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RESEARCH ARTICLE

# Policy Learning in Governing Complex Technologies: The Pendulum Swing of China's Central Government

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**Abstract**
As an emerging science and technology (EST), stem cell therapy presents a highly dynamic and complex landscape, posing significant challenges for the Chinese central government and requiring substantial policy learning. Delving into the realm beyond the traditional literature on Chinese government's policy learning, which primarily focuses on conventional policy areas and local government experiments, this article examines how the technical and interest complexities, along with the fragmented authoritarian structure of central departments, influence policy learning in the field of stem cell therapy. The findings reveal a recurring pendulum swing pattern, wherein top decision makers direct central departments to engage in multiple rounds of policy swings, navigating between developmental objectives and regulatory objectives.

**摘要**
作为一种新兴科技，干细胞疗法具有高度动态性和复杂性。这给中国政府的治理带来了挑战，也对其政策学习提出了更高的要求。中国政府政策学习的相关研究大多聚焦于传统政策领域和地方政策试验。本文则旨在分析技术复杂性和利益复杂性以及中央职能部门的碎片化威权结构如何影响了干细胞疗法领域的政策学习。研究发现，中国政府的政策学习呈现出钟摆模式，即主管领导部门引导中央职能部门在发展目标和监管目标之间反复调整以实现政策调适。

**Keywords:** Chinese government policy; policy learning; pendulum swing pattern; stem cell therapy
**关键词:** 中国政府政策; 政策学习; 钟摆模式; 干细胞疗法

Emerging science and technologies (EST) are known for their inherent uncertainties as well as their potential benefits and risks. They give rise to complex, open-ended, intractable and unpredictable problems that lack clear-cut solutions and interventions, which may lead to unintended consequences. Given these characteristics, a more experimental approach to problem solving is required. Scholars have put forward concepts like reflexive governance, adaptive governance, experimentalist governance and tentative governance to address these challenges.[1] These governance approaches are all centred around policy learning, which involves adjusting current policies based on the interpretation of previous experiences and new information. The goal is to improve the effectiveness of governance.[2]

Stem cell therapy stands as a typical example of an EST. It aims at repairing and transplanting human tissues and organs by directing the differentiation and self-renewal of stem cells.[3] As a cutting-edge biomedical technology, stem cell therapy is an area of considerable technical complexity, rapid development and high risks, with strong material interests and ideological biases. Consequently,

1 Kuhlmann, Stegmaier and Konrad 2019.
2 Hall 1993; Sabatier 1988.
3 Haider and Aziz 2018.

it requires stringent regulation.[4] However, owing to the lack of mature governance experience in foreign countries to draw upon, China has had to rely on policy learning to navigate this field.

Since the emergence of stem cell therapy in China in the 1990s, as many as 28 central government departments have issued policies to govern its use. Inter-departmental policy conflicts have frequently occurred. The central government's policies have swung between strengthening and relaxing regulation, as well as encouraging and restricting technology use. On the other hand, lower-level government policies have veered between aggressive promotion and self-restraint. Through nearly 30 years of policy learning, China has gradually achieved more effective governance of the complex EST arena. The question arises of how exactly has the Chinese central government conducted policy learning in such a challenging field?

In the realm of political science and public policy, there is a consensus among scholars that China has established an experimental structure to facilitate policy learning.[5] This notable structure has been captured by various concepts, such as "experimentation under hierarchy," as proposed by Sebastian Heilmann, and "directed improvisation," as argued by Yuenyuen Ang.[6] These studies primarily focus on central–local relations and address conventional and macro policy domains including healthcare, rural governance, industrial development, and finance, among others.

The case of stem cell therapy, however, involves multiple central departments and therefore diverges from the interests and behavioural patterns of local governments. This distinction arises owing to the "fragmented authoritarian" nature of the central government, as described by Kenneth Lieberthal and Michel Oksenberg.[7] Furthermore, stem cell therapy serves as a significant example of an EST, exhibiting greater complexity in terms of both interest and technical aspects compared to traditional policy areas. Consequently, it presents substantial challenges to the government and necessitates policy learning. It is therefore crucial to delve deeper into how the characteristics of central departments and EST influence the policy-learning process within the Chinese central government.

This article takes an in-depth case study approach, focusing on stem cell therapy, to establish a conceptual framework. Additionally, it thoroughly examines the behaviour patterns of the Chinese government within the case study and analyses the institutional logics and structural forces that underlie these patterns within the realm of stem cell therapy. The article concludes based on the findings and suggests potential areas for future research.

## The Organizational Learning Pattern of the Chinese Central Government in EST: A Conceptual Framework

The considerable increase in volatility and complexity within the public sector in recent decades has given rise to an experimental approach to governance. This approach offers a flexible mechanism for policy adaptation and operating outside the traditional government structure and allows for continuous learning.[8] Originating from studies of organizational learning in psychology and business,[9] the concept of policy learning has gained prominence in the study of political science and public policy.[10] In the Chinese context, central–local relations have provided a flexible mechanism for policy learning. Faced with various constraints, the central government usually sets broad and provisional objectives, leaving local governments to construct meso- and micro-level objectives and to devise local solutions within an open policy framework ("improvisation").[11] At the same time,

4 ISSCR 2021.
5 Mei and Liu 2014; Husain, Bloom and Xiao 2023.
6 Heilman 2008; Ang 2016.
7 Lieberthal and Oksenberg 1988.
8 Wolfe 2018.
9 Busenberg 2001.
10 Sabatier 1988; Hall 1993; Sabel and Zeitlin 2010.
11 Ang 2016.

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the central government continuously guides and monitors the wide range of experimental activities undertaken by local governments through policy performance checks and feedback ("direction").[12] This virtuous loop enables the Chinese government to compare different local practices and draw lessons from local experiences through "learning by doing" and "learning by monitoring."[13] As a result, two types of changes take place within the government: technical or behavioural changes, which involve new policy goals and policy instruments under the same problem-defining and problem-solving framework, and conceptual or cognitive changes, which involve new problem-defining and problem-solving frameworks.[14]

The case of stem cell therapy provides a new arena for discussion of the policy learning process of the Chinese government where the characteristics of complex technologies (as the policy object) and departments (as policy actors) play important parts. Stem cell therapy encompasses dual characteristics of development and regulation. As a cutting-edge biotechnology, it holds a strategic position in policies aimed at international scientific and technological competition. Moreover, it offers broad social benefits through the treatment of various diseases. Stem cell therapy is characterized by its technical aspects of personalized treatment, wide diversity, high complexity and rapid development. These characteristics give rise to political and ethical concerns relating to life and health, necessitating regulatory measures.[15] However, China's top decision makers have found it hard to maintain an appropriate degree of development and regulation. There exists a need to swiftly implement new stem cell therapies to facilitate technological advancement and ensure that patients receive timely and effective treatment. Simultaneously, it is essential to regulate these therapies to prevent potential risks to health and safety.[16] Furthermore, the current regulatory system lacks clear definitions regarding the classification of stem cell therapies as either drugs or medical technologies. This ambiguity poses challenges for top decision makers in determining the primary regulatory authority responsible for overseeing stem cell therapies and establishing the appropriate procedures and criteria. The governance of stem cell therapy, as a classic example of an EST, encounters significant challenges because of the immense technical complexities and interest complexities involved. The technical ambiguity and intricacy of the problems result in uncertain outcomes and effects of policy solutions. Additionally, this area involves multiple or competing stakeholders, including the top decision makers, several central departments, businesses, researchers, and doctors and patients, which increases the difficulty in negotiation and policy implementation.[17]

This policy ambiguity gives central departments more flexibility and negotiating space to interpret and experiment.[18] In a structure of fragmented authoritarianism, central departments have separate missions and interests and equal levels of authority.[19] Thus, their interpretation and responses to the top decision makers diverge and even conflict. This provides the top decision makers with a range of policy solutions for comparison and leaves them in a position to judge and intervene in the outcome.

When the policy solutions implemented by departments lead to severe consequences that cross established boundaries, top decision makers respond by adjusting the balance between development and regulation. Often this adjustment takes a different direction to the previous round of policies,

12 Ibid; Zhu and Zhao 2021; He, Fan and Su 2022.
13 He et al. 2022.
14 Hall 1993; Mah and Hills 2014.
15 ISSCR 2021.
16 Here, top decision makers refers to the small number of people with the highest political decision-making power in China, including the Political Bureau of the CPC Central Committee, the Standing Committee of the National People's Congress and the State Council. Departments refers to ministries and commissions directly under the jurisdiction of the State Council, such as the Ministry of Science and Technology.
17 Chen, Haidan 2009a.
18 Zhi and Pearson 2017.
19 Lieberthal and Oksenberg 1988.

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resulting in a swing in policy. In response, the central departments align their actions with the preferences of the top decision makers and are driven by their own interests such as mitigating the risk of political and legal accountability, protecting and expanding their domains, and increasing available resources. The departments leverage their flexibility to interpret and experiment with policy implementation. Through multiple rounds of policy swings between developmental goals and regulatory goals, the Chinese central government gradually forms a new problem-defining and problem-solving framework and continuously improves its problem-solving capacity. This is summarized in this article as the pendulum swing of policy learning (see Table 1).

## Methods

This article engages in a process-tracing analysis to study how the Chinese central government has carried out policy learning. The data were collected from interviews, policy texts and literature; the reliability of the data was ensured by cross-checking information from different sources and channels.

We collected 121 documents from Chinese central departments, 21 policy documents issued by the State Council, nine relevant important speeches by national leaders, and 59 local government documents and eight association documents in the field of stem cell therapy, as well as other relevant industrial and medical archives, yearbooks and articles. These data helped to illustrate the evolution of stem cell policy and identify important phases, events and actors.

The snowball approach was used to conduct interviews, which were carried out over the course of three years (2020–2022). First, we tracked a team of researchers who had been working on stem cell therapy for more than 20 years, achieving technological breakthroughs. Guided by the team's experience, we explored the technical characteristics and industrial development of stem cell therapy as well as the external policy environment. To further enhance our understanding of the policy changes and their impact on the development of stem cell therapy, we reached out to other researchers and doctors via the recommendations of the team and by participating in industrial conferences. Additionally, we interviewed relevant officials from the Ministry of Science and Technology (MOST), the Ministry of Health (MH) and the China Food and Drug Administration (CFDA)

**Table 1.** Policy Learning Pattern of the Chinese Central Government

| Factors | Characteristics | Description |
|---|---|---|
| Learns what? | The governance of EST (stem cell therapy) | • A high degree of technical complexity and interest complexity |
| Who learns? | The top decision makers | • Director<br>• Centralized power |
| | Central departments | • Improviser<br>• Fragmented authoritarianism |
| What pattern? | Pendulum swing | • Policy swings between developmental goals and regulatory goals<br>• Various interpretations and experimentation by central departments<br>• Direction and control by the top decision makers |
| To what effect? | Technical or behavioural change | • Policy goals and policy instruments |
| | Conceptual or cognitive change | • Problem-defining and problem-solving framework |

*Source*: Authors.

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to learn about the perceptions, attitudes and regulatory practices of the three departments regarding stem cell therapy. To gain first-hand information and insights on how the policies were being implemented at the local level, we conducted interviews with officials from local governments. In all, 30 practitioners from hospitals, industry, academia and government were interviewed.

## The Pendulum Swing in the Case of Stem Cell Therapy

Stem cell therapy emerged in China in the 1990s, and the Chinese government began to govern this field almost immediately. The three main departments currently in charge of stem cell therapy are the MOST, the MH and the CFDA.[20] Western countries such as the United States began to formally regulate stem cell therapy in 2005 using a traditional drug regulatory approach, with a greater emphasis on the supervision and control of stem cell therapy. This approach takes randomized controlled trials as the gold standard and follows international best practice guidelines such as GCP (good clinical practice), GTP (good tissue practice) and good manufacturing practice (GMP), etc. It aims at obtaining systematic evidence to demonstrate the safety and efficacy of stem cell products. However, this route greatly restricts the freedom of clinical research and clinical trials, thus hindering the development of stem cell therapy.[21] During the early 2000s, the Chinese government attempted to adopt the same model but found it to be ineffective. As a result, it started exploring alternative governance approaches to find a balance between regulation and development in the field of stem cell therapy.

### *Stage I (1990s–2009): overemphasis on developmental goals*

Initially, the State Council treated developmental goals and regulatory goals more like a zero-sum game. To pursue high economic growth and industrial development, it prioritized developmental goals in the field of stem cell therapy but did not specify which phase (for example, basic research, preclinical application) should be heavily developed or how. The State Council did not take a clear stance on regulation, meaning it did not call for either tighter or more relaxed regulation. Following the State Council's vague signals, the three departments demonstrated responsiveness and searched for policy instruments. The MH and CFDA found a conflict between developmental goals and their regulatory functions. To mitigate regulatory risks and potential political repercussions, the two departments opted to deviate from their intended regulatory role and instead implemented regulations loosely. This strategic decision was made in alignment with the State Council's objective of creating an accommodating environment for the advancement of stem cell therapy. A big push for developing stem cell therapy and a regulatory vacuum triggered what has been termed "stem cell chaos" (*ganxibao luanxiang* 干细胞乱象), a social sensation at home and abroad. This created external pressure for the next stage of policy learning, as did the debate between the CFDA and MH over which of the two agencies should be tasked with regulating stem cell therapy.

From the 1990s to 2009, the State Council regarded economic development as the focus of all its work and it knew little about the risks of stem cell therapy to patients. The guidance issued by the State Council to the three departments was to promote the rapid development of stem cell therapy. Meanwhile, the policy vagueness provided enough space for the three departments to interpret the vague signals, set specific goals and construct policy solutions.

20 While these three agencies have been in charge since the introduction of stem cell therapy in China, their names and configurations have changed over time. The MH was called the National Health and Family Planning Commission and the National Health Commission. The CFDA was called the State Food and Drug Administration and the National Medical Products Administration. The CFDA came under the jurisdiction of the MH or the State Administration for Market Regulation in some periods, but it has played an important role in the governance of stem cell therapy, so it is regarded as an independent actor.

21 Rosemann and Chaisinthop 2016.

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The MOST emphasized that more research funding should be invested in creating cutting-edge technologies such as stem cell therapy. According to one interviewee:

> You know, stem cell therapy was a totally new thing then. We were excited by its potential to help China gain an advantage and enhance China's global technological competitiveness. Of course, it was good for our department.[22]

The MOST thus incorporated stem cell therapy into its science and technology planning and funding system and regarded the funding results (such as the number of patents, the number of papers, etc.) as its performance indicator when reporting to the State Council. In this way, the MOST became the most direct driver of stem cell therapy among the three regulatory agencies and obtained more national financial support and greater control over the stem cell sector.

Both the CFDA and MH considered the regulation of stem cell therapy as burdensome and debated whether stem cell therapy should be classified as a class of drugs or a medical technology. Their objective was to convince higher authorities that the jurisdiction for regulating stem cell therapy belonged to the other agency. Ultimately, the two were locked in a standoff, with neither of them providing a legal pathway to market for stem cell therapy. The CFDA did not clarify the technical principles and governance methods of stem cell therapy and lacked reference standards and products. As such, it took a cautious and contradictory approach. As an official said:

> We were in a bind. The central leadership supported technological development, and we should also give positive feedback. Have you heard of the corruption scandal in 2006? At that time, our department leader fell and the department reform was up-coming, so everyone was very nervous and nobody wanted to cause trouble.[23]

For example, the CFDA received a new drug application for a stem cell product from the Center for Basic Medical Research, Chinese Academy of Medical Sciences, in 2003.[24] The agency held discussions with the research group and gained, from US experience, a general understanding of the principle and characteristics of the product and the evaluation rules. It approved the product for stage I and stage II clinical trials during 2004 and 2006. However, when the agency realized the technical difficulties and political risks involved with the stem cell product, it refused to approve stage III clinical trials of the product in 2008 and did not open up a viable channel for the stem cell therapy the group had developed to become a marketable drug.[25]

The MH began exploring an institutionalized approach to regulating stem cell therapy as a medical technology. Before 2009, it issued a series of regulatory policies, such as technical guidelines, to fulfil its regulatory functions. However, in practice, it did not undertake any supervision. An interviewee explained the reasons:

> We did not follow the technical guidelines. Believe it or not, we heard little about them then. We did not really know who was performing stem cell treatments. Even if we knew, no one wanted to intervene. Why take on unnecessary risks and responsibilities?[26]

22 Interview with an official from the MOST, Beijing, May 2021.

23 Interview with an official from the CFDA, Beijing, February 2021.

24 The application came from the group headed by Professor Chunhua Zhao 赵春华. This application indicates that China was leading the way in new drug research on adult stem cells. "Woguo ganxibao zhuanli shijie disan ganxibao zhiliao heshi zhaojin xianshi" (China's stem cell patents reach world's third largest, when will stem cell therapy become a reality?). *Health.huanqiu.com*, 2015, https://health.huanqiu.com/article/9CaKrnJHmZ0. Accessed 24 February 2022.

25 Chen, Haidan 2009b.

26 Interview with an official from the local MH, Ningbo, November 2020.

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In 2009, the MH included stem cell therapy in its list of tightly controlled, non-approved technologies, and entrusted a team of experts from industry associations to review applications. However, the experts failed to reach a consensus on developing reasonable operational review guidelines, so the MH did not approve any stem cell therapy work.[27] The CFDA and the MH both failed to establish a legal pathway to market for stem cell therapy and neither institution imposed strict regulations or prohibited its practice.

The actions taken by the three departments led to a regulatory vacuum within the stem cell sector. Consequently, local governments and various market players engaged in a competitive race to develop stem cell therapy. As a result, what both an MH official and a researcher referred to as high-level stem cell treatments, conducted by responsible researchers and public institutions under the MH's jurisdiction, experienced delays. Meanwhile, privately run stem cell applications that carried higher risks continued to proliferate.[28] This triggered an enormous problem in 2010. Unproven, risky stem cell therapies of low quality were carried out nationwide for thousands of dollars during the period of "stem cell chaos."[29] These treatments attracted negative attention domestically, such as in special reports on CCTV radio in-country and articles in the scientific journal, *Nature*.[30] The ensuing debate and the practical exploration of regulatory approaches to stem cell therapy by the CFDA and MH, along with the chaos caused by inadequate supervision, served as a valuable experience for the State Council, helping it to identify the existing problems and develop solutions for the next phase of learning.

### *Stage II (2010–2015): overemphasis on regulatory goals*

Despite the last phase of policy learning, the State Council did not achieve any conceptual or cognitive changes. It continued to work within a problem-defining and problem-solving framework in which regulatory goals and developmental goals were binary opposites. As a result, one goal lost out to the other. Specifically, the development of clinical applications of stem cell therapy was seen as a potential source of social disruption that needed to be restricted with a campaign of regulations. To govern the stem cell chaos, which was identified as a systemic crisis, the State Council moved to prioritize regulatory goals. This was a policy swing away from its macro-level goal in Stage I that overestimated development and overlooked regulation.

Following the guidance of the State Council, the three departments shifted their focus away from promoting development and towards strengthening regulation in order to mitigate potential political and social risks. Again, the three departments leveraged the flexibility permitted by the State Council to search for policy instruments through trial and error. The MOST began supporting basic research only, ceasing its promotion of the whole innovation process of stem cell therapy. This shift was driven by concerns over the risks involved in clinical trials and applications of stem cell therapy as well as the ethical considerations associated with such endeavours. Moreover, stem cell basic research was more visible and computable in the form of articles and patents, which served as a good indicator for the MOST's political performance. In contrast, clinical trials and clinical applications of stem cell therapy usually have longer production cycles than basic research, which means that they do not translate well as effective, immediate political performance indicators.[31]

27 Interview with an official from the local MH, Shanghai, December 2020, and a doctor from a public hospital, Wuhan, November 2020.

28 Interview with a researcher from Capital Medical University, Beijing, October 2020.

29 Chen, Yongjie 2012.

30 Cyranoski 2009; 2012; "CCTV jingji banxiaoshi jiemu: ganxibao shenqi liaoxiao diaocha" (Investigation on "magical effect" of stem cells in CCTV economic half hour programme). *CNTV*, 17 April 2011, http://jingji.cntv.cn/20110417/103541.shtml. Accessed 6 May 2021.

31 Interview with a researcher from Capital Medical Hospital, Beijing, October 2020.

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The MH and CFDA attached great importance to regulatory goals, mobilizing social resources on a large scale to implement policies strictly within their jurisdictions and paying little attention to actors elsewhere. The developmental goals of the MOST conflicted with the regulatory goals of the MH and CFDA, leading to a distortion of the healthy development of stem cell therapy. This created a new external pressure for the next stage of policy learning. Moreover, the MH's exploration of the institutionalized regulatory approach provided direction and framework for Stage III.

Some researchers and pharmaceutical companies who sought a broader market for standard stem cell products continued to appeal to the State Council to classify stem cell therapy as a class of drugs, but the CFDA was relegated to a subordinate agency of the MH and had less autonomy in choosing a regulatory approach. Thus, the medical technology regulatory approach, as supported by the MH, became the mainstream practice during this period. As the main regulator of stem cell therapy, the MH strengthened the supervision of stem cell therapy clinical applications. To rectify the stem cell chaos, around 2012 the MH and CFDA mobilized resources and organized working groups from central to local levels to carry out special inspections of the illegal applications of stem cell therapy. However, in practice, the MH selectively implemented regulatory policies: it imposed a strict regulatory regime within its jurisdiction but tended to ignore the medical institutions beyond its jurisdiction to minimize its exposure to risk. Bounded by jurisdictional limits, the MH was only able to govern its affiliated public hospitals and lacked the policy tools to regulate a large number of other medical institutions including private hospitals, small clinics and hospitals affiliated to local governments, and military hospitals. Moreover, broad and complex industrial interests were vested in stem cell therapy and tightening regulation would harm these stakeholders. The MH was reluctant to impose regulation for fear of offending these interests and faced strong resistance when it tried to do so. One researcher shared his concerns:

> We [public hospitals and medical universities] were so heavily regulated by the government, and it was hard to get funding for clinical research. I heard the private practices were unaffected. They were the most problematic areas, but they were out of the government's control.[32]

Recognizing that mobilizational governance was unsustainable and could not solve fundamental problems, the MH began to explore a dual filing system (*shuang bei'an zhi* 双备案制) for clinical research projects and institutions to give stem cell therapy access to the market between 2013 and 2015. However, there was no institution that could legally engage in stem cell applications in this period. As an official explained, "Frankly speaking, we did not know how to review at that time and who the suitable reviewers were was also unclear, so we did not start the actual review."[33] The MH took advantage of this void to take regulatory action, thereby enhancing its status and influence.

The misaligned practices of the three departments created mis-regulation and a pressurized environment within the stem cell sector. Many high-level stem cell clinical research projects were over-regulated and had to be interrupted, while unqualified businesses were under-regulated and continued to charge patients for unproven and potentially risky therapies, leading in some cases to the death of patients.[34] This greatly hindered the heathy development of China's stem cell industry, especially in clinical applications. According to one researcher:

32 Interview with a doctor from a public hospital, Suzhou, June 2020.

33 Interview with an official from the MH, Beijing, May 2021.

34 Called the "Wei event" (*Weizexi shijian*), the incident concerns the death of Wei Zexi in 2016. Wei had received a form of unqualified immunotherapy that had been banned abroad in a domestic clinic.

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> Unfortunately, we had to stop our clinical trials and many other researchers had to do so [too]. These studies would have been cutting-edge, but they were a decade late owing to over-regulation. [35]

The resulting systemic crisis triggered the next stage of policy learning. In addition, the dual filing system initiated by the MH laid the foundation for the institutionalization and refinement of the medical technology supervision approach taken in Stage III.

### *Stage III (2016 to present): goal balancing*

To prevent over-regulation from hampering the development of the stem cell industry, the State Council revised its approach to the relationship between developmental goals and regulatory goals. Instead of perceiving them as separate and even contradictory objectives, the State Council recognized the need for their mutual reinforcement. Under the new problem-defining framework, it defined the policy goal as using regulation to promote healthy development. Guided by this broad goal, the three departments reviewed their interpretation and carried out policy experimentation. Through policy learning, the State Council and the three departments have formed a clearer understanding of the governance objectives, principles and means of stem cell therapy, and they have developed a new problem-solving framework with new policy goals and instruments. With a clear structure of division and coordination, policy conflicts among the three departments have eased. Government regulation of stem cell therapy is moving towards adaptive governance, but problems such as exceptional regulation in the free-trade zone remain to be addressed in the next stage of policy learning.

Since 2016, there has been a prevailing focus on high-quality stem cell research and technology that prioritizes both the improvement of people's health and the advancement of the economy. Recognizing that excessive regulation during Stage II hindered the development of stem cell clinical applications, the State Council started to acknowledge the significance of regulation as a necessary foundation for sound development in the field of stem cell therapy. As a result, the three departments have competed to show how their effective regulatory measures have contributed to the promotion of safe and effective stem cell therapies.

A clearer division of labour has emerged. The MOST has a greater say in almost every plan and project it funds, including stem cell therapy. It aims to advance the application of stem cell therapy even in basic research projects that are far from clinical application and has thus far received more central financial support.

The MH and CFDA have developed two different regulatory approaches, treating stem cell therapy as a medical technology and drug, respectively. The MH continues to be the main regulator in the field of stem cell therapy. It has, however, changed its performance definition and has granted stem cell therapy access to market as a medical technology. Between 2016 and 2018, to implement the dual filing system initiated in the previous phase, the MH and CFDA established leading groups, academic committees and ethics committees for stem cell clinical research, from the central to provincial levels, to conduct reviews. In 2019, the MH implemented significant regulatory reforms in the field of stem cell therapy. These reforms included notable changes such as granting an enhanced status and functions to the ethics committee – members are now required to meet specific expertise requirements and substantive requirements for ethical review have been codified. Moreover, the MH oversees quarterly inspections and the dynamic management of registered agencies and projects through an electronic data system that facilitates reporting, feedback and review processes. An official described the current regulation system as follows:

35 Interview with a researcher from Capital Medical University, Beijing, October 2020.

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> We need to put the dual filing system in place, and the central leadership will look at this when they evaluate our work. Other annual regulatory filings and actions are also required. The free-trade zone is relatively freer.[36]

In 2013, the CFDA became a distinct department separate from the MH. Since then, the CFDA's performance measures have been based on the extent to which the market gains access to stem cell therapy drugs. It provides viable regulations and technical guidelines for stem cell drug applications. It also accelerates access to market for stem cell drugs while ensuring their safety and effectiveness.[37]

During this period, the three departments have carved out their own territories within the stem cell sector. The MOST governs the science and technology funding system, which mainly involves research institutions and their staff seeking public funding. The MH is in charge of clinical research and the application of medical technology, which mainly affects hospitals, clinics and other medical institutions as well as their staff who conduct stem cell clinical research and applications. The CFDA is responsible for drug approval and has a greater influence on enterprises seeking commercial applications of stem cell drugs. The central government has formed a differentiated governance system in the field of stem cell clinical applications, moving towards adaptive governance. This approach is in line with the current mainstream international governance trend and strikes a better balance between developmental goals and regulatory goals, ensuring safety and quality as well as allowing for freedom in clinical research and clinical trials.

Thanks to this adaptive governance approach, China's stem cell industry has ushered in a period of rapid development. At the end of 2020, China, with 294 trials, had overtaken the United States (216 trials) as the country with the most stem cell clinical trials, out of a total of 1,520 trials being conducted worldwide.[38] At the end of 2022, China had close to 140 filing institutions and more than 100 filing projects in the field of stem cell clinical applications, and had approved more than 30 stem cell products as investigational new drugs.[39] China's stem cell therapy market is forecast to grow from 1.3 billion yuan in 2021 to 58.4 billion yuan in 2030, with an average annual growth rate of 53 per cent.[40]

At the same time, the governance approach of the free-trade zones is still undetermined and the associated risks are not fully regulated, which could again lead to market disorder. This is likely to trigger a new round of interactive learning led by the State Council and the three involved departments.

The central government's behaviour in the case of stem cell therapy can be summarized as exhibiting a pendulum swing pattern (shown in Table 2 and Figure 1).

## The Causes behind the Pendulum Swing Pattern

The characteristics of complex technology (as the policy object) and departments (as policy actors) deeply influence the features and dynamics of the pendulum pattern.

First, the technical and interest complexities associated with stem cell therapy present significant challenges for the State Council in terms of maintaining a suitable balance between development and regulation and developing an effective governance approach. Given the evolving nature of the field, the State Council may need to continually adjust its goals and even redefine the

36 Interview with an official from the MH, Beijing, May 2021.

37 Interview with a researcher from Capital Medical University, Beijing, October 2020, and the manager of a biotech company, Suzhou, November 2020.

38 Data were collected from ClinicalTrials.gov, which is a clinical trial database operated by the National Library of Medicine (NLM) of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). At the time of writing, it was the largest clinical trial register in the world.

39 Data were collated from information released by the National Health Commission, the Chinese Medical Biotechnology Association and the Health Bureau of the Logistics Support Department of the Military Commission. See the following official websites for details: http://www.nhc.gov.cn/; http://www.cmba.org.cn/.

40 Data were collected from the globally well-known market research firm, Frost and Sullivan.

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**Table 2.** The Policy Learning Pattern of the Chinese Central Government in Stem Cell Therapy

| | Stage I (1990s–2009) | Stage II (2010–2015) | Stage III (2016–present) |
|---|---|---|---|
| Problem-defining and problem-solving framework | Developmental goals and regulatory goals are binary opposites. | Developmental goals and regulatory goals are binary opposites. | Developmental goals and regulatory goals are mutual reinforcement. |
| National goal | Prioritizing developmental goals to stimulate rapid industrial development. | Prioritizing regulatory goals to ensure safety. | Balancing developmental goals and regulatory goals to promote healthy development. |
| Departmental goal and policy instruments | • MOST:<br>Pursuing developmental goals overall.<br>Actively funded the development of stem cell therapy.<br>• CFDA:<br>Setting regulatory goals in name and allowing developmental goals in practice.<br>Explored the drug regulatory approach.<br>• MH:<br>Setting regulatory goals in name and allowing developmental goals in practice.<br>Explored the medical technology regulatory approach. | • MOST:<br>Pursuing developmental goals mainly in basic research.<br>Actively funded the development of stem cell basic research.<br>• CFDA:<br>Pursuing regulatory goals to ensure safety.<br>Strictly regulated stem cell clinical applications.<br>• MH:<br>Pursuing regulatory goals to ensure safety.<br>Strictly regulated stem cell clinical applications.<br>Explored the medical technology regulatory approach. | • MOST:<br>Pursuing developmental goals especially in clinical trials.<br>Actively funded the development of stem cell clinical applications.<br>• CFDA:<br>Pursuing regulatory goals to ensure safety and promote development.<br>Established the drug regulatory approach.<br>• MH:<br>Pursuing regulatory goals to ensure safety and promote development.<br>Established the medical technology regulatory approach. |
| Learning effects | Technical or behavioural change | Technical or behavioural change | Conceptual or cognitive change |
| Policy performance (industrial development) | Triggered the stem cell chaos. | Inhibited the healthy development of China' s stem cell industry. | Promoted the healthy development of China' s stem cell industry. |

*Source:* Authors.

problem-solving framework through practical experience and continuous learning. This iterative process often results in policy swings between different stages of policy implementation.

### *The governance requirements of stem cell therapy initially exceeded the abilities of the State Council and the three departments*

In the planned economy period, the Chinese central government faced the governance situation where local drugs and medical technologies were relatively simple, had limited types and updated slowly. The government had no appropriate governance experience or knowledge for a new era characterized by diverse, highly complex and rapidly evolving medical technologies.[41] This lack of knowledge and experience was exacerbated by the specific experiences of the three departments.

41 Liu 2011.

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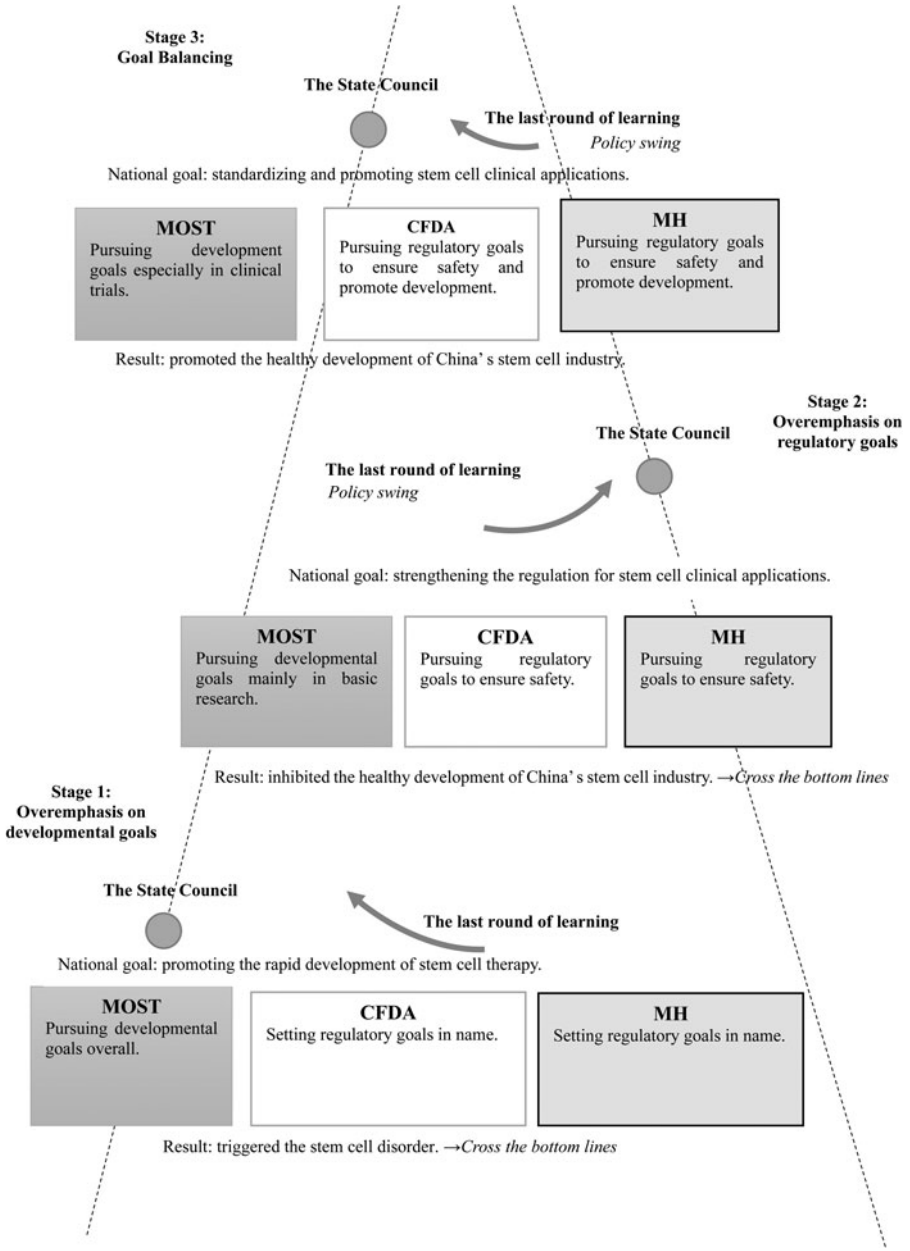


**Figure 1.** The Pendulum Swing in the Case of Stem Cell Therapy
*Source:* Authors.

During the government contractual reform after the 1980s, the MH relinquished its control over public hospitals and thus no longer had effective channels through which to obtain continuous information and accumulate professional knowledge. It knew very little about the clinical use of stem cells in the hospitals under its jurisdiction.[42] The MOST was historically only responsible for the preparation and supervision of science and technology plans in the medical and health

42 Rosemann and Sleeboom-Faulkner 2016.

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fields, rather than directly managing the implementation process, so it had insufficient resources and capacity in the related fields.[43] The CFDA was established in the late 1990s, and its knowledge and skill acquisition was quite limited.[44] Owing to its limited number of experts and the sparseness of its information network within the industry, the Chinese central government could only master more visible and quantitative information in stem cell basic research, such as patents, published papers, government research projects and other indicators. Thus, it knew little about the actual situation of stem cell clinical research and application.[45]

### *The government policies swing as the State Council and the three departments adjust their policies*

Owing to gaps in its governance capability and knowledge of stem cell therapy, the State Council often lags behind rapidly changing industrial developments or makes mistakes in policies, so it sets broad goals and constantly adjusts policy goals as well as the problem-defining and problem-solving framework according to the actual situation. The State Council changes its goals continually, from weak regulation to strong regulation and then to moderate regulation. The MH, MOST and CFDA follow the State Council and undergo similar changes.

### *The policy ambiguity of the State Council enables the three departments to search for different policy solutions*

Owing to the technical and interest complexities of stem cell therapy, the State Council only sets a broad goal without a complete policy design. In addition, removed from the actual practices of the new technology and dependent on the long information feedback chains of the administrative system, the State Council cannot obtain enough information from departments to implement any timely or effective supervision of their behaviour. Therefore, the three departments carry out different experiments during the same phase. For instance, from the 1990s to 2008, the State Council adopted the goal of rapid development, underestimating the needs of regulation. As a pioneer in driving technological development, the MOST vigorously promoted stem cell therapies in all stages of the industry chain. The MH and CFDA should have assumed regulation to be their main function. Instead, the MH implemented loose regulation and let stem cell therapy develop freely while the CFDA started the evaluation procedure for certain new stem cell products to keep up with the State Council. This eventually led to a period of stem cell disorder, endangering market order and people's health.

### *A structure of fragmented authoritarianism catalyses interdepartmental policy conflicts*

Stem cell therapy involves cooperative productive relationships between basic research, clinical research and clinical application as well as between medical health, the industrial economy, social politics, ethics and the law.[46] It is difficult to classify stem cell therapy according to the jurisdiction of a single department and it often falls into blurry and intersectional areas. Moreover, the three departments have the authority to formulate policies according to their own positions in a structure of fragmented authoritarianism. As a result, there is often a conflict between the interests of the different departments as they compete for power and resources yet attempt to pass on responsibility when there are high risks. From the 1990s to 2008, the three departments pursued different

43 Editorial Committee of China's Health Yearbook 1983; Wu, Heng, and Yang 1991.
44 Yu 1997; Liu 2011.
45 Wu, Fei, et al. 2013; Yuan 2016.
46 Chen, Haidan 2009b.

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performance indicators around the central strategy that emphasized developmental goals: the MH and CFDA relaxed its regulation of hospitals and relevant medical projects. Meanwhile, the MOST actively promoted the development of stem cell therapy. Even in the period of strong regulation, there was still a conflict between the developmental objectives of the MOST and the regulatory objectives of the MH and CFDA. This is because the clinical research and clinical application of stem cell therapy promoted by the MOST did not come under the MOST's responsibility but obviously increased the regulatory pressures for the MH and CFDA.

*The State Council plays a crucial role in guiding the policy experiments conducted by the three departments.*

The State Council facilitates the comparison of policy solutions that result from the pooling of departmental experiments and adjusts national policy goals based on ongoing situations. Through several rounds of policy learning between the State Council and the three departments, distinct technical and conceptual changes are facilitated, representing policy adaptation and progress.

From the 1990s to 2008, the State Council pitted regulatory goals against developmental goals and prioritized the latter. Accordingly, the MOST actively pursued its developmental task and accelerated the State Council's goals, while the CFDA and MH selectively performed their regulatory functions and shirked their responsibility to regulate stem cell therapy in an attempt to allow more freedom for technological development.[47] The debate on regulatory approaches between the CFDA and MH created both a regulatory vacuum and a learning experience. When the stem cell chaos appeared around 2010, partly because of the big push for rapid development and lack of regulation,[48] the State Council realized the risks and adverse impacts of the wild development of the stem cell industry and made a policy swing to strongly endorse regulatory goals. Based on the experience gained in the previous stage that indicated that the unfettered promotion of stem cell clinical applications carried with it high risks and might result in uncontrollable disorder without an appropriate regulation system, the MOST restricted its scope to supporting only basic stem cell research.

The MH also learned from Stage II that insufficient regulation tended to bring it trouble rather than allow it to avoid blame. So, it also performed a policy swing and carried out substantive regulatory tasks using mobilizational governance to regulate the stem cell therapy market in the absence of institutionalized supervision.[49] As the MH found mobilizational governance to be unsustainable and ineffective for regulating stem cell therapy, and as it acquired more knowledge of the sector's attributes, risks and regulatory methods through learning by doing, it started to explore a way of regulating stem cell therapy as a medical technology and initiated an institutionalized regulatory approach, namely a dual filing system. In 2015, however, the MH lacked a comprehensive understanding of the selection of experts and working mechanisms, and so did not carry out any actual reviews.[50]

After the stem cell industry generally blamed the regulatory system for distorting its healthy development, the State Council concluded that over-regulation using mobilizational governance was not sustainable, because it tended to waste resources and distort goals, and that institutionalized governance was more important for better development. The State Council thus turned to balancing regulatory goals and developmental goals to promote healthy industrial development. Under this new goal, the three departments have gradually formed a clearer division of labour through learning and

47 Ibid.

48 Chen, Yongjie 2012.

49 See relevant policy texts.

50 Interview with an official from the local MH, Shanghai, December 2020, and a doctor from a public hospital, Wuhan, November 2020.

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exploration. By expanding the scope of the funding system, the MOST integrates more institutions and researchers engaged in stem cell therapy research into its own information network. Moreover, it grasps the existing resources, capabilities and progress made in the stem cell field with the help of its stem cell expert group, and it has formed a more reasonable future plan for the stranglehold problems of stem cell technology development, support priorities and performance evaluation methods.[51] The MH has boosted its professionalism and expertise by establishing academic and ethical committees at every level. In addition, its information system allows it to engage with and better monitor the progress of stem cell clinical applications more widely, and to receive timely feedback and make dynamic adjustments.[52] It can therefore check the qualifications of practitioners and better monitor and control their behaviour. In the process of formulating and implementing stem cell regulations and technical guidelines, the CFDA has communicated with researchers and manufacturers to form a more in-depth and systematic understanding of the characteristics, evaluation methods and indicators of the safety and effectiveness of stem cell products.[53] Therefore, it can better guide and standardize the whole chain of research, development, clinical trials and marketing of stem cell products.

In summary, the collaboration between the State Council and the three departments has facilitated a notable shift in the problem-defining framework of stem cell governance. Initially centred around the regulation versus development debate, it has evolved into a regulation for development perspective. This shift has led to the establishment of an improved problem-solving framework that addresses crucial aspects of stem cell therapy, including technical characteristics, scientific standards, management rules, professional ethics and responsibilities, and ethical and political considerations. This approach has allowed for the development of a differentiated regulatory strategy that spans all phases of stem cell research and clinical transformation. Consequently, these policy learning and adaptation processes have contributed to the healthy growth of China's stem cell industry, unlocking greater potential for stem cell therapy and positioning China at the forefront of global advancements in this field.

## Conclusion and Discussion

This article focuses on examining the policy-learning process of the Chinese central government specifically in the field of EST, with stem cell therapy as the case study. The analysis reveals the existence of a pendulum swing pattern, whereby top decision makers guide the central departments in experimenting and learning through successive policy swings between developmental and regulatory objectives.

While the policy learning of the Chinese government has been extensively studied in the fields of political science and public policy, the exploration of EST policy areas, as opposed to conventional and macro policy domains, and the involvement of central departments, rather than local governments, remain largely unexplored by the majority of researchers. This article highlights the influence of the characteristics of central departments and EST on the policy-learning process, which deviates from traditional research on policy learning, especially policy experimentation. The mechanisms of variation, selection and niche creation, as emphasized by Ang and other scholars, play a crucial role in policy learning and adaptive governance.[54] However, in the domain of EST with its technical and interest complexities, these mechanisms can sometimes become dysfunctional.[55] In a hierarchical and punitive system, where top decision makers struggle to strike a balance between developmental

51 Interview with an official from the MOST, Beijing, May 2021.
52 Interview with an official from the local MH, Shanghai, June 2021.
53 Interview with an official from the CFDA, Beijing, February 2021, and a researcher from Capital Medical University, Beijing, May 2022.
54 Ang 2016.
55 Kim and O'Brien 2021; Yasuda 2023.

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and regulatory goals and communicate vague signals, central departments may initially be reluctant to explore new solutions, thereby inhibiting policy variation. Furthermore, the absence of clear benchmarks for evaluating policy trials at the outset creates differentiation and conflicts among departmental policies within the fragmented authoritarian structure, undermining the effectiveness of the selection mechanism. These two factors make the process of niche creation challenging and protracted. As the pendulum swing of the learning process progresses, top decision makers gradually gain clarity regarding setting goals and selection criteria. This clarity, in turn, encourages departments to actively develop and refine new policy options with stable expectations.

The identified pendulum swing in policy learning highlights the need for a balance between development and regulation in the context of EST. Given the technical and interest complexities inherent in EST, policymakers should adopt an open and inclusive stance to foster an adaptive governance approach. It is crucial to recognize that the growth of the central government's abilities, as facilitated by the pendulum pattern, has limitations and cannot automatically extend to other fields or future governance without investing in new learning. Moreover, it is important to acknowledge that the pendulum swing of policy learning carries social costs that cannot be completely eliminated. Therefore, addressing the methods to minimize these costs within the context of the pendulum swing pattern becomes imperative.

This article represents an initial exploration of the learning pattern of the central government and paves the way for further research. Future studies could delve into the causal mechanisms of policy learning and industrial development, employing extended periods of historical process-tracing analysis. In addition, conducting comparative case analyses would shed light on how different technological and departmental characteristics may impact the government's learning pattern. Such research endeavours would contribute to a more comprehensive understanding of policy learning in the context of EST.

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