The Current Status, Trend, and Development Strategies of Chinese Biopharmaceutical Industry With a Challenging Perspective

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Abstract
Biopharmaceutical technology is one of the most promising biotechnologies in the world. With the development of modern biotechnology, biopharmaceuticals are thriving and developing rapidly as a global high-tech biotechnology industry, bringing the unprecedented market prospects to biopharmaceuticals in China and the world. Today, world is witnessing that Chinese biopharmaceutical industry is booming and growing up. The national biopharmaceutical industry of China, especially the development and industrialization of biological medicines with genetic engineering drugs as its core fields, has already reached a certain market scale after over 20 years of development. The biopharmaceutical industry will be one of the most active economic sectors in China, whereas the biotechnological revolution with modern biopharmaceutical technology has become the lifeblood of maintaining human health and food safety in the future. The article systematically analyzed and evaluated the current status and trend and explored the main existing problems of Chinese biopharmaceutical industry with some development strategies in a challenging perspective. It probes into Chinese biopharmaceutical industry and its bases too. The future development prospects of Chinese national biopharmaceutical industry are much optimistic but challenging.

Keywords
biopharmaceutical technology, biopharmaceutical industry, status, development trend, strategy

Introduction
There are generally two composite concepts of the biopharmaceutical industry in the broad and narrow definitions (Walsh, 2001, 2014). The broadly defined “biopharmaceutical industry” refers to a class of enterprises or companies engaged in similar business to make products for prevention, treatment, diagnosis, and other uses in pharmacy. The narrowly defined “biopharmaceutical industry” is the biomedical products for the prevention, diagnosis, and treatment of human diseases. Today, biopharmaceuticals mainly include biochemical drugs, bioengineering drugs and genetic engineering drugs, genetic engineering vaccines, new vaccines, and diagnostic reagents, micro-ecological preparations, blood products, and other biological agents. Among them, the most important technology applied in biopharmaceutical industry is genetic engineering technology, which uses cloning technology and tissue culture technology to cut, insert, link, and recombine DNA fragments to gain useful biopharmaceutical products. In practice, biopharmaceutical products mainly include three major categories, that is, genetic engineering drugs, biological vaccines, and biological diagnostic agents, that play an important role in the diagnosis, prevention, control, and eradication of infectious diseases to protect and extend human health and longevity.

Modern biopharmaceutical industry is marked by the establishment of Genentech biopharmaceutical company on April 7, 1976 (Crunkhorn, 2014; Eissa, 2017; Farid, 2019; Hummel et al., 2018; Kadam et al., 2016; Kensaku et al., 2019; Maa & Prestrelski, 2000; Shimaoka & Springer, 2003; Somasundaram et al., 2018; Walsh, 2014). The biopharmaceutical industry becomes one of the promising industries in the 21st century. Biopharmaceutical industry is now characterized by high technology, high investment, high risk, high profitability, and long cycle. It is one of the most active and fastest growing fields in bioengineering application and development (Eissa, 2017; Farid, 2019; Huang et al., 2011; Somasundaram et al., 2018; Walsh, 2014). The biopharmaceutical industry becomes one of the promising industries in the 21st century. Biopharmaceutical industry is now characterized by high technology, high investment, high risk, high profitability, and long cycle. It is one of the most active and fastest growing fields in bioengineering application and development (Eissa, 2017; Farid, 2019; Huang et al., 2011; Somasundaram et al., 2018; Walsh, 2014).

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Hummel et al., 2018; Kadam et al., 2016; Kensaku et al., 2019; Somasundaram et al., 2018; Walsh, 2014; Zhang et al., 2007). For instance, monoclonal antibodies continue their march on the markets, and the optimized so-called bio-better versions of existing biologies are gaining ground too (Eissa, 2017; Farid, 2019; Hummel et al., 2018; Somasundaram et al., 2018; Walsh, 2014). Many countries regard the biopharmaceutical industry as one of the strategic industries for national development, and continuously increase policy support and capital investment in the biopharmaceutical industry (Farid, 2019; Hsu et al., 2005; Kadam et al., 2016; Kensaku et al., 2019; Langer & Rader, 2017; Rai, 2002; Somasundaram et al., 2018; Valérie et al., 2010; Walsh, 2014). Therefore, biopharmaceutical industry is booming and half of the world’s pharmaceuticals are biosynthesized in modern industry. Particularly, when combining drugs with complex molecular structures, it is not only simpler than chemical synthesis but also has higher economic benefits. Developing the biomedical products will help humans solve many current diseases that cannot be human, and reform the food production and eliminate human malnutrition. These biomedical products will extend human life and improve people’s lives.

The biopharmaceutical technology is a new flourishing industrial technology. Although it started relatively late, it has developed very rapidly and achieved unprecedented results in just a few decades. Since the launch of Human Genome Project, the worldwide public media has continuously drawn a beautiful picture and reveals the genetic mystery of life to the public and global people (Crunkhorn, 2014; Shimaoka & Springer, 2003). However, genetic information is not directly involved in lives but indirectly guides the metabolism of the organism by controlling the form of proteins. The genetic information contained in a gene, through a series of complex reactions, eventually leads to the formation of the corresponding protein(s) involved in various activities of life. Therefore, functional genomics and proteomics naturally become hotspots in the biological research fields today. Proteins, the carriers of gene function (especially enzymes involved in metabolism), are the executives of life activities. In the human genome, most of the genes and their functions need to be studied, revealed, and elucidated at the protein level. As a result, the development prospects of biopharmaceutical technology are bright with more and more companies engaged in biopharmaceutical industry and relevant technology research, from the previous small-scale decentralized industry to the large-scale centralized large-scale industry. At the same time, some countries have increased their emphasis on biopharmaceutical technology, and these countries invest a large amount each year to encourage companies to be developed and innovated. With the strong backing of the country, biopharmaceutical technology is even more powerful. Companies engaged in biopharmaceutical technology are springing up all over the world. The drugs from the biopharmaceutical industry will enter the streets and all over the world soon. Biopharmaceutical industry will become the world’s largest industry. It is globally the fastest growing industries that are actually the potential driver of future economic growth (Eissa, 2017; Huang et al., 2011; Hummel et al., 2018; Kensaku et al., 2019; Langer & Rader, 2017; Liu & Li, 2016; Ottoo, 2018; Somasundaram et al., 2018; Valérie et al., 2010; Walsh, 2014; Zhang et al., 2007). Research of biopharmaceutical technology is a strong support for countries in the world to implement national healthy living and development policies. Biopharmaceutical research can develop new drugs that can prevent and treat various diseases, improve human life, improve human living standards, and allow humans to longevity. Biopharmaceutical industry is a sunrise industry in China (Eissa, 2017; Hummel et al., 2018; Kensaku et al., 2019; Langer & Rader, 2017; Somasundaram et al., 2018). The biopharmaceutical industry will be the most active and most influential emerging industry in China. It will have an important impact on solving major problems related to human survival and development, such as human health, resources, environment, agriculture, and industry. Based on the review of previous reports and the data search of biopharmaceutical industry in China, this article aimed to evaluate the current status and trend of Chinese biopharmaceutical industry with some development strategies in a challenging perspective.

**The Development of Modern Biopharmaceutical Industry**

The trends and scopes of biopharmaceutical technology in various countries and regions are not uniform. Meanwhile, modern biotechnology has a wide range of practical applications in biopharmaceuticals, environmental protection, food, genetic research, and so on, among which biopharmaceutical industry is now the important application of biotechnology. More than 60% of human biotechnology achievements are concentrated in the pharmaceutical industry, to develop new specialty drugs or to improve traditional medicines, which has caused major changes in the pharmaceutical industry, and biopharmaceutical technology has developed rapidly. More than 2,200 biotech drugs have been developed globally, of which more than 1,700 have entered clinical trials (http://s.askci.com/data/year/).

The rapid increase in the number of biotech drugs worldwide shows that industrialization of the world medicine in the 21st century is gradually entering the investment harvest period, and the global biopharmaceutical industry is growing rapidly. Since the 1990s, global biopharmaceutical sales have grown at an average annual rate of more than 30%, much higher than other industries with an annual growth rate of less than 10%. The biopharmaceutical industry is rapidly developing into the most promising high-tech pillar industry.

Although the world’s first medical biotechnology product has been around for less than 20 years, about 270 million people worldwide have benefited from drugs and vaccines
made from biotechnology. Nearly 100 biotech drugs and vaccines have been put on the market to date, and more than 350 biotech drugs are in the final clinical trial phase. Biopharmaceutical technology is recognized as one of the crucial strategic technologies for the 21st century. Many countries develop their development and management policies in favor of biopharmaceuticals to enable the biopharmaceutical enterprises to acquire competencies in the field. The global biopharmaceutical technology and industries present the development trend of industrial agglomeration. The main agglomerated areas or large centers of biopharmaceutical industry are concentrated in the United States, Europe, Japan, India, China and other countries (Bianchi et al., 2011; Pharmaceutical Research and Manufacturers of America [PhRMA], 2015, 2016; Valérie et al., 2010), whereas the developed countries, e.g., the United States, occupy dominant positions (see Table 1).

The biopharmaceutical industries in the United States and Europe usually have the following characteristics. First, the merger of companies is common in the development process of biopharmaceutical industries (Goldsmith & Varela, 2016). After the merger, the strength of biopharmaceutical technology companies has grown. For example, two biopharmaceutical companies, Celltech and Shire, have been ranked among the top 100 companies in the United Kingdom (Goldsmith & Varela, 2016). The second is to make joint operations with the traditional companies. In the process of struggle for survival and development, more and more emerging biopharmaceutical companies are uniting with traditional pharmaceutical companies. The third is to frequently increase investment in the scientific research of biopharmaceutical industries. The deciphering of human genes has shown attractive prospects for biopharmaceutical technology and has become the most advanced research project in the biotechnology field. Up to date, there are three genetic cracking research centers in the world, i.e., two in the United States and one in the United Kingdom. Fourth, the biopharmaceutical technology companies are gradually maturing. The U.S. and European biopharmaceutical companies that have survived the stock market storms seem to be maturing, and the companies have shown more stability and closeness to the market. Today, more and more biopharmaceutical companies are targeting the development and promotion of new drugs. Fifth, the investment markets are broad in biopharmaceutical industries. In the past 20 years since the birth of the biopharmaceutical industry, 75 drugs, vaccines, and diagnostic tests have passed the certification of FDA (Food and Drug Administration), changing traditional medical practice and producing billions of dollars in sales. There are presently more than 5,000 global biotechnology companies, of which public companies account for about 16% and private companies account for about 84%. Furthermore, more than 2,200 biopharmaceuticals and vaccines have been put on the market, of which more than 1,700 entered clinical trials.

In 2016, a research report had been analyzed and published by PhRMA (2016) on the Biopharmaceutical Competitiveness and Investment (BCI) of the 28 major economies (countries and areas) in the world (see Table 1). The report was commissioned by the consulting firm of Pugatch Consilium of PhRMA, in which they found that different policies in different economies are the main factors affecting BCI scores (PhRMA, 2016). Furthermore, those countries introducing and encouraging innovation were at the forefront of biopharmaceuticals in the report (PhRMA, 2016). The research report mainly scores BCI from the five major economies in the world, with a score of 100. These five aspects include scientific and technological strength and infrastructure, intellectual property protection, clinical research and framework systems, regulatory systems, market access, and funding. Their questionnaires were conducted by senior managers of biopharmaceutical companies in various countries. These senior managers clearly have a deeper understanding of the biopharmaceutical market. Given that emerging market and mature market issues are slightly different, their questionnaires cover 25 questions in five aspects, and the answers to each question are available in four levels. They are ranked based on these answers to the BCI score of each country.

In the 2016 BCI survey, different national policies on innovation in biopharmaceutical industries are the main factors affecting BCI. We know that the different policies of countries or areas (economies) are mainly determined by their economic development. Therefore, we see from the above table (refer Table 1) that the economic development status (per capita GDP [gross domestic product]) is basically positively correlated with BCI. However, the BCI indicators of various economies have little to do with their market capacity (total GDP). We can see that China, India, Brazil, Russia, and other big countries are behind, while Singapore, South Korea, Taiwan, and Israel are equivalent to emerging markets that came to the forefront. The report pointed out that in emerging markets, the top BCI countries have introduced relevant policies and set up a large number of special funds to support and stimulate biopharmaceutical innovation and technology transformation. On the contrary, emerging countries with lower BCI rankings are far from enough in these areas. Most of the commonalities in these countries are to continuously improve the standards for patent applications. Other unfavorable policies include policies with local protectionism. Even BCI in mature market countries cannot avoid the impact of government policies. For example, Canada has strengthened its regulation of patent utilization, whereas Australia’s policy of joint liability punishment has been observed as having a negative impact on R&D (Research and Development) and the investment environment. Thus, their BCI indicators have lower scores. Conversely, mature market countries (United States, Switzerland, United Kingdom, etc.) that give R&D,
regulatory, market access, and a good policy environment for IP systems have high BCI scores.

### The Biopharmaceutical Industry and Its Development Trend in China

The Chinese biopharmaceutical industry started in the early 1980s (Chan & Daim, 2018; Yan, 2014; Zhou & Li, 2013). In 1983, the Ministry of Science and Technology of China established the first national bioengineering development center. In 1989, China approved the first genetically engineered drug produced in China. From 1986 to 1995, the state invested in three centers of research and development (R&D), including those of genetic engineering drugs and biological products and vaccines, specializing in the research and development of bioengineering products and systematically implementing industrialization (Chan & Daim, 2018; Yan, 2014; Zhou & Li, 2013). Between 1996 and 2000, the Ministry of Science and Technology of China specially formulated the “1035 Plan” to effectively promote the research and development of new drugs. Here, “10” represents the research and development of 10 innovative drugs, 10 new drugs listed for the first time, and 10 genetic engineering drugs. And, “35” means five new drug screening centers, five genetic laboratory quality specification centers, and five genetic clinical testing quality standards centers.

Under the guidance and promotion of Chinese national policies, research centers of biopharmaceutical technology have been established in various regions of China (Eissa, 2017; Farid, 2019; Langer & Rader, 2017; Liu & Li, 2016; Yan, 2014; Yang et al., 2019; Zhou & Li, 2013). For example, in 1993, China established the Bioengineering Society and Shenzhen Kexing Biological Products Inc., the largest genetic engineering manufacturer in China. This indicates that China has a certain amount of biotechnology product research and development and is capable of genetic engineering techniques and production purification techniques. Since 1999, Chinese government has successively introduced laws and policies

### Table 1. Ranking of the Competitiveness and Investment Environment of Biopharmaceutical Industry in the Worldwide Major Economies (Countries and Areas).

| Rank | Country and area        | BCI score | Market type     |
|------|-------------------------|-----------|-----------------|
| 1    | United States           | 85.55     | Mature market   |
| 2    | Singapore               | 85.35     | Emerging Market |
| 3    | United Kingdom          | 81.59     | Mature market   |
| 4    | Switzerland             | 81.01     | Mature market   |
| 5    | Korea                   | 77.94     | Emerging Market |
| 6    | Germany                 | 77.70     | Mature market   |
| 7    | Japan                   | 77.48     | Mature market   |
| 8    | Ireland                 | 77.21     | Mature market   |
| 9    | Taiwan                  | 76.67     | Emerging Market |
| 10   | France                  | 75.90     | Mature market   |
| 11   | Israel                  | 75.38     | Emerging Market |
| 12   | Galata                  | 72.42     | Mature market   |
| 13   | Australia               | 67.25     | Mature market   |
| 14   | Italy                   | 67.17     | Mature market   |
| 15   | United Arab Emirates    | 66.67     | Emerging Market |
| 16   | Saudi Arabia            | 66.14     | Emerging Market |
| 17   | Mexico                  | 65.32     | Emerging Market |
| 18   | South Africa            | 64.60     | Emerging Market |
| 19   | India                   | 58.72     | Emerging Market |
| 20   | Turkey                  | 56.85     | Emerging Market |
| 21   | China                   | 54.54     | Emerging Market |
| 22   | Russia                  | 53.76     | Emerging Market |
| 23   | Colombia                | 53.64     | Emerging Market |
| 24   | Brazil                  | 53.52     | Emerging Market |
| 25   | Egypt                   | 53.49     | Emerging Market |
| 26   | Argentina               | 53.22     | Emerging Market |
| 27   | Thailand                | 49.23     | Emerging Market |
| 28   | Indonesia               | 46.25     | Emerging Market |

Note. The 2016 scores of BCI (Biopharmaceutical Competitiveness and Investment) and global competitiveness were collected by the website of Pugatch Consilium of PhRMA (Pharmaceutical Research and Manufacturers of America). Please see “The Race for Biopharmaceutical Innovation: BCI Survey 2016” for details (http://www.pugatch-consilium.com/reports/BCI2016-Race_for_Biopharmaceutical_Innovation.pdf).
related to pharmaceutical manufacturing R&D activities, such as “Medical Science and Technology Policy (2002–010)” and “Bio-Industry Development Eleventh Five-Year Plan.” With these policy documents, Chinese government directly supports and promotes innovative activities in the pharmaceutical manufacturing industry. Since 2000, Chinese bio-industry has entered a stage of rapid development. From 2000 to 2008, the annual sales growth of industrial products reached 20.45%. In 2005, China Development and Reform Commission issued “The Notice on Organizing the Implementation of High-tech Industrialization of Biological Vaccines and Diagnostic Reagents.” Since then, the government decided to provide financial support for companies that meet the specialization of industrialization. In 2005, the National Medium- and Long-Term Plan for Science and Technology Development (2006–2020) re-emphasized the focus of biotechnology as a key development direction for the country’s medium- and long-term science and technology development. In 2006, a number of supporting policies for the planning outline were introduced, providing various aspects of safeguards for the implementation of the planning outline. In 2006, the state promulgated a series of rectification measures, including drug price reduction, commercial bribery, rectification, and regulation of the drug market order. Although the entire industry is experiencing pains, in the long run, the regulated market is more conducive to the pharmaceutical industry and continues to develop. In 2008, the total output value of Chinese biotechnology industry reached nearly 250 billion Yuan, and the total scale of the Chinese bio-industry was nearly 1.1 trillion Yuan. In 2009, the Chinese government promulgated a new national health care reform plan, and introduced a number of supporting policies, such as the basic drug policy, the new medical insurance catalog policy, and the drug price policy. These policies have a certain impact on the biopharmaceutical industry. In August 2009, the State Council of China promulgated the “Implementation Opinions on Establishing a National Essential Drug System.” In 2010, the State Council of China and the National Development and Reform Commission issued a “Notice on the Basic Supervision of Electronic Drugs for All Kinds of Drugs,” to a certain extent, which guides the company’s financial direction in investment and technological innovation. In August and November 2009, the Ministry of Human Resources and Social Security issued a new medical insurance catalog, with an overall product expansion of 16%. For those pharmaceutical companies with more varieties, they will enter the medical insurance catalogue and get funds and time from the generic pharmaceutical production for the transformation of innovative drugs. In 2015, the total scale of Chinese biotechnology industry has reached nearly 700 billion Yuan. Chinese “Eleventh Five-Year Plan,” “Twelfth Five-Year Plan,” and “Thirteenth Five-Year Plan” all regard the biological industry as the key development direction. For example, in December 2016, the State Council issued the “13th Five-Year National Strategic Emerging Industry Development Plan,” proposing to accelerate the cultivation and development of five pillar industries with an annual output value of 10 trillion Yuan, and established the bio-industry as the key position in the future development of the national economy (Eissa, 2017; Farid, 2019; Yang et al., 2019). The “Plan” proposes that by 2020, the scale of the bio-industry will reach 8 to 10 trillion Yuan. Since then, the “13th Five-Year” Bio-Industry Development Plan issued by the China Development and Reform Commission pointed out that during the “Thirteenth Five-Year Plan” period, Chinese bio-industry scale should maintain medium-high-speed growth, and the ratio of bio-industry added value to GDP is more than 4% and has become the leading industry of the national economy. Although Chinese biopharmaceutical industry started relatively late, it is growing at a faster rate. After more than 20 years of development, China has more than 500 biopharmaceutical-related companies. The sales of Chinese biopharmaceutical industry accounted for about 6% of the total pharmaceutical industry. The biopharmaceutical industry has become an important economic sector in China.

Eight of the world’s top 10 biopharmaceuticals have been produced and put into the market in China. Furthermore, nine new drugs with independent intellectual property rights in China, such as recombinant human α-1b interferon (IFNaα-1b), recombinant bovine alkaline Fibroblast growth factor (rbFGF), recombinant streptokinase (rSK), and so on. Particularly, most of these new drugs have independent intellectual property rights. Some of the biopharmaceutical products have a high market share, such as Shenzhen Kexing’s interferon alpha-1b with an annual output value of 300 million Yuan and annual profits of more than 60 million Yuan in domestic market. The booming development of Chinese biopharmaceutical industry has attracted international pharmaceutical industry giants to set up R&D centers in China. In 2002, Denmark’s Novo Nordisk Company took the lead in setting up a research center in China. In 2004, Roche’s laboratory was officially established, focusing on the development of drugs for the treatment of cancer. In May 2006, AstraZeneca, a joint venture between the United Kingdom and Sweden, announced that it would invest $100 million in a research center in China, with a focus on cancer. After 2006, some companies in the international pharmaceutical industry, such as Eli Lilly and Pfizer, have set up R&D centers in China to promote the transformation of Chinese global factory base into complex value-added projects such as laboratory R&D services. In addition, China is predicted as the next India. After more than 20 years of development, the overall technical level of Chinese biopharmaceutical industry has improved significantly. It is capable of producing almost all mature biopharmaceuticals, and China already has a strong foundation in biopharmaceutical research and development. In addition, the rapid development of Chinese biopharmaceutical industry is also boosted by various factors at home and abroad, such as the government support, the growth of domestic and foreign venture capital, and the entry
of a large number of multinational biopharmaceutical companies into China, a strong power. During the “Twelfth Five-Year Plan” (2011–2015), China has completed the industrial upgrading of the pharmaceutical industry and occupied the high point of biopharmaceuticals through the development of resource-saving and environment-friendly biopharmaceutical technologies.

Figures 1 and 2 show the 2015 annual data of Chinese top listed biopharmaceutical companies released on April 30, 2016. In 2015, there are 33 listed companies in the biopharmaceutical industry, with operating income of 50.587 billion Yuan and net profit of 9.243 billion Yuan. In the top 10 listed companies, Fuxing Pharmaceutical Company’s operating income was ranked first with 12.609 billion Yuan, whereas those of Haiwang Biological Company and Changchun High-tech Company were ranked second and third with 11.118 billion Yuan and 2.402 billion Yuan, respectively. In the net profit, there were 33 listed companies in the Chinese biopharmaceutical industry, among which 31 were profitable and two suffered losses. Among them, Fuxing Pharmaceutical Company’s net profit was ranked first with 2.87 billion Yuan, while those of Shanghai Lai Shi Company and Hualan Biological Company were ranked second and third with 1.48 billion Yuan and 582 million Yuan, respectively. Watson Bio has the largest net profit loss of 925 million in 2015.

The Development Status of Chinese Biopharmaceutical Industry

With the rapid development of Chinese economy, changes in living environment, changes in people’s health concepts, and the acceleration of the aging process of the entire society, the biopharmaceutical industry, which is closely related to the quality of human life, has maintained a continuous growth trend in recent years. Up to now, the biopharmaceutical industry has become one of the fastest growing industries in
the world, and China, as the world’s second largest economy, has also played an important role in the biopharmaceutical industry. The scale of Chinese biopharmaceutical companies continues to increase, and the domestic biopharmaceutical industry is structurally stable and tends to be rationalized. Comparing the data in recent years, we can find that the sales revenue of Chinese biopharmaceutical industry has increased continuously in 2010–2017 (see Figures 3–6), and maintained a relatively fast growth rate (shown in Figures 3 and 6). Among them, the industry sales revenue in 2010 was 106.245 billion Yuan, a year-on-year increase of 41.12%, the largest increase in recent years. In 2017, the market size of the biopharmaceutical industry was 341.171 billion Yuan. However, the scale of Chinese biosimilar drug market is still relatively small in recent years, in line with the global rate of biosimilar approvals in a dramatic slowdown in recent years (Kadam et al., 2016; Walsh, 2014). The market growth will accelerate from 2018 to 2022, with an average annual compound growth rate of 70.9%, and is expected to reach 16.9 billion Yuan in 2022. The continued growth of Chinese biosimilar drug market has accelerated significantly. The main reason for this may be that Chinese biopharmaceutical market is usually aging with the population, increasing chronic diseases, improving R&D and production capacity of Chinese biopharmaceutical companies, and reaching a wider range of patients in China. The cost advantages of Chinese biopharmaceutical companies lie in the huge patient groups and the possibility of being included in the national medical insurance reimbursement list soon. In addition, China has recently established a regulatory system...
for biosimilar drugs (also known as generic drugs) and advantageous policies to encourage the R&D of biosimilars. Therefore, many best-selling biopharmaceuticals are selling well in the market.

According to the regional distribution of Chinese biopharmaceutical industry, the sales revenue of biopharmaceuticals in Shandong, Jiangsu, and Henan provinces ranked the top three in 2017 (shown in Figure 4). In 2017, Shandong achieved sales revenue of 102.161 billion Yuan, accounting for 30.96% of the total industry sales revenue. Jiangsu Province ranked second, with sales revenue of 43.272 billion Yuan in 2017, accounting for 13.12%. The sales revenue of the top 10 provinces with sales revenue in China accounted for 80.68%, and the regional distribution of the industry was relatively concentrated.

The biopharmaceuticals sold in the Chinese market mainly include the development of pharmaceutical products such as blood products, vaccines, diagnostics, and monoclonal antibodies (shown in Figure 5). In 2017, the sales revenue of Chinese blood products industry was 29.693 billion Yuan, accounting for 69.76%, while the proportion of diagnosis and vaccine was 10.39% and 7.97%, respectively, and other biopharmaceuticals accounted for 9% (see Figure 5).

With the rapid development of the Chinese vaccine market, the number of vaccines issued in 2010–2017 has shown a continuous decline. In 2015, it dropped to 565 million. In 2016, it gradually recovered. By 2017, the number of vaccines issued in China has rebounded sharply. It reached 650 million people, an increase of 0.62% over the same period of the previous year.

**Analysis of the Development Trend of Chinese Biopharmaceutical Industry**

The developed countries and developing countries have taken biopharmaceutical industry as the strategic focus of national development for leading a new round of economic growth and coping with the financial crisis. As the world’s largest developing country and most promising emerging market, the accelerated biopharmaceutical industry is not only a strategic choice, but also a realistic economic need to promote Chinese national development.

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**Figure 3.** The market scales of Chinese biopharmaceutical industry in each year of 2010–2017.

Note. The data were collected and analyzed according to the websites of the National Bureau of Statistics of China (http://www.stats.gov.cn/), the Oriental Fortune Network website (http://data.eastmoney.com/), and the Big Database of China Business Industry Research Institute (http://s.askci.com/data/year/).
industrial upgrade and structure optimization. It is of great significance to accelerate the growth of new industries, the development of new economies, the cultivation of new kinetic energy, and the construction of “healthy China” in the commanding heights of the scientific and technological revolution. Compared with the biopharmaceutical industry in the world’s developed countries, Chinese biopharmaceutical industry is still relatively backward, but the state and local governments are constantly increasing the development of the industry, and constantly increasing from policies and funds investment. At present, China has developed biopharmaceuticals as a key industry for economic development and a pillar industry for high technology. Some economically developed regions are constantly establishing state-level biopharmaceutical industry bases and initially formed biopharmaceutical industry clusters in China. All of these have played a very good role in the development of Chinese biopharmaceutical industry. Overall, Chinese biopharmaceutical industry is full of hope and prospects in the future, and Chinese biopharmaceutical industry will continue to grow. The overall level of biopharmaceutical research in China cannot be compared with the level of foreign research and development. Although technology research and industrial development of Chinese biopharmaceutical industry started later than those in developed countries, Chinese biopharmaceutical industry is booming and growing up. The national biopharmaceutical industry of China, especially the development and industrialization with genetic engineering drugs as its core fields, has already reached a certain market scale after over 20 years of development. There are presently more than 200 biopharmaceutical technology companies officially registered in China, and many of them have obtained approvals for trial production or production of genetic engineering drugs, which are distributed throughout the country. In the last decade, China has independently developed some new special effects drugs, which have determined the production technology problems of drugs that could not be produced or produced at a particularly expensive cost in the past. These drugs not only can effectively fight against some intractable diseases but also have great advantages in avoiding side effects.

**Figure 4.** The proportions of the top 10 regions in the Chinese biopharmaceutical industry in 2017 (unit: %).

*Note.* The data were collected and analyzed according to the website of the National Bureau of Statistics of China (http://www.stats.gov.cn/) and the website of the Oriental Fortune Network website (http://data.eastmoney.com/).
pharmaceutical companies lack the ability to produce innovative products and implement innovative research, and they have not created a true pharmaceutical giant. However, a few domestic Chinese pharmaceutical companies have precipitated their core competitiveness indeed in the development process. Meanwhile, with the regulation of the industrial environment and fierce competition, the biopharmaceutical companies will intensify the survival of the fittest in China. To enhance their competitiveness, these biopharmaceutical companies’ restructuring and integration process are accelerating.

The radiation capacities of Chinese biopharmaceutical industrial bases are increasingly strengthened, while the industrial development trend of regional concentration and differentiation is obvious in China. It is an important purpose of scientific research to shift biopharmaceutical technology from scientific research to industrialized production. Only by transforming technology into productivity can the social living standard be improved. A large part of Chinese biopharmaceutical technology still stays in scientific research and has not been effectively converted into productivity. They not only waste a lot of resources but also make Chinese production practices unable to keep up with R&D, resulting in a lag in production. The promotion of biopharmaceutical technology to industrialization requires companies to establish technology alliances through entrusted outsourcing strategies, and to form complementary advantages. Thus, they should focus on their own expertise, thereby reducing production costs and enhancing competitive advantages. In the future, Chinese biopharmaceutical companies are suggested to develop the trend of technology alliances through the outsourcing of new drug development, subcontracting the strong R&D content to small companies with research strength, and giving full play to small companies. The technological advantages of these fields will jointly develop new drugs, greatly improve the efficiency of new drug development, shorten the development cycle of new drugs, and achieve complementary technologies and funds in China. The industrial characteristics and competitive advantages of industrial clusters determine that industrial parks are the strategic development choices for Chinese biopharmaceutical industry in the future, whereas the biopharmaceutical industry has the characteristics of high investment and high risk. The industrial parks developed by clusters can effectively reduce risks, and Cost has a great role in promoting the pharmaceutical industry. At
present, Chinese Yangtze River Delta, Bohai Rim, and Northeast China have concentrated the vast majority of the Torch Program and the industrial base center’s radiation capacity. To accelerate the cultivation and development of the bio-industry, the National Development and Reform Commission has approved four batches of 22 national bio-industry bases since 2005. In addition, the Ministry of Science and Technology of China has established 39 Torch Plan Bio-industry Industrial Bases since 1997. Excluding duplicate and non-biopharmaceutical bases, a total of 56 bio-industry bases were determined by the two ministries. In the large economic regions of the country, Yangtze River Delta, Bohai Rim, and Northeast China have 18, 12, and eight biopharmaceutical industrial bases, respectively. In addition to these biopharmaceutical industrial bases, 11 in the Central South and seven in the Western Region hold the 18% and 12% of households in domestic market, respectively. Two major national pharmaceutical cities, namely Jiangsu Taizhou and Jilin Tonghua Medicine High-tech Industrial Development Zone, have become the core areas of Chinese biopharmaceutical development. At the same time, more than 80 regions (cities) in China have made efforts to build medical science and technology parks, bio-parks, and medicine valleys. There are 22 national bio-industry bases in the country, and many newly developed high-tech industrial parks in various regions have taken bio-industry as Focus on the object. Among the more mature industrial parks are Shanghai Biopharmaceutical Technology Industrial Base, Zhongguancun Life Science Park, Taizhou China Pharmaceutical City, and Changsha National Bio-Industry Base. In addition, Chinese biopharmaceutical core city industrial clusters and industrial ecosystems or synergistic circles centered on core cities are accelerating. The core city has relatively perfect talent base, scientific research foundation, enterprise foundation, policy system, and capital system. Its biopharmaceutical industry started earlier. At present, China has formed a relatively complete biopharmaceutical industry cluster, such as Shanghai, Beijing, Suzhou, and Guangzhou. And other core cities, and China has formed some important biopharmaceutical industry center production areas, such as Changzhou City (Anhui Province), Changzhou City (Hebei Province), Fuzhou City (Fujian Province), Guangzhou City (Guangdong Province), Anguo City (Hebei Province), Heze City (Shandong Province), Tonghua City (Jilin Province),

Figure 6. The market scales of Chinese vaccines issued in each year of 2010–2017 (unit: 100 million copies).
Note. The data were collected and analyzed according to the website of the National Bureau of Statistics of China (http://www.stats.gov.cn/) and the website of the Oriental Fortune Network website (http://data.eastmoney.com/).
Kunshan City (Jiangsu Province), Taizhou City (Zhejiang Province), Wuxi City (Jiangsu Province), Xinxing City (Henan Province), Enshi City (Hubei Province), and the industrial ecosystem or synergy circle formed by the spill-over of the biopharmaceutical industrial regions, such as the Yangtze River Delta region, the Bohai Rim, and the Zhujiang River Delta.

**Chinese biopharmaceutical industry is developing in a cluster-like manner with the trend of regional clustering and modernization.** The development of industrial clusters has obvious development advantages and can greatly promote the rapid development of the industry. As a high-tech industry, biopharmaceutical industry needs support in infrastructure, upstream, and downstream supporting industries. Furthermore, it also needs to be combined with education, professional services, technology transfer centers, and other related services to take advantage of its high efficiency. Chinese economy is currently driven by the rapid development of the biotechnology industry. After years of development and market competition, and the government has not lost the opportunity to guide, Chinese biotechnology, talent, and capital-intensive regions have gradually formed a biopharmaceutical industry cluster. Thus, a relatively complete biopharmaceutical industrial chain and industrial cluster have been formed. These industrial clusters play an important role in promoting the development of the biopharmaceutical industry, which has optimized the overall biopharmaceutical industrial chain and greatly improved its production efficiency. Chinese biopharmaceutical industry will continue to develop rapidly in this area. The government will also increase investment and focus on building industrial clusters in infrastructure, ancillary services, research and development, service innovation, education and training, and venture capital. In terms of development and innovation, it provides a good development environment for the development of biopharmaceutical industry clusters. One of the key points of Chinese biopharmaceutical development plan is to accelerate the reorganization of the industry and increase the concentration of the industry. In the next few years, the industry will face a rapid increase in industrial concentration, sustained and rapid growth of the industrial profit margin, and rapid expansion of market share.

With the continuous breakthrough of biotechnology and the orientation of policies in China, the concentration of Chinese pharmaceutical industry will gradually increase. In the near future, these core development areas, such as Changjiang and Zhujiang, will have higher concentration due to their higher talents and scientific research. The wave of artificial intelligence and the development of the Internet have also led to the development of biopharmaceuticals in the direction of intelligence and digitization. The development of Chinese pharmaceuticals is in high technicalization, and combined with artificial intelligence, while the R&D process and efficiency will be increasingly improved. The development of digitalization will strengthen the information transmission between the more dispersed industrial chains in China.

In addition, the promulgation of the “Healthy China 2030” policy document marks the real coming of Chinese big health industry era. The whole medicine industry has expanded from the traditional biopharmaceutical industrial APIs (or pharmaceutical raw materials), medical devices, circulation, and medical services to cover the five subdivided fields of medical, health, nutrition, health care, and medicine.

**There are emerging biopharmaceutical companies, industrial parks, and geographical divisions of Chinese biopharmaceutical industrial belts, and the focus of the industrial structure has become increasingly prominent in China.** At present, Chinese biopharmaceutical industry is characterized by industrial linkages and geographical proximity of industrial belts. It has formed three key development areas: the Bohai Sea, the Yangtze River Delta, and the Zhujiang River Delta. The Bohai Sea includes Beijing, Tianjin, Hebei, and Shandong. Beijing has become a research and development center for biopharmaceuticals with its highly concentrated scientific research personnel. Tianjin is an export-oriented transformation base for key technologies, whereas Hebei and Shandong have good and rich medical bases. Those biological resources are the most important biopharmaceutical manufacturing provinces in the Bohai Rim region.

The Yangtze River Delta is centered on Shanghai and Jiangsu as the biopharmaceutical industrial park with two wings. Shanghai has gathered the world’s top 10 pharmaceutical companies, with intensive research and development and good financing conditions. It is Chinese R&D and achievement transformation center. Jiangsu is the most active region for biopharmaceutical industry growth, with biopharmaceutical output ranking first in the country. The Zhujiang River Delta is led by Guangzhou and Shenzhen. Guangzhou developed the biopharmaceutical industry earlier and gathered a group of excellent biopharmaceutical companies. Shenzhen has strong independent innovation capability, good international environment, large-scale investment by multinational corporations, and outstanding advantages in biomedical industry equipment. With the establishment of gene banks, the status of the core cities of the southern biopharmaceutical industry has been consolidated. In addition to the Northeast, regional biopharmaceuticals such as the Central Region also have a good foundation.

**Some of the basic research and development results are close to the advanced levels of international peer research.** The biopharmaceutical industry is highly correlated with modern bioengineering technologies. Thanks to the strong support of national policies, part of Chinese biotechnology field has achieved rapid development. It already has a research team that has begun to take shape and has certain competitiveness. In some fields, such as transgenic technology, stem cell technology, and embryo cloning technology, other aspects are in the forefront of the world.
There are totally 15 genetically engineered drugs and several vaccines approved for marketing in China, and a dozen other genetic engineering drugs are being clinically proven, and dozens of drugs are still under investigation. The continuous development, production, and listing of domestic genetic engineering drugs have broken the long-term monopoly of foreign biological products in China. At present, the domestic market share of domestic interferon alpha has exceeded imported products. A new type of recombinant human gamma interferon pioneered in China has the ability to transfer technology and contract engineering abroad, and a new generation of interferon is being developed.

*The innovation trend of generic drugs is more and more obvious in Chinese biopharmaceutical industry.* Generic drugs (or biosimilars) refer to the need for too much capital and cutting-edge technology to be applied to clinical treatments in the international or domestic market and in a large range. The safety and effectiveness of clinical applications are relatively clear and mature. The processes of introducing, simulating, developing, and producing new drugs are accomplished by means of the synthetic methods, prescriptions and preparation processes, as well as the quality control standards and methods. In 2017, the pharmaceutical sector in Chinese stock market fell sharply, and the continuous introduction of heavy policies to the generic pharmaceutical industry in the biopharmaceutical industry ushered in a change. In 2018, China promoted the “National Organizational Drug Centralized Procurement Pilot Program,” which led to the passage of patented drugs. Whether it was original research drugs or generic drugs, large-scale research and development was not easy, and the ceiling and life cycle of single product market were significantly reduced. Thus, innovation in generic drugs is the general trend of Chinese biopharmaceutical industry.

*Marine medicine has become the hot spot for scientific research and development in Chinese biopharmaceutical industry.* The modern marine pharmaceutical manufacturers are located in various provinces and cities in Chinese coastal areas. For example, in Shandong, the research and development industry system for marine medicines and health products consisting of biopharmaceutical companies such as Guofeng, Huaren, and Boxin Bio, and universities and scientific research institutions has taken shape. In recent years, Chinese marine biopharmaceutical industry has continued to maintain rapid growth, with an average annual growth rate of around 35%. In the future, China will form a group of marine drugs and health products, and play an important role in anti-AIDS, anti-tumor drugs, and health care.

*The development of upstream biotechnology in the genome era has brought about a profound impact on the Chinese biopharmaceutical industry.* People attach great importance to the sequencing of viruses, bacteria, plants, animals, and human genomes. On this basis, many products have been formed, and they have become rampant, blooming everywhere, and eventually forming vicious competition. Many companies have gone bankrupt. Companies that survived the competition are also badly hurt, and it is difficult to further organize technological transformation. In summary, as a high-tech industry, the biopharmaceutical industry needs continuous technological innovation to continuously solve the problems in the development of the industry and continuously meet the requirements for improving the level of medicine. China has achieved good results by continuously increasing its research level and participating in international frontier biological development issues, such as international development research in the human genome and functional genetics. Meanwhile, Chinese drug-related gene pharmacology research has also achieved great results. The development has an important role in promoting the level of gene therapy in China. The development of biopharmaceutical emerging technologies will continue to be applied to the development of the industry, thereby promoting the improvement of industrial technology and the social medical standards.

**Problems in the Practical Operation of Chinese Biopharmaceutical Companies**

The problems are caused by the relatively low levels of innovation in the development of Chinese biopharmaceutical industry, due to the insufficient capacity of R&D. Chinese biopharmaceutical industry and its technology research and development started relatively late. Although after over 20 years of development, Chinese biopharmaceutical industry is still facing many problems (Liu & Li, 2016; Yan, 2014; Zhou & Li, 2013). The primary problem is lack of R&D innovation in Chinese current biopharmaceutical industry. This is because after Chinese accession to the World Trade Organization, it needs to comply with the TRIPS Agreement and copy a new drug during the patent period (Treasure & Kesselheim, 2016). The developer has the right to claim $41 billion in claims. This has made Chinese biopharmaceutical industry always in a weak state, with only a few independent intellectual property rights of biopharmaceuticals. In the development and research of some of the best-selling drugs in the market, I still have a certain gap in the world level. As most of Chinese biopharmaceutical companies are still lagging behind in the ideology of research and development, the process of research and development of new drugs still follows the way of academic work. Starting from the index of the literature, it still takes the path of imitation, lack of originality. The reason is possible that Chinese biopharmaceutical research and innovation capabilities are lacking.

The second problem is that the financing channels of Chinese biopharmaceutical industry are not smooth, while the domestic investment is insufficient in innovative research and development funds, especially in the early stages. The biopharmaceutical industry is a traditional high-tech industry in China (Huang et al., 2011; Liu & Li, 2016; Zhang et al.,
2007). Its pre-production of drug products requires a large amount of capital investment, and there are two main sources of funds, one is the profit of the company itself and the other is the funding of the government. For example, Chinese government’s capital investment in innovative research and development funds of the biopharmaceutical industry is developed as follows. After the development climax of Chinese biopharmaceutical industry in 1999–2000, biopharmaceutical investment began to decline sharply in 2001, and the domestic investment in biopharmaceutical listed companies also quickly fell back. Compared with the highest years of 1999–2000, the amount of investment in Chinese biopharmaceutical listed companies shrank by nearly 15%. The lack of funds has seriously hindered the development of Chinese biopharmaceutical industry, which has greatly reduced its independent innovation capability and its market share has been declining.

The third problem is that the domestic industrial structure of Chinese biopharmaceutical industry is not yet fully mature. Chinese biopharmaceutical industry has not yet formed a certain pattern, and the barriers to production of products are low, and it is difficult for companies to have exclusive property rights (Yan, 2014; Yang et al., 2019; Zhou & Li, 2013). One of the typical characteristics of the pharmaceutical industry is the continuous technology-led industry, which requires companies to have high industrial concentration, so that companies can concentrate enough investment strength to form a stable technical output. At present, Chinese biopharmaceutical industry has not formed a large cluster pattern. It has not achieved high industrial concentration, which is not conducive to the rapid and effective development of the biopharmaceutical industry, resulting in the inability of Chinese biopharmaceutical industry.

In addition, due to imperfect laws and policies related to intellectual property protection in China, the domestic companies pay insufficient attention to intellectual property protection. At the same time, a series of serious human resources problems such as the loss of biopharmaceutical technicians are also common among Chinese biopharmaceutical companies.

The Development Strategy of Chinese Biopharmaceutical Industry

First, appropriate restructuring strategies should be selected to accelerate the reorganization of pharmaceutical companies and optimize the regional industrial structures according to the characteristics of the enterprises. In the future market, the cross-border integration between industries will continue to increase, mainly because the division between industries become increasingly blurred. Meanwhile, the cooperation between companies will increase too. Many companies engaged in the production of medicine, agriculture, environment, and energy are engaged in biotechnology production too. In particular, some manufacturers engaged in the traditional chemical industry have also entered the new biopharmaceutical fields of biotechnology. Therefore, local biopharmaceutical companies should implement vertical restructuring and realize regional economic structure. They should also realize the complementary advantages of the new groups in brand, capital, technology, and market network resources. This can expand their overall advantage. For example, the integration of Taiji Group and Tongjiunje is a very successful example. The “overlay effect” generated by the establishment of the new group is very obvious, and the two sides have thus determined their position in the Chinese pharmaceutical industry.

Second, the biopharmaceutical companies should enhance their horizontal joint cooperation with different enterprises and medical research institutions, whereas the cooperation can complement each other in product structure and effectively avoid the duplication of investment to expand the efficiency of enterprises’ funds. At present, the R&D cooperation activities between companies are frequent. Due to the wide range of biotechnology, many biochemical companies have their own expertise, and their cooperation for commercial interests is also very active. In addition, with the participation of manufacturers engaged in traditional industries, due to technical and production reasons, they also cooperate with companies engaged in biotechnology development and production. All of this makes the horizontal joint research and development cooperation between companies in the Biopharmaceutical industry more and more extensive. For example, the biopharmaceutical companies of Sanjiu Group have invested heavily in horizontal restructuring and acquired more than 40 large pharmaceutical companies, such as Ya’an Pharmaceutical Factory and Sichuan Changzheng Pharmaceutical Company to achieve a large-scale organizational structure.

Third, the development strategy should introduce venture capital and accelerate the industrialization of Chinese biopharmaceutical industry. For instance, the advanced and mature technologies can help the biopharmaceutical industry to obtain the basic conditions for introducing venture capital with broad market prospects. Meanwhile, Chinese biopharmaceuticals have passed the blind heat of end-expiration. Therefore, the silence gradually entered the stage where it can be viewed more rationally. In addition, the global biopharmaceuticals are closely related to human self-security, and there are inevitably many administrative interventions in Chinese biopharmaceutical industry. Thus, when the biopharmaceuticals are becoming the focus of investors’ attention, we need to introduce risk funds in a timely manner to expand the competitive advantages of biopharmaceutical companies in China.

Finally, the intellectual property strategy should be improved in the national biopharmaceutical process. The perfection of the intellectual property protection system is one of the important factors related to the development of innovative drugs. The intellectual property protection system not only protects its own interests but also respects others’
property rights only, and protects its own intellectual property rights from being infringed. It is to give a full play to its own advantages and maximize its own value.

Conclusions and Remarks

In summary, Chinese biopharmaceutical industry is booming and growing up. Although technology research and industrial development of Chinese biopharmaceutical industry started later than those in the developed counties, Chinese biopharmaceutical industry is booming and growing up. The national biopharmaceutical industry of China, especially the development and industrialization with genetic engineering drugs as its core fields, has already reached a certain market scale after over 20 years of development. At present, there are more than 200 biopharmaceutical technology companies officially registered in China, and many of them have obtained approvals for trial production or production of genetic engineering drugs, which are distributed throughout the country. At the same time, the competitive advantage of the industrial cluster of Chinese biopharmaceutical industry determines that the industrial park is the strategic development choice for Chinese biopharmaceutical industry in the future.

The biopharmaceutical industry will be one of the most promising and most active economic sectors in China. For this purpose, all regions of China are vigorously promoting their development, and the “star fire” of the biopharmaceutical industry is showing its potential on the land of China. After more than 20 years of hard work, China has built an innovative drug incubation base with companies as the mainstay, and has upgraded the national biopharmaceutical research and development innovation capability and industrialization level. China has formed a research and development team of specialized new drugs with a certain scale, which has enhanced the technological innovation abilities of various companies in Chinese biopharmaceutical industry. With the continuous breakthrough of technology in the biopharmaceutical industry and the continuous introduction of policies, the development of Chinese biopharmaceutical industry has shown a trend of concentration and digitization, and the importance of bio-pharmaceutics in industrial innovation is growing up.

During the “Thirteenth Five-Year Plan” period, the central government and companies will invest much money to create new drugs. Chinese biopharmaceutical industry has four characteristics of innovation and development. First, it attaches importance to develop biotechnology drugs, anti-infection, cardiovascular, digestive system, and anti-tumor drugs. Second, due to the low level of originality, it will be difficult to bring new drugs with great benefits soon, especially the very hot teniposide drugs. Meanwhile, it is more difficult to resist the foreign similar and same target drug market. Third, the basic characteristics of high-risk, high-input research and development have gradually been accepted by people. Fourth, the subjective role of innovation in private companies is gradually becoming clear. In addition, Chinese biopharmaceuticals, medical informatization, and high-performance medical devices are listed as the country’s three promising areas during the 13th Five-Year Plan period in China. In short, Chinese biopharmaceutical industry is booming and growing up, whereas the future development prospects of Chinese biopharmaceutical industry are much optimistic but challenging.

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