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CHINA'S HEALTHCARE SYSTEM AND THE RISE IN PHARMACEUTICAL FRAUD

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INTRODUCTION

Since 1949, healthcare in China has experienced drastic changes to all parts of its sectors. The Maoist era saw the establishment of a universal healthcare system—The Cooperative Medical Scheme (CMS) where healthcare was controlled and financed by the central government. The economic reforms of the 1970s pushed for heavy investment into introducing a partly privatized healthcare system, where policy implementation and control was decentralized to county governments. Financial contribution from the central government dropped compared to previous decades, which limited economic capacity for regional healthcare development. As seen with China's 12th Five-Year Plan (FYP), efforts to focus on quality of healthcare, as well as expanding its Basic Medical Insurance (BMI) scheme, that can accommodate its growing urban and rural residents has continued to be the focus point for future healthcare reforms.

In March 2011, China's National People's Congress (NPC) approved a new national development strategy for its next FYP—2011-2015.¹ As stated by the Ministry of Health, the strategy will focus on addressing concerns such as enhancement drug quality supervision and improving quality and management of healthcare services.² However many of these changes have been restricted due to fiscal restraints at the local level. Challenges including chronic-underfunding particularly for local governments in rural regions, problems of affordability and the inaccessibility of medical insurance continue to be problems Chinese citizens face. A more recent and concerning challenge is the rise in pharmaceutical fraud in relation to state agents and international organizations.

The paper will focus on the rise in fraudulent activities in China's healthcare system. Firstly it will provide a summary on changes made to China's healthcare from 1950s to the system nowadays. The mixed effects of healthcare policies in China will also be considered, particularly forms of pharmaceutical fraud. Recent examples of illegitimate activity within China's healthcare system will also be addressed including GlaxoSmithKline (GSK) and the execution of China's former Head of State Food and Drugs Administration (SFDA), Zheng Xiaoyu. Lastly the paper will provide explanations for the importance of pharmaceutical fraud; and ways in which

¹ "China's 12th Five-Year Plan."

² "China's 12th Five-Year Plan."



current developers in China, and those looking to invest in China in the future can mitigate forms of fraud.

BACKGROUND: CHINA'S HEALTHCARE SYSTEM 1950s-1970s

During the 1950s-1970s, both China's urban and rural population were covered by various healthcare policies. Individuals in rural regions were protected by the Cooperative Medical Scheme (CMS), which was managed by agricultural communes or a danwei.³ The structure provided a three-tiered system: barefoot doctors in clinics acted as primary care, followed by commune health centers, while seriously ill patients were referred to county clinics which were staffed by senior professionals in the trade.⁴ Urban residents were under the coverage of the Labour Insurance Scheme (LIS), which provided healthcare insurance for employees working within State Owned Enterprises (SOEs).⁵ Funding, policy implementation and healthcare services were centralized under the strict control of the central government, which discouraged costly procedures or over prescription of medicine. Efforts to combat infectious diseases were limited to pre-emptive rather than curative measures, as investment in sanitation expanded.

Beginning with the reform and opening of economic reforms, China's healthcare system has undergone a process of partial privatization and become more decentralized. Healthcare, compared to previous years, is slowly becoming an individual's responsibility rather than the state. The shift in responsibility from the center to individuals and local governments—an attempt to increase efficiency of policy implementation,⁶ has increased financial pressures; as local governments have had to generate funds themselves while percentage of individual out-of-pocket payments increase. With the staggering costs of pharmaceutical drugs and limited economic support, some individuals have had to opt for illegal alternatives including counterfeit medicine, or in the case of local governments, allowed pharmaceutical fraud to subsidize medical expenditures. As forms of fraud continue to emerge, quality of healthcare can only continue to be jeopardized.

Figure 1: Healthcare Expenditure in China from 2010 to 2012 (Financing Agents)

³ A danwei refers to the work unit an individual belongs to. During the Maoist era, a danwei was responsible for providing everyday necessities for an individual including food, healthcare and education.

⁴ Chow, "Analysis of Healthcare in China."

⁵ "Health Insurance Systems in China," WTO.

⁶ "Health Insurance Systems in China," WTO.



Countries	Indicators	2010 Value	2011 Value	2012 Value
China	Out of pocket expenditure as % of PvtHE	77	79	78
China	Out of pocket expenditure as % of THE	35	35	34
China	Private insurance as % of PvtHE	7	6	7
China	Total expenditure on inpatient care as % of THE	:	:	:
China	Government expenditure on inpatient care as % of GGHE	:	:	:
China	Total expenditure on health / capita at exchange rate	216	274	322

Source: Health expenditure series, World Health Organization, Geneva, (latest updates are available on GHED <http://who.int/nha/database/>)

The statistics provided above reaffirm the increase in out-of-pocket payments for health costs. Between 2010 and 2012, individual expenditure remained as high as 77-79%. In China, insurance coverage is also a problem for many. Private insurance companies are often costly, with limited coverage of procedures or medications they are likely to reimburse. As seen during 2010 and 2012, the percentage of expenditure reimbursed to individuals by private insurance companies remained at around 6-7%. With restricted health insurance, and soaring prices of medicine, cheaper options including counterfeit drugs will continue to be a better option for those unable to afford the genuine treatment.

THE MIXED EFFECTS OF RECENT GOVERNMENT MEDICAL POLICY

Issues related to compliance, conduct and conflicting interests have been able to leak into the system, which in turn has led to the rise in fraudulent activity in China's healthcare system. Fiscal



constraints have meant that in some cases, appropriate treatment is not in accordance with a patient's condition. As costs for county governments and medical personnel continue to rise, illegitimate means of generating funds to sustain economic growth are being favoured over a patient's medical need. Existing actors in the system or local governments themselves have shown an inability to keep out illegitimate practices. The breaching of ethical codes by medical personnel have also meant that foreign companies such as GSK have been able to abuse China's healthcare system for personal benefits. This is a problem that shows no signs of going away.

Chronic Underfunding

Although the Chinese government has shown a growth in financial commitment to the healthcare system with its 12th FYP, concerns on whether funds will be more accessible to foreign investors is an issue many county governments face. The next five years will see policy backing and funding from central plan, but as officials have said, emphasis will remain on foreign investors.⁷ This leaves county governments and medical personnel burdened with the task of finding the funding needed for local resources. A large share of funds comes from tax revenues. The problem of chronic underfunding particularly threatens governments in poorer, less developed regions, as money collected from taxation is often insufficient to maintain the existing infrastructure. As a result, the economic capacity of a local government often determines the conditions and healthcare services provided. This means the level of public spending and quality of healthcare services is dependent on the fiscal base of the local government in that region.⁸ Without support from the center, there is little doubt that county governments will turn to methods of generating money rapidly.

With local governments in poorer regions, illegitimate transactions including bribery or other forms of fraud become necessary just to maintain current healthcare infrastructure. Rapid economic growth that comes from counterfeit drug production means that local governments can meet quota-driven aims for medical expenditure whilst keeping some for personal profit. With the case of GSK, the lack of a supervised body meant that forms of corruption including bribery were allowed to take place, which put GSK products into the domestic market at a faster rate whilst producing rapid profit.

⁷ "China's 12th Five-Year Plan."

⁸ "Health Insurance Systems in China," WTO

Without a sufficient fiscal base, money that should be invested into supervising and monitoring drug production is compromised, meaning that international regulations and domestic health standards are not always met. Therefore a controlled, disciplined body that overlooks processes including drug distribution or production is crucial to drive off any forms of fraudulent behaviour.

Out-of-Pocket Payments

The decline in subsidies from the central government for healthcare expenses has led to an increase in out-of-pocket payments. With the case of healthcare, out-of-pocket payments can refer to fraud in the form of bribery. For those who are unable to provide sufficient funds, access to healthcare is often restricted. An extreme, yet relevant example of these effects on individuals is the case of a Chinese farmer in 2012, who saw no choice but to cut off his own leg because he was unable to raise enough money to pay for relevant treatment.⁹ Although efforts have been made to provide subsidies to villagers, including rural health insurance schemes, there is still much to be done to ensure full economic support to China's rural residents.

Under China's current healthcare policies, where a universal healthcare coverage scheme is absent, those unable to pay have no choice but to opt for cheaper alternatives. This has led to the rise in counterfeit pharmaceuticals, as certain individuals begin to realize the potentials of a market that can provide cheaper, yet ineffective drugs to such a large and expanding population. By 2016, the Economist Intelligence Unit (EIU) suggests that China's population will reach 1.36 billion, many of which are unable to pay for genuine healthcare treatment. With China, fraud is not only becoming a concern of intellectual property, but a risk of health and safety for Chinese citizens.

For those who can afford out-of-pocket payments, this has also produced negative effects. According to a variety of data sources, more than 70% of Chinese hospital patients gave providers 'under the table payments or gift payments' to redeem quick and efficient medical assistance. Improper and illegitimate payments range from entertainment to cars and technology. On average, it was estimated that outpatients paid 140 to 320 yuan per hospital visit, to ensure

⁹ Abrahams, "Chinese Farmer."

quick and efficient treatment.¹⁰ Such grants equate to government subsidies.¹¹ Instead of putting it towards healthcare development, in some cases it is abused for individual interests. Out-of-pocket payments allow medical personnel to meet or even exceed medical expenditures and in some cases keep parts of payments for personal benefits.

For-Profit Incentives

The drive for a commercialized and partly privatized healthcare system has increased the opportunity of turning medical services into a for-profit enterprise, as ethical and regulatory compliance is subject to authoritative abuse or misconduct. Types of misconduct and improper treatment include over-prescription of drugs, over utilization of procedures that only increase out-of-pocket payments whilst doing little to better patient conditions. An investigation that examined detailed records of appendicitis and pneumonia patients discovered that one third of drugs prescribed were unnecessary and actually produced negative effects for patients.¹² Likewise, during 2000 and 2003, hospital visits dropped by almost 5% whilst profits increased by a staggering 70%.¹³ What this means is that medical personnel are continuing to keep illegitimate forms of payments for personal use, instead of investing into long-term healthcare upgrades. This suggests that the marketization of healthcare will continue to hold opportunities to jeopardize individual medical needs over financial funds. What the government can realize from the example is the importance of establishing a supervisory body that controls transactions and ensures legitimate activity. Without this, there is no guarantee that even medical personnel themselves can regulate on-going processes.

Given this, efforts to combat the arbitrary pricing and subscription of drugs and procedures are emerging. As seen with the National Development and Reform Commission (NDRC), measures to regulate medical care prices have been considered.¹⁴ Proper conduct and compliance to pharmaceutical regulations are all aimed at combatting incentives for doctors to over-prescribe or utilize costly medical procedures. The most crucial component for China's healthcare system is to

¹⁰ "Comparison of Health System in China and India."

¹¹ "Comparison of Health System in China and India."

¹² "Comparison of Health System in China and India."

¹³ "Comparison of Health System in China and India."

¹⁴ Wong, "China's Pharmaceuticals Market."

enhance coverage quality and to increase the extent of insurance coverage.¹⁵ Limited medical insurance coverage will only mean that individuals with lower incomes will continue to resort to counterfeit drugs, which are far cheaper than the genuine drugs.

Despite its challenges, China's healthcare system has continued to develop in a moderately sustained and beneficial way. By the end of 2011, it was estimated that medical and healthcare institutions across the country totaled at 954,000, an increase of 148,000 since 2003. Licensed doctors reached just under 2.5 million or 1.8 per thousand people, compared to 1.5 per thousand people as recorded in 2002; while the number of hospital beds reached 3.8 per thousand people, as compared to 2.5 in 2002.¹⁶ It is likely that China will also seen improvements to its insurance schemes in recent years. Under the New Rural Cooperate programme as well as the Urban Resident BMI programme, the next five years should see out-of-pocket payments limited to 30 percent by the end of the 12th FYP.¹⁷ Whether these reforms will follow through is often not certain.

Current and future reforms have also made China's healthcare more equitable, regardless of demographic factors. Systems have been put in place, aimed at reforming the livelihood of its urban and rural residents. Healthcare packages providing residents with free access to up to 41 basic public health services, including healthcare for children under the age of 6, healthcare for the elderly, maternity, healthcare supervision and so on, have been established all over the country.¹⁸ Key public specific healthcare programs specialized in addressing groups with specific diseases including Hepatitis B and AIDS are also becoming common in China; as now patients with diseases including malaria and leprosy are now provided medicine and treatment free of charge. The expansion of specialized facilities has also meant that infectious and threatening diseases can now be brought under control.¹⁹

¹⁵ Wong, "China's Pharmaceuticals Market."

¹⁶ State Council PRC, "Medical and Health Services in China."

¹⁷ "China's 12th Five-Year Plan."

¹⁸ State Council PRC, "Medical and Health Services in China."

¹⁹ State Council PRC, "Medical and Health Services in China."

PHARMACEUTICAL FRAUD CASE STUDIES:

As the government recognized the need for more investment, more money was put aside as seen with the 12th FYP. But more money in the system often means more opportunities for individuals, particularly those in authority to breach codes and abuse finances. The case in 2007 against China's former chief of SFDA confirms this. The former chief—Zheng Xiaoyu was accused of accepting bribes equating 6.5 million yuan from 8 different companies, then later executed.²⁰ The case of Zheng Xiaoyu especially, suggests that even those inherently loyal to the state and its people are willing to bypass regulations and standards by accepting illegitimate bribes. What the Chinese government now faces is how it will go about tackling current issues of fraud, and relevant policies it will need to establish that can help deter future fraudulent acts. Whether Xi Jinping's anti-corruption campaigns will continue to seek out “the tigers” of China's healthcare system is a persistent question.

A more recent example of pharmaceutical fraud were the allegations made against GSK—a British based pharmaceutical company in 2013. The firm was accused of bribing influential doctors within the healthcare system. This included expense-paid holidays often covered up as conferences or for meeting purposes.²¹ The details of the allegations made in the whistleblower's email also suggested that the firm falsified its records to conceal illegal practices including bribery and promoting the use of drugs, which had yet to be approved by the Chinese government.²² From the perspective of the Chinese government, examples like this reiterate just how willing medical personnel are willing to accept bribes and how necessary it is to prevent fraudulent acts from taking place in the future.

The case of GSK is particularly crucial for the government, as it suggests how easy it is for foreign companies to abuse weaknesses in China's healthcare system for personal use. Without instilling discipline into the system, opportunities for individuals to prioritize personal gain over public interest will continue to be a persistent problem.

²⁰ China Daily, “Chief SFDA executed.”

²¹ Gracie, “Systematic Bribery.”

²² Gracie, “Systematic Bribery.”



Recent cases in China have shown just how significant and damaging the production of counterfeit drugs can be. Exponential production and growth in unauthorized copies of one particular drug resulted to a decrease in sales to about \$242,000 U.S. dollars. After damages were addressed and those responsible were targeted, sales soared as high as \$1.2 billion U.S. dollars.²³ The total loss was just over \$1 billion U.S. dollars. Scott Davies from Pfizer, stressed the importance of addressing pharmaceutical fraud during an interview with BBC's Asia Business Report, stating that "governments need to see pharmaceutical fraud more than just an issue of intellectual property, more importantly as a health and safety issue". Otherwise the lack of compliance, regulatory capacity and proper conduct can only continue to fuel the growth of the counterfeit industry.

As a result of the rise in pharmaceutical fraud, many international companies are now encouraging the securing of source and supply chains of drug production and distribution, as well as increasing in the awareness of the country.²⁴ In December 2013, more than 1,300 people were arrested with accusations of selling counterfeit drugs online.²⁵ One way in which the government has tried to respond is by joining efforts between institutions to increase the transparency of supply chains, while informative methods of education including white papers have been distributed to relevant industries, alerting them of the possibility of illegitimate drug production.

PHARMACEUTICAL FRAUD—WHY SHOULD WE CARE?

The conduct of risk assessments and management to avoid any forms of pharmaceutical fraud is proving to be significant to businesses moving into China, particularly pharmaceutical organizations. Only recently, has there been a growth in institutions featuring services including international screening, conduct and compliance. Companies looking to invest in China require professional assistance when vetting for suppliers, partners or vendors.

²³ Developing Nations 511.

²⁴ Wong, "Drug Watchdog."

²⁵ Wong, "Drug Watchdog."



Concerns that need to be addressed may include:

- What is the history of fraud in this area? Would you consider it a high risk or a low risk?
- What is the risk assessment of this supplier within the last few years?
- Will importing these products in China pose as a threat to the community?
- Do existing sites in the area meet compliance demands, if not, how can we ensure that security processes meets such demands?

As a result, specialized services to tackle fraud as well as background checks on vendors and suppliers are now common services accessible in China. Providing relevant companies with strategies to mitigate risks is crucial to any company of any trade. Locating fraud gives organizations the knowledge of the causes and conduct of such behaviour, whether it is in the pharmaceutical or industrial sector. To ensure risk is being averted and that compliance and conduct by being followed by employees and employers, companies need to understand the driving forces behind the misuse and illegitimate methods of counterfeit production. This idea can be translated directly to the Chinese government, in relation to both challenges facing the healthcare system as well as the rise in pharmaceutical fraud in the state. Although pharmaceutical fraud continues to be a problem plaguing China, efforts made by international organizations as well as state actors that either tackle or help mitigate the issue are clear indicators that the problem has at least been acknowledged.

CONCLUSION

Despite reforms to upgrade parts of its sectors, pharmaceutical fraud continues to pollute China's healthcare system. The transition from a centralized, universal healthcare system to a partly privatized and decentralized service has provided leeway for issues including profit-for incentives, issues of funding and affordability. With China's growing population, many of who are unable to pay out-of-pocket payments for genuine drugs, cheaper, counterfeit drugs will continue to be on high demand if the coverage of medical insurance is not expanded. Accompanying this is the increase in opportunities for individuals to engage in fraudulent acts including bribery and misconduct of drug circulation as seen with the GSK and China's former chief of SFDA. Both examples show the lack of supervision and proper monitoring of processes and drug circulation that is evident within the healthcare system.



The reliance on local governments and the marketization of healthcare facilities has proven to be unsuccessful in preventing medical personnel and agents of the state in engaging in pharmaceutical fraud. What China now faces is what sort of reforms are necessary to identify current forms of pharmaceutical fraud, and what steps are vital to prevent this from happening in the future.

It is clear that while improper compliance and management continues to threaten existing businesses and institutions in China, there will continue to be a growing demand and need for specialized services to investigate fraud, and for due diligence to be conducted throughout the production, supply and distribution of chains.

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