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Working Paper

The Politics of Blood Safety Regulation in China: The Blood Plasma Economy and the Making of China's Blood Safety Regulatory Regime

Working Paper, No. 285

Provided in Cooperation with:

George J. Stigler Center for the Study of the Economy and the State, The University of Chicago Booth School of Business

Suggested Citation: Yang, Dali L. (2018) : The Politics of Blood Safety Regulation in China: The Blood Plasma Economy and the Making of China's Blood Safety Regulatory Regime, Working Paper, No. 285, University of Chicago Booth School of Business, Stigler Center for the Study of the Economy and the State, Chicago, IL

This Version is available at:

<https://hdl.handle.net/10419/262687>

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Stigler Center

for the Study of the Economy and the State

**The Politics of Blood Safety Regulation in China:
The Blood Plasma Economy and the Making of
China's Blood Safety Regulatory Regime**

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December 2018

New Working Paper Series No. 30

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The Politics of Blood Safety Regulation in China:
The Blood Plasma Economy and the Making of China's Blood Safety Regulatory Regime

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Abstract: In the 1980s, Chinese regulators were quick to impose tough restrictions on the import of blood products into China when HIV/AIDS first came to light in industrialized countries. In spite of such precautions, China still ended up with a massive blood-related HIV/AIDS crisis, particularly among blood sellers in Henan Province.

This study examines the evolution of China's blood safety regulatory regime in the age of market-oriented reforms and HIV/AIDS. I first describe how the push by local authorities in Henan to develop a blood plasma economy turned into a blood plasma fever that spread HIV/AIDS with deadly efficiency in spite of central government efforts to prevent the spread of HIV/AIDS through the use of imported blood products. I next examine the responses or non-responses to the ensuing tragedy. Warning signals were ignored and suppressed, whistleblowers were pushed out, and for years the HIV/AIDS carriers were left on their own. It was not until the 2003 SARS crisis that China's new leaders took public health issues seriously and adopted decisive measures to tackle the HIV/AIDS crisis in Henan. Meanwhile the (then) Ministry of Health responded with greater alacrity to adopt vigorous reforms of the blood collection and supply system.

By dissecting the politics of China's efforts to remake its blood safety regulatory regime, this study offers a unique lens for better understanding China's struggles to reform the economy and build a regulatory state.

Advances in medical procedures and treatments have dramatically increased the demand for blood and blood products. The increased demand, however, has strained the capacity of many societies to meet it, in terms of both quantity and quality. Blood can be the carrier of a variety of blood-borne diseases, including hepatitis B and C, HIV/AIDS, viral hemorrhagic fevers, and syphilis, as well as diseases that are normally transmitted by insects, such as malaria. Thus the growing use of blood and blood products has been accompanied by the need to ensure the safety of blood supply.

In the mid-1980s, a scourge quietly descended on the hemophiliac population that depended on blood products and tens of thousands of recipients of blood transfusion. This scourge, caused by HIV-tainted blood and blood products, spread disaster across the industrialized countries in North America and Europe as well as Australia and Japan. It sent shock waves through these societies, and the ensuing scandal politics shook up the blood establishment in every country.¹

This study examines the evolution of China's blood safety regulatory regime in the age of market-oriented reforms and HIV/AIDS. I first note that Chinese regulators were quick to impose tough restrictions on the import of blood products when HIV/AIDS first came to light in industrialized countries. This regulatory move did not prevent the spread of HIV/AIDS in China, however. Instead, the imposition of tough restrictions on the import of foreign blood products was accompanied by a massive drive to take advantage of China's "clean" blood to develop a blood products industry within China, but without implementation of China's own regulations on blood collection and processing. This combination resulted in a massive tragedy, especially in Henan Province. The second portion of this study thus describes how the push by local authorities in Henan to develop a blood plasma economy turned into a blood plasma fever that spread HIV/AIDS with deadly efficiency.

The study next turns to the responses to the ensuing tragedy. Warning signals were ignored and suppressed, whistleblowers were pushed out, and for years the HIV/AIDS carriers were left on their own. It was not until the 2003 SARS crisis that China's new leaders took public health issues seriously and adopted decisive measures to tackle the HIV/AIDS crisis in Henan. Meanwhile the (then) Ministry of Health responded with greater alacrity to adopt vigorous reforms of the blood collection and supply system.

By focusing on the crisis and transformation of China's blood regulatory system, this study not only allows us to better understand the political struggles over the development of this system per se but also permits us to open a special window onto China's development and governance in the post-Mao era.

The Global HIV/AIDS Crisis and China's Development of Indigenous Blood Products

Isolated from the rest of the world during the era of Mao, China was late to the global trends described above. In the late 1970s, as China began to emerge out of isolation, experts in biological products research, led by Liu Junxiang (刘隽湘), eagerly followed international developments and advocated the adoption of plasmapheresis for the collection of blood plasma in order for China to begin producing blood plasma and blood products. In 1979, the Chinese Ministry of Health (MOH) approved plasmapheresis.

Plasmapheresis using fractionation was initially adopted in blood stations affiliated with China's biological products research institutes based in major cities (Beijing, Chengdu, and Wuhan) and drew on the college population as donors. Soon plasmapheresis spread beyond the major cities to populous provinces such as Hebei, Henan and Shandong. In 1985 the number of blood donations for plasmapheresis reached more than 800,000.² Nonetheless, China at the time was heavily dependent on imported blood products.

It was around this time that public health officials in the major industrialized countries discovered infections with the human immunodeficiency virus (HIV) among the large number of hemophilia sufferers who used blood products as well as tens of thousands of people who received blood transfusions.³ HIV was found to cause the acquired immunodeficiency syndrome (AIDS), which was first recognized by the US CDC (Centers for Disease Control and Prevention) in 1981. According to Zeng Yi, a Chinese professor who acquired a supply of plasma-derived Factor VIII (Antihemophilic Factor or AHF) from Armour Pharmaceutical Company, four of the Chinese patients who used this product between 1983 and 1985 became infected with AIDS.⁴

Wary Chinese regulators watched the discovery of HIV/AIDS with vigilance. In 1984, the Chinese Customs Administration, the Ministry of Health, and the Ministry of Foreign Trade and Economic Cooperation jointly announced precautionary measures against imported blood products. The directive noted that China was spending a considerable amount of precious foreign

exchange to import blood products. AIDS had already killed several thousands of people in the United States and other countries, and there was concern that AIDS could be spread through the use of blood products. The directive recognized that China still lacked adequate capacity to detect AIDS and thus, as a precautionary measure, would strictly limit the import of human plasma and blood products such as human albumin, human immunoglobulin, and Factor VIII.⁵ The following year, with the discovery of HIV infections from the use of Factor VIII, the partial restriction was converted into an outright ban (some exceptions were allowed, subject to strict approval procedures).⁶

The restriction on foreign imports to keep HIV/AIDS outside of China was coupled with a call for boosting domestic production capacity. China then produced only about 1.2 tons of human albumin per year, an amount that was far below demand. With approval by the State Planning Commission, two biological products research institutes then under the MOH were authorized to import foreign technology and equipment for plasmapheresis in order to raise China's human albumin output to 12 tons.⁷ This move marked a major push for China's blood-based bio-products sector, and the number of blood products manufacturers in China grew rapidly.

China then did not have the equivalent of the USFDA to regulate drug manufacturers.⁸ Instead, the MOH, then led by Dr. Chen Minzhang (陈敏章), served as the de facto regulator. Dr. Chen was a pioneer in hospital reforms in the early 1980s at the Capital Hospital (now PUMC Hospital) and became health minister in April 1987. As Minister, Chen showed a special interest in public health issues. In April 1988, the MOH recognized that "many units producing blood products had chaotic management and the quality of their products was poor."⁹ The MOH directive asked provincial-level health bureaus to "rectify" production management of blood products. Blood givers were to be tested for HBV and HIV. Blood products manufacturers were expected to improve quality management under the supervision of health bureaus. The provincial-level health bureaus were also told to suspend the approval of new producers of blood products.¹⁰ In fall 1988, the MOH issued a set of detailed rules for blood products makers "to conduct self-checks" prior to approval by health administrators.¹¹

The 1988 "rectification" had a limited effect at best. Two years later, the MOH issued at least three new documents to regulate blood products production as well as blood transfusion. These documents referred to the proliferation of blood products producers, the

commercialization of blood, the intense competition among blood stations, the existence of underground blood banks and stations, the exploitation of blood donors by “blood heads (who connected the donors with the blood banks or stations),” the adulteration of blood with water, the trading of blood plasma, and the failure to conduct proper tests. The documents stipulated rules concerning the sourcing of blood, including a ban on underground blood stations, and reiterated the need to strictly regulate the issuance of production licenses and permits for the production of blood products.¹² In short, many problems in the sourcing and supply of blood that would be blamed for the HIV/AIDS epidemic in Henan were already in existence by 1990 and were not confined to Henan Province alone.

Developing China’s Blood Plasma Economy: Profit at the Expense of Public Health?

By the turn of the 1990s, much of the Chinese state sector was losing money. In contrast, the production of blood products was recognized for its investment potential because of growing domestic demand and severe restriction on foreign imports. Foreign exchange was scarce in China, and leaders saw the blood products industry as having export potential for earning foreign exchange.¹³ There was also a palpable sense among certain policymakers that, following decades of draconian Communist rule, Chinese society was largely free of the ills that Chinese propaganda commonly associated with the “decadent” West (and Japan) and thus had a vast reservoir of population with clean blood that could be mobilized for this emerging sector.

Following Deng Xiaoping’s Southern Tour in 1992 to reinvigorate the economic reform agenda, China’s leadership—with Jiang Zemin as General Secretary and President—shifted gears from emphasizing economic austerity in the aftermath of Tiananmen to the promotion of economic reforms. Chinese society responded to the new policy initiatives with enthusiasm and went into a “business fever”, or, literally known as “the entire people go into business”, *literat* (全民经商). Responding to Deng’s call for reforms, Health Minister Chen Minzhang led the drafting of a set of guidelines on deepening health reforms. These guidelines, promulgated in September 1992, called for raising funds from multiple sources to invest in health. Medical and health establishments were urged to actively develop sidelines and other industries that were extensions of medical and health services so as to generate revenue that could be plowed back into support for medicine.¹⁴ In short, health and medicine became part of the national business fever.

Amid this business fever, attention was directed toward the development of a blood plasma economy that focused on the collection of human blood and the processing of that blood into plasma and other blood products. Such an opportunity attracted special attention in the predominantly agricultural areas of China, which had difficulty attracting manufacturing industry investment. In the early 1980s the Chinese countryside enjoyed an income boom from institutional reforms and price support, but by the turn of the 1990s the agricultural areas of China had entered into a period of stagnant growth and heavy “peasant burdens.”¹⁵ The province of Henan in central China became well known for its blood plasma economy because of the explosion of HIV/AIDS cases there, but other provinces, including major agricultural provinces such as Anhui, Guizhou, Hebei, Hubei, and Shandong, also became significant players.

The key policy entrepreneur of Henan’s blood plasma economy was Liu Qunxi (刘全喜), who was appointed as Director General of the Henan Provincial Health Department in 1992. Liu saw major potential in the blood plasma economy. Speaking at a meeting of health officials in Henan in early 1993, Liu called for vigorously setting up more blood stations as a route to economic development:

Henan has more than 90 million people and more than 80 percent of them are farmers. Even if only 1-3 percent of the 70-plus million farmers are willing to sell blood once to twice a year each, we would be able to create 100 million yuan in value if we collect the blood and sell it to biological products companies. [This measure] may also count as a method for helping farmers to escape poverty. Why don’t we open our minds and use our brains this way? Each official must work to benefit his area. I think one way [for us to bring such benefit] is to set up blood stations; we should make major efforts and produce real results. [We should] make domestic and foreign linkages and attract foreign capital. Our country doesn’t have AIDS and boasts of clean blood that should be desirable abroad. We should bring together funds in society and mobilize the entire society to set up blood stations.¹⁶

Liu Quanxi gave a push to the blood plasma economy by having the Health Department sign a contract with the Henan Red Cross Blood Center. The “responsibility contract” more than doubled the financial target to be met by the Red Cross Blood Center to 20 million yuan, with specific targets for the output of human albumin and globulin.¹⁷ Liu and the Health Department also promoted the experiences of the ancient city of Kaifeng in building blood stations and thus

set an example for others to emulate. Liu Quanxi also personally led delegations to visit the United States in 1993 and 1994 in the hope of persuading American blood products manufacturers to invest in Henan.

In spring 1993, prompted by new findings that showed growing numbers of hepatitis infections among blood sellers (more on this later), Health Minister Chen Minzhang made a tough-minded decision to “rectify” blood plasmapheresis operations across the country.¹⁸ In March 1993, the MOH issued a set of regulations on the management of blood sourcing and supply organizations and of blood quality, to become effective on July 1, 1993.¹⁹ The regulations stipulated that provincial-level health departments had the authority to issue permits for establishing and operating whole blood and blood plasma collection stations and central blood banks and to set the standards and various qualifications for successful applications. It also directed provincial-level health departments to tighten planning so that each city or county should establish a single blood station or central blood bank and avoid duplication (Art. 9). In August 1993, Henan issued its own “Henan Province Essential Standards for Blood Plasma Stations” (河南省单采血浆站基本标准).

Despite the promulgation of the MOH standards and regulations, the Henan Health Department led by Liu Quanxi didn’t exercise restraint in issuing permits for blood stations and instead focused its efforts on boosting the blood plasma economy.²⁰ Organizations under the supervision of the Health Departments, including Health and Epidemic Prevention Stations (卫生防疫站) and some hospitals, generally had few significant money making opportunities and naturally were first in line to receive permits. Yet, numerous other interests were also enticed by the opportunity to make some quick money and to boost employment. Such sentiment wasn’t confined to Henan, either. “It was then more lucrative doing blood plasma than selling illegal drugs,” said Chen Changjian (陈昌建), who worked at the Guizhou Provincial Blood Center in the 1990s.²¹

Inundated with requests by non-health related interests to set up blood plasma collection stations, the Henan Health Department allocated permits quite liberally. There were blood stations affiliated with the army, the police, the militia, the coal industry and bureaus of materials supply, factories, township enterprise offices, and even a county people’s congress.²² Blood products research institutes affiliated with the Jinan Military Region and the Air Force, as well as the Shanghai Bio-products Research Institute, all established dedicated blood collection stations

in Henan.²³ And Liu Quanxi's own family also had a slice of the cake; with Liu's backing, Liu's sister set up a blood plasma collection station in Yancheng (郾城) that became a virtual monopoly for the area.²⁴

A "fever" for building blood stations swept across Henan. In Taikang County of Zhoukou Prefecture, the number of blood plasma collection stations jumped from only one in 1991 to seventeen in 1993. They were mostly operated by the Epidemic Prevention Center or by the county hospital.²⁵ At the height of the blood station fever, Henan Province had a total of between 230 to 400 blood stations.²⁶ Some underground stations also came into being. Much of the blood plasma collected was exported to other provinces for further processing. To capture the value added from the plasma economy, the Henan Provincial Biological Products Institute (河南省生物制品研究所) ramped up its production capacity for human albumin.

While Henan became especially notorious for the number of blood stations launched during this time, a number of other provinces were also building more blood stations. In Guizhou's Huishui County (惠水县), the county hospital pooled funds from hospital employees to set up a blood plasma collection station. The province set a uniform price for blood plasma collected from the counties for sale to blood products enterprises.²⁷

Plasmapheresis and the Blood Plasma Fever

We have so far focused on the desire by local officials and organizations to profit from the blood plasma economy on the assumption that many people would give blood. Yet such demand is at variance with the long existing fear of losing blood in Chinese culture. In modern Chinese literature and historical writing, the color or flow of blood is often invoked to signify a heavy price paid or sacrifices made, as it was in Lu Xun's novel *Medicine* (药), where human blood from a condemned revolutionary was turned into medicine for a sick child. More recently, in Yu Hua's *To Live*, Youqing, a fifth grader and the son of the protagonist Fugui in the novel, was made to donate so much blood for the wife of the county magistrate that Youqing died from the blood loss.²⁸ In common language, the Chinese media today is full of references to "losing blood" (失血) when writers or reporters write about house price drops, stock price declines, or the fear of Chinese culture losing its vitality. In this cultural context, it is not surprising that most Chinese people view giving blood as harmful to their body and their body's integrity.²⁹

To secure the blood needed for transfusions and blood products, Chinese regulators from early on fudged the boundary between blood as a donation and blood as a commodity. Officially, those who gave their blood were not paid for the blood. They would be donating their blood and engaged in a glorious act to help others and to save lives. At the same time, the government also provided each blood donor with a “nutrition fee.” In the early 1980s, the amount of the nutrition fee was almost as much as an average monthly wage in urban areas. At a time when cash was scarce for many families, this nutrition fee was highly attractive. Many people who gave of their blood did it partly for the compensation, and thus they are often referred to as “selling blood.” Yu Hua’s *The Chronicle of a Blood Merchant* (originally published in 1995) describes a place where, since the 1950s, men had been selling their blood in order to be able to afford a marriage. In the local culture as depicted by Yu Hua, these men were respected because they were physically strong enough to earn such blood money.³⁰ In urban areas peopled with salaried employees, the Chinese government has resorted to imposing quotas for blood donations on urban work units such as factories or universities.

The introduction of plasmapheresis was the game changer. After drawing blood from donors, the blood station kept only the blood plasma and reinfused the remnants back to the donor. This saved the blood stations from having to dispose of the remaining fluids after taking the blood plasma and also reduced compensation to each donor by five yuan. Staff at blood plasma collection stations extolled the benefits of plasmapheresis over giving whole blood and compared blood giving to a process of renewal that was conducive to the generation of fresh blood and metabolism. “It’s beneficial and harmless to the body. Your body is considered unhealthy, indeed, sick, if you do not go and sell blood.”³¹ Without the reinfusion, the blood donors were told, they would likely develop anemia. Needless to say, all donors gladly accepted the reinfusion, even though doctors such as Zhang Ke point out that this idea was a myth nurses invoked to make the donors feel good.³² Thus plasmapheresis made blood giving much more palatable beyond the official slogan of “Giving Blood Is Glorious and Life-saving” (献血光荣, 救死扶伤). In early 1993, the magistrate of Sui County (睢县) went on local TV to encourage farmers to give blood at the local blood station. His pitch: “Give blood plasma and get prosperous” (要想奔小康, 就去卖血浆).³³

Once the fear of bodily loss was dramatically mitigated by plasmapheresis, financial considerations began to loom large for blood givers. In each instance of blood giving, a blood

donor first would have 800cc (two bags) of blood drawn. After the removal of blood plasma by plasmapheresis, about half of the fluid or 400cc, comprised mostly of red blood cells, was injected back. For each donation, the donor was given about 40 to 50 yuan.³⁴ As of 1993, Henan Province had about 90 million people, and rural per capita net income in Henan was 697 yuan per year.³⁵ Assuming that a farmer donated twice a month for a net profit of 40 yuan each time, the donor would net nearly 1,000 yuan per year—a considerable amount at the time. This money could be used to build houses so that sons could afford to marry, and children could afford to go to school. Cheng Yongli (程勇力) had served as a migrant worker in Guangdong in 1990 and made around 600 yuan per month, but even he felt that working hard on a job couldn't compare to selling a few bags of blood.³⁶

Whereas the official handbook for blood donations stipulated that there be a certain interval before a blood donor would be allowed to donate blood again, many donors were caught in the mentality of “getting rich quickly” and made frequent trips to blood collection stations to give blood. Some of the interviewees at Wenlou Village, the epicenter of the Henan AIDS epidemic, gave blood “at least 300 times [a year], basically once a day and on some days two or three times.”³⁷ To skirt existing rules on the presentation of blood donation permits (献血证), they roamed from one blood collection station to another, and staff at the stations made no effort to restrain them. Many blood stations were filled with donors who came by the truckloads, on trucks that some hospitals sent out to fetch the donors. The so-called “blood heads” (血头) emerged to help organize the donors and bring them to selected blood plasma collection stations, often with false blood donation permits. The recommended age for blood donors was between 18 and 55, but some seniors dyed their hair dark to pretend they were younger than 55 and some teenagers faked their age in order to be allowed to give blood.³⁸

The writer Yan Lianke, who wrote a chronicle of a Henan village caught in the AIDS vortex, had stayed at the house of the oldest of three brothers. The oldest brother was a blood head for a blood station, responsible for recruiting donors, and would later serve as the village head. He didn't allow his younger brothers to give blood at his station, but the brothers couldn't resist the urge of making quick money from selling blood and went to other blood stations instead. Both younger brothers later contracted HIV/AIDS. Another young man was one day walking to school and saw a crowd of people getting on a truck. He was invited to jump on the

truck, which soon arrived at a hospital. Everyone was there to sell blood. The young man gave blood just that one time and contracted HIV/AIDS.³⁹

Whereas the officially sanctioned blood banks and plasmapheresis blood centers invested in the proper equipment, small blood centers, especially ones set up without official approval, often made do with makeshift equipment, such as using a small tractor to drive the centrifuge and reusing plastic pipes and needles. Dr. Zhang Ke of the Beijing You'an Hospital reports that Li Keling (李克林), the Party Secretary of Xiaolizhuang Village in Henan, invited a blood head to set up a blood plasma collection station in his own courtyard to make it easier for his fellow villagers to give blood and get rich. Li's move ended tragically. More than one hundred people in the village became HIV positive, including all six of Li Keling's brothers.⁴⁰

In short, the introduction of plasmapheresis allowed human blood from China's vast rural areas to be collected for processing in urban centers. The transformation of blood plasma into blood products in turn would help those in China and beyond who were in medical need, such as hemophilia sufferers. In this respect, the market for blood and other body parts marks the triumph of globalization and neoliberalism.⁴¹ This side of the story is poignantly captured in the Chinese film *Ermo*, directed by Zhou Xiaowen (1995), in which the protagonist Ermo used the earnings from selling off her blood to purchase a much coveted possession and status symbol: a large-screen TV set.

In these markets for blood and tissue, critics would be quick to see manifest relations of power and class.⁴² Those who parted with their blood for money tended to be from economically disadvantaged groups and they used their blood money to build houses, send children to school, or pay off debts.⁴³ Technology and the markets thus allowed blood givers in places such as Henan, Guizhou, Anhui, Hebei, Shaanxi, Shanxi, Hubei, and Hunan to convert their blood into a "renewable resource."⁴⁴ With the growing supply of blood products, Chinese consumers, especially members of the upper class, began to use human albumin as a health booster. In the winter season, some people would seek injections of human albumin to help boost their bodies' strengths.⁴⁵ When the blood plasma economy became an engine for the spread of diseases, however, both blood sellers and blood products users suffered.

The Blood Plasma Economy and the Spread of HIV/AIDS: How Did It Go So Terribly Wrong?

As we noted earlier, the initial impetus for restricting imports of foreign-made human blood products and for developing China's own blood plasma processing capacity was the fear of HIV/AIDS from other countries. Regulators in the central government were clearly aware of the potential risk that could be posed by blood-borne pathogens.

Chinese pioneers of blood plasmapheresis such as Liu Junxiang (刘隽湘) were concerned about poor practice as plasmapheresis spread. After conducting a survey of blood plasma collection stations in multiple provinces, Liu and his team published their *Handbook on Techniques of Plasmapheresis* in 1987 and spelled out good practices and procedures.⁴⁶ By the early 1990s, as plasmapheresis became widely adopted and the spread of HIV/AIDS became better understood, the national health leadership recognized the need for better regulation of blood sourcing and supply. While Liu Quanxi in Henan was vigorously promoting the development of the blood plasma economy in Henan, the Chinese Ministry of Health promulgated the aforementioned regulations on blood sourcing and supply that became effective on July 1, 1993.⁴⁷

Liu Quanxi would probably not have imagined that the industry he so eagerly promoted would become a massive engine for the spread of HIV/AIDS and other infectious diseases in China. From Liu's perspective, the industry would allow everyone to profit, from blood givers to blood stations to bio products makers to users of blood products. How did it happen that a system that was intended to benefit all could turn so deadly for so many people? How could safety warning signals be repeatedly ignored or suppressed?

Blood Collection, Fractionation, and the Sources of Contamination

Because of the number of possible blood-borne pathogens, handling human blood for processing or transfusion requires care. In many countries where human blood is donated, hospitals nonetheless still charge hefty prices for the use of the blood because of the rising costs for testing and processing required to ensure blood safety.

In collecting blood for plasmapheresis, there were multiple ways contamination could occur. At some stations, the scissors and forceps used in the blood collection process were sterilized only during the night and then used on multiple blood donors. Even in the best circumstances, the centrifuges and tubing used for fractionation could be tainted and cause contamination. The situation was often much worse for a number of reasons. Many blood

stations used high capacity centrifuges that could hold up to 24 bags of blood. In some stations, makeshift equipment was used. With high-speed spinning, the bags in the high capacity centrifuges were easily damaged, allowing fluids to mix and thus cross-contaminate if the fluids were injected to the donors.⁴⁸

The *Handbook* stipulated that mixing blood from different individuals should be avoided to prevent the spread of hepatitis and malaria. This reference paradoxically suggests that even in the 1980s such practice of mixing different donors' blood existed. It is now conventional wisdom that such mixing of blood for centrifugation also occurred in Henan. "Yet some blood stations did such mixing all year round for operational convenience and lower cost so as to reap the most profits," a veteran staff member at a blood station was quoted as saying.⁴⁹ At the same time, reinfusion of the fluid remnants from fractionation became standard practice.

The combination of blood mixing and reinfusion coupled with inadequate screening virtually guaranteed the transmission of blood-borne pathogens among the donors if a small number of donors were carriers of such pathogens. Even if only a small number of blood stations engaged in the practice of blood mixing, the number of infections would still be large because many blood givers gave blood frequently and moved from station to station. These blood stations would in effect become highly efficient centers for transmitting blood-borne diseases among the donors. Because there was no testing for HIV/AIDS at the time, further transmission of the virus could occur through transfusion and via the injection of blood products.

Warning Signals

Even before the major push for the blood plasma economy in Henan, a variety of signals would have alerted infectious disease experts to the dangers of blood-borne diseases. In 1991, Dr. Gao Yaojie, then a delegate to the Henan Provincial People's Congress, learned from some delegates from the countryside that hepatitis had become endemic among blood sellers in some parts of the province. She proposed that the management of blood selling be strengthened.⁵⁰ Soon Wang Shuping, an infectious disease doctor then working at a blood plasma collection station in Zhoukou Prefecture of Henan, tested 64 blood donors at the station for HCV (hepatitis C) and found that one third of them were HCV-positive because of multiple sources of contamination.⁵¹

Of the infectious diseases associated with plasmapheresis in Henan, the one that did receive serious attention was malaria. In 1993, the Henan Health Department noted that the number of malaria cases in Henan quadrupled. Its investigations concluded that malaria was spread among blood donors via reinfusion of blood fluids following blood donation or in blood transfusion because some blood stations did not follow proper operating procedures in taking blood. This prompted the Health Department to call on blood (plasma) stations to take measures to prevent the spread of malaria through the plasma donation process.⁵² In October 1993, the Henan Health Department ratcheted up its demand with an emergency directive that all plasmapheresis operations in Henan “must suspend operations” beginning on October 5, 1993, except for blood stations (banks) needed to guarantee the supply of blood for clinical use.⁵³

The emergency directive indicates that health authorities in Henan knew that plasmapheresis operations were at the root of the malaria outbreak then spreading among plasma donors. By extension, they should have known that other blood-borne diseases could also be spread via the same process. Yet the emergency directive fell on deaf ears and was not followed up with serious enforcement action. By chance, the emergency order was issued in the fall of 1993, the season when both mosquitoes and the number of malaria cases vanished. Thus the health administration conveniently dropped the subject. It was not until the following summer that malaria again forced itself onto the public health agenda in Henan. An emergency meeting to deal with the spread of malaria among blood donors was held in Kaifeng on June 4, 1994. This time there was no emergency order to suspend blood stations.

Whistleblowing and the Making of the HIV/AIDS Tragedy

The lack of appreciation for Wang Shuping’s work was a powerful indictment of the political pathos that prevailed in Henan. When she and her colleagues found the high incidence of HCV in 1992, she alerted the blood station leadership of the need to protect blood donors from contamination. She was told that measures to protect the blood donors “would increase costs.” Frustrated with the local leadership, Wang reported to the MOH in July 1992, and the report helped inform the MOH’s July 1993 decision to require that blood donors be tested for HCV.⁵⁴ Rather than being praised for her contribution to public health, however, the blood station leadership in Henan expelled Wang for undermining the blood station’s business.

In 1994 Wang received the Zhoukou Health Bureau's permission to establish a Clinical Testing Center to help with blood quality control in hospitals. By then, she had known that both HCV and HIV could be transmitted among blood donors because of contamination and was worried about HIV spreading through the blood donation system. Her worries turned into reality in March 1995 when she found that an HIV-positive blood donor, a returnee from Yunnan (where there was a serious drug problem), had given blood in blood stations spread across three counties over a two-week period.⁵⁵ Dr. Wang reported the results to the Health Administration Division of the Henan Health Department and recommended that all blood plasma stations in Henan screen for HIV antibodies. The response she got, however, was that "it would be too costly and couldn't be done." Wang subsequently used her own savings to collect 409 blood samples from three blood stations. Her tests of these samples revealed that 13% of the samples were HIV-positive.

When Wang Shuping reported the alarming findings to Wei Liwen (魏礼文), director of the Zhoukou Prefectural Health Bureau, Wei praised Wang for "having done a major good deed that the people will be thankful for." Following discussions with the prefectural and provincial health officials, however, Wei's attitude cooled toward Wang, and no corrective measures were adopted to follow up on Wang's findings. Wang was then able to have the HIV-positive samples retested and confirmed at the Virology Institute of the Chinese Academy of Preventive Medicine with the intervention of Zeng Yi, then the Academy's President. Alarmed, Zeng Yi immediately reported the results to the MOH leadership (Minister Chen Minzhang), and the MOH quickly called Henan. The Henan leadership had initially praised Wang Shuping for discovering the HIV/AIDS epidemic but now turned against her for drawing unwelcome attention. Instead of dealing with the epidemic, they concentrated on hiding it and continuing to profit from the blood plasma economy (more below).

The severity of the Henan epidemic was driven home months later when experts at the Chinese Academy of Preventive Medicine conducted further tests. As Vice Minister Wang Longde (王陇德), tells it, an infectious disease expert at the Identification Center (鉴定中心) needed HIV-positive blood samples and decided to purchase them from the underground blood market in Henan. He went to Henan's Zhoukou Prefecture and located a blood head. The expert purchased 113 bags of human blood and then asked how many more the blood head could

provide each month. “Fifty thousand,” came the shocking answer. All 113 bags of blood subsequently tested positive for HIV!⁵⁶

In early March 1996 this infectious disease expert sought out Wang Longde who was appointed Vice Minister of Health in charge of health administration (including blood sourcing and supply) in 1995. Prior to his MOH appointment, Wang had served as director general of the Health Department of Gansu Province and spent more than a decade combatting plague. Astounded by the expert’s findings, Wang, a Henan native, went to see Minister Chen Minzhang. Chen directed Wang to immediately go visit the Henan leaders who were then in Beijing for the annual session of the National People’s Congress. Unlike nearly a year earlier with Wang Shuping’s findings, Wang Longde was able to persuade the Henan leadership to take immediate and decisive action.⁵⁷ What ensued was a massive crackdown on blood stations, and the leaders of some blood stations in Henan were arrested. Underground blood stations that emerged to satisfy the demand for blood plasma from blood products companies were also closed by sustained nationwide enforcement action by 1997.⁵⁸ When the officially sanctioned blood stations reopened, tests for HIV/AIDS were mandated.

National Regulatory Capacity and Local Compliance

The dreadful developments in Henan raise questions about the role of national regulators, especially about what the Ministry of Health did and could have done to mitigate the situation.

During the period that saw the outbreak of HIV/AIDS in Henan and other provinces, Health Minister Chen Minzhang promoted market-oriented reforms in health and medicine and also paid special attention to rural health and infectious diseases. In view of his abiding concern for public health issues, Chen would appear to be the right person to lead China’s responses to a growing number of infectious diseases including HIV/AIDS. In 1988, a year after Chen became health minister, the MOH conducted the first “rectification” of blood products manufacturers. Because China was then suffering from very high rates of Hepatitis B infections, Chen Minzhang championed a national program of Hepatitis B vaccinations that has since dramatically reduced the prevalence of Hepatitis B in China. When the virologist Liu Chongbai (刘崇柏) called attention to the spread of hepatitis among blood donors/sellers in 1993, Chen quickly responded with measures to mitigate and prevent the spread of hepatitis in blood plasmapheresis operations across the country.⁵⁹

Chen also recognized the looming threat of HIV/AIDS. In 1992, he proposed to the State Council leadership that a national body be established to lead the prevention and treatment of AIDS. Whereas Chen's proposal wasn't fully adopted because the national leadership did not yet consider AIDS a serious threat in China, State Councilor Li Teying did agree to the creation of a quasi-governmental association, with participation from relevant government departments. On November 30, 1993, the China Association for the Prevention and Treatment of STDs and AIDS (中国性病艾滋病防治协会) was established.⁶⁰ Chen Minzhang himself served as the Association's honorary president.

Also in 1993 (July), the MOH announced the creation of the National Committee for Blood Quality Management (全国血液质量管理委员会), which was set up in accordance with Art. 39 of the Regulations on the Management of Blood Sourcing and Supply Organizations and of Blood (采供血机构和血液管理办法 1993). This committee was tasked to assist the MOH in setting national regulations and standards concerning blood sourcing and supply organizations and the management of blood. It would also set the terms for evaluating organizations involved in the sourcing and supply of blood and provide technical guidance to blood sourcing and supply organizations across the country. In implementing these regulations and standards, the committee was to conduct assessment of province-level blood centers and make blood quality spot-checks at blood sourcing and supply organizations across the country. It would also supervise the management of blood sources.⁶¹

Yet the makeup and bureaucratic location of the Blood Quality Committee were suggestive of the Committee's limited capability. It was situated in the Chinese Society of Blood Transfusion and not a formal government regulatory entity. Its initial membership was recommended by provincial health departments/bureaus and entities directly affiliated with the MOH.⁶² In short it was largely an advisory body and was not equipped to take on a vigorous policing role against wayward local authorities. Had the Health Department of Henan Province fully implemented the 1993 regulations on blood sourcing and supply, the severity of Henan's HIV/AIDS crisis would have been mitigated substantially. That was clearly not the case. The MOH-sponsored national organizations on HIV/AIDS and on blood quality were largely ineffectual in confronting wayward local health administrators.

Even admirers of Minister Chen Minzhang lament that "his gentlemanly style [adversely] affected his ability to implement, and his ideals and good ideas fell short of getting carried out.

When AIDS raged in the central plains [of Henan], he at one point sought to meet with a senior Henan official to talk about the severity of the situation but the Henan official cavalierly sped away.”⁶³ In the words of former Vice Minister of Health Wang Longde, Henan “local authorities did not take much action” to address the large-scale outbreak of HIV/AIDS infections between 1995 and 2003.⁶⁴

Securing China’s Blood Supply

The remark by former Vice Minister Wang Longde succinctly captures the lack of action on the part of the Henan authorities and by implication the MOH’s impotence in addressing the HIV/AIDS epidemic in Henan. Indeed, for years after the crackdown on blood stations and until 2003, a bifurcated approach came into being. For more than half a decade, efforts to treat those who became afflicted with HIV/AIDS and other diseases through giving or receiving blood or the use of blood products were minimal in China. It was not until 2001, when the Chinese government released an Action Plan on HIV/AIDS Prevention and Containment (2001-2005), that the Chinese government partially revealed the existence of a blood-related AIDS crisis. On August 23, 2001, the MOH released details of findings about six natural villages of Wenlou brigade (pop. 3170) in Henan’s Shangcai County. Of the 1,310 people who regularly sold blood prior to 1995, 43 percent had contracted HIV/AIDS. In Wenlou village, with about 800 people, more than 300 sold blood and only a small number didn’t contract HIV/AIDS.⁶⁵ The year after, the Chinese government launched a free antiretroviral therapy program in Shangcai. But Wenlou was only the tip of the iceberg.

Full and vigorous national action to treat HIV/AIDS patients had to wait until the SARS crisis of 2003, which highlighted the enormous social and political consequences of epidemics. During the SARS crisis, President Hu Jintao and Premier Wen Jiabao installed Vice Minister Wu Yi as health minister. Wu Yi, known for her no-nonsense style and decisiveness, soon turned her attention to HIV/AIDS and especially the crisis in Henan. At the end of 2003, the policy of “Four Free and One Care” was introduced, offering free testing, free antiretroviral drugs to AIDS patients in rural areas and those without insurance in urban areas, free drugs to pregnant women, free schooling for AIDS orphans, and care and assistance to families with HIV/AIDS sufferers.⁶⁶ Additional initiatives followed and were backed up with expanded budgets and vigorous

implementation. At the same time, there has been little official effort to assign blame and accountability and to seek redress and justice for victims.

In contrast to the prolonged delay in offering treatment to HIV/AIDS patients, the MOH acted vigorously to reform the regime on blood quality and prevent further blood-based contamination. Whereas the MOH was stymied in Henan in the late 1990s, the MOH leadership acted aggressively to revamp China's blood donation and supply system. Besides closing down numerous blood stations, the MOH's major focus was to leverage on the widespread public concern about health issues, and especially the safety of blood supplies, to secure the legal foundations for strengthening China's blood supply and, more broadly, public health. Working closely with the State Council Office of Legal Affairs, the MOH provided key input into the revamp of the Criminal Law and the drafting of the Law of the PRC on Blood Donation.

In March 1997, China's national legislature (National People's Congress) approved a revamp of the Criminal Law. Among the changes incorporated into the new Criminal Law was a new section "crimes of endangering public health" (Ch. 6, Sec. 5). Art. 333 provides for imprisonment and fines on those who organize or force others to sell blood. Art. 334 provides for imprisonment and fines on those who collect and provide blood or manufacture and supply blood products in violation of government standards and cause bodily harm; offenders who cause especially serious consequences can be sentenced to more than 10 years in jail and even life imprisonment.⁶⁷

On December 29, 1997, following months of consultations, reviews and discussion, the Standing Committee of the Ninth National People's Congress enacted the PRC Law on Blood Donation (effective on October 1, 1998).⁶⁸ In addition to the new law on blood donation, the MOH also promulgated a set of (Interim) Management Measures for Blood Stations and disbanded the ineffectual National Committee for Blood Quality Management.⁶⁹

While the revamped Criminal Law (1997) provided legal backing for the ongoing crackdown on illegal blood stations, the Law on Blood Donation takes inspiration from Richard Titmuss' seminal book *The Gift Relationship* and stipulates that only donated blood can be used for clinical purposes.⁷⁰ As to be expected, it includes articles on blood donors, blood centers, and blood testing. It also stipulates responsibility for wrongdoing, including providing compensation to blood donors who have been harmed (Art. 19). Legislators recognized, however, that it was not realistic for China to make the transition to unremunerated blood donation overnight and

included in the Law various incentives for blood donors, such as subsidies (Art. 6), honors (Art. 17), and exemptions from payment of expenses when the donor or the donor's spouse or lineal relatives need blood for clinical use (Art. 14). The Law also encourages autologous (self-use) and cooperative blood donations (Art. 15).

Bolstered by the Law on Blood Donation, the MOH has led a national drive to boost the percentage of blood from unremunerated donations and to thus bring China toward a genuine blood donation system. The Law calls for social mobilization to boost blood donation, and Art. 7 in particular calls on "State functionaries, active servicemen and students of institutions of higher learning to take the lead in donating blood, setting a good example in fostering new social values (Art. 7)." In addition to the mobilization of grassroots units, in 2005 the MOH released the ranking of provincial units according to the percentages of unremunerated blood donations in 2004, in order to bring pressure on laggard localities. According to the MOH, between 1998 and 2004, the percentage of blood for clinical uses from unremunerated donations rose from 22 percent to 91.3 percent; of these, truly voluntary donations rose from 5.5 to 71.5 percent. In February 2005, the MOH announced that China had formally established a nationwide unremunerated blood donation system and that 100% of the blood for clinical uses would be from unremunerated donors by 2007 (of which 80% would be voluntary rather than mobilized).⁷¹ By 2007, the comparable figures had reportedly reached 99.74% (98.23% voluntary).⁷²

These numbers most likely underestimate the percentage of people who are pressured to make blood donations in units/organizations (these are known as mobilized donations) or through a practice known as "blood for blood."⁷³ They do, however, point to a systemic transition. Yet with the imposition of tough regulation, the Chinese blood supply regime has also been plagued by periodic and seasonable shortages in blood donations and a general shortage in the availability of certain blood products. When the reputation of the Chinese Red Cross was on the line because of allegations of financial mismanagement, public trust in the blood donation system as well as the willingness to donate blood plummeted. There have also been occasional reports of illegal blood operations, but these appear to be isolated.

Discussion and Conclusion:

The history of China's blood supply system since the 1980s highlights the massive struggles China has experienced in the remaking of the Chinese economy and the development

of a regulatory state. The story of the blood plasma economy in China was initially one of triumph of materialist wants and human greed. It was based on good intentions to bring income to blood donors, profits to blood station operators and blood products manufacturers, and much needed medical help to users of blood products.

Yet soon the blood plasma economy in Henan was overtaken by a variety of unruly and opportunistic behaviors. Opportunistic behaviors in other spheres of the economy, such as smuggling, helped reduce prices for consumers and sometimes prompted authorities to adopt much needed reforms.⁷⁴ In the collection of blood plasma, however, the unruly behaviors spread infectious diseases such as HIV/AIDS and hepatitis by large numbers and turned the blood plasma economy into the cause of a massive humanitarian disaster. Many tens of thousands of blood donors and untold numbers of users of blood products became infected with HIV/AIDS and HCV.

The tragedy that struck Henan was on the surface the result of a suspension of good judgment and indeed the exercise of gross misjudgment by key individuals, especially Henan's health regulators, in an episode reminiscent of what occurred during the Great Leap Forward, during which Henan was also a major epicenter.⁷⁵ Our review of the evidence shows, however, that a number of deep-seated factors in the Chinese system were at play in Henan that resulted in the local regulators and blood station operators largely disregarding the 1993 MOH regulations on the operation of blood stations and adopting a variety of unsanitary practices in the collection and processing of blood. When Dr. Wang Shuping and others found out the gravity of the HIV/AIDS crisis, the same system enabled the local authorities to suppress information, refuse assistance, and hide the scope and severity of the crisis for years. Reporters and photographers seeking to uncover the truths were put on "Most Wanted" lists, and those local reporters who were caught by the authorities were dismissed from their posts.⁷⁶ Thus the evidence suggests that local officials deliberately and intentionally sought to hide the AIDS calamity in Henan and to deny many HIV/AIDS sufferers the care and treatment they desperately needed.

It was not until after the 2003 SARS crisis that a new generation of Chinese leaders recognized the importance of public health issues. In early 2004, a group of photographs of the AIDS villages by the photographer Lu Guang won a major international photography award and helped to focus international and domestic attention on the AIDS sufferers.⁷⁷ By 2004, the national authorities began to vigorously promote the provision of care and treatment for

HIV/AIDS carriers. Under pressure, the Henan provincial authorities dispatched a high-powered team of officials to help the AIDS villages.

The divergence of behavior between the MOH's goals and the behavior of local health regulators in Henan is a striking illustration of the sort of fragmented authoritarianism that scholars of China have long noted.⁷⁸ In many areas, Chinese authorities have been willing to live with significant fragmentation of authority and remarkable disparities in policy implementation. While the MOH failed to work with Henan to provide timely care and treatment for HIV/AIDS sufferers, it did invoke the massive crisis in the blood collection and supply system to overcome the resistance of parochial interests, unify the regulation of blood supply management on a national basis, and dramatically revamp the blood safety system.

The chaotic development of the blood plasma economy in China and the ensuing HIV/AIDS tragedy and government responses thus offers a unique lens for understanding the arduous struggles China has undergone to build a regulatory state. Whereas China has made substantial progress in enhancing regulation in the last two decades, the Chinese food and drug regulatory system remains a work in progress. The massive vaccine scandal in summer 2018 has again sapped public confidence even while the Chinese leaders have acted quickly and decisively to crack down on perpetrators.⁷⁹

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⁵¹ 王淑平, "向陈秉中医生致敬-他勇敢揭发河南艾滋病污血案激励着我," 参与, 2012-09-26, <http://canyu.org/n60449c6.aspx>.

⁵² 河南卫生报, 1993-10-15, quoted in 张可, *河南艾滋病五年调查报告*, 2005-01-29, <http://www.usc.cuhk.edu.hk/PaperCollection/Details.aspx?id=4955>.

⁵³ 河南卫生报, 1993-10-15, cited in Zhang Ke.

⁵⁴ The following paragraphs on the role of Wang Shuping is drawn on 王淑平, "向陈秉中医生致敬-他勇敢揭发河南艾滋病污血案激励着我," 参与, 2012-09-26, <http://canyu.org/n60449c6.aspx>; 王淑平, "是谁导致了河南艾滋病灾难?" 参与, 2014-05-26, <http://canyu.org/n88683c6.aspx>. Results of the study by Wang Shuping and others were published as 王淑萍, 丁红, 张红旗, 鲁玉周, 杨金才, 赵其凯, 耿洪海, 朱万孚, "单采浆还输血球献血员中的丙型肝炎病毒感染的调查报告 (Hepatitis C Virus Infection Among the Plasmapheresis Donors)," *中华流行病学杂志*, no. 2 (1994), 71-73.

⁵⁵ For background on illegal drugs in China in the early 1990s, see Dali L. Yang, “Illegal Drugs Policy Change and State Power: The Case of Contemporary China,” *Journal of Contemporary China*, 2:4(1993), 14-34.

⁵⁶ 陈融雪, “王陇德的战争与和平”, 瞭望东方周刊, December 13, 2013, <http://www.lwdf.cn/wwwroot/dfzk/current/260403.shtml>.

⁵⁷ 陈融雪, “王陇德的战争与和平”, 瞭望东方周刊, December 13, 2013, <http://www.lwdf.cn/wwwroot/dfzk/current/260403.shtml>.

⁵⁸ 高昱, 于彦琳, “血祸--走访河南‘艾滋村’”, 三联生活周刊, September 5 2001, <http://news.sina.com.cn/c/2001-09-05/348657.html>.

⁵⁹ 金冬雁, 不当院士的学者型部长陈敏章, 2011-05-27, <http://blog.sciencenet.cn/blog-216627-448531.html>

⁶⁰ 魏铭言, “中国防治艾滋病 19 年政策之变,” 新京报, 2004-03-30, <http://news.sina.com.cn/c/2004-03-30/13243076459.shtml>. By putting AIDS together with STDs, however, this diverted potential attention to blood-borne HIV/AIDs transmission.

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⁶² “卫生部关于成立全国血液质量管理委员会的通知,” July 16, 1993, at <http://law.people.com.cn/showdetail.action?id=2569829>.

⁶³ 金冬雁, 不当院士的学者型部长陈敏章, 2011-05-27, <http://blog.sciencenet.cn/blog-216627-448531.html>

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⁶⁶ Zunyou Wu, Sheena Sullivan, Yu Wang, Mary Jane Rotheram-Borus, Roger Detels, “Evolution of China’s Response to HIV/AIDS,” *The Lancet*, vol. 39, February 24, 2007, 679-690.

⁶⁷ 中华人民共和国刑法 (2011 年 2 月 25 日最新修正版刑法), accessed at <http://www.szxingshi.com/95w9.html>.

⁶⁸ State Councilor Peng Peiyun (彭珉云) and Health Minister Chen Minzhang provided explanations to the NPC for the draft law on November 1, 1997.

⁶⁹ “卫生部关于撤销全国血液质量管理委员会的通知,” 卫医发(1999)第 72 号, February 14, 1998, at <http://www.gsfbz.gov.cn/FLFG/GJFZ/200508/35308.shtml>. The Chinese Society of Blood Transfusion Association continues to have a Committee on the work of blood quality management (血液质量管理工作委员会).

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⁷⁷ *Lens* Interview with photographer Lu Guang, December 20, 2012, posted at <http://www.g4photos.com/viewthread.php?tid=13350>, accessed May 1, 2013.

⁷⁸ Kenneth Lieberthal and David Lampton, *Bureaucracy, Politics, and Decision Making in Post-Mao China*, Berkeley: University of California Press, 1992.

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