Comparative Study on the Regulation Modes of Chinese and American Pharmaceutical Industries

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Abstract This paper studies the policy regulation of the pharmaceutical industry in China and the United States. The main points of this paper is analyzing the formative factors of these regulation modes. There is multiple similarity when the two countries were founded. Then, as time goes on and they have embarked on different paths of development and established completely different regulation model. This paper illuminates the formation reasons about these regulation modes by analyzing the historical and social background of two countries.

Keywords Regulation · Modem · Industrial security · Social background

1 Introduction

In the conference papers of previous years, the author has compared the regulation modes of the pharmaceutical industries in China and the United States through analyzing the relevant laws of the two countries for the pharmaceutical industry. From a macro perspective, the regulation modes of the pharmaceutical industries in the two countries are completely different. This situation comes from the fact that there are few similarities between the two countries in terms of political systems, economic models, industry scale and contents of relevant laws and policies.

However, if we compare the historical background and social conditions of China and the United States during the periods of their founding, we will find that the pharmaceutical industries in the two countries were quite similar at the beginning of their development, and they have formed the current regulation modes in the historical development context. By comparing the historical background of the two's development, this paper combines the current safety conditions of the two countries' pharmaceutical industries to analyze the historical background and realistic significance of such difference.

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2 Literature Review

From a macro perspective, the regulation modes of the pharmaceutical industries in China and the United States are shown in the following Figs. 1 and 2.

As shown in the figures above, the regulation modes of the two countries are completely opposite. China adopts unified legal norms and hierarchical management from top to bottom; while the United States adopts the game-type regulation mode in which the political forces of all parties' target at industry development.

In previous articles, the author has analyzed the regulation mode of the two countries. And the author analyzes the effect of the regulation mode in the two countries. In effect, both regulation modes of two countries have achieved their goals and protected the pharmaceutical industrial security. In the United States, the consultation process among pharmaceutical enterprises, government and industry associations is a process of multi-party game. The main objective of the game is the benefit balance. Since American is leading the world in the medical technology. Its industrial regulation only needs to protect the development vitality of pharmaceutical enterprises and the technical advantages of practitioners. In China, the main approach is government regulation. The reason for using this method is the bargaining cost savings. Since Chinese medical technology is not advanced. The international competitiveness of

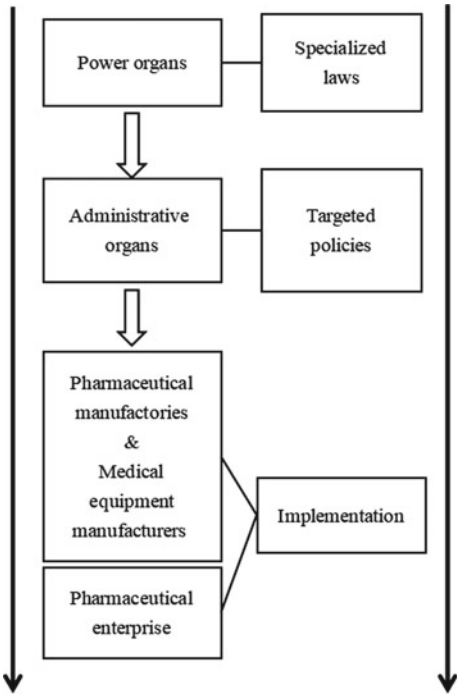

Fig. 1 China's mode: top-down linear mode

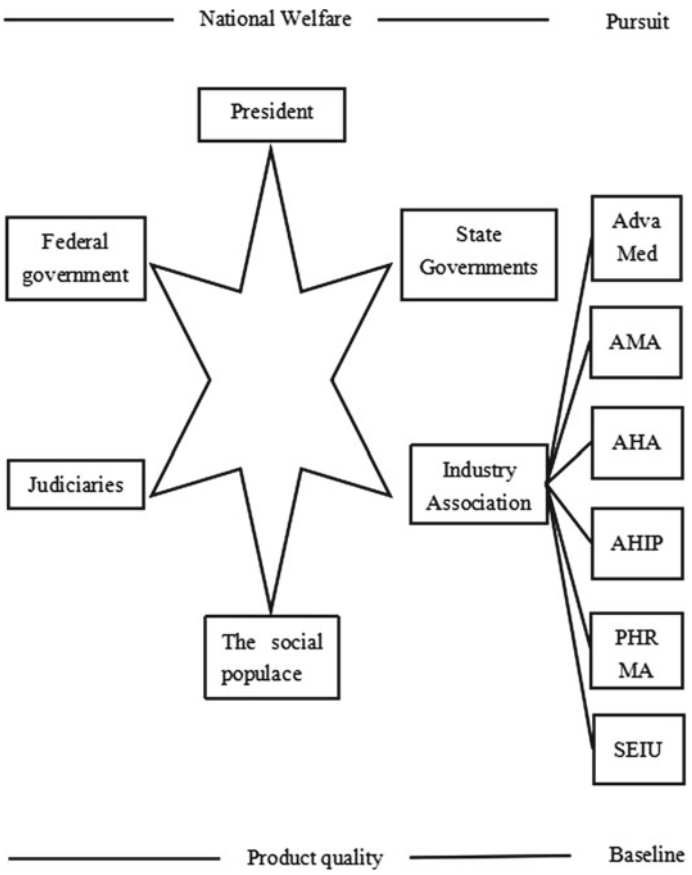

Fig. 2 American mode: an equilibrium mode of multi-party game

this industry is weak. Therefore, the pharmaceutical industry needs to make overall planning and long-term decisions. This has produced the current industrial model.

But there are few research achievements about industrial regulation model in two countries. in the related field, American scholars are more inclined to study medical economics. The main concerns are the quality of services and the behavior of pharmaceutical enterprises. And Chinese scholars are more inclined to study law and policy. The main concerns are the legal interpretation and system reform.

3 Analysis

The reason for the above-mentioned difference lies in the fact that, since the founding of the two countries, they have chosen significantly different development paths,

guiding ideology and value pursuit. However, it is worth noting that there were several similarities in social background of China and the United States during their founding. The similarities are as follows:

Backward technological environment: before the War of Independence, the United States mainly served as a source of raw materials for developed countries in Europe. As for its economic production, it mainly produced industrial raw materials and agricultural products. In the field of talents, there were mostly low-level laborers such as adventurous gold diggers, religious losers and those reclaiming wastelands. High-level talents in the field of science and technology did not favor it. During the founding of new China, the long-term war had almost depleted the domestic industry. The high-level technological talents did not gradually return from foreign countries until several years after China's founding, so it was difficult for them to immediately devote themselves to construction in various industries in a short period of time.

International relations dilemma: after the War of Independence, the original interests of the colonial countries could not be guaranteed in the short term. Moreover, the Second War of Independence happened soon after the founding of the United States, so both the United Kingdom which was most powerful in the world at that time and the former colonial countries in Western Europe rejected the development of the United States. Also, after the founding of the United States, Washington, who was the first president of the country, determined the "isolated foreign policy". Due to the background of the Cold War, it was even more difficult for China to be accepted by developed countries in the world at the time of its founding.

Backward infrastructure: generally speaking, from the economic point of view, China and the United States were both agricultural countries at the time of their founding. Their overall development modes were based on extensive development and they did not have a complete industrial system.

To sum up, there were a lot of similarities between China and the United States in terms of their social problems and international environment at the time of their founding. They both adopted the extensive development mode, lacked talents and technologies and had poor industrial foundation and development prospects which were difficult to be expected. However, two non-economic reasons created huge development space for the United States, causing the most fundamental difference in the development of China and the United States:

Based on the value orientation for the founding of the United States and Adam Smith's free economic theory, the United States was urged to pursue free value in a method which was almost like faith and build its own political and economic system mode by taking it as a philosophical basis. Ultimately, it formed a nearly completely liberalized economic market and loose economic policies, which attracted European investment in a large amount for a long time after its founding. Although the United States did not intervene in the European disputes in the political and military aspects [1], it had huge appeal to European capital in the business aspect, particularly in terms of its domestic production under slavery.

In the context of long-term colonial history, at least long-term for the American history at that time, the United States and the United Kingdom and even the entire developed regions of Western Europe did not have significant "civilization or cultural

conflict" [2], so the capitalists in the Western European countries were more inclined to invest capital in the United States. It can be imagined that, in the period of the first and second generations after the founding of the United States, the social ideas in Western Europe still regarded the United States as an affiliate of Britain and other colonial countries although the United States was already independent, so the United States was still the best choice for Western European powers headed by Britain at that time to settle down and invest. Therefore, although the United Kingdom used some means to impose economic sanctions on the United States after American Wars of Independence (including the first and second independence wars), these policies were quickly canceled and the United Kingdom recognized the status of ally of the United States [3]. Of course, from another perspective, investors did not do it for the development of the United States, but for their own economic benefits, so such situation directly resulted in increasingly expanded "speculative investment". However, there was very little "development-oriented long-term investment" (There was even American railway investment, which was a well-known economic bubble in history.) As a result, the early US economy still adopted the main economic modes of "specialty export" and "transportation" [4]. Later, the First World War stimulated the independent development of American science and technology and the Second World War enabled the United States to complete its original accumulation and begin to become the most powerful country in the world.

It can be seen from the above analysis that there are many similarities between the United States and China, especially New China at the beginning of its founding. The solutions are nothing more than the following:

To attract talents and technology from the advanced countries in the international league—In fact, China's earliest technological study was originally from the Soviet Union, which was its international "ally".

To give play to its own characteristics and use various means to complete primitive accumulation—China's various economic reforms starting from its founding can be seen as such work and it has made remarkable results by finally establishing a complete nation-wide industrial system.

To seek international allies through value recognition to achieve mutual benefit and assistance—this was the only point which was a huge difficulty for China. Japan and South Korea, which belonged to the same Chinese cultural community, were not China's allies at that time.

More importantly, various indicators were relatively weak in the aspects of talent introduction through the Second World War and development through its own scientific and technological concept, or it was so at least in the initial stage of founding. In other words, the connection between the United States and Europe never stopped even when the industry safety index was extremely low. More importantly, to a certain extent, European developed countries headed by the United Kingdom were in fact the backup bases for the United States in terms of talents, technologies and funds. As an immigrant country with no history, the United States was able to do its utmost to absorb all kinds of high-quality resources and constantly develop its own potential; let alone its local rich natural resources.

However, the situation in China was not ideal. It could not compare to the United States during its founding in terms of political ideas and resource reserves. Interestingly, from the perspective of historical heritage, the national pride and self-confidence of the United States came from victory of the Second World War and even the Cold War, but it neither had much "ambition" nor demanded "American leadership in the world" in the mode of national propaganda at the beginning of its founding. Due to its federal political system and legal mode, the central government of the United States did not have too many political resources to make planning for the industries of the entire country. In other words, it was not able to pay huge administrative cost to meet the requirement of adjustment of national industries. Therefore, in both the objective and subjective aspects, the United States at that time should and could select a path for slow development.

However, it was on the contrary in China. No matter it was because of the communist ideal in the period of founding of the country or the national identity inherited from ancient civilization, both China's central government and ordinary people did not accept that China was an "emerging and promising country without the need to formulate big goal planning". Since the beginning of the founding of new China, it already had the direct goal of "establishing a great new China" and "uniting people of the world". At the same time, from the perspective of historical inheritance or path dependence, its administrative system of being uniformly accountable to the central government and the unity-based national system led to the fact that China could bear huge administrative cost to carry out industrial planning at the state level. Therefore, new China inevitably chose an industrial development path which was completely different from that of the United States.

On this development path, the role of law is totally different, which has caused a number of differences in the choices made by China and the United States. To be specific, the differences include:

Because the United States had different overall national construction goals and thus had different planning for its own industry development, it could bring in capital in accordance with its own characteristics to develop its own industries. However, China had to complete economic construction to improve national confidence and cohesion. This difference can be seen from the preambles of the constitutions of China and the United States. There was only one sentence in the preamble of the Constitution of the United States and the part expressing the basic work of the country was "in order to form a more perfect Union, establish justice, insure domestic tranquility, provide for the common defense, promote the general welfare… (The full text for the preamble of the Constitution of the United States is "We the people of the United States, in order to form a more perfect Union, establish justice, insure domestic tranquility, provide for the common defense, promote the general welfare, and secure the blessings of liberty to ourselves and our posterity, do ordain and establish this Constitution for the United States of America."). By contrast, the preamble of the Constitution of the People's Republic of China consisted of 14 paragraphs covering many aspects such as "historical trace, revolutionary course, party leadership, core ideas, cross-strait relations, ethnic relations and national systems", which showed evidently far-reaching goals.

In terms of domestic situation, at that time, the states of the United States were still separated, the federal regime was not stable and the federal legal rights were not guaranteed. The militia system laid a huge hidden danger for the social stability of the United States at that time. Therefore, except for the development path of liberalizing free market economy, the United States was not able to pay the high administrative costs even if it wanted to plan its own domestic economic development on the whole in a uniform mode. By contrast, China's army and navy forces were quite excellent after the founding and its systems of People's Congress and democratic centralism were highly uniform, so all types of domestic remnants could not pose a threat to the country on the whole. Therefore, China could select the planned economic system with unified planning.

From the perspective of the development pattern of the pharmaceutical industry, a contingent factor determined the difference between the layout of the pharmaceutical industries in China and the United States. It was the international military factor. After the victory of the Second War of Independence [4], the international military environment for the United States was safe at least at that time. It supported the internal development of the United States and more importantly led to the fact that its leadership did not have to pay too much attention to the development of the pharmaceutical industry, because medicine provided by Europe could meet the demand of the United States and all countries did not pay much attention to the pharmaceutical industry at that time. Until the First World War, the United States did not need to focus on developing its own pharmaceutical industry. However, the First World War provided an illustration for the world's research on industrial economic safety, that is, pharmaceutical production and industrial development plays a significantly role in a country's livelihood and economy and even determines the survival of a country [5]; (Before the First World War, Germany occupied the world's top technologies in the pharmaceutical industry, which significantly helped improve their military strength. Also, in the early 20th century, the global flu caused great harm to the United States.) in any case, if the United States could not guarantee its own pharmaceutical supply, its overall national security could not be guaranteed; in particular, it was very difficult for the United States to get the latest pharmaceutical technology after it engaged in war with Germany, causing great impact on its national policy of valuing "latest technologies". Meanwhile, also due to the military factor, inevitability surpassed contingency for China. After its founding, China's layout of the pharmaceutical industry was mainly to ensure military needs and was designed based on two basic requirements of "all people being soldiers" and "preventing foreign enemies" due to historical reasons, the psychology of victims precipitated in the minds of the public and nationwide tide of militarization in addition to the above-mentioned "national ideals". As a result, as is described in Sect. 3 of the report, most of the provinces and key areas of China has established their own manufacturers to ensure essential medicine supply. In other words, the initial development layout of China's pharmaceutical industry was not for the purpose of economy, but for politics and military.

From the perspective of skopos theory, it is called the United States and China's pharmaceutical industry development mode is relatively stable because the medicine

industry development trend of two countries has met the development of the industry planning. For the United States, it is already achieved the highest achievement in the world about the pharmaceutical industry in the business category. And for China, it can keep pharmaceutical industry develops itself at home.

For United States, National Health Expenditure (NHE) is the highest of the world. It is expected to exceed $4.3 trillion by 2018, accounting for one-fifth of GDP [6]. The health care system receives 35 million inpatients, 64 million surgeries, 900 million visits to medical clinics and 3.5 billion prescriptions every year [7]. The National Institute of Health is the largest biomedical research institute of the world. There are 6,000 scientists and an annual budget of $30.5 billion [8]. And the most obvious example is there are four American pharmaceutical companies have entered the world rankings. They are Johnson & Johnson (U.S.), Pfizer Inc. (U.S.), Merck & Co., Inc. (U.S.) and Gilead Sciences, Inc. (U.S.). Meanwhile, in the new pharmaceutical research and development area, American pharmaceutical companies at the top, too. As follows date to show. Even from the perspective of probability theory, supported by large-scale systematic research and development and huge funding, American pharmaceutical industry will not lose its dominant position in the short term. As follows (Table 1):

The paper wants to reiterate here is that the reason of two countries can keep their pharmaceutical industries safe. It is the objective situation and industrial demand of the two countries are different. American have to hold the head. That would make it attractive to global money to keep the industry development. On the contrary, China needs to limit international competition and use local resources to help the pharmaceutical industry. The concept of industrial security includes security and development [10]. In both cases, China and the United States have not clear failure.

4 Conclusion

The last required a bit of explanation that the paper aim to explain why the public can except the regulation mode in two countries, and the medical industries in these countries still maintain good development. If you use the economic model, you can see this. In the theory of domain about regulation:

$$\frac{C}{B} = \frac{\sum_{i=1}^{\infty} D_i}{S * P} \tag{1}$$

In this model, C means “Closed force polygon of Social”, B means “Institutional stability” (There are so many ‘S’s or ‘I’, so I use this letter.) D means “The number of Demands”, S means “Social Approval Degree”, P means “Path-dependence index”. It should be noted that the model is used to illustrate correlation.

On this basis:

$$S = O * A * T_1 \tag{2}$$

Table 1 Ranking of the world pharmaceutical companies

Rank	Company	Total revenue, 2015 (USD Million)	Annual revenue growth, 2014 to 2015 (%)	Revenue from pharmaceutical segment 2015 (USD Million)	Proportion of revenue from pharmaceuticals segment (%)	Total R&D expenses, 2015 (USD Million)
1	Johnson & Johnson (U.S.)	70,074	−5.73	31,430	44.85	9,046
2	Hoffmann-La Roche AG (Switzerland)	50,111	−3.50	38,855	77.54	9,972
3	Pfizer Inc. (U.S.)	48,851	−1.52	48,851	100.00	7,690
4	Novartis AG (Switzerland)	49,414	−5.30	30,445	61.61	8,935
5	Bayer AG (Germany)	51,407	−6.44	15,253	29.67	4,751
6	Merck & Co., Inc. (U.S.)	39,498	−6.48	34,782	88.06	6,704
7	Glaxo Smith Kline plc (U.K.)	36,566	−3.54	36,566	100.00	5,441
8	Sanofi (France)	34,542	8.99	34,542	100.00	5,082
9	Gilead Sciences, Inc. (U.S.)	32,639	31.13	32,639	100.00	3,014
10	Astra Zeneca plc (U.K.)	23,641	−9.40	23,641	100.00	5,997

$$P = \frac{T_2}{M} \tag{3}$$

In these models, *O* means "The public opinion", *A* means "The area of public opinion", and *T1* means "The publicity time duration"; *T2* means "The duration of the system (years)", *M* means "The number of system modification" (Tables 2 and 3).

It can be seen that the lower number of policy adjustments and the longer time of system exists, means the higher degree of path dependence. Therefore, it is more difficult to promote institutional reform. Correspondingly, the lower degree of social recognition and the shorter existence time of the system, means the less difficult the reform.

Table 2 The basic data of the world pharmaceutical companies

Rank	Company	Total expense ration, 2015 (%)	Total income ration, 2015	Total revenue from top. 3 pharmaceutical products, (%)	Proportion of revenue from top-3 pharmaceutical products, (%)	Revenue per employee, 2015 (USD Thousand)
1	Johnson & Johnson (U.S.)	72.61	21.99	11,266	35.84	551
2	Hoffmann-La Roche AG (Switzerland)	71.29	18.81	19,632	50.53	546
3	Pfizer Inc. (U.S.)	81.65	14.25	13,233	27.09	499
4	Novartis AG (Switzerland)	83.80	36.01	9,494	31.18	416
5	Bayer AG (Germany)	86.51	8.85	5,144	33.72	440
6	Merck & Co., Inc. (U.S.)	86.33	11.29	8,540	24.55	581
7	Glaxo Smith Kline plc (U.K.)	89.10	32.96	7,863	21.50	361
8	Sanofi (France)	84.64	13.06	10,038	29.06	299
9	Gilead Sciences, Inc. (U.S.)	32.00	55.48	22,599	69.24	4,080
10	Astra Zeneca plc (U.K.)	87.11	10.52	10,907	46.14	393

Data Sources SEC filings and annual reports

Table 3 Research and development investment of pharmaceutical enterprises [9]

International conglomerate	Research input (%)
JNJ (Johnson & Johnson)	31.00
Hoffmann-La Roche AG (Switzerland)	25.30
Merck & Co., Inc. (U.S.)	21.30
Eli Lilly and Company	19.80
NVS (Novartis)	19.40
Pfizer Pharmaceuticals Ltd.	17.30
Bayer AG	17.20
Glaxo Smith Kline plc	15.80
Sanofi-aventis	15.60
AstraZeneca	13.40

These models above cannot calculate the number. It shows the forms and relationships of the resultant forces. As the research moves along, there must be something new parameters to join.

We can use the formula of the degree of association between industrial competitiveness and industrial adaptation to verify the theory above [11].

$$C_i^m \sum_{j=1}^{t} \frac{\eta_{ij}^m}{t} \tag{4}$$

In this equation, $i = 1, 2, \ldots, 12, m = 1, 2, \ldots 9, j = 1, 2, \ldots, t, C_i^m$ means the degree of association between industrial competitiveness and industrial adaptation, i means industrial competitiveness and m means industrial adaptation. So bringing the hi-techinnovation capacity and government control ability into this formula. It can be concluded that the correlation is constant, the higher one side, the lower the other. Take the United States as an example. As the Fig. 2 shown, if those six organizations plan to keep the local government or presidents' low control, they have to develop the science and technology.

In summary, although there were many similar objective conditions between China and the United States during their founding, the two countries have developed and formed two completely opposite modes in the aspect of regulation of the pharmaceutical industry due to the difference in some subtle parameters.

In addition, from the perspective of industrial safety, there is no apparent huge risk in current development of the pharmaceutical industries in China and the United States. More in-depth research is needed for assessing the safety index of the pharmaceutical industries in the two countries.

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