Appendix II

Drafting Statement for the Draft Compliance Guidelines for Healthcare Companies to Prevent Commercial Bribery Risks (Draft for Public Comment)

In order to implement the decisions and arrangements of the CPC Central Committee and the State Council, prevent and curb commercial bribery in the healthcare industry, provide guidance to healthcare companies on strengthening compliance management, maintain fair competition in the healthcare market, safeguard the health-related rights and interests of the people, and promote the construction of Healthy China, the State Administration for Market Regulation drafted the Draft Compliance Guidelines for Healthcare Companies to Prevent Commercial Bribery Risks (hereinafter referred to as the "Draft Guidelines") in accordance with the Anti-Unfair Competition Law of the People's Republic of China, the Drug Administration Law of the People's Republic of China, and other laws and regulations.

I. Drafting Background

Healthcare is a key industry related to the national economy and the people's livelihood, and is related to the most direct and practical health-related rights and interests that the general public are most concerned about. In recent years, commercial bribery in China's healthcare industry has occurred from time to time. The illegal conduct is highly concealed and the patterns are constantly updated. This not only damaged fair competition in the healthcare industry, but also directly affected the vital interests of the people in seeking medical treatment, and restricted the healthy and sustainable development of the healthcare industry, which had received strong responses from all sectors of society.

The CPC Central Committee attaches great importance to the high-quality development of the healthcare industry, and always puts the protection of the people's health in a strategic position for prioritized development. The State Administration for Market Regulation has conscientiously implemented the decisions and arrangements of the CPC Central Committee and the State Council, continued to increase law enforcement efforts, severely cracked down on illegal conduct relating to commercial bribery violations in the healthcare industry, investigated and dealt with a number of key cases, and effectively safeguarded fair competition in the healthcare market and the life, health, and safety of the people. In order to further improve the effectiveness of controls over commercial bribery in the healthcare industry, and to eradicate the breeding ground for commercial bribery at its source, it is necessary to give full play to the main role of healthcare companies while strengthening supervision and law enforcement, and promote transferring the key control point in commercial bribery governance in the healthcare industry from post-event enforcement to pre-event prevention, in order to promote the construction of a long-term mechanism for control of commercial bribery in the healthcare industry, and create a good industry environment with a clean and upright atmosphere. It is necessary, within the framework of existing laws and regulations, to research and formulate specialized compliance guidelines for preventing commercial bribery risks based on the business characteristics and behavior patterns of healthcare companies, summarize and systematize the commercial bribery risk areas in marketing in the healthcare

industry, refine and clarify compliance operations and risk prevention, and to provide specific, clear, and operational guidance and references for healthcare companies to establish and improve compliance systems, continuously standardize and cleanse the healthcare industry market, and promote the healthy and orderly development of the healthcare industry.

II. Drafting Process

1. Conduct extensive research and visits, build industry consensus. We used a combination of on-site visits and organized discussions to fully conduct in-depth research on the current status of the healthcare industry, and achieve a close combination of theory and practice. We conducted specialized research at a number of domestic and foreign healthcare manufacturing companies, distributors, promotional companies, healthcare industry associations, industry self-regulatory organizations, and other entities for in-depth communications and discussions on the need for prevention of commercial bribery risk in the healthcare industry under the existing legal framework, the current status of companies' compliance, and legal research on commercial bribery, thereby building a broad consensus on governance.

2. Conduct in-depth research and analysis, solve key problems. We researched and sorted out typical cases of commercial bribery in the healthcare industry, referred to and learnt from the achievements of compliance systems in the healthcare industry both domestically and abroad, and collected and sorted out typical practices and advanced experiences found in this research. Based on an in-depth understanding of the healthcare industry's business model, an accurate grasp of the reasonable promotional needs of companies, and an understanding and reflection on the internal compliance standards of companies, we conducted in-depth analysis of the commercial bribery risks which exist in procurement and sales within the healthcare industry in the current environment, as well as the difficulties faced by healthcare companies in carrying out compliance work relating to commercial bribery. We focused on finding the weaknesses in, root causes of problems with, and solutions for preventing commercial bribery risks, and carried out targeted research.

3. Fully solicit opinions, revise and improve repeatedly. We organized ten specialized seminars on the Draft Guidelines, and invited representatives of domestic and foreign healthcare companies, industry associations, well-known scholars and lawyers in the fields of competition law and criminal law, and representatives of local Administrations for Market Regulation for specialized discussions and communications, and fully listened to opinions and suggestions. Representatives from all sectors of society who participated in the discussions generally believed that the Draft Guidelines were in line with the actual situation of the industry and were highly practical, which would help prevent and curb commercial bribery in the healthcare industry, and guide and help healthcare companies to operate compliantly. They expressed support and expectations for the release of the Draft Guidelines. We strengthened coordination and communication between government departments, and solicited opinions from relevant government ministries and commissions in writing. We studied and analyzed the provisions one by one, in combination with the opinions and suggestions solicited, and collected all reasonable opinions available raised by all sectors of

society. After repeated revisions and improvements, the Draft Guidelines were finally formulated.

III. Main Content

The Draft Guidelines consist of 49 articles in four chapters. The four chapters are: General Provisions, Compliance Management System Construction for Healthcare Companies to Prevent Commercial Bribery Risks, Identification and Prevention of Commercial Bribery Risks in Healthcare Companies, and Handling Commercial Bribery Risks in Healthcare Companies.

Chapter 1: General Provisions. This chapter systematically explains the objectives, significance, basic principles, scope of application, and definition of terms of the Draft Guidelines, and clarifies that the Draft Guidelines are intended to provide a reference for healthcare companies to carry out compliance management in preventing commercial bribery risks.

Chapter 2: Compliance Management System Construction for Healthcare Companies to Prevent Commercial Bribery Risks. Drawing on the PDCA [1] management concept in management science, this chapter provides guidance for healthcare companies to build compliance management systems, encourages management to improve compliance awareness, supports the construction of compliance management systems, and encourages healthcare companies to establish compliance management organizations, compliance systems, compliance operating mechanisms, and to focus on the construction of compliance culture.

Chapter 3: Identification and Prevention of Commercial Bribery Risks in Healthcare Companies. This Chapter lists nine specific areas, including Academic Visits and Communications; Hospitality; Service Fees [e.g., speaker fees] to HCPs; Outsourcing Services; Discounts, Rebates, and Commissions; Donations, Sponsorships, and Grants; Free Placement of Medical Devices; Clinical Research; and Retail Sales, and introduces each area in detail according to the same framework structure, which includes three parts: definition and content; matters under regulation; and risk identification and prevention.

Chapter 4: Handling Commercial Bribery Risks in Healthcare Companies. This chapter provides guidance to healthcare companies on effectively controlling risks by improving internal control measures and cooperating with law enforcement. This chapter also provides guidance to companies on proactively reporting their own risks of illegal conduct in advance and cooperating with Administrations for Market Regulation in investigations in accordance with the law, and offers reminders of situations where administrative penalties may be lowered, reduced, or exempted.

[1] Plan-Do-Check-Act management cycle, also known as the Deming Cycle.

IV. Innovation and Highlights

1. Highlighting Industry Characteristics and Focusing on Concrete Description and Practical Guidance

Based on domestic anti-bribery laws, taking foreign anti- bribery laws and industry consensus codes of conduct as references, and combining domestic administrative law enforcement practices, and based on the industry's characteristics, business models, management structure, and other actual conditions in the healthcare industry, the Draft Guidelines summarize and organize commercial bribery risks that cover the entire business, entire process, and entire chain in nine areas of the healthcare industry. The Draft Guidelines provide positive guidance through regulatory matters, provide negative warnings through risk identification and prevention, and provide specific and operational guidance and suggestions for the compliance management of healthcare companies to prevent commercial bribery risks.

2. Focusing on Content Cohesion, Effectively Exert Joint Efforts in Commercial Bribery Risk Prevention and Control

The Draft Guidelines strictly follow the relevant provisions of current legislations such as the Anti-Unfair Competition Law and the Administrative Penalty Law, and define and distinguish between companies' general business risks and commercial bribery compliance risks, and combine the management regulations of industry regulatory departments such as the Health Commissions and the Medical Product Administrations to clearly identify key risk areas in various aspects of the healthcare industry such as manufacturing and research, and procurement and sales.

3. Risk Classification and Prevention to Guide Companies to Correctly Identify Risk Levels

The Draft Guidelines are formulated based on criminal and administrative laws and regulations, regulatory documents of the healthcare industry, typical cases of commercial bribery in the healthcare industry, and companies' compliance systems. The Draft Guidelines use a combination of quantitative and qualitative analysis methods to assess risk factors in various specific areas of healthcare companies, and determine the priority of risk control and classified prevention and control measures based on the severity of the conduct.

With regard to the regulatory requirements for business conduct in various specific scenarios, the regulatory suggestions are divided into four categories: "Required," "Permitted," "Suggested," and "Encouraged." Within these categories, the business compliance obligations of companies clearly set forth in the current laws and regulations such as the Anti-Unfair Competition Law and the Drug Administration Law, as well as international standards or national standards such as the *Anti-bribery Management Systems — Requirements with Guidance for Use* and the *Compliance Management Systems — Requirements with Guidance for Use*, are referred to as regulatory requirements in the "Required" category in the Draft Guidelines. Those that are related to industry consensus, and compliance with the relevant management requirements of the Health Commissions and the Medical Product

Administrations and other industry regulatory authorities, and do not belong to the business compliance obligations of companies are referred to as regulatory requirements in the "Permitted" category of the Draft Guidelines. The advanced compliance experience and typical practices of healthcare companies in preventing commercial bribery risks that have been studied and demonstrated make up the "Suggested" category of the Draft Guidelines. Those that are conducive to providing guidance to companies in establishing and implementing long-term mechanisms for governing commercial bribery, and promoting high-quality development of the medical and health industry are referred to as regulatory requirements in the "Encouraged" class in the Draft Guidelines.

The risks that healthcare companies should identify and prevent are classified and regulated according to the degree of illegality of the risk, and are also classified into four categories: "Prohibited," "Avoided," "Restricted," and "Noted." Among them, for commercial bribery conduct that is clearly prohibited by the current Anti-Unfair Competition Law, Drug Administration Law and other laws and regulations, as well as conduct identified in typical cases of commercial bribery in the healthcare industry investigated and dealt with by Administrations for Market Regulation, companies are reminded to explicitly prohibit such conduct in their operations. For conduct that is not clearly prohibited by law, but may assist or facilitate the commission of commercial bribery based on current law enforcement practices and industry consensus, companies are reminded to avoid such conduct as much as possible in their operations. For medium- and low-risk business conduct that is not consistent with the general compliance principles of the company and may lead to commercial bribery under specific conditions, companies are reminded to reasonably restrict and properly note such conduct in their operations.

4. Improve Risk Management, Help Companies Effectively Implement Risk Prevention and Control

In order to guide healthcare companies to accurately identify, evaluate, and classify commercial bribery risks, the Draft Guidelines emphasize the classification [i.e. evaluation] of commercial bribery risks and development of mitigation plans. The Draft Guidelines provide guidance to companies on establishing a sense of responsibility, and enhance their motivation for proactive compliance management. For risk issues that have not yet become illegal or criminal misconduct, it notes that healthcare companies should pay full attention to the discovery of commercial bribery risks during the process of compliance management, and promptly take reasonable and necessary internal control measures, including internal investigations, risk assessment, and remediation to effectively rectify such misconduct. The Draft Guidelines encourage healthcare companies to improve long-term mechanisms to avoid similar risks from happening again. For illegal issues that implicate commercial bribery, the Draft Guidelines note that healthcare companies should take timely and effective measures such as proactive reporting before [regulators open a formal] case, cooperating with the investigation during the case [i.e., during a government investigation], and rectification and evaluation after the case [i.e., after the government investigation closes] on the basis of reasonable internal mitigation.