, for instance, are providing subsidies and other financial incentives for filing patent applications. However, such incentives have also contributed to a moral hazard problem through the proliferation of low-quality "junk" patents. As one of our sources observed, it is not uncommon for researchers to split one invention into multiple patent claims to meet various grant requirements and advance their careers.

In lieu of official data on technology transfer rates, the Chinese government has instead measured the patent exploitation rate. According to the 2008 version of the Patent Law, the patent exploitation rate is the ratio of patents made, used, sold, or promised for sale to the total number of valid patents. According to one policy brief, this rate for most universities was below 33% in 2011, suggesting that a significant number of patents are unexploitable.[18] According to a survey by MOST and the National Statistics Bureau of patent exploitation from the premier 863, 973, and Technology Support Programs, during 2009–12 the exploitation rates for universities and public research institutes were 42% and 45%, respectively.[19] Of the patents exploited in universities, 74% were transferred or licensed, whereas over 77% of patents exploited in public research institutes were used internally, which suggests that universities in China are not a significant source of

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17 State Intellectual Property Office (PRC), "Guojia san da zhuti keji jihua xiangmu youxiao faming zhuanli yunyong zhuangkuang yanjiu zhi xueyan danwei pian" [Effective Exploitation of Patents Generated under the Three Major National Science and Technology Programs—Academic Research], Patent Statistical Brief, no. 156, March 10, 2014, http://www.sipo.gov.cn/tjxx/zltjjb/201509/P020150911515451537791.pdf.

18 State Intellectual Property Office (PRC), "Zhongguo faming zhuanli zhiliang zhibiao tixi yu fenxi baogao" [China Invention Patent Quality Indicator System and Analysis Report], Patent Statistical Brief, no. 152, December 5, 2013, http://www.sipo.gov.cn/tjxx/zltjjb/201509/P020150911515436691470.pdf.

19 State Intellectual Property Office (PRC), "Guojia san da zhuti keji jihua xiangmu youxiao faming zhuanli yunyong zhuangkuang yanjiu zhi xueyan danwei pian."

technology start-ups and spin-offs.[20] In the survey, over 75% of respondents from both universities and public research institutes cited the lack of funding and investment and the proliferation of early patents not ready for commercialization as the main obstacles to patent exploitation.[21] The gap between upstream research and downstream commercialization thus remains large in China.

Supporting Industry

To strengthen the capacity of China's technology industry farther downstream, the government has established a variety of tax and subsidy incentives for firms in all seven of its strategic emerging industry priority sectors, including biotech (along with advanced ICT, new materials, and alternative energy vehicles). These schemes include conventional preferential tax breaks for high-tech firms; tax deductions for R&D-related activities; public subsidies for key inputs such as land, raw materials, and capital investments; and loan interest subsidies. Proponents for the life science sector have advocated for more preferential policies—such as those extended to firms in China's software industry—but have so far been rebuffed. That said, life science firms do potentially benefit from preferential government drug-procurement policies, such as products listed in the Shanghai (locally administered) basic medical insurance formulary and other government-sponsored procurement programs.[22]

The establishment of the Torch Program during the 1980s ensured the government an important role in facilitating the development of start-up commercial technology firms. For instance, the program sparked the creation of thousands of R&D industry parks throughout China. In the life science field specifically, there are currently estimated to be at least four hundred provincial and national biotechnology parks and clusters in China, many of which are located around the Shanghai-Suzhou area, Beijing, and Guangzhou.[23] Suzhou's BioBay, nested within the Singapore-Suzhou industrial park, for example, is one of China's most promising bio-nanotech incubators. BioBay currently hosts around 400 companies, of which 105 are engaged in drug discovery and 34 in contract research. Since the industrial park opened in 2007, BioBay-based labs and firms have submitted 58 applications for clinical trials; the CFDA has approved 18 of them, 2 of which qualify as novel Class 1.1 drugs (i.e., drugs that have not been approved and marketed in any other country).[24] With a number of drug candidates expected to enter commercialization soon, BioBay is partnering with neighboring cities to set up production bases. BioBay is also one of the R&D-intensive biotech and pharmaceutical clusters chosen by the central government to

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20 State Intellectual Property Office (PRC), "Guojia san da zhuti keji jihua xiangmu youxiao faming zhuanli yunyong zhuangkuang yanjiu zhi xueyan danwei pian." Though China's universities are not a large source of conventional technology spin-offs (in the manner of the Stanford model), they do promote university-run enterprises. The 522 universities that participated in the latest round of nationwide surveys conducted by the Ministry of Education reported 5,279 university-run enterprises, generating revenue totaling around 208 billion renminbi ($33 billion). See Department of Finance of the Ministry of Education (PRC), "Gaodeng xuexiao xiaobanqiye tongji gaiyao gonggao" [Statistical Summary Report on Enterprises Run by Higher Education Institutions], December 31, 2014, http:// moe.gov.cn/ewebeditor/uploadfile/2014/12/31/20141231165824709.pdf. Unlike spin-offs in the United States, university-run enterprises in China remain within the university administration sphere (i.e., 75% of such enterprises surveyed are owned by the state or a university). A detailed comparison of U.S. spin-offs and Chinese university-run enterprises can be found in Chunyan Zhou, "The Path to the Entrepreneurial University in China: A Case Study of Northeastern University, China," in *Building Technology Transfer within Research Universities: An Entrepreneurial Approach*, ed. Thomas J. Allen and Rory P. O'Shea (Cambridge: Cambridge University Press, 2014), 307–29.

21 Zhou, "The Path to the Entrepreneurial University in China."

22 General Office of Shanghai Municipal People's Government, "Guanyu cujin Shanghai shengwu yiyao chanye fazhan de ruogan zhengce (2014 ban)" [Several Opinions on Promoting the Development of Shanghai Biopharmaceutical Industry (2014 Version)], August 19, 2014, http://www.stcsm.gov.cn/gk/zcfg/gfxwz/fzfwj/338012.htm.

23 Zero Power Intelligence, "2014–2018 China Biopharmaceutical Industry Park Market Analysis and Trend Report," 2014, 132.

24 Suzhou Industrial Park Administrative Committee, promotional displays at the BioBay Exhibition Center, June 26, 2015.

pilot the marketing authorization holder system, which is expected to expedite local firms' drug development and encourage the growth of specialized contract manufacturing clusters in China.[25]

In addition, to mitigate risk in venture capital financing for technology start-ups, in 1999 the Chinese government created the Innovation Fund for Small Technology-based Firms, also known as Innofund. Similar to the United States' Small Business Innovation Research program, Innofund provides early-stage grants, loan-interest subsidies, and in some cases equity investments. Around 10% of Innofund's financing was allocated to the life science sector in 2013.[26] Venture capital–based activity in the private sector has been on the rise as well. Shanghai-based TriRiver Capital, for instance, specializes in early-stage investment, with pharmaceutical and medical device start-ups making up 70% of its portfolio.[27] According to TriRiver's CEO,

> there are probably at most five venture capital firms in China, TriRiver included, that specialize in early-stage investments in bio and healthcare start-ups. There are, of course, a lot of VC firms which also invest in other sectors. But generally speaking, there're not enough early-stage funds, both in quantity and the total investment size, to meet the current need.[28]

The fact remains, however, that many venture capitalists in China, like elsewhere, are reluctant to invest in early-stage technologies and firms in the life science sector. Biotech remains, simply, too risky a bet. Thus, in 2006 the State Council established venture capital guiding funds (VCGF), which work with private venture capital firms to co-invest in promising technology start-ups.[29] Between 2009 and August 2014, approximately 9.1 billion renminbi ($1.5 billion) was allocated from the central fiscal budget for the creation of VCGFs.[30] By Zero2IPO's estimate, a total of 192 government-sponsored VCGFs (including all VCGFs set up alone or jointly by local and central governments) were established over 2006–14 (see **Figure 7**). The year 2014 alone saw an addition of 39 such funds totaling roughly 196 billion renminbi ($32 billion). The State Council recently announced plans to create a 40 billion renminbi ($6.4 billion) VCGF to support China's emerging strategic industries, including funds targeting the biopharmaceutical sector exclusively.[31] Currently, the healthcare industry is the most heavily invested sector by VCGFs (see **Figure 8**).[32]

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25 Authors' interview with the director of business development and the director of customer service from Changshu Suyu Biomedical Industrial Development Corporation, June 26, 2015. The company was set up by the Changshu municipal government and the Singapore-Suzhou industrial park to run the BioBay Changshu industrial park, where the production of new drugs developed in BioBay will be carried out.

26 Innofund, "Innovation Fund 2013 Annual Report," September, 9, 2014, 15, http://www.innofund.gov.cn/2/ndbg/201409/972000d0e5a343dcb2a5e46438479c51/files/f4da9973fbe6401287d36b3e18e0b879.pdf.

27 Cuihua Yang, "How Bio Start-ups Get VC in China" (presentation at the 17th Shanghai International Forum on the Biotechnology and Pharmaceutical Industry, Shanghai, June 10, 2015).

28 Ibid.

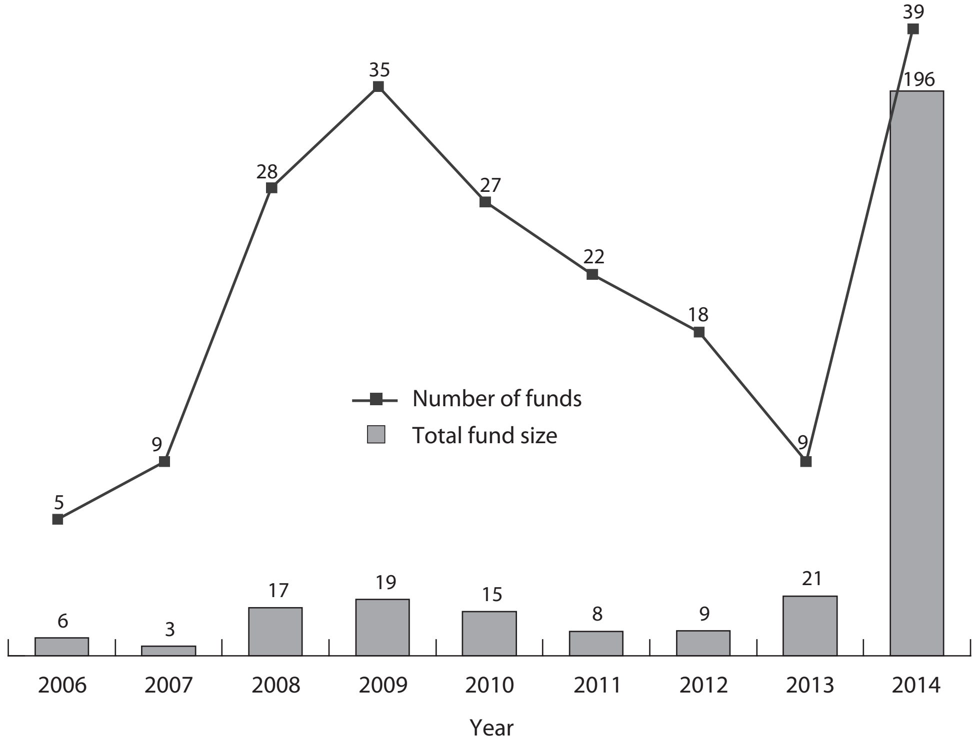
29 Information Office of the State Council (PRC), "Guowuyuan guanyu yinfa shishi guojia zhongchangqi kexue he jishu fazhan guihua gangyao (2006–2020 nian) ruogan peitao zhengce de tongzhi" [Notification of the State Council on the Circulation of Several Measures Supporting the Implementation of the National Medium and Long-Term Science and Technology Development Plan (2006–2020)], February 26, 2006, http://www.gov.cn/gongbao/content/2006/content_240246.htm.

30 Ministry of Finance (PRC), "Fahui zhengfu chuangtou yindao zijin daidong zuoyong cujin xinxin chanye fazhan" [Leveraging Government Venture Capital Guiding Funds to Promote the Development of Emerging Industries], August 12, 2014, http://www.mof.gov.cn/zhengwuxinxi/caizhengxinwen/201408/t20140812_1125513.html.

31 "Li Keqiang zhuchi zhaokai guowuyuan changwu huiyi, jueding sheli guojia xinxing chanye chuangye touzi yindao jijin" [Premier Li Keqiang Chaired the State Council Executive Meeting, Decided to Establish a Government Venture Capital Guiding Fund for Strategic Emerging Industries], Xinhua, January 14, 2015, http://news.xinhuanet.com/politics/2015-01/14/c_1113997033.htm.

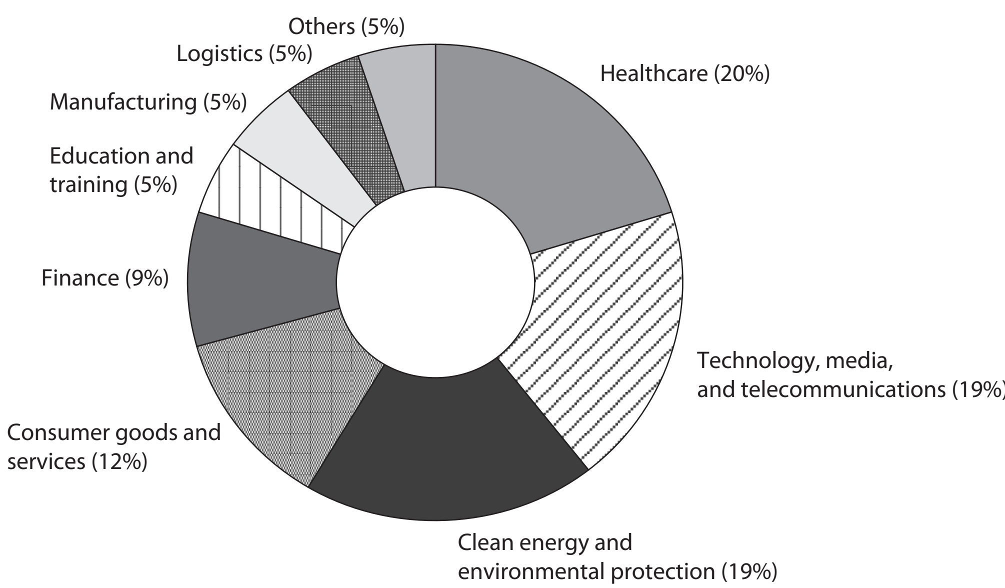
32 "2014 nian zhengfu yindao jijin baogao: 209 zhi zhengfu yindao jijin chengli" [2014 Government Guidance Funds Report: 209 Funds Have Been Established to Date], ChinaVenture, July 20, 2015, http://research.chinaventure.com.cn/report_1030.html.

FIGURE 7 Size (in billions of renminbi) and number of new venture capital guiding funds established annually by central and local governments, 2006–14



SOURCE: Zero2IPO, "2015 nian zhongguo zhengfu yindao jijin fazhan baogao jianban" [China Government Guidance Fund Report 2015 Executive Summary], February 28, 2015.

FIGURE 8 Investment target area of venture capital guiding funds by sector



SOURCE: China Venture Research, "2014 nian zhengfu yindao jijin baogao" [2014 Government Guidance Fund Report], July 20, 2015, http://research.chinaventure.com.cn/report_1030.html.

Output

Efforts by the Chinese government to support the growth of life science industries are beginning to generate returns. It is too early to precisely assess the long-term prospects of China's life science industries, though the government's programs to mitigate some of the risks of entry into the very uncertain biotechnology sectors are nonetheless associated with considerable success, especially for a latecomer to the field. With respect to upstream research, China ranks second to only the United States in high-quality academic publications (see Figure 5). Dedicated spending for life science R&D, especially for commercial development, continues to be on the rise. Human capital investment in S&T personnel has grown as well, in terms of both domestic training and the attraction of life science R&D talent from abroad. In 2013, there were 855 above-scale (i.e., large-scale, revenue-generating) biopharmaceutical firms in China, a 14% increase from 2012.[33] Revenues generated from sales of biomedical products grew at an annual rate of over 20% between 2003 and 2013.[34] Though China's life science industries are currently far from being globally dominant, the present growth trend in output in the life science sector, from upstream research to commercial returns, is remarkable.

China's Global Strategy for the Life Science Industry

To develop China's life science innovation ecosystem, the Chinese government has played a supportive role through public policies to mitigate the risks inherent in innovation. As we intimate above, China is not unique in this regard; all governments keen on promoting knowledge-intensive innovation industries employ similar kinds of risk-mitigation policies. However, this is not to say that the Chinese government has eschewed a more active and strategic role in creating advantages for Chinese labs and firms in the global life science sector. Though stopping short of what we might consider highly interventionist industrial policies, the government has attempted to leverage aspects of China's innovation ecosystem to its distinct advantage.

Adaptation for Global Collaboration

The global life science industry is being transformed at the moment, and Chinese firms have adapted by positioning themselves to benefit from a more open and globally disaggregated model of innovation. In the past, the global pharmaceutical industry was dominated by relatively few firms—"big pharma"—selling innovative products to relatively small but rich markets. Things have changed, however. Big pharma firms' pipelines, once fully stocked in the post–World War II period, have begun to dry up. Meanwhile, the search for innovative and potentially lucrative new drugs has become prohibitively expensive, leading to a productivity deficit among globally leading firms. Today, the cost of developing a new prescription drug that gains marketing approval is estimated to be around $2.6 billion, a 145% increase (adjusted for inflation) over the past decade.[35] Big pharma firms, which previously conducted their innovative R&D exclusively in-house, have begun to exploit a more open innovation strategy, reducing costs by partnering with smaller and nimbler labs and firms around the world. One study estimates, for instance,

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33 "2014–2018 China Biopharmaceutical Industry Park Market Analysis and Trend Report," 55

34 Ibid., 54.

35 "Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion," Tufts Center for the Study of Drug Development, November 18, 2014, http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.

that approximately 25% of R&D spending among UK pharmaceutical companies now occurs outside the United Kingdom.[36] In other words, the global value chain in life science industries has become disaggregated, with more opportunities for latecomers to plug in and generate value.

China has adapted to this new globalized reality effectively by mobilizing domestic resources and leveraging its scale advantages. For example, the central government recently announced a slate of policies to encourage the development of China's technology services industry and growth of contract research organizations (CRO) to meet the demands of global innovation firms, such as big pharma. Projected to grow at almost 25% per year, China's large CRO industry is expected to more than double its market revenues to 40 billion renminbi ($6.4 billion) by 2017.[37] In the life science sector specifically, local industry reports estimate that three of China's leading health technology firms account for nearly 15% of the total market value among domestic CROs. Local governments have also been proactive in encouraging local firms to plug into the global innovation landscape. Shanghai's municipal administration, for instance, has put together a multiyear CRO plan that aims to achieve 30 billion renminbi ($4.8 billion) in revenue by 2017.[38] As a result, the CRO sector in Shanghai tripled revenue from 5 billion renminbi ($800 million) to 15 billion renminbi ($2.4 billion) between 2008 and 2012.[39]

Global life science firms, especially in the biomedical field, have set up their own R&D centers in China since 2004 (see **Table 1**). Shanghai, for instance, is home to R&D centers for all the major global drug companies, including Roche, Pfizer, GlaxoSmithKline, AstraZeneca, Novartis, and Eli Lilly. In 2014, Johnson & Johnson recently opened its Asia Pacific Innovation Center in Shanghai, with the company citing China's growing capacity in biotech innovation as a key motivation for its decision to base its Asian operations there.[40] To date, the innovation center has established three R&D partnerships with Chinese universities (China Pharmaceutical University, Beijing University, and Zhejiang University), a partnering office in Suzhou's BioBay life science industry park, and a commercial deal with WuXi AppTec, China's largest domestic CRO, to internationally source and advance promising new drugs.[41]

As relative latecomers to the biotechnology field, Chinese labs and firms are far from the cutting edge of life science innovation and the development of the biotech industry. However, through partnerships and contract research arrangements with globally leading companies, Chinese firms are quickly developing biotech industry capacities, while at the same time plugging into and generating value from what is an increasingly disaggregated global value chain in life science innovation. Suzhou's Innovent Biologics recently entered a $450 billion partnership with

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36 Cited in Rahim Rezaie et al., "Emergence of Biopharmaceutical Innovators in China, India, Brazil, and South Africa as Global Competitors and Collaborators," *Health Research Policy and Systems* 10, no. 18 (2012), http://www.health-policy-systems.com/content/10/1/18.

37 "2014–2018 China Biopharmaceutical Industry Park Market Analysis and Trend Report."

38 Shanghai Municipal Development and Reform Commission and Shanghai Municipal Science and Technology Commission, "Shanghai shi shengwu yiyao chanye fazhan xingdong jihua (2014–2017)" [Shanghai Biopharmaceutical Industry Development Action Plan (2014–2017)], March 3, 2014, http://www.stcsm.gov.cn/gk/ghjh/336089.htm.

39 Ibid.

40 "J&J Is On the Hunt for Chinese Innovation," *Forbes*, November 18, 2014, http://www.forbes.com/sites/medidata/2014/11/18/jj-is-on-the-hunt-for-chinese-innovation.

41 "Johnson & Johnson Innovation Launches Asia Pacific Innovation Center and Announces New Alliances," Johnson & Johnson, October 28, 2014, http://www.jnj.com/news/all/Johnson-Johnson-Innovation-Launches-Asia-Pacific-Innovation-Center-and-Announces-New-Alliances; and "New Collaboration Model Gives Entrepreneurs and Transformational Asset Owners an Edge," Johnson & Johnson, June 11, 2015, https://talk.jnjinnovation.com/article/new-collaboration-model-gives-entrepreneurs-and-transformational-asset-owners-edge.

TABLE 1 R&D presence in China of the top-twenty pharmaceutical multinational companies

Company	R&D site	Year	Details
Novartis	Shanghai	2007	Located in Zhangjiang High-Tech Park; signed a memorandum of understanding with Shanghai municipal government in 2009 to expand the center and make it one of Novartis's top-three global research bases
	Changshu	2009	Located near Shanghai
Pfizer	Shanghai	2005	Located in Zhangjiang High-Tech Park; serves as Pfizer's Asia-Pacific R&D center
	Wuhan	2010	Located in the Biolake Industrial Base
Sanofi	Shanghai	2008	Upgraded to Sanofi's Asia-Pacific center in 2010
Roche	Shanghai	2004	Located in Zhangjiang High-Tech Park
Merck	Beijing	2009	One of Merck Serono's four main global R&D hubs
Johnson & Johnson	Shanghai	2009	Serves as Asia R&D headquarters; upgraded to Asia-Pacific R&D innovation center in 2014
	Suzhou	2011	Located near Shanghai; focuses on the development of medical devices
AsraZeneca	Shanghai	2007	Located in Zhangjiang High-Tech Park; upgraded to Asia R&D center in 2010
GlaxoSmithKline	Shanghai	2007	Located in Zhangjiang High-Tech Park; focuses on neurodegeneration research
Teva	N/A		
Gilead	N/A		
Allergan/Actavis	N/A		
Amgen	Shanghai	2014	Focuses on biomedical research; located on the campus of Shanghai Tech University; signed a collaboration agreement with the university's two life science research institutes
Eli Lilly	Shanghai	2010	Located in Zhangjiang High-Tech Park; focuses on diabetes research
Abbvie	Shanghai	2009	Located in Zhangjiang High-Tech Park
Bayer	Beijing	2009	Serves as Bayer's Asia R&D center; signed a partnership with Peking University to establish a joint research center for translational research
Boehringer Ingelheim	N/A		
Novo Nordisk	Beijing	2012	Located in Zhongguancun Life Science Park
Takeda	Shanghai	2012	Focuses on clinical development activities
Otsuka	Shanghai	2008	Located in Zhangjiang High-Tech Park
Mylan	N/A		

NOTE: Boehringer Ingelheim established its Asian Veterinary R&D Center in Zhangjiang High-Tech Park in 2012, which is not included in the table as it does not engage in the development of pharmaceutical products for human use.

Eli Lilly to collaborate on R&D and potentially commercialize three new cancer treatments.[42] BeiGene, located in Beijing's Zhongguancun Life Science Park, licensed out two drug candidates to Merck in 2013.[43] Both deals involve the licensing of future marketing and development rights outside China to big multinational firms. This approach appears to be a common strategy consciously adopted by small Chinese innovators to mitigate their high R&D costs as well as exploit market opportunities overseas.[44]

Global Talent

China has made great strides in cultivating its domestic human capital base for a knowledge-intensive, innovation-driven economy. Universities in China are not only generating world-class scientific research but also educating highly skilled S&T personnel. Furthermore, the government has actively recruited talent from abroad. Since 1985, sixteen major overseas talent recruitment programs have been established by China's central government; many more have been created by local administrations. As the head of Johnson & Johnson's Asia Pacific Innovation Center noted, the lack of experienced local innovators remains one of the biggest challenges for Asian countries.[45] China is the envy of Asia for its ability to attract and keep scholars, experts, and entrepreneurs with overseas education and work experience to fill this gap.[46] The 2008 Thousand Talents Program is among the most successful central government recruitment schemes and has attracted over 4,000 highly trained personnel to work in China.[47] To date, the various central-level overseas talent programs have recruited more than 30,000 personnel to China, most of whom are engaged in basic scientific research, commercial technology R&D, entrepreneurship, and financial management.[48]

Another significant source of global talent for China is the massive number of highly skilled and educated returnees from overseas. Mirroring Taiwan's experience—in which the Silicon Valley–Hsinchu connection was instrumental to the growth of Taiwan's IT sector during the 1980s—China has also attracted professional returnees, who are drawn by the promise of higher wages, a robust funding environment for R&D, and a significantly improved IP-protection regime. Between 1987 and 2014, more than 3.5 million Chinese studied abroad, and over half of them (1.8 million) have returned to work in China.[49] According to the Center for China and Globalization, 7.4% of returnees are employed in the biotechnology and healthcare sectors,[50] and unofficial estimates calculate that nearly one-third of those returnees are engaged in high-value R&D activities. For example, the founder and CEO of Innovent, Michael Yu, was a postdoctoral fellow at the University of California–San Francisco and was subsequently recruited through

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42 "Lilly and Innovent Biologics Announce a Strategic Alliance to Bring Potential Oncology Therapies to Patients in China and around the World," PR Newswire, March 20, 2015, http://www.prnewswire.com/news-releases/lilly-and-innovent-biologics-announce-a-strategic-alliance-to-bring-potential-oncology-therapies-to-patients-in-china-and-around-the-world-300053590.html.

43 "Merck Serono Signs Licensing and Development Deal with BeiGene," BeiGene, May 31, 2013, http://www.beigene.com/pdf/2013-05-312.pdf.

44 Rezaie et al., "Emergence of Biopharmaceutical Innovators."

45 Dong Wu, "Shaping a Healthcare Ecosystem through Innovation" (presentation at the 17th Shanghai International Forum on the Biotechnology and Pharmaceutical Industry, Shanghai, June 9, 2015).

46 Ibid.

47 "Qianren jiahua jieshao [Introduction to the Thousand Talents Program]," 1000Plan, http://www.1000plan.org/qrjh/section/2?m=rcrd.

48 Wang and Miao, "Annual Report on the Development of Chinese Returnees (2013) No. 2."

49 Ministry of Education (PRC), "2014 niandu woguo chuguo liuxue renyuan ingkuang" [2014 Annual Cases of Students Studying Abroad], March 5, 2015, http://www.moe.gov.cn/publicfiles/business/htmlfiles/moe/s5987/201503/184499.html.

50 Wang and Miao, "Annual Report on the Development of Chinese Returnees (2013) No. 2."

the Thousand Talents Program. The executive team at Innovent includes two Americans, both of whom are veterans of pharmaceutical R&D in global firms. Of the firm's researchers, twelve are returnees.

China's life science industry has benefited enormously from attracting overseas talent and specifically returnees. Overseas talent brings academic and professional experience from abroad, entrepreneurial skills, and global networks. BeiGene is a good example of how the recruitment of global talent has jump-started China's life science industry. The firm was founded in 2011 in the Zhongguancun Life Science Park in Beijing by John Oyler, Peter Ho, Pearl Huang, and Xiaodong Wang. Ho and Huang spent most of their academic and professional careers in the United States working in global pharmaceutical firms before deciding to move to China to start the BeiGene venture. Wang, who is Chinese-American and a member of the U.S. National Academy of Sciences, also started his career overseas before he was invited back to China in 2003 to run the National Institute of Biological Science. Having raised $200 million in the domestic market since 2011, BeiGene is currently developing its pipeline of molecule candidates targeting oncology drugs.[51] Four molecules are currently in clinical trials in Australia.

Making Markets

China's economic rise, which began in the late 1970s, has been driven in part by the promise of the enormous Chinese consumer market. Though the country is still relatively poor on a per capita basis, Chinese consumption has fueled global and domestic manufacturers, from textiles to automobiles and electronics to medicines. Domestic technology firms, especially in the ICT sector (e.g., Huawei and Xiaomi), are thriving by selling their products in China to Chinese and foreign consumers. The lure of the Chinese market is evident in the life science sector. Global big pharma firms have established a base in China not only to restock their candidate pipelines but also to be close to Chinese manufacturers, retailers, and consumers. The promise of China's market has driven the growth of domestic firms as well, from increasingly high-tech CROs to producers of medical devices to companies that research new and innovative drugs. China is currently the second-largest pharmaceutical market globally after the United States, and its per capita spending is expected to grow by over 70% between 2013 and 2018.[52]

The point is simple: there is room to expand China's market in the global biotech sector. Though the country's pharmaceutical market is already huge—at around $98 billion in sales in 2013, or nearly 10% of total global sales[53]—biological drugs (as opposed to conventional chemistry-based drugs) accounted for just 5.4% of the drug market, compared with 11.7% globally.[54] To be sure, of the one hundred largest pharmaceutical and drug firms in China, only seven are biologics producers.[55] Thus, despite the enormity of the country's pharmaceutical market at the moment, there remains considerable room for the biological drug market to grow. China wants its firms to supply that market.

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51 Zhao Yongxin, "Make the World's Best Anti-cancer Drugs (Dream Chaser)," BeiGene, May 27, 2015, http://www.beigene.com/pdf/2015-05-27.pdf.

52 IMS Institute for Healthcare Informatics, "Global Outlook for Medicines through 2018," November 2014, http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=266e05267aea9410VgnVCM10000076192ca2RCRD.

53 Ibid.

54 Yongtai Wu, "Gongsi/hangye xinwen" [Industry Brief: Sansheng Pharmaceutical], China Galaxy International, September 14, 2015, http://www.chinastock.com.hk/ewebeditor/uploadfile/20150914181017339.pdf.

55 Southern Medicine Economic Research Institute, "Blue Book on the Development of Chinese Medical and Pharmaceutical Market in 2014—Part of Industrial Economy(I)," *Progress in Pharmaceutical Sciences* 38, no. 6 (2014): 401–8, http://www.cpupps.cn/ch/reader/create_pdf.aspx?file_no=20140601&flag=1&journal_id=yxjz&year_id=2014.

But markets, especially highly regulated markets such as in the biotech and life science industries, are created, shaped, and influenced by government policies. The government understands that biotech markets have to be made and that in order for China's life science markets to grow, proper policies and processes need to be put into place. Challenges remain: Approval processes in the CFDA continue to be lengthy in terms of time to market and also susceptible to corruption. The processes for listing and pricing drugs remain arduous, requiring approvals by the National Development and Reform Commission, the various provincial governments, and even individual hospitals. The approval, listing, and pricing of new drugs in China are difficult to coordinate. Existing processes are also prone to corruption, as evidenced by the recent pricing scandal involving GlaxoSmithKline.

Outlook for China's Life Science Strategy

Reforms

The landscape of China's life science industry continues to change, with new discoveries exploited, deals made, and partnerships formed. The innovation landscape is evolving, and the Chinese government continues to reform its policies. It is noteworthy, however, that recent reforms regarding the promotion of the life science industry and innovation in China have not moved toward more state intervention and targeted industrial policy. Notwithstanding some areas in which the government has maintained a heavy hand—for instance, restrictions on foreign investment in stem cell and gene therapy research—recent reforms and the overall direction of reform have tended to involve the state further distancing itself from the direct administration of life science innovation and entailed a more significant role for market forces and nongovernmental actors. Four key developments are highlighted below.

Price reform. In May 2015, in a joint policy-reform program for drug pricing, multiple government agencies, including the powerful National Development and Reform Commission and the National Population and Family Planning Commission (China's main health regulator), eliminated government-set prices for virtually all drugs.[56] At the same time, the government is trying to implement a pricing-reform initiative that would eliminate price markups imposed by hospitals. These reforms are intended to reduce healthcare costs, promote greater market competition in drug pricing, and curtail side payments, overprescription by physicians, and corruption.

Administrative streamlining. Although the government continues to fund its many S&T programs, such as the 863, 973, and Technology Support Programs, government agencies will no longer manage and evaluate specific S&T projects. Currently more than a hundred national S&T programs are administered by over 40 government agencies.[57] In line with President Xi Jinping's efforts to streamline government functions and improve overall efficiency within the state apparatus, management of specific S&T programs will be delegated to professional project

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56 National Development and Reform Commission (PRC), "Guanyu yinfa tuijin yaopin jiage gaige yijian de tongzhi" [Notice on Issuing the Opinions Concerning the Drug Price Reform], May 4, 2015, http://www.ndrc.gov.cn/zcfb/zcfbtz/201505/t20150505_690664.html.

57 "Wan Gang: Zhengfu buzai guan juti de keyan xiangmu" [Wan Gang: The Government Will No Longer Manage S&T Programs], *Caixin*, March 11, 2015, http://topics.caixin.com/2015-03-11/100790186.html.

management institutions.[58] This move is accompanied by Xi's recent efforts to foster specialized advisory bodies that can provide independent policy analysis and consultation services.

IP reform. The government has proposed amendments to the Patent Law and the Law on Promoting the Transformation of Scientific and Technological Achievements, with the former still pending approval and the latter passed by the National People's Congress in August 2015. The revisions clarify the ownership of IP and the distribution of returns from commercialized IP for inventions generated under programs receiving government funds.[59] In addition, rather than being subjected to lengthy government approval processes, universities and public research institutes will have the autonomy to commercially exploit such IP as they see fit.[60] These reforms are intended to address low rates of technology transfer inside Chinese institutions and firms.

Encouraging entrepreneurialism. The State Council created a policy in May 2015 to allow researchers at universities and public research institutes to retain their academic positions for up to three years upon starting their own venture firms.[61] This policy intends to reduce the risk of entry for would-be entrepreneurs among publicly employed researchers with potentially commercializable IP. Prior to this reform, publicly employed researchers were reluctant to create start-ups for fear they would lose their positions.

Opportunities and Challenges

Although the near-term outlook for China's life science sector is very positive, the country does not pose an immediate or even medium-term challenge to existing global biotech leaders, as we have stressed throughout this essay. Notwithstanding China's extraordinary scale advantages in terms of talent, capital, global position, and potential market size, the Chinese innovation ecosystem is still a relatively recent development. In this respect, China is playing institutional catch-up to existing global leaders. The government continues to assume an important leadership role, though no more than governments do in other countries. To be sure, there is little evidence that the Chinese state intends to employ industrial policies in ways similar to the highly interventionist Asian developmental states of the postwar period.

Many challenges remain that need to be addressed if China intends to realize its ambitions for its life science industries. Publicly funded research institutes, including universities, have not been particularly effective in generating and transferring promising technologies downstream or in spinning off entrepreneurial start-ups. With respect to the domestic market, existing regulations for drug approval, listing, and pricing are cumbersome. Risk capital in China, meanwhile, tends to be risk-averse, and many potentially commercially viable firms fail to secure the needed investment to bring products to market. As we outlined in the previous section, the Chinese government has responded to these challenges by continuing to reform its policies, institutions, and the innovation ecosystem more generally.

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58 Ministry of Science and Technology (PRC), "Guanyu shenhua zhongyang caizheng keji jihua (zhuanxiang, jijin deng) guanli gaige de fang'an" [Notification of the State Council on the Circulation of Reform Plans Concerning the Management of S&T Initiatives (Projects and Funds) Financed by the Central Government], January 7, 2015, http://www.most.gov.cn/tpxw/201501/t20150106_117285.htm.

59 Ministry of Science and Technology (PRC), "Quanguo renda changweihui tongguo yuanyu xiugai cujin keji chengguo zhuanhua fa de jueding" [National Congress Passed the Amendment to the Law on Promoting the Transformation of Scientific and Technological Achievements], August 31, 2015, http://www.most.gov.cn/kjbgz/201508/t20150831_121408.htm.

60 Ibid.

61 Information Office of the State Council (PRC), "Guowuyuan guanyu jinyibu zuohao xinxingshi xia jiuye chuangye gongzuo de yjian" [Opinions of the State Council on Further Fulfilling the Work of Employment and Entrepreneurship in the New Situation], May 1, 2015, http://www.gov.cn/zhengce/content/2015-05/01/content_9688.htm.

Implementing reform, however, is not easy in the Chinese context. Despite the conventional wisdom that the state, due to its centralized power and authority, can easily and efficiently impose reforms from above, the fact of the matter is that the process of reforming the innovation ecosystem has been plagued by significant—some would argue insurmountable—coordination challenges. Entrenched interests make it difficult for actors to concede reforms; for example, hospitals have resisted efforts by the government to reform the drug-pricing system and have dragged their feet on implementing such reforms. In the meantime, drug firms have resisted the pricing reform because profits are expected to shrink.[62]

The vast size of the state apparatus also contributes to horizontal coordination challenges, as various ministries, agencies, and commissions contest for government resources and authority. As many observers of Chinese political economy have long noted, the vertical coordination of center-provincial initiatives is likewise extremely difficult, particularly as local and provincial governments have continued to increase their investments in life science innovation and compete for talent, opportunities, and foreign investment. Last, despite the many informal channels linking the state with stakeholders in the biotech industry, the absence of formal policymaking mechanisms through which the state and firms can interact presents formidable challenges to coordinating public and private sector actors in the life science field.

Conclusion

China is a relative latecomer to knowledge-intensive innovation industries, including the life science sector. Although the country continues to lag behind industry leaders, growth in inputs (e.g., gross expenditure on R&D) is associated with growing success in outputs (e.g., scientific publications, commercial returns, and firm creation). China's main advantage in life science innovation is its size and scale. This is evident, for instance, in the large number of S&T personnel in China, as well as the scale of R&D investment from both public and private sources. The government plays an important supporting role in this process, primarily to mitigate the risks and uncertainties of life science innovation. Notably, government policies have ensured human capital development (e.g., skilled S&T personnel), facilitated technology transfer, and nurtured downstream growth in the biotech industry. Chinese policymakers have also strategically exploited their country's distinct advantages, notably through developing firms and organizations capable of plugging into global networks and life science value chains, recruiting overseas talent, and leveraging the promise and size of the Chinese market.

Many challenges remain, however. These include relatively low rates of technology transfer in the life sciences; few university start-ups; lengthy and arduous approval, listing, and pricing processes; and a relatively undeveloped market for innovative biotech industry products and services. As such, the ecosystem for life science innovation in China continues to evolve as the government has initiated and attempted to implement reforms. Particularly noteworthy is the fact that the general trajectory of reforms is not toward a more interventionist developmental state but rather toward a state that is more distant from the direct administration of the life science field. Reforms appear to favor market and nongovernmental institutions and to streamline the state apparatus. Yet despite the government's intention to initiate reforms, the actual reform process

[62] "Pharmaceuticals in China: So Long, Easy Money," *Economist*, June 14, 2014.

faces severe coordination challenges between entrenched interests—both horizontally across agencies and vertically between the central and local governments—and between the state and the biotech industry.

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Priming the Pump: Applying Lessons Learned from High-Tech Innovation to the Life Sciences in China

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EXECUTIVE SUMMARY

This essay explores parallels between China's approaches to clean technology and the life science sector in order to better understand the potential impact of Chinese innovation on the development of the global life science industry.

MAIN ARGUMENT

The success of China's efforts to close the gap with Western high-technology sectors, and in the case of clean technology to actually become a global leader, points toward the potential—but not the inevitability—of similar outcomes in the life sciences. Still, there are reasons to believe that the country's policies to develop domestic success stories may fall short of similar endeavors in other segments of China's economy. While the pursuit of indigenous drug discovery aligns with the country's overarching objective to develop higher-technology industries, the time frame within which life science innovation creates tax-paying entities is much longer than in other sectors. In addition, the paucity of dedicated reimbursement for innovative molecules limits the country's ability to use financial triggers to foster domestic champions. Moreover, a significant obstacle to domestic innovation in China remains the slow pace of the drug approval process. None of this is to suggest that Chinese stakeholders lack insight or ideas specific to innovative therapies that may well benefit global health; rather, it is to say that China's efforts in the life sciences are likely to lag behind the outcomes, efficacy, and disruptiveness of analog endeavors in other sectors that were set in motion by coordinated policies from the central government.

POLICY IMPLICATIONS

In order to ensure that China's development proceeds in a way that benefits Chinese stakeholders, multinational companies, and the global market, the following three policy objectives are most important:

- Western companies and governments should use this moment to pay attention to domestic reforms that ensure that their respective markets remain globally competitive. The life science community needs a very unique ecosystem that combines government funding, strong intellectual property laws, academic research, venture capital, stable public equity markets, and mature healthcare reimbursement systems.
- In order to ensure that China's goals do not create unnecessary tension with its trading partners, Western governments need to continue advocating for additional and accelerated reforms within the China Food and Drug Administration, an argument made most credibly by focusing on how these reforms benefit domestic Chinese innovators.
- The Chinese government must update its pharmaceutical reimbursement standards to provide transparency and to articulate and provide substance to its view on the connection between innovation and reimbursement.

Released in March 2016, China's thirteenth five-year plan (5YP) establishes a focus on "innovative development" that emphasizes, among other things, "biological technology."[1] While China's 5YPs have always been aspirational, the foundation for much of the country's economic success over the last 30 years is the pursuit of a deliberate objective established through this planning process. Industries as varied as automotive and telecommunications have been significantly affected—for both good and bad—as a direct result of policies that a 5YP set in motion. Earlier 5YPs focused on one industry in particular, clean technology, which holds important lessons for other high-technology sectors such as the life sciences.[2]

The emergence of China's clean-technology industry was disruptive in a number of ways. It strained global trade accords whose design did not fully capture the intricacies of high-technology manufacturing; introduced unhelpful political friction between China, Europe, and the United States; reprioritized the commercialization strategy of many emerging technologies; and changed the geographic location of the ecosystem where cutting-edge clean-technology innovation took place. While the tension that these various issues caused the industry has largely abated, much of the policy approach that animated how China fostered a clean-technology sector remains in place and will shape similar endeavors in other industries, one of which is the life sciences. For the life sciences, the analog to clean technology should help preempt similar problems and ensure that the concerns of all stakeholders—government, business, and individual families—are channeled into productive policymaking.

Handled properly, China's pursuit of a domestic life science sector can benefit the world. Scientists in China are capable of contributing their own insights into new treatments for various diseases. Bench science conducted in China offers the potential for cost savings, which increases the probability of new blockbuster drugs being developed in a more capital-efficient manner when contrasted with higher-cost markets. In addition, China's public health problems mirror those of other large underdeveloped economies. As China develops solutions for its own people, many of the products that emerge could become front-line solutions within countries currently unable to afford more expensive treatments. The same barriers that currently limit the speed and success that entrepreneurs in the Chinese life science sector are capable of achieving similarly limit the ability of multinational pharmaceutical companies that want to develop meaningful R&D programs in China. The machinery of innovation that fosters the development of new life science technologies in the country should benefit every stakeholder.

Each of these opportunities has another side, however: handled improperly, China's pursuit of a domestic life science industry could create additional tension with its trading partners. Much of what has allowed the modern era of globalization to advance has been the promise that higher-technology industries would remain safe from the advances of China and other emerging economies. The quid pro quo put forward to Western citizenry has been to allow low-skilled manufacturing jobs to exit developed economies, with lower-priced imports that offset inflationary pressures in other parts of these economic systems as the benefit that accrues to the West. For the last 30 years, this trade-off has resulted in economic growth, political stability, and overall beneficial interdependencies. Yet the 2016 U.S. presidential election makes clear that the American

1 "Xinhua she shouquan fabu 'shisanwu' guihua gangyao" [Xinhua News Agency Authorized Release of "Thirteenth Five-Year" Plan], http://news.10jqka.com.cn/m588608238_headline/?isshare=1&from=timeline&isappinstalled=0.

2 For the purposes of this analysis, "clean technology" refers to three sectors: clean coal, wind, and solar. China's own definition of what constitutes clean technology has historically been quite broad but is limited to only these three areas in this essay.

electorate is weighing the benefits and costs of globalization differently from how this exchange has been viewed in years past. Consequently, policymakers in both China and the United States will need to be more proactive in the identification of potential sticking points and causes of alarm as expressed by the citizens of both countries.

As sectors such as clean technology and the life sciences come into focus for China's policymakers, Western governments must address whether they are making similarly concerted efforts not only to ensure what policymakers sometimes refer to as a level playing field but also to encourage ongoing investment in the innovative capabilities of domestic companies within the countries where they are domiciled. At a time when coordinated policy action by Western governments has degraded significantly, China's endeavors in almost any field hold the potential to appear more threatening to established interests than they in fact are.

This analysis first establishes as a foundation the Chinese government's primary objectives in pursuing a clean-technology sector. The second section then presents the key policies that China used to foster a domestic clean-technology industry. With these two components in mind, the essay discusses the structural barriers—whether internal or external to China—that Chinese innovators and entrepreneurs confronted when trying to scale up their technologies. Finally, the essay outlines ways in which China's success in clean technology has created tension with its global trading partners. Within each of these points, the clean-technology sector is considered only as a prism through which to explore how the life science community might encounter similar challenges and move toward resolutions, progress, and policies more preemptively than what occurred with clean technology.

The Chinese Government's Primary Objectives

The Chinese government's efforts to foster a domestic clean-technology sector were guided by five primary objectives that are also relevant to the life science community. First, China's economic policymakers wanted to see higher-technology industries begin to replace low-technology manufacturing. This objective should be understood as a desire not only to move the country up the value curve into higher-value exports but also to transition the country's workforce into higher-skilled and higher-wage jobs. Second, China viewed clean technology and renewable energy projects as critical to addressing an emerging point of public frustration and anger that held the potential to be directed toward the Chinese government: environmental degradation. Third, China believed that clean-technology companies could emerge reasonably quickly as tax-paying entities, both as a result of access to a growing global market for renewable energy and because the demand for clean-technology solutions across China was enormous. Fourth, Chinese policymakers believed that clean technology represented a sector in transition from core R&D to applied engineering. Because China has no qualms with subsidizing state and nonstate actors to facilitate technologies in such a transitory phase, the country designed incentive schemes that encouraged companies to perform any remaining development or proof-of-concept work within China, where the benefits would most likely accrue to domestic players, whether intentionally or through seepage. Whether this was an efficient utilization of capital, as measured purely through traditional Western return-on-investment analysis, is not the salient point for this analysis. Rather, the objectives, policy infrastructure, and outcomes—both good and bad—that resulted from these policies are relevant to other high-technology sectors such as the life sciences.

Fifth, a driving motivation for China's investment in clean technology was a strong preference for indigenous solutions to address Chinese needs, in part to keep the country's reliance on imported technologies low.

Pursue Higher-Technology Industries

China's economic success has also created the potential for economic failure: as incomes have risen in China, so too have labor inputs for manufacturing-intensive industries.[3] With rising wages comes increased demand for improved food, water, healthcare, and housing. Each of these has had a pronounced inflationary effect along China's eastern seaboard, where much of the country's factories reside. As these costs have gone up, some producers have relocated their facilities farther inland; however, this increases transit time and introduces other costs. At the same time, the Chinese government has advocated for higher wages, not only as a reflection of its desire to be seen as fighting for the benefit of workers but also from an interest in encouraging certain low-technology industries to either relocate within China or leave entirely. For its economic success story to continue, China must identify higher-technology industries that can absorb labor. The country's offer to foreign investors with higher-technology capabilities is twofold: lower-cost manufacturing and access to the Chinese market.

For "made in China" to become trusted by consumers both within and outside the country, China will need to develop sectors whose presence is reliant on more sophisticated capabilities than what the country has offered to date. With the exception of a handful of Chinese companies that have been successful building their brands in export markets, most Chinese industrial power is located outside the consumer's line of sight.[4] One example is Huawei, whose manufacturing prowess stands in stark contrast with most consumers' lack of awareness of its critical role in the manufacturing of telecommunications equipment. Because much of the realized value of consumer goods lies with the brand, Chinese policymakers and business leaders recognize that they will need to either acquire trusted brands that already exist or begin to fundamentally redefine what "made in China" means.

Economies that have a vibrant life science community feature high-paying jobs, systems that deliberately foster innovation within academic institutions, robust protections for intellectual property (IP), and a sophisticated manufacturing infrastructure. In addition, economies that feature global champions in these high-technology fields create benefits for other industries domiciled within the same geography. The characteristics of economies that have successful life science sectors easily complement the policy agenda of the Chinese government to reframe what "made in China" represents to its own people and the world.

China has already achieved success as a producer of active pharmaceutical ingredients (API).[5] APIs can be thought of as the engine that ensures that a finished pharmaceutical product such as a pill works as intended. China's growing role in and responsibility for the global supply chain of APIs is a critical foundation for any future policies designed to foster domestic Chinese drug manufacturing. Making the transition from producing APIs for export to manufacturing the

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3 "A Tightening Grip: Rising Chinese Wages Will Only Strengthen Asia's Hold on Manufacturing," *Economist*, March 14, 2015, http://www.economist.com/news/briefing/21646180-rising-chinese-wages-will-only-strengthen-asias-hold-manufacturing-tightening-grip.

4 Michael Lipin, "Chinese Brands Little Recognized in U.S., but Innovation Helping," Voice of America, December 29, 2014, http://www.voanews.com/content/chinese-brands-little-recognized-in-us-but-innovation-helping/2578088.html.

5 Melanie Lee and Ben Hirschler, "Special Report: China's 'Wild East' Drug Store," Reuters, August 28, 2012, http://www.reuters.com/article/us-china-pharmaceuticals-idUSBRE87R0OD20120828.

final product (also for export) is not an unimaginable leap from a technological or processing point of view. What is less clear is whether a sufficiently meaningful cost-benefit would accrue for multinational corporations (MNC) that reposition their manufacturing and supply chains to purchase finished goods from Chinese manufacturers versus only APIs. To make such a move, China will need to address pervasive problems around the enforcement of good manufacturing practice standards.[6] If the China Food and Drug Administration (CFDA) takes the appropriate steps to strengthen its enforcement capabilities, these measures will also benefit domestic companies that want to craft a brand trusted by both the domestic and foreign consumer.

Address a High-Profile Point of Public Frustration

China's emphasis on clean technology was more than an attempt to reposition Chinese manufacturing for both internal and external stakeholders. It was also a reflection of very loud voices within the country that were becoming frustrated with China's environmental degradation. The pressing need for more energy consumption outside heavy-polluting infrastructure had the potential to create an unresolvable tension, absent coordinated policies by the Chinese government. As only one example, problems around air and water pollution implicated China's coal-fired power grid, and clean technology offered an alternative vision of how to address the country's increasing demand for power without relying on a portfolio of technologies that were aggressively polluting the earth. The possibility that China could develop a domestic industry that would offer an alternative held the potential to not only remedy this domestic ill but also offer a similar vision outside China.

The life science sector maps onto this objective quite nicely. Because of how China's public healthcare financing scheme works, pharmaceutical sales have become a critical source of revenue for hospitals and graft for doctors. Pharmaceuticals in general have become a lightning rod, and China's healthcare financing system is now an even more acute source of public anger than environmental degradation, as evidenced by the over seventeen thousand incidents of violence against hospital workers that occur every year in China.[7]

Public frustration over the healthcare system will ultimately require the country's policymakers to emphasize how pharmaceuticals in particular are produced, priced, and distributed across China. Just as public frustration over environmental issues was a key trigger for the country's focus on clean technology, so too will public animus drive efforts to improve the policy environment around how the domestic pharmaceutical industry is incentivized and regulated. Of all the policy issues that could disrupt market access for both domestic and foreign life science companies, the political nature of healthcare financing in China—given the severity of the problems—holds the potential to be the most destabilizing.

Such an outcome can be averted, however, if three things happen. First, China must increase funding for its public insurance system. Second, China must begin to raise the income level for healthcare workers and make explicit the relationship between rising wages and the need for "red envelope" practices and other graft to cease.[8] Third, it must increase subsidies and reimbursements

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[6] Good manufacturing practices are formally promulgated guidances issued by regulatory bodies both within a specific geography and globally, such as the World Health Organization, that serve to establish standards around how pharmaceuticals are to be manufactured, how quality control is to be established, and what testing protocols are needed to ensure that the finished product is safe for human consumption.

[7] "Violence against Doctors: Heartless Attacks," *Economist*, June 21, 2012, http://www.economist.com/node/21559377.

[8] Wei Yang, "How Does the Pharmaceutical Industry Influence Prescription? A Qualitative Study of Provider Payment Incentives and Drug Remunerations in Hospitals in Shanghai," *Health Economics, Policy and Law* (2016), http://dx.doi.org/10.1017/S1744133116000086.

for the development of innovative products that cost-effectively mitigate pressing public healthcare burdens that are unique to China.

China's initial innovative successes in the life science space will likely overlap in two ways: they will address public health problems unique to developing economies at price points that are unattractive to the traditional sources of industry-funded R&D. Some of China's most pressing public health problems in oncology, cardiology, neurology, endocrinology, and immunology can be managed by existing therapeutics; however, in many cases these treatment protocols are too expensive to be accessible to either the Chinese consumer or even the government. The March 2016 announcement by the National Health and Planning Commission that a group of on-patent pharmaceuticals would face a mandatory 50% price cut in order to be part of China's basic medical insurance is a good example of the price pressure faced by both MNCs and domestic innovators as new products are brought to market in China.[9] While the Chinese market for pharmaceuticals is in theory numerically large, questions around affordability—both from the Chinese government as the driver of the country's healthcare financing system and from families with similar concerns—may well limit the upside potential of the domestic market, in particular as the country's economy slows and public funds for healthcare alongside consumer discretionary spending come under pressure.

Chinese families remain deeply frustrated over healthcare costs, and government officials recognize that demographic and morbidity trends—both of which have been negatively affected by the government's lack of attention to public health—could quickly become overwhelming. In addition, Chinese officials have every reason to anticipate that they will exercise more control over pricing with domestic companies than they currently do with foreign MNCs.

Develop Tax-Paying Entities

China's pursuit of a domestic clean-technology sector also had a very practical side: if successful, these businesses would employ thousands of workers and create a new stream of revenue as tax-paying entities. A study released in March 2015 by the China Coal Consumption Cap Plan and Policy Research Project estimated that, "by 2020, energy efficiency services required to meet a national coal cap in the building, iron and steel, and cement sectors will create 300,000, 450,000, and 390,000 new jobs respectively, bringing hundreds of thousands of direct new jobs and millions of indirect jobs to the market."[10] The job-creation objective is one of the easiest to understand from the point of view of party cadres, whose promotion to higher office relies on successfully achieving the economic goals set out by the central government.

In this way, the life science sector presents a less clear point of comparison. While the life science community typically produces high-paying jobs, the workforce that it absorbs tends to be more highly educated than that employed in traditional industrial manufacturing. In addition, it is not clear even in the United States that the production of advanced science and engineering degrees always translates to stable employment.[11] When Chinese officials outline their primary concerns,

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9 "NHFPC: On-Patent Drugs Face 50%+ Price Cuts in Return for BMI Coverage," GBI, GBI Daily Dose, March 10, 2016.

10 "China's Coal Cap Policy Will Increase Country's Clean Energy Jobs," Natural Resources Defense Council, China Coal Consumption Cap Plan and Policy Research Project, March 26, 2015, http://www.nrdc.cn/coalcap/index.php/English/project_content/id/551.

11 Brian Vastag, "U.S. Pushes for More Scientists, but the Jobs Aren't There," *Washington Post*, July 7, 2012, https://www.washingtonpost.com/national/health-science/us-pushes-for-more-scientists-but-the-jobs-arent-there/2012/07/07/gJQAZJpQUW_story.html.

stable employment and predictable absorption of rural migrant workers are much higher concerns than the needs of white-collar workers.[12]

Chinese officials traveled to Boston in 2015 as part of a study tour to understand what has been called the "Boston model." Among the points of discussion was how to foster collaborations between academia, government, venture capital firms, and industry. In addition, these officials wanted to understand the impact of the unique ecosystem Boston has developed on the local economy. Absent the ability to clearly identify how a life science industry creates tax-paying entities, many municipal officials will only pay lip service to policies that stem from the thirteenth 5YP around how to foster a domestic life science sector.

In particular, much of what animates the development of life science incubator parks is the direct result of two factors, each unique to China. The first is the party-cadre mentality that understands and interprets the country's various planning statements as aspirational and then determines that officials' primary responsibility is to build physical infrastructure (i.e., buildings, parks, and campuses). Second, this interpretation easily fits into what has proved to be a job- and wealth-creating activity in China: build, build, build. The Biolake Innovation Park in Wuhan, which is a government-subsidized biotech park, presents a good example of the benefits of offering subsidized rent to life science companies. But it has only been in the last year that more critical services that will make innovation happen more seamlessly, such as the colocation of a CFDA office, were introduced on the campus.

Identify Sectors Transitioning from Core R&D to Applied Engineering

China was able to achieve many of its development goals in clean technology not through funding science but rather through subsidizing the massive buildout of manufacturing platforms that had unclear economic rationales and, as such, were unlikely to be funded privately through either venture capital or industry.[13] While this strategy is not without risks, the government's investment in subsidization schemes for clean-technology manufacturers emphasized platforms with established science, though lacking a clear return on invested capital.

China's success in clean technology and other sectors such as computer hardware or telecommunications relies on what Dan Breznitz and Michael Murphree characterize as second-generation innovation: "the mixing of established technologies and products in order to come up with new solutions—and the science of organizational, incremental, and process innovation."[14] Alongside clean technology, China's pursuit of a domestic commercial aviation manufacturer fits the idea of second-generation innovation quite easily; however, the life science industry is less conducive to such innovation.

The sort of advancements that result in blockbuster drugs rarely stem from established science that only needs incremental operational gains or improvements in process efficiencies. This painful reality is partially why the costs of new innovative treatment protocols are frequently so expensive: the technology at play represents foundationally new science whose efficacy is the result of decades of experimentation. China's innovation ecosystem, as embodied in what the

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12 Fang Cai, Albert Park, and Yaohui Zhao, *The Chinese Labor Market in the Reform Era* (Cambridge: Cambridge University Press, 2008), 10.

13 Keith Bradsher, "On Clean Energy, China Skirts Rules," *New York Times*, September 8, 2010, http://www.nytimes.com/2010/09/09/business/global/09trade.html.

14 Dan Breznitz and Michael Murphree, *Run of the Red Queen: Government, Innovation, Globalization, and Economic Growth in China* (New Haven: Yale University Press, 2011), 4.

country was able to achieve in clean technology, has yet to prove that it can deliver the same type of disruptive technologies.

None of this is to say that China will permanently lack innovative capabilities.[15] Rather, the point is that Chinese officials are wary of deploying the full force of their policymaking authority in favor of sectors that will require decades of infrastructure building before they come up with a breakout technology that can be monetized by the entrepreneurial community or the local municipality. Chinese innovation in the life sciences will likely be on a case-by-case basis that reflects the unique talent of a handful of the country's premier academics and entrepreneurs rather than a coordinated government action.

Develop Indigenous Solutions

The best example of China's explicit preference for indigenous solutions in clean technology may be the National Indigenous Innovation Products Accreditation Program. Developed and launched in 2009, this program set in motion a spate of trade disputes focused on whether China's so-called indigenous innovation catalog violated World Trade Organization standards by exempting large swaths of the Chinese economy from global trade accords. China's rationale for this policy was threefold. First, it wanted to ensure that the economic benefits of the stimulus plan that the central government had put in place to incentivize investment in clean-technology infrastructure and the creation of new manufacturing capacity accrued to domestic rather than foreign interests. Second, China wanted to maximize the alignment of policies between the central government's 5YP and secondary guiding documents that were put in place to facilitate the development of a domestic clean-technology sector populated by Chinese-run entities. Third, China hoped to minimize where possible its reliance on foreign technology.

With respect to the life sciences, these three objectives compare unevenly. The first—to ensure that the benefits of stimulus specific to the life sciences accrue to domestic over foreign interests—cannot be said to exist in as pure a form as it did with clean technology. China's overall policy environment for the life sciences is still highly fragmented and lacking in funding—specifically around the question of reimbursement through public insurance plans. While China's tendering policies, such that they are, do have a pronounced bias in favor of domestic manufacturers, these same policies harm innovators from both domestic and foreign markets because the tendering process is unpredictable and gives too little, if any, weight to innovation.

The second rationale—to maximize alignment of the central government's policies—does not favorably compare. Clean technology benefited from a coordinated set of policies that went all the way down to specific tax incentives and technology-transfer expectations that were understandable and in turn implementable by local governments. To date, the most coordinated policies for the life science community in China have to do with the creation of certain types of infrastructure (e.g., bioparks, local CFDA review offices, and academic institutes). While such investments are important, they fall short of the type of coordinated top-down policies that benefited the clean-technology space.

The third and final rationale—to minimize reliance on foreign technology—admits of a more precise comparison between clean technology and the life sciences. For China to achieve healthcare outcomes more in line with the developed West, it will need to address very basic

[15] Regina M. Abrami, William C. Kirby, and F. Warren McFarlan, "Why China Can't Innovate," *Harvard Business Review*, March 2014, https://hbr.org/2014/03/why-china-cant-innovate.

questions around affordability. The best chance to drive costs down in China is to foster domestic production. The Chinese government recognizes that while Western life science companies offer innovation, this comes with a cost that to date neither the Chinese consumer nor government can afford en masse. In addition, most governments around the world recognize that the need to ensure access to basic medicines is a predicate element for their people to trust them. As such, reliance on foreign-made pharmaceuticals, in particular, is a clear policy concern in China.

Key Domestic Policies That Foster Innovation

To understand whether China's policy environment for the life sciences is likely to develop domestic champions with robust product portfolios offering innovative therapies, it is helpful to consider how China approached the clean-technology sector. Specifically, what policies were utilized to incentivize innovation?

Tax Incentives Specific to Infrastructure Investment

China's pursuit of a clean-technology sector began in earnest during the eleventh 5YP with a set of industries defined as strategic sectors. This announcement was followed with an investment of 3 trillion renminbi ($439.2 billion) focused on capacity building, tax incentives, and subsidy schemes to facilitate the sector's domestic expansion.[16] The most critical incentives offered by the Chinese government to clean-technology companies have been the three-year exemption from and additional three-year 50% reduction in China's corporate income tax, the 10% offset against current-year taxes for equipment related to energy conservation, and tax holidays for companies operating in certain special economic zones.[17]

China is early in its efforts to create similar tax incentives for the life science community. One reason is that many of the tax policies that are applicable to life science companies stem from a broader set of incentives crafted for high-technology industries in general. Those that are most applicable and appropriate for life science players are covered in China's policies for the development of new high-technology enterprises. Companies stand to realize a 15% reduction in their corporate income tax, but only if they meet a list of R&D criteria, including specific ratios of R&D spending to revenue.[18] Through both the new high-technology enterprise and technologically advanced service enterprise classifications, life science companies can access a 150% pretax "super deduction" on certain R&D spending.[19]

Corporate income tax exemptions are possible for the transfer of technologies, but to date these exemptions have been most specific to the semiconductor sector and do not have as specific applications in the life science space. The exception is the fifth type of qualified technology transfer—new biological and medical variety—that could apply to life science companies.[20]

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16 Edward Barlow, "Opportunities in China's Green-Tech Sector," *China Business Review*, September 2, 2009, http://www.chinabusinessreview.com/opportunities-in-chinas-green-tech-sector.

17 "Selected Tax Incentives in China's Renewable Energy Sector," *China Briefing*, June 15, 2011, http://www.china-briefing.com/news/2011/06/15/selected-tax-incentives-in-chinas-renewable-energy-sector.html.

18 "China's High and New-Technology Enterprise (HNTE) Program," U.S.-China Business Council, June 2013, https://www.uschina.org/sites/default/files/2013%20HNTE%20Backgrounder.pdf.

19 "Worldwide R&D Incentives Reference Guide: 2014–15," EY, 42, http://www.ey.com/Publication/vwLUAssets/EY-worldwide-randd-incentives-reference-guide/$FILE/EY-worldwide-randd-incentives-reference-guide.pdf.

20 Amy Cai, Steven Wong, and Charles Leung, "Tax Incentives for High Technology Industries in China," *A Plus*, May 2011, 40, http://app1.hkicpa.org.hk/APLUS/1105/pdf/38-40-china-tax.pdf.

Thus, when compared with sectors such as clean technology or chip manufacturing, China's tax incentive schemes are not as specific or favorable to life science companies—both domestic and foreign. As such, the sector has not enjoyed the benefits that would be reaped from a more closely tailored set of incentives.

Capacity Building

In 2013, China surpassed the United States in terms of spending on a critical piece of infrastructure, the smart grid.[21] In the year prior, China became the world's largest market for wind energy.[22] Globally, the world has 55 gigawatts of solar panels installed, and 14 gigawatts of that capacity exists in China.[23] This capacity-building exercise reflects a key domestic policy priority in China, as expressed in a number of policy documents and programs, such as the 2006 National Medium- and Long-Term Plan for the Development of Science and Technology, the 973 Program, and the Ministry of Science and Technology's national eleventh five-year development plan. In these initiatives, China's policymakers emphasize specific technologies such as 2–3 megawatt wind turbines, transmission equipment, fuel cells, and clean coal.[24]

China's record of promoting capacity building for the life science community is less impressive. While there are now more than 30 government-sponsored life science biotech parks across China, many of which reside in special economic zones, the supporting policy infrastructure is not as specific or guided. Where clean technology offered the benefit of very tangible infrastructure and capacity, the life science sector is less satisfying because the primary type of capacity is technocratic and requires the clustering of academic, regulatory, and commercial stakeholders.

This trend could easily change, however, especially as China begins to assign economic costs to specific diseases that will become more prevalent due to the nature of its modernization. Should China begin to identify the costs of satisfying specific long-term care needs in the same way as it began to quantify the costs of its environmental challenges, a similar trigger for the development of additional hard capacity in the life science sector could occur. Good examples of types of diseases that are likely to have high economic costs are chronic respiratory problems, kidney failure, and lung cancer. In these cases, China could create specific subsidy schemes that would encourage domestic and foreign companies to invest in R&D capacity oriented to explore these conditions.

Government Spending on Finished Work Product

The previously referenced market size for clean technology in China reflects the government's willingness to spend on completed projects. Here, the comparison to the life sciences requires an important distinction: while China's leaders are similarly willing to spend on infrastructure such as biotech parks, the funding mechanism within the country's public healthcare insurance system does not yet reward innovation. As such, until the government is willing to spend more on innovative molecules, the full potential of both domestic Chinese and foreign MNCs will not

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21 Jeff St. John, "Report: China Outspent U.S. on Smart Grid in 2013," Greentech Media, February 20, 2014, http://www.greentechmedia.com/articles/read/report-china-outspent-u.s.-on-smart-grid-in-2013.

22 "China Was World's Largest Wind Market in 2012," Bloomberg New Energy Finance, February 4, 2013, http://about.bnef.com/press-releases/china-was-worlds-largest-wind-market-in-2012.

23 Katie Fehrenbacher, "China Is Utterly and Totally Dominating Solar Panels," *Fortune*, June 18, 2015, http://fortune.com/2015/06/18/china-is-utterly-and-totally-dominating-solar-panels.

24 Xiaomei Tan and Zhao Gang, "An Emerging Revolution: Clean Technology Research, Development and Innovation in China," World Resources Institute, Working Paper, December 2009, 2, 5–6, http://www.wri.org/publication/emerging-revolution.

be realized within China. It is easy to mistake the Chinese government's willingness to spend on buildings for a willingness—and in fairness ability—to spend more on public healthcare programs that would incentivize innovation.

There are five key reforms, all related to the Chinese government's spending on life science outputs that would drive innovation for both domestic and foreign companies. First, China needs to remedy its fragmented and counterproductive tendering policies by either regularly updating the National Reimbursement Drug List or creating a new one. The list is perceived by nearly every stakeholder as having no policy or predictive value. If the government cannot commit to regularly update it, a formal policy that establishes the rights and responsibilities of provincial tendering should be put in its place. The oft-referenced Anhui model points toward the sclerotic and misguided attempts by provincial authorities to craft a tendering program that tries to align policy mandates from the central government with the on-the-ground funding challenges faced by local officials.[25] For both domestic and foreign pharmaceutical companies, the inability to identify relevant government officials around specific reimbursement matters stymies the commercialization of innovative products.

Second, China must weigh whether its current pilot projects that attempt to relocate where pharmaceuticals are being sold (from inside to outside the hospital) simply physically move a problem that will only be resolved through additional funding for healthcare services. China's ability to spend more on healthcare will have to compete with a number of growing financial commitments tied to the country's current economic situation. To the extent that Chinese leaders understand their legitimacy as being tied to the country's economic growth, headwinds related to a bad debt crisis, underperforming state-owned enterprises, and turmoil in the public equity and bond markets will all compete with healthcare spending for increasingly limited government funds.

Third, China should offer further incentives to private sector providers of commercial healthcare insurance to expand their service offerings. One of the most important ways the government could facilitate such an expansion would be to force additional disclosure of healthcare and treatment datasets from public hospitals. The paucity of good data for building insurance products is among the most significant issues that continue to plague private insurance providers, both foreign and domestic.

Fourth, China must increase patient choices by further streamlining the CFDA approval process and ensuring that families are offered the chance to purchase innovative products. While China's national formulary may never have the same level of reimbursement as its Western peers can offer, it is critical that market access for both domestic and foreign pharmaceutical companies be maintained and that no barriers, either formal or not, be put into place that block the ability of patients to choose other products, even if these other products must be paid for out of pocket.

Fifth, China should establish a more targeted incentive scheme focused on developing innovative and cost-effective solutions for those chronic diseases that are likely to be the most costly to treat. Part of the country's public health burden will fit patterns in Western countries, most noticeably with respect to cardiovascular disease and diabetes; however, because of China's air pollution and smoking rates, respiratory problems will be an outsized issue from both a

[25] The Anhui model is a blind bid and tender process that is composed of two stages. The first is an envelope that holds the confirmation that a company can manufacture a particular pharmaceutical product according to China's quality standards. This is rarely reviewed. The second stage is the submission of bids for the lowest price for the pharmaceutical in question. Companies have one shot at this submission, and as such this tendering model has been very effective at driving down prices on particular products.

patient care and cost point of view. China already bears the burden of a level of noncommunicable diseases that is widely higher than that of either its regional or global peers: these account for 85% of deaths in China today, compared with a global average of 60%.[26] Similar efforts focused on kidney and liver diseases would have a significant effect on reducing the financial burden of China's cumulative healthcare costs.

Acceptance of Global Standards

Clean technology does not offer a compelling comparison with the life science, chip manufacturing, or telecommunications sectors on the matter of how the acceptance of global standards can foster innovation. Relative to the key question of what policies drive domestic innovation for life science companies in China, there are two fronts where the acceptance of global standards is critical.

First, the drug lag issue, where products already approved outside China are only approved by the CFDA three or more years later, is not only a problem for large foreign MNCs. This issue reveals very real structural barriers to the development of domestic innovation. While domestic pharmaceutical companies may have a slight advantage when it comes to more expeditious approvals, local companies still express extreme frustration at the speed of reforms. As the CFDA continues to create additional technocratic capacity internally through increased drug registration prices, the industry will be closely watching how this additional money is spent and how the newly built capacity translates into a more transparent and scientific approval process. Handled properly, China could develop a review process that not only facilitates the development of innovative molecules for domestic consumption but also lays the groundwork for expeditious development, approval, and export by the country's nascent domestic champions.

Second, China must fundamentally improve its good manufacturing practice standards and enforcement mechanisms. Should the country suffer from an additional spate of high-profile problems with quality, human safety, or efficacy—either domestically or internationally—during a period when it is attempting to send products into overseas markets, its various objectives will fail. On this front, China's own domestic companies want to see additional oversight and controls put in place by the CFDA. Much of this concern reflects a very real awareness on the part of business interests that the life science sector cannot afford to be perceived by markets as unsafe, especially amid its commercialization efforts.

Beyond the previously mentioned questions around technocratic capacity and political will specific to the CFDA's reforms, key stakeholders within the domestic Chinese life science community are pushing against simply replicating the Western drug approval process. As one key expert who leads a roundtable within the CFDA shared privately with me during a May 2015 interview in Shanghai, before the CFDA reform process advances much further, Chinese officials and policymakers need to answer four questions:

- Can China develop a cheaper and more expeditious drug approval process than what exists in the West? To state this question differently, which parts of the Western drug approval process should be replicated in China, and which parts reflect unique aspects of Western political economies?

[26] Charles Hugh Smith, "The Cost of China's Industrialization: 700 Million People with Diabesity/Cancer/Lung Disease," Of Two Minds, June 8, 2015, http://www.oftwominds.com/blogjune15/China-disease6-15.html.

- Why has China given all the power to the U.S. Food and Drug Administration in establishing the drug approval process and its ensuing costs and complexities?
- Can China look at the risk-to-reward relationship around new drug approval differently than the West does? Will it have to, given the scope of its healthcare spending needs over the next twenty years? If so, how should this be reflected in the CFDA's approval process?
- Is the U.S. Food and Drug Administration's approval process actually designed to create barriers that potentially benefit Western pharmaceutical MNCs and thereby also introduce structural barriers that make it harder for domestic innovation to take place inside China?

If China were to establish healthcare standards similar to those that exist in the West, even at 60% of the cost delivered in Western economies, such an increase in spending would bankrupt the Chinese government. As only one example of this problem, if China treated acute renal failure according to Western standards, such an approach would consume 8% of all China's existing public spending on healthcare.[27] This challenge has been captured in other sectors as a "bottom of the pyramid" issue and has been best reflected in product designs for fast-moving consumer goods.

China's embrace of global standards, specifically in the area of new drug approval, will continue, but there will be limits to how far and how quickly the Chinese government can implement these standards.[28] Changes to the CFDA's approval process do not address the most critical concerns of the central government—specifically, the mounting costs of expanding access to and improving the quality and affordability of healthcare. The strongest advocates for additional reform will not be foreign pharmaceutical MNCs but rather domestic innovators. The latter recognize that the gaps between the CFDA's approval process and global standards will undermine the central government's policy objective to see the life sciences become one of the country's technologically rich export sectors.

Intellectual Property Protection

China's track record on IP has been well-established.[29] But what is not as well-known is the many ways in which China's own domestic innovators—for example, in the clean-technology and renewable energy sectors—have been as forceful in advocating for improved IP laws as have foreign players. This reflects the simple reality that as Chinese companies bring more genuinely innovative products to market, they have the same concerns as their foreign counterparts. On this front, as with the issues specific to the CFDA, China's primary objectives are aligned with both domestic and foreign interests.

Clean technology has benefited globally from specific IP advances, not least of which through the introduction of fast-track patent application and review. Designed to accelerate the review of clean-tech patents, these processes have been replicated in China. According to one leading law firm specializing in this field, "applicants must submit a search report by a qualified entity or a

[27] This calculation was shared by a CFDA stakeholder who asked not to be identified. The analysis reflects a specific morbidity that is the focus of a discussion within the CFDA around the tension between the need to allocate bureaucratic resources to accelerate approvals—which would benefit both domestic and foreign companies—and the need to address more basic concerns, such as modernizing quality-control systems to resolve rampant quality issues within the country's domestic manufacturing base.

[28] Dan Stanton, "AstraZeneca: China Formulated Anaemia Drug on Fast-Track, but Timeframes Vague," in-PharmaTechnologist.com, February 9, 2016, http://www.in-pharmatechnologist.com/Regulatory-Safety/AZ-Chinese-made-anaemia-drug-on-fast-track-but-timeframes-vague.

[29] U.S. Patent and Trademark Office, "Report on Patent Enforcement in China," 2012, http://www.uspto.gov/ip/global/China_Report_on_Patent_Enforcement_%28FullRprt%29FINAL.pdf.

translation of a search report issued by another country. Once a request for prioritized examination is granted, a first office action is expected to issue within 30 days and prioritized examination is expected to be completed within one year."[30] The CFDA is attempting to develop a similar fast-track approval process modeled on the U.S. Food and Drug Administration's fast-track process—specifically for therapies that meet the agency's standard for accelerated approval and priority review.[31] In the case of clean technology, China's willingness to create unique channels to address IP review and patent grants was a by-product of the needs of domestic industry. In the case of the life science sector, similar pressures should create equivalent movement forward within the CFDA.

China's clean-technology sector has benefited more dramatically than the life science sector with respect to domestic IP reforms. However, these sectors share two barriers to the development of new IP laws in China: first, implementation of promulgated law and, second, the willingness of domestic companies to balance competing short- and long-term financial goals (with the latter having largely motivated China's life science sector for the last twenty years).[32]

Structural Barriers That Limit Innovation within China

While China's success in clean technology is admirable, the country does not have a blemish-free record on this front. There have been notable failures, as a result of both excessive government involvement and problems that are at some level unique and endemic in the evolution of Chinese public and private initiatives.

Overly specific policy guidance in fields with emerging technologies. There are three levels of policy guidance available to any nation-state crafting industry policy. The first is national and sets a top-level focus on a strategic sector, such as the life sciences. Chinese policy is partly guided by such a top-down emphasis. The second is vector-specific, such as targeting a particular type of technology platform or disease. China does this in other high-technology sectors outside the life sciences, but thus far it has not taken the step of focusing the country's policies around a specific set of diseases or healthcare outcomes. As has been previously discussed, some experts believe that the country could benefit from an additional level of policy guidance at this intermediate level, simply to ensure that a degree of focus is brought to bear on the most critical cost drivers within China's public health system. The third level of policy guidance is to actually require that policies focus on a particular pathway within the second level. This type of industrial guidance is foreign to most Western governments but has good—if ineffective—parallels in centrally planned economic systems.

Confusing building infrastructure with creating an ecosystem. The most pressing problem for China's life science sector is that while China is building significant biotech parks that offer world-class infrastructure, the underlying ecosystem that supports meaningful innovation does not yet exist. Partnerships between academia and the start-up community are ad hoc and suffer from competing interests within the academic sphere that unnecessarily complicate the ability to do pioneering research and develop commercial partnerships. Åse Linné observes that "innovation

30 "Global Initiatives to Accelerate Examination of Cleantech Patent Applications," Sterne, Kessler, Goldstein, and Fox, March 11, 2015, http://www.skgf.com/uploads/1232/doc/New_Global_Initiatives_to_Accelerate_Examination_of_Cleantech_Patent_Applications_UPDATE.pdf.

31 "Fast Track," U.S. Food and Drug Administration, http://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm.

32 Yahong Li, *Imitation to Innovation in China: The Role of Patents in Biotechnology and Pharmaceutical Industries* (Cheltenham: Edward Elgar Publishing, 2010), 174–75.

processes are more delicate and sophisticated than investments in science and transfer from science to an industrial setting, and instead new drugs are created through a systematic combining of resources across organizational and national borders."[33] These "delicate processes," as she calls them, require more than just infrastructure. They require an ecosystem that creates time and incentives for pure research as well as an ecosystem within which these innovations can be trialed.

Veracity of research. China has a problem with academic fraud that is a very real and specific challenge to the creation of a vibrant, collaborative, and trusted market for innovation. In 2015 a number of high-profile retractions of supposedly peer-reviewed medical research occurred within China.[34] The country suffers from a particularly acute form of the "publish for promotion" problem.[35] Some MNCs conducting pharmaceutical research in China have discovered similar issues within their own Chinese R&D teams.[36] These problems with the veracity of data and research findings add another layer of complexity to a due-diligence process that is already difficult to manage. As China desires to see more innovation drawn from its R&D facilities and academic campuses, it must ensure that findings are accurate.

Misreading the role of global standards. To its credit, China has by and large come to understand that it has a vested interest in the development of global standards for high-technology products and services. The more complex the goods being offered to the global market, the more standardization is critical to ensure compatibility and quality. Handled properly, global standards become an important facilitator of innovation because they establish a foundation that ensures compatibility.

China's life science entrepreneurs, including a number who have access and influence within the CFDA, have begun to push back against a wholehearted embrace of some of the reforms that the CFDA is in the process of implementing. One Chinese entrepreneur leading a biotech startup made the following comment about reforms:

> We need to be sure that in the development of a more robust CFDA capability we do not simply replicate the U.S. and European systems. Much of what works for them may not work for us, and now is the time for us to make sure we are not applying the wrong set of standards to our domestic industry before it has time to emerge.[37]

Areas of Tension

Practical

There are three pressing practical areas of tension that will require additional time and investment to ensure that the agendas of both domestic and foreign life science companies are met. First, the CFDA reforms need to continue, and the nature of the technocratic capacity

33 Åse Linné, "China's Creation of Biopharmaceutical Drugs: Combining Political Steering, Military Research, and Transnational Networking" (PhD diss., Uppsala University, 2012), 187.

34 Michael Woodhead, "Academic Fraud in China: 43 Medical Cases Retracted," China Medical News, March 20, 2015, http://www.chinesemedicalnews.com/2015/03/academic-fraud-in-china-43-medical.html.

35 "Lunwen yadao shoushu dao yisheng ping zhicheng fangfa gai gaile" [Academic Findings Call into Question Surgeon's Suggestions for the Way His Profession Should Change], *Xinmin*, February 8, 2015, http://health.xinmin.cn/jkzx/2015/02/08/26760156.html.

36 John Carroll, "GlaxoSmithKline's Research Chief in China Fired for Data Fraud," FierceBiotech, June 11, 2013, http://www.fiercebiotech.com/story/glaxosmithklines-research-chief-china-fired-data-fraud/2013-06-11.

37 Author interview, Shanghai, summer 2015.

China is building needs to roughly follow what has worked in Japan, where a similar endeavor was successful. Second, as has been previously outlined, absent meaningful changes in how China reimburses companies for innovative therapies, the country is unlikely to develop a meaningful domestic R&D capacity to meet either its economic planning goals or public health objectives. Third, China must formally address the ways in which market access is becoming more unpredictable and unstable for pharmaceutical companies. While MNCs are currently very concerned about this issue, the reality is that much of what is animating market access challenges (e.g., lack of funding and poor coordination of policies between central, provincial, and municipal governments) will also have a negative impact on domestic companies. An extremely encouraging finding is that each of these three practical areas of tension is felt by both domestic and foreign players, which suggests that the Chinese government is likely to move to create remedies to these problems.

Political

The United States' current political environment has struggled to adapt to the realities of the globalized world that the country's businesses and entrepreneurs must compete within. This is particularly the case with debates that center on whether the U.S. government should be "in the business of picking winners and losers in the marketplace."[38] China's economic planners are not engaged in a similar debate. China has been willing to invest significant amounts of capital and political energy into targeted industries that align with its objectives. Many of these investments are capital inefficient but are viewed as politically necessary in order to achieve the goals outlined in the second section of this essay.

As China pursues these primary objectives, the very nature of this pursuit creates turbulence globally. Tension is growing over whether the United States has a viable alternative to the Chinese model of development and which model is most likely to generate economic growth. Rather than look for the ways in which the Chinese model of fostering innovation may have lessons for U.S. policymakers, the current political climate in the United States has made recrimination the path of least resistance. In addition, the U.S. policymaking community spends too little time and energy working to ensure that the United States remains the most attractive place globally to conduct bench science, drug trials, and commercialization. While monitoring China's pursuit of a domestic life science industry is important, U.S. policymakers should double down on their efforts to address inefficiencies and other challenges in the United States' own FDA review and approval process, outmoded patent system, and reimbursement scheme.

Conclusion

China has proved surprisingly capable of achieving its economic goals over the last three decades; however, as the Chinese economy has grown and become more complex, so too has the nature of those industries within which the country will need to be successful if it is to reposition itself along the value chain. High-technology sectors such as telecommunications, chip manufacturing, and clean technology all fit into a more refined manufacturing environment. The life sciences, by contrast, do not. This disconnect does not assure China of failure at achieving its

[38] Bernd G. Janzen, "The Cleantech Subsidy Wave: A New Source of Trade Conflicts?" *International Law News* 39, no. 3 (2010).

goals in this field; rather, it points toward the type of structural reforms that will continue to be required if China is to achieve success in an even more technologically complex field than any it has explored to date.

The interests of China's domestic life science companies, foreign MNCs, and the Chinese government are all more closely aligned than not. While pressures over affordability are not going away and may limit the type of innovation that is brought to market in China, these same challenges could also drive a type of innovation by Chinese entrepreneurs that will address the needs of a domestic market to which foreign MNCs are unlikely to pay attention.

Life science innovation in China is not inevitable. But with Chinese government officials paying increasing attention to the sector, its returning scientific talent, and the endeavors of various domestic R&D initiatives funded by MNCs, success is more likely than not. For such success to ultimately benefit both the domestic and foreign markets, China and its trading partners will need to anticipate the impacts on their economies, ensure that consumer safeguards are in place, and establish global trade policies that reflect the additional complexities created with high-technology sectors such as the life sciences.

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For more info on these programs, please contact Clara Gillispie, NBR's Director of Trade, Economic, and Energy Affairs, at eta@nbr.org.

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