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CHANGSHENG BIO-TECHNOLOGY CO. LTD. (CHINA): FALLOUT FROM the VACCINES SCANDAL[[1]](#endnote-1)

Professor Thompson S. H. Teo and Jialiang Liu wrote this case solely to provide material for class discussion. The authors do not intend to illustrate either effective or ineffective handling of a managerial situation. The authors may have disguised certain names and other identifying information to protect confidentiality.

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By 2017, China was the world’s largest producer of human vaccines, and the Chinese vaccine market was highly competitive with more than 40 vaccine manufacturers.[[2]](#endnote-2) In November 2017, Changsheng Bio-Technology Co., Ltd. (Changsheng), a pharmaceutical company based in Jilin Province, was reported for having falsified the production data of its diphtheria, pertussis, and tetanus (DPT) vaccines and for having sold 252,600 substandard DPT vaccines to Shandong Province.[[3]](#endnote-3) As a result, Jilin authorities fined the company US$380,610[[4]](#endnote-4) and confiscated $126,683 of assets from its vaccine sales.[[5]](#endnote-5)

Only months later, the company was again reported for having falsified the production and inspection data for a Vero cell rabies vaccine.[[6]](#endnote-6) When this news was anonymously released through social networking sites WeChat and Weibo, it quickly sparked an unprecedented outrage among the public. The falsification of the data was later publicly confirmed by the China Food and Drug Administration (CFDA) investigation team in July 2018.[[7]](#endnote-7)

The estimated loss of six month’s net profit could potentially have amounted to ¥140 million[[8]](#endnote-8) due to the recall of vaccines, not to mention the tremendous loss in the company’s goodwill and reputation.[[9]](#endnote-9) As Changsheng was one of the market leaders in vaccine production and sales, what had motivated it to repeatedly resort to manufacturing substandard vaccines and fabricating its production and inspection data? What actions could Changsheng take to mitigate the effect of this scandal?

CHANGSHENG BIO-TECHnology

Changsheng was founded on August 18, 1992, with its headquarters in Changchun, China. In Chinese, the name *Changsheng* refers to “long life.” It was the second-biggest Chinese supplier of rabies vaccines and chickenpox vaccines in 2017.[[10]](#endnote-10) Changsheng was a state-owned enterprise until it was privatized in 2003 when a management buyout occurred. At that time, Gao Junfang, the company’s former chair, had a 35 per cent stake amounting to ¥40 million. Before the emergence of the vaccine scandal, Changsheng had a market value of about ¥24 billion.

Led by Gao, Changsheng enjoyed robust growth over the next 15 years. Gao was more famously known as China’s “vaccine queen,” and was acknowledged as being one of the wealthiest women in China. According to her former colleagues, Gao was extremely knowledgeable in the field of finance. With her easy-going personality and commendable social skills, she was well liked by her superiors when she first joined the company.[[11]](#endnote-11)

The company had been actively engaged in research and development (R&D), as well as the sale of human vaccines, such as DPT, rabies F and V, influenza, and varicella. Over the past five years, Changsheng had achieved an average gross profit margin of 64.87 per cent, with nearly 98.3 per cent of sales coming from mainland China in 2017.[[12]](#endnote-12)

Changsheng was one of the dominant players in the Chinese biopharmaceutical industry, and its R&D expense-to-revenue ratio amounted to 7.87 per cent in 2017, which was significantly lower than both its domestic competitors—BioKangtai at 10.27 per cent and Walvax Biotechnology Co. at 49.87 per cent—and international industry giants GlaxoSmithKline at 14.80 per cent and Pfizer at 14.47 per cent.[[13]](#endnote-13) While other domestic and international competitors aimed for their R&D efforts to remain competitive, Changsheng was more conservative, perhaps in an attempt to reduce costs.

With the full implementation of China’s two-child policy in effect since October 2015, the projected number of newborns in China remained approximately 18 million per year for the next five years. This projection created a consistent demand for children’s immunizations in the domestic market. Prior to the scandal, Changsheng’s net profit for the first half of fiscal year 2018 had increased by 30 per cent to 60 per cent,[[14]](#endnote-14) which was largely attributed to the considerable increase in sales revenue of its vaccine products.

PARTIES INVOLVED

Several parties and entities were involved throughout the scandal—Changsheng, the Chinese government and its regulatory bodies, and the Chinese media. The sections below discuss how each of the key parties played a role in the events.

Changsheng

As a key player in the biopharmaceutical industry, Changsheng produced about 23 per cent of China’s rabies vaccines in 2017. Rabies vaccines accounted for over 50 per cent of the sales revenue for the company, and the fabrication of production and sales data seemed to serve as a cost-cutting measure.[[15]](#endnote-15) It was later discovered that Changsheng had been violating regulations in its vaccine production and sales processes by falsifying relevant data since April 2014.[[16]](#endnote-16) However, no significant actions were taken by Changsheng before the scandal, and the company kept yielding favourable gains from the practice. According to findings from the government investigation, Gao led the company with the goal of maximizing its profit margins, which led to managers neglecting the production protocols necessary to ensure quality products, forging production data, and other misconduct.[[17]](#endnote-17)

Further, in the past decade, Changsheng was reported to have been involved in at least 10 bribery cases, according to court rulings accessed through China Judgments Online. For example, a staff member from a disease prevention and control centre in Suxian County was found guilty of having, since July 2011, accepted bribes of more than ¥1 million from vaccine makers or agencies, including ¥124,680 from Changsheng. He was fined ¥200,000 and jailed for 18 months. However, in such reported cases, companies that paid bribes were rarely prosecuted, as the bribe amount was often insufficient to invoke a harsher penalty, and many other companies were offering bribes. Changsheng’s involvement in bribery cases did not have a substantial impact on its profits.[[18]](#endnote-18) However, the company was adversely affected in July 2018 when an unannounced inspection found that it had falsified data and produced substandard human vaccines.

Chinese Government and Regulatory Bodies

The Jilin Provincial Food and Drug Administration (JPFDA) started its investigation into the faulty DPT vaccines in October 2017. Changsheng was later fined ¥3.4 million for this issue on July 20, 2018.[[19]](#endnote-19)

On July 15, 2018, the China Food and Drug Administration (CFDA) conducted a Good Manufacturing Practice (GMP) inspection unannounced on Changsheng’s Vero cell rabies vaccines based on an anonymous insider report. It turned out to be an abrupt turning point for Changsheng. During the investigation, some batches of vaccines were discovered to have been mixed with expired ingredients during the production process. Inconsistencies were also observed in terms of batch production dates and batch numbers of vaccines.[[20]](#endnote-20) The faulty vaccines were identified as having been administered in Chongqing, Hebei, and Shandong, and it was likely that they were also administered in other areas.[[21]](#endnote-21)

The inadequate supervision from government regulators, the irresponsible inspections, and the lack of media coverage had propagated a culture of deception and profit manipulation in Changsheng, and ultimately resulted in the “China vaccines scandal.” The scandal affected President Xi Jinping’s plan to regulate and grow the pharmaceutical industry as part of his “Made in China 2025” industrial policy. By assigning the State Council to immediately investigate the incident, the Chinese government acted quickly to mitigate fallout from the scandal.[[22]](#endnote-22)

The State Council found that 252,600 substandard DPT vaccines were sold to disease control and prevention centres in Shandong Province in East China, and over 113,000 rabies vaccines were proven to have been substandard.[[23]](#endnote-23) The company’s GMP certificate was revoked by the JPFDA under the request of the CDFA shortly after,[[24]](#endnote-24) and its pharmaceutical production licence was also revoked by the JPFDA.[[25]](#endnote-25)

The Drug Regulatory Process in China

With regard to vaccines, China had adopted a state-controlled drug approval system that comprised two major categories.[[26]](#endnote-26) Category 1 vaccines, such as those for hepatitis and measles, were included in the mandatory government immunization program and were administered free of charge. Category 2 vaccines, such as those for pneumonia and varicella, were administered voluntarily and could be sold for a profit. Approximately 80 per cent of the vaccines available in China were Category 1 vaccines and were mostly supplied by Chinese companies. The remaining 20 per cent consisted of Category 2 vaccines, which could be imported from foreign companies. The government’s mandatory immunization program restricted the involvement of foreign pharmaceutical products. The DPT vaccine was in Category 1 while the rabies vaccine was in Category 2.[[27]](#endnote-27)

Chinese firms were expected to meet government regulation standards, which were less strict than those applied to the same vaccine products by foreign drug makers. The CFDA had renewed Changsheng’s rabies vaccine licence three months before the scandal broke out in July 2018.[[28]](#endnote-28) China had adopted a protectionist stand in its vaccine policy, and the Chinese pharmaceutical companies had thrived in that market. For example, the licence for Pfizer to sell Prevenar 7 (a pneumococcal vaccine) was not renewed in 2015, and no reason was given, although a Beijing-based finance magazine speculated that this move was taken to give domestic pharmaceutical companies more time to develop their own pneumococcal vaccines.[[29]](#endnote-29)

The Chinese Media

Media control was a common practice under the Chinese government. It was noteworthy that the previous misconduct in the manufacture of Changsheng’s DPT vaccines was discovered in November 2017. In fact, the distribution and use of substandard DPT vaccines in Shandong Province was halted,[[30]](#endnote-30) and parents of infants missed any opportunity to protect their children.

The news that Changsheng had fabricated records and was then forced to cease manufacturing rabies vaccines exploded on social media in July 2018. The scandal was driven by an online essay that alleged that these misdoings, including the act of bribing officials to allow the sale of poor-quality products, had been going on for many years. Although the origin of the post was unverified, news had spread quickly, as millions of online users shared the essay on social media. The result was a public outcry of a sensitive national issue. One mother commented, “We always say kids are the nation’s future, but if we can’t ensure the safety of such a future, what does the future hold for us?” The pressure on the investigation authorities eventually led to further revelations. Regulation authorities announced that the production of DPT vaccine had stopped at Changsheng and a new corruption investigation would be opened. A commenter on the Weibo blogging site responded: “If you’re just investigating yourself, what kind of results will come out?”[[31]](#endnote-31)

The public was outraged by this scandal because it endangered the lives and health of babies. Celebrities criticized the misconduct on Weibo, despite a government attempt at censorship.[[32]](#endnote-32) The Baidu search index for “vaccines” was five times greater within a couple of days,[[33]](#endnote-33) which led to a rare protest by about a dozen people outside the National Health Commission (formerly the Ministry of Health) in Beijing. Videos of the protesters holding banners with captions focusing on the subjects of justice and accountability circulated widely on social media. The protesters were shown shouting, “Legislation for vaccines is imperative! Handle this properly and responsibly!” The protesters were quickly removed from the scene, and it was not known what happened to them afterward. Note that Chinese security personnel often reacted quickly to stop public expressions of dissent.[[34]](#endnote-34)

Shortly after the scandal broke out and as word began to spread online, the Chinese word for “vaccine” became one of the most censored words on Weibo. In addition, a Shenzhen media group reported that authorities had issued an order to ban all coverage of the scandal. A father who suspected that a DPT vaccination was the cause of his son having developed epilepsy in 2013, responded that “there is no press freedom, no judicial fairness. . . . If these [fundamental] rights granted by the constitution can’t even be guaranteed, relying on government-initiated investigations won’t make much of a difference.”[[35]](#endnote-35)

The public faith in Chinese-made products fell drastically. Despite media coverage of the Chinese government’s immediate actions, parents began sending their infants to Hong Kong for vaccinations.[[36]](#endnote-36)

REMEDYING THE SITUATION

Government Reactions, Recall, and Inoculation

All production of related rabies vaccines was halted across Changsheng’s plants, and vaccines on the market were recalled. Production was suspended indefinitely until further notice was provided to the public.

Premier Li Keqiang urged for an immediate government investigation into the entire process chain of vaccine production. He even stated that the company’s misconduct had “crossed a moral line.”[[37]](#endnote-37) During a diplomatic visit to Africa, President Xi Jinping ordered Jilin authorities to proceed with a full-scale investigation to restore social stability, and criticized Changsheng’s misconduct as “serious and appalling.”[[38]](#endnote-38) Immediately after several government officials made their responses regarding the scandal, many parents took to social media to express their skepticism. A hashtag that referred to the scandal received millions of views on Weibo.[[39]](#endnote-39)

The director of the Immunization Management Department at the Shandong Centre for Disease Control and Prevention, Song Lizhi, was responsible for approving the administration of the rabies vaccines in Shandong. Approximately 210,000 children had been administered the faulty vaccine in that province. On July 24, 2018, it was reported that Song had attempted suicide.[[40]](#endnote-40)

On August 8, the National Health Commission (NHC) and the CFDA issued a follow-up inoculation plan for all people, especially the infants, who had received rabies vaccines produced by Changsheng.[[41]](#endnote-41) All such patients could receive follow-up vaccines for free. Within two weeks, about 76 per cent of the affected infants had been administered remedial medication. By the end of the State Council investigation, there was no report of children being harmed by the substandard rabies vaccines.[[42]](#endnote-42)

On August 18, six senior officials at the JPFDA were dismissed due to their inadequate supervision.[[43]](#endnote-43) Later, two more officials—Liu Changlong, the mayor of Changchun, and Li Jinxiu, the vice-chairman of the Chinese People’s Political Consultative Conference Jilin Provincial Committee—resigned from their positions.[[44]](#endnote-44) According to Article 82 of China’s *Civil Servant Law*, a leading member should voluntarily resign as a leader if he or she was responsible for a serious negligence of duty. Anyone who failed to do so would be ordered to resign.[[45]](#endnote-45)

After the Changsheng scandal, the State Drug Administrator (SDA) announced an expansion of the investigation into vaccine drug-making companies. The SDA dispatched multiple teams in the investigation of the production chain of each individual Chinese vaccine producer. Officers from the National Supervisory Commission, the Ministry of Public Security, the National Health Commission, and the China Securities Regulatory Commission reported directly to these teams.[[46]](#endnote-46) This move was intended to regain public confidence in Chinese vaccines.[[47]](#endnote-47)

Apology and Arrest

On July 15, the company expressed its “deepest apology”[[48]](#endnote-48) and recalled the faulty rabies vaccines. Immediately afterward, Changsheng’s stock price dropped by the daily limit of 10 per cent. The scandal then blew up on July 21, 2018, as an anonymous Chinese blogger posted an article about Changsheng on WeChat, and it went viral.[[49]](#endnote-49)

On July 29, 18 executives of Changsheng, including Gao Junfang, the board chair, were arrested on suspicion of illegal production and sale of substandard DPT and rabies vaccines. On October 16, 14 executives who were directly responsible for the scandal, including Gao Junfang, were banned for life from engaging in drug production or other related activities.[[50]](#endnote-50) China’s top security regulator imposed on Changsheng a fine amounting to ¥9.1 billion,[[51]](#endnote-51) which included the net worth of the confiscated DPT and rabies vaccines. An individual fine of ¥300,000 was also imposed on each of the four executives who were found to have been directly responsible for the scandal. Many users on social media expressed their views on the fine—one user wrote on Weibo, “Shouldn’t the [US$1.3 billion] fine be used to compensate victims . . . instead of filling the state coffers?”[[52]](#endnote-52)

The vaccines scandal inevitably led to emotional outbursts among the public, and further deteriorated the public’s confidence in the safety of Chinese-made products, which was already evidenced by their changes in consumption behaviours after the notorious Sanlu milk scandal in 2008.[[53]](#endnote-53)

REPEATED INCIDENTS

Over the past decade in China, several incidents of faulty human vaccines had been reported. In 2009, over 320,000 doses of a human rabies vaccine were proven to be contaminated with nucleic acid, an illegal catalyzer that was intended to enhance the vaccine’s overall effectiveness but had not yet been approved for human use.[[54]](#endnote-54)

In 2010, a five-year old boy died after being injected with a counterfeit rabies vaccine. Further investigation identified more than 1,600 people who were treated with the same batch of the vaccine, leading to further public distrust and anger.[[55]](#endnote-55) Nevertheless, amid the widespread public concern, the World Health Organization (WHO) expressed confidence in the Chinese vaccines and stated that the illegal misconduct would not lead to further sanctions after thorough investigations.[[56]](#endnote-56) Gauden Galea, China’s representative to the WHO, stated that “We can rest assured that there will now be more unannounced inspections.” Galea also mentioned that clinical trials, and assessments of safety, purity, and efficacy were going to take place more often.[[57]](#endnote-57)

In March 2016, a former doctor and her daughter were accused of having illegally stored and sold vaccines worth ¥570 million through a private distribution network over a five-year period.[[58]](#endnote-58) Over 300 dealers in 24 provinces were involved.[[59]](#endnote-59) As a result, more than 357 officials were dismissed, and 202 suspects were arrested.[[60]](#endnote-60) Tighter regulations to prevent illegal private distribution of vaccines and increased punishments were widely anticipated.

FINAL THOUGHTS

With its increasing global influence, China had been actively engaged in regional economic initiatives such as the Belt and Road Initiative and the Asian Infrastructure Investment Bank. However, the vaccine scandal tarnished China’s reputation as a global exporter and downgraded the country’s credit rating as a manufacturer. It was therefore important to analyze why a market-dominant player such as Changsheng had taken such audacious moves.

Based on financial data,[[61]](#endnote-61) Changsheng had outperformed the industry by a substantial margin over five years, from 2013 to 2018. With such a lucrative business and long-proven success, what factors had driven the CEO of Changsheng to ignore the laws and regulations for profit gain? What actions could Changsheng take to mitigate the effect of the scandal?

Exhibit 1: TIMELINE OF EVENTS in the changsheng bio-technology co. ltd. vaccines scandal

|  |  |
| --- | --- |
| **Time** | **Event** |
| November 2017 | Changsheng was reported for having falsified the production data of a diphtheria, pertussis, and tetanus (DPT) vaccine and having sold 252,600 substandard DPT vaccines. The substandard vaccines might not have provided effective immunization for infants. As a result, Changsheng was subjected to a fine of US$380,610 and confiscation of US$126,683 worth of assets.  Hospitals were ordered to stop the administration of vaccines from the faulty batches. Changsheng stated that although the vaccines were faulty, they were only ineffective and not detrimental to the health of patients. |
| July 15, 2018 | The China Food and Drug Administration (CFDA) conducted an unannounced Good Manufacturing Practice (GMP) inspection on Changsheng’s Vero cell rabies vaccines based on an anonymous report.  All production and sales of the related rabies vaccines were halted in the following days after Changsheng was confirmed as having falsified data during its operation processes.  Changsheng recalled the rabies vaccine and expressed its “deepest apology.” |
| July 20, 2018 | Changsheng was fined ¥3.4 million due to its faulty DPT vaccines. Jilin Provincial Food and Drug Administration (JPFDA) started its investigation into the DPT vaccines in October 2017. |
| July 21, 2018 | An anonymous Chinese blogger posted an article about Changsheng on WeChat, and it went viral. It was deleted a day later. |
| July 22, 2018 | Li Keqiang (the incumbent Chinese premier) urged for a government investigation into the entire process chain of all vaccine production and sales. He emphasized the conduct “. . . crossed the moral line.”  During his diplomatic visit to Africa, Xi Jinping (the incumbent Chinese president) ordered the JPFDA to form an investigation team and proceed with investigations immediately to restore social stability. He commented, “The violations by Changchun Changsheng Bio-Technology are serious and appalling.” |
| July 29, 2018 | Authorities arrested 18 executives of Changsheng, including Gao Junfang, Changsheng’s board chair, on suspicion of illegal production and sales of vaccines that failed to meet the safety standard. |
| August 6, 2018 | The investigation team from the State Council announced that Changsheng had been violating regulations in its production and sales processes of vaccines since April 2014.  Some batch vaccines were discovered to have been mixed with expired ingredients during production. Discrepancies were also noted in the batch production dates and the batch numbers of vaccines. |
| August 7, 2018 | The National Health Commission and the CFDA issued a follow-up inoculation plan for the patients who had received rabies vaccines produced by Changsheng. |
| September 19, 2018 | Changsheng’s GMP certificate was officially revoked. |
| October 16, 2018 | The JPFDA confiscated Changsheng’s pharmaceutical production licence.  Fourteen executives at Changsheng, including Gao Junfang and others who held direct responsibility for the scandal, were banned for life from engaging in drug production or other related activities.  China’s top security regulator imposed on Changsheng a fine of ¥9.1 billion (including the confiscation of illegally produced vaccines) and an individual fine of ¥300,000 on each of the four executives who were found to have been directly responsible through the investigation.  The suspects were held criminally responsible and prosecuted for their involvement in the production and sales of substandard DPT and rabies vaccines. |

Note: ¥ = RMB = Chinese yuan; ¥1 = US$0.15 in November 2017.

Source: Preetika Rana, “China to Investigate Vaccines after Safety Problem,” MarketWatch, July 23, 2018, accessed October 23, 2018, www.marketwatch.com/story/china-to-investigate-vaccines-after-safety-problem-2018-07-23; Xuequan Mu, “China’s Vaccine Maker Ordered to Stop Production, Subject to Investigation,” Xinhua, July 23, 2018, accessed October 23, 2018, www.xinhuanet.com/english/2018-07/23/c\_137341693.htm; Xinhua, “Li Says Vaccine Scam Crossed Moral Line, Production Stopped,” *China Daily*, July 23, 2018, accessed October 23, 2018, www.chinadailyhk.com/articles/79/163/67/1532340686749.html; Ziyan Chen, “Follow-up Inoculation Plan Issued for Defective Rabies Vaccine Recipients,” *China Daily*, August 8, 2018, accessed October 23, 2018, www.chinadaily.com.cn/a/201808/08/WS5b6a9798a310add14f384a83.html; “Vaccine Maker Changsheng Fined $1.8 Billion in Safety Scandal,” Asia One, October 17, 2018, accessed November 23, 2018, www.asiaone.com/china/vaccine-maker-changsheng-fined-18-billion-safety-scandal; Adam Jourdan, “The Unfolding of China’s Changsheng Vaccine Scandal,” Reuters, July 24, 2018, accessed June 7, 2019, https://uk.reuters.com/article/uk-china-vaccines-timeline-factbox/the-unfolding-of-chinas-changsheng-vaccine-scandal-idUKKBN1KE1M4.

ENDNOTES

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