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U.S. Drug Manufacturers Beware: Application of the PRC Antibribery Law to Drug Marketing and Promotional Practices in China

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I. INTRODUCTION

China's ongoing economic growth and tremendous market potentials have presented many opportunities for American businesses, no exception to the pharmaceutical industry. According to a report issued by the Pharmaceutical Research and Manufacturers of America (PhRMA), an organization representing the country's leading research-based pharmaceutical and biotechnology companies, up to April 2000 there are 17 major American research-based pharmaceutical companies in China which enjoy a 12 percent share of the Chinese pharmaceutical market of US\$6 billion, or around US\$720 million in annual sales. PhRMA member companies employ almost 20,000 workers directly in their operations in China and have invested some US\$1 billion

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in China over the past decade.² Doing business in China, however, the U.S. pharmaceutical companies are in a business and legal environment that is remarkably different from what they are familiar with in their home country.

Among other barriers, restrictions on the communication between pharmaceutical companies and physicians/pharmacists recently caused significant concerns of the industry. In a policy statement prepared in December 2001, the PhRMA summarized these concerns as follows:³

“An additional market access concern revolves around a persistent practice in some jurisdictions of banning pharmaceutical sales representative access to hospitals. Beginning in late 1999, a number of Chinese provinces and cities began to enact regulations that prohibit pharmaceutical sales representatives from entering jurisdiction hospitals with the intent to promote pharmaceutical products to physicians and pharmacists. Although the measures may be well intentioned, PhRMA companies operating in China believe that these policies are shortsighted, and do not sufficiently consider the long-term interest of the physician and the patient in China.”

The Chinese government’s recent enforcement actions resulted from the market irregularities mostly committed by domestic Chinese pharmaceutical companies, but have had serious negative impacts on the business of foreign pharmaceutical companies in China as well. Since the U.S. research-based pharmaceutical industry

²STATEMENT FOR THE RECORD OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURES OF AMERICA (PhRMA), SUBMITTED TO THE HOUSE WAYS AND MEANS COMMITTEE: THE FUTURE OF THE WORLD TRADE ORGANIZATION, April 13, 2000, at <http://www.phrma.org>.

³SUBMISSION OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) FOR THE NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE) 2002 (the “PhRMA NTE Submission”), December 17, 2001, at <http://www.phrma.org>.

has long employed the communications with prescribing physicians by sales representatives as an effective and efficient method of promotion and marketing, these enforcement actions may substantially reduce the U.S. pharmaceutical manufacturers' competitiveness. The PhRMA report estimates:

“[We] are concerned that these rules diminish the role of the pharmaceutical sales representative, and significantly impair the ability of pharmaceutical companies to:

-

Ensure that prescribing physicians are fully informed on the proper use of medications.

- Obtain key information on the use and adverse events of launched products: *not all adverse events can be monitored in post-marketing studies. Quite a number of adverse events come under the form of questions from the doctor to the sales representative who report to the medical departments in the pharmaceutical companies.*
- Keep the physician informed on the latest advances and developments in key therapeutic fields.
- Obtain important feedback from physicians, pharmacists and hospital administrators on *their personal development needs and interests.*

The Chinese government's enforcement actions are based on a roughly-drafted set of regulations targeting the corrupt practices in general commercial transactions, and other rules that are particularly applicable to the health care industry. In this article, these regulations are collectively termed as the “PRC antibribery law.” In the following sections of this article, we will examine the background for the Chinese government to initiate stringent scrutiny over the health care industry (Section II), and then analyze the pitfalls and loopholes of the

PRC antibribery law (Section III) and its application to the U.S. pharmaceutical manufacturers' promotional and marketing activities in China (Section IV). We will also briefly discuss the guidelines provided by the American Medical Association (AMA) and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) which might be of some reference to U.S. companies' China operations (Section V), and propose certain responding strategies for the industry and rules-changing suggestions for the regulator (Section VI).

II. BACKGROUND

China's record in improving the health status of its population in a relatively short period of time is impressive.⁴ In urban areas, health insurance systems established in the 1950s covered most medical costs for employees and retirees of government agencies and state-owned enterprises, and their dependants. Some kind of comprehensive health insurance benefits covered about 50 percent of urban residents. In rural areas, the rural cooperative medical system (CMS) was developed. This system required all commune members to contribute to a group medical fund, thus placing medical expenses on the commune rather than on an individual or a single family. Under this system, rural health stations delivered basic medical services, dispensed medications and provided partial reimbursement for services received at township and county hospitals. At its peak, the CMS covered 90 percent of the rural population.⁵

⁴As an indicator of progress, infant mortality rates were 200 per 1,000 live births in 1949 when the Communists took power, but had dropped to 33 per 1,000 by 1997. Average life expectancy was only 35 years in 1949, but had reached 70 by the 1990s. Most of this progress can be attributed to government investments in public health and preventive medicine, immunizations, hygiene and sanitation. See Christine Beasley, *Health Care: The Sick Man of China*, www.chinaonline.com, February 7, 2001.

⁵Id.

Even where they functioned best, however, neither the rural nor the urban systems of health care financing and delivery were ideal by Western standards. There were problems of quality control, mismanagement and lack of fiscal accountability at various levels of both systems.⁶ Therefore, the reform of China's health care system has long been a priority on the government's agenda. Since 1990s, both the urban and rural medical insurance systems have undergone significant changes. The government funds have gradually withdrawn from providing full medical coverage to government/state-owned enterprises employees and rural residents. The burden of medical coverage has become shifted from the government to the private parties (private employers and residents).⁷

The reform has unavoidably influenced the interests of virtually everyone, and thus aroused heated debates and complaints in many aspects. Over the recent years the cost of pharmaceutical products has been of particular concern. According to a 1998 report by the U.S. Foreign and Commercial Service, drug costs constitute 60% of health care spending in China, in contrast to 8% in the United States. Because the domestic pharmaceutical industry is characterized by low R&D investment and sluggish innovation, price competition has been the main battleground among suppliers. Hospitals, which dispense most medicines in China, have relied on the sale of drugs to patients and their leverage over suppliers to maximize their revenue.⁸

The roaring drug prices have seriously preventing many Chinese citizens from accessing to effective and economic health care services. In response to this situation, the Chinese government started its efforts in reducing the price of pharmaceutical products and eradicating abuses in connection with the sales and purchases of pharmaceutical products since the early 1990s.

In 1994 a series of regulations and directives were issued by the central government with the intention of cleaning up corrupt practices in the health care industry. The government agencies involved in this endeavor

⁶Id.

⁷See, in general, the *Decisions on the Reform and Development of the Health Care System*, jointly issued by the Central Committee of the Chinese Communist Party and the State Council of the People's Republic of China on January 15, 1997.

⁸Lester Ross and Walter Hutchens, *A Legislative Prescription for the Ills of the Drug Industry*, *China Law & Practice*, Volume 15, No. 3 (April 2001), pp. 20-24.

are the Office of Correction of Corrupt Industry Practices under the State Council,⁹ the State Development & Planning Commission,¹⁰ the State Economic & Trade Commission,¹¹ the Ministry of Health,¹² the State Administration of Industry & Commerce¹³ and the State Drug Administration.¹⁴

The government inspections since then have discovered that there were a lot of pharmaceutical companies, mostly domestic Chinese ones, engaging in corrupt practices in return for the sales of drugs.¹⁵ Despite government attempts to clamp down on these corrupt practices, however, the enforcement of antibribery law in the health care industry has not seemed to be satisfactorily successful; therefore renewed and reinvigorated attempts are being made to treat these ills.¹⁶

III. PRC ANTIBRIBERY LAW

Unfair Competition Law

⁹The State Council is the central government of the People's Republic of China. The Office of Correction of Corrupt Industry Practices is a permanent inter-ministry agency directly under the State Council charged with inspection and correction of "corrupt industry practices" of a wide range of industries. It has the ministerial status within the government hierarchy.

¹⁰The State Development & Planning Commission is one of the two most important "macro-controlling" departments under the State Council. Among its responsibilities is setting the price framework of the pharmaceutical products that are statutorily under the control of the government.

¹¹The State Economic & Trade Commission is the other most important "macro-controlling" department and has extensive responsibilities ranging from formulating industrial policies to regulating the market order.

¹²The Ministry of Health is the top regulator of the health care industry and charged with the regulation of all hospitals and physicians in China.

¹³The State Administration of Industry & Commerce is the government agency charged with, among other things, regulating fair trading, protecting consumer interests, and drafting legislation for commerce and industry. It is the major enforcement agency of the competition law. See detailed discussion below in Section III of this article.

¹⁴The State Drug Administration is the top regulatory body of the pharmaceutical industry. It supervises the development, licensing, manufacturing, marketing and consumption of drugs, medical devices and biotechnology products in China.

¹⁵See Circular on Further Strengthening the Administration on Pharmaceutical Products, issued by the State Council of the People's Republic of China, September 29, 1994. Also see Circular on Continuing to Rectify and Regulate the Production and Marketing of Pharmaceutical Products and Strengthening the Administration issued by the State Council of the People's Republic of China, April 16, 1996. These two "Circulars" briefly summarized the periodic results of the government's inspection and enforcement actions and requested further actions.

¹⁶See 2001 Implementation Opinions on Correction of Corrupt Practices in Purchases and Sales of Pharmaceutical Products, jointly issued by the State Council's Office of Correction of Corrupt Industry Practices, the State Development & Planning Commission, the State Economic & Trade Commission, the Ministry of Health, the State Administration of Industry & Commerce and the State Drug Administration on May 22, 2001. Also see the PhRMA NTE Submission, *supra* note 2.

It was not until the early 1990s saw the introduction of the PRC Law Against Unfair Competition (the “Unfair Competition Law”).¹⁷ The Unfair Competition Law was enacted to “safeguard the healthy development of the socialist market economy” and to restrain “unfair competition.”¹⁸ It defines “unfair competition” as:

*“Acts of business operators that, contravening the provisions of this Law, damage the lawful rights and interests of other business operators or disturb the social or economic order.”*¹⁹

When challenging the promotional and marketing practices of pharmaceutical manufacturers, the enforcement agencies generally claim that such practices are in violation of the provisions pertinent to “commercial bribery” contained in the Unfair Competition Law. Commercial bribery, as one of the “unfair competition practices” enumerated by the Unfair Competition Law, is loosely defined as:

*“The use of valuables or other means by a business operator to bribe the other transaction party in order to secure the sale or purchase of goods.”*²⁰

The pitfalls in this wording are immediately apparent, for example, the circular use of “bribe” to define bribery. It is also unclear about the meanings of “valuables” and “other means” employed to bribe.

The Unfair Competition Law authorizes the State Administration of Industry and Commerce (SAIC) as the

¹⁷Promulgated by the 8th Standing Committee of the PRC National People’s Congress on September 2, 1993 and effective as of December 1, 1993.

¹⁸Unfair Competition Law, art.1.

enforcement agency of the law.²¹ The Fair Trading Bureau of the SAIC applies the Unfair Competition Law by means of administrative enforcement measures available to the SAIC under administrative procedural law.²² The SAIC may investigate irregularities or violations of the law on its own initiative, or it can respond to complaints received from outside parties.²³

To implement Article 8 the Unfair Competition Law, the SAIC issued the Provisions on Prohibition of Commercial Bribery on November 15, 1996 (the “SAIC Commercial Bribery Provisions”). It was made clear in the SAIC Commercial Bribery Provisions that “*valuables*,” as used in Article 8 of the Unfair Competition Law, refers to any valuables “in cash or in kind, including payments under the guise of promotion, advertisement, sponsorship, grants for scientific research, service fees, consulting fees or commissions, as well as the reimbursement of various expenses.”²⁴ The “*other means*” used in Article 8 of the Unfair Competition Law refers to “provision of benefits other than valuables in cash and in kind,” such as offer of all expenses-paid vacations within China and overseas, etc.²⁵

Article 8 of the Unfair Competition Law also deals with kickbacks and draws a line between kickbacks and other legitimate business incentive arrangements such as rebates and commissions. The law reads:

²¹Unfair Competition Law, art.3.

²²The PRC Law on Administrative Punishment was promulgated by the PRC National People’s Congress on March 17, 1996 and became effective as of October 1, 1996 (the “Administrative Punishment Law”). Article 8 of the Administrative Punishment Law defines the different categories of administrative punishment as being: 1) Warnings; 2) Fines; 3) Confiscation of illegal income or illegal assets; 4) Order to cease production and business; 5) Suspension or cancellation of permit or license; 6) Administrative detention (only can be enforced by the Police Department); and 7) Other administrative punishments specified by laws and regulations.

²³Unfair Competition Law, arts.16, 4.

²⁴The SAIC Commercial Bribery Provisions, art.2.

²⁵Id.

“Any kickbacks provided off-the-book and covertly to the other transaction party or its individual employee shall be treated as offer of bribes. The acceptance by the other transaction party or its individual employee of the kickbacks off-the-book and covertly shall be treated as the acceptance of bribes.

*A business operator may, in an express manner, provide rebates to the other transaction party in the sales and purchases, and provide commissions to the middleman. The rebates provided to the other transaction party and the commissions provided to the middleman must be truthfully recorded on the books by the business operator. The recipient of the rebates or commissions shall truthfully record on its book the rebates and commissions.”*²⁶

Here the law sets two parameters to characterize a payment as kickback: “off-the-book” and “covertly” provided. The different between kickbacks and rebates or commissions is whether they are duly recorded on the books of both the provider and the recipient. It should be noted, however, that these two parameters are only applicable to kickbacks. In other words, if an action falls into the category of bribery stipulated by the first sentence of Article 8 (“*The use of valuables or other means by a business operator to bribe the other transaction party in order to secure the sale or purchase of goods*”), there is no requirement for it being provided off-the-book and covertly.

Article 22 of the Unfair Competition Law provides that the SAIC may impose two types of administrative sanctions on any violations of Article 8 that do not constitute a crime: (1) a fine in the amount of RMB10,000 to RMB200,000 (approximately US\$1,200 to US\$24,000, and/or (2) confiscation of any illegal gains generated from the bribing practices.²⁷

²⁷Unfair Competition Law, art.22.

Drug Administration Law

Another set of antibribery rules applicable to the pharmaceutical industry is contained in the PRC Law on Drug Administration which was originally enacted in 1984. On February 28, 2001 the Standing Committee of the PRC National People's Congress significantly amended the law (the PRC Law on Drug Administration, as amended, is hereinafter referred to as the "Drug Administration Law").

The Drug Administration Law strengthens the legislative foundation over pharmaceutical regulations, including approvals, manufacturing, storage, packaging, prescriptions, advertising and pricing. Several changes merely codify, at the legislative level, what had already been implemented through administrative regulations or in practice. The Drug Administration Law, which has become effective as of December 1, 2001, is applicable to foreign-invested pharmaceutical companies and foreign market participants even though domestic issues within the PRC pharmaceutical industry and its evolving regulatory system largely drive the amendments.²⁸

The core provision of the Drug Administration Law against corrupt practices in sales and purchases of pharmaceutical products is contained in Article 59. The first paragraph of Article 59 prohibits the payment of "kickbacks" or "other material benefits" in drug sales and purchases:

²⁸Lester Ross and Walter Hutchens, *supra* note 7.

*“Pharmaceutical manufacturers, pharmaceutical dealers and medical institutions are prohibited from offering or accepting kickbacks or other material benefits off-the-book and covertly in the sales and purchases of pharmaceutical products.”*²⁹

There is not express definition of “kickbacks” and “other material benefits,” but two parameters are indicated here: “off-the-book” and “covertly,” which are same as the provision of Article 8 of the Unfair Competition Law.

The wording of the second paragraph of Article 59 is more problematic:

*“Pharmaceutical manufacturers, pharmaceutical dealers or their agents are prohibited from offering any valuables or other material benefits under any guise to the responsible personnel, drug purchasers or physicians of the medical institutions that use their pharmaceutical products. The responsible personnel, drug purchasers or physicians of a medical institution are prohibited from accepting any valuables or other material benefits under any guise provided by pharmaceutical manufacturers, pharmaceutical dealers or their agents.”*³⁰

The distinction between the first and the second paragraphs of Article 59 appears to be that the first attempts to attack the kickbacks provided off-the-book and covertly (as opposed to legitimate rebates and commissions) whereas the second is directed at “commercial bribery.” Similar with the relevant provisions of the Unfair Competition Law, under the Drug Administration Law, the commercial bribes are not necessarily provided off-the-book and covertly.

Articles 90³¹ and 91³² of the Drug Administration Law deal principally with discipline and punishment of violations of Article 59, including among others the providers and recipients of proscribed benefits.

The antibribery provisions of the Drug Administration Law are also primarily enforced by the SAIC and its local branches, with the assistance of the departments of drug administration in case of need.³³

Ambiguity of Law and Confusion in Practice

The PRC antibribery law applicable to the pharmaceutical industry, as above analyzed, is ambiguous in many aspects, and thus results in broad and discretionary interpretations by enforcement agencies and puts the pharmaceutical manufacturers in a continuing conundrum. On the one hand, pharmaceutical manufacturers – who, after all, are in the business of selling their products for maximum profit – are pushed by the economics of the evolving health care market to develop data showing that their products are cost-effective, and by competitive pressures to sell more of those products than the alternatives made by their competitors. On

³¹Article 90 of the Drug Administration Law reads in its entirety as follows: “*The pharmaceutical manufacturers, pharmaceutical dealers and medical institutions which offer or accept kickbacks or other material benefits off-the-book and covertly in the sales and purchases of pharmaceutical products, and the pharmaceutical manufactures, pharmaceutical dealers or their agents which offer any valuables or other material benefits to the responsible personnel, drug purchasers, physicians or other relevant persons of the medical institutions that use their pharmaceutical products, shall be punished by the department of administration of industry and commerce by (1) imposing a fine in the amount of RMB10,000 up to RMB200,000; and/or (2) confiscating illegal gains if any; and/or (3) canceling the business licenses of the pharmaceutical manufactures or dealers, and requesting the department of drug administration cancel their [special] licenses for pharmaceutical manufacturing and dealing. If the violations are serious enough to constitute a crime, the criminal charges shall be initiated.*”

³²The second paragraph of Article 91 of the Drug Administration Law reads in its entirety as follows: “*The responsible personnel, drug purchasers, physicians or other relevant persons of the medical institutions who receive valuables or other material benefits provided by pharmaceutical manufacturers, pharmaceutical dealers or their agents shall be imposed upon administrative sanctions by the departments of health or the medical institutions of these persons, and confiscated illegal gains if any. The physicians who committed serious violations shall be disqualified as practicing physician by the departments of health. If the violations are serious enough to constitute a crime, the criminal charges shall be initiated.*”

³³Drug Administration Law, arts.90 and 91.

the other hand, manufacturers have little real guidance from legal authorities as to when pursuit of these ends through financial arrangements or other communications with their customers – many of which would be both common and lawful outside the health care industry, and many of which actually may be beneficial to the health care professionals and, ultimately, the patients – will be treated as unlawful bribing practices.³⁴

Specifically, the lack of clear definition of “commercial bribery” under the Unfair Competition Law (Article 8, and the relevant articles of the SAIC Commercial Bribery Provisions) and the extremely broad prohibition of “benefits” under the Drug Administration Law (Articles 59, 90 and 91) have created a climate that could inhibit normal and genuine promotional activities of pharmaceutical companies, including those that provide educational benefits to Chinese health care professionals and thereby assist in the development of China’s health care system. It is of great concern to the PhRMA members as they stated in the recent national trade estimate report.³⁵

This is not a hypothetical concern. In the recent past some members of the PhRMA have been investigated by local Government agencies in China ostensibly applying rules against “commercial bribery” under the Unfair Competition Law. In such cases a recurring issue has been where to draw the line between marketing irregularities that could constitute unlawful “commercial bribery” and, for example, lawful *bona fide* sponsorship of the attendance by health care professionals at educational symposia.³⁶

³⁴Such dilemma is also found in other countries including the U.S. See commentary made by Thomas N. Bulleit, Jr. and Joan H. Krause, *Kickbacks, Courtesies, or Cost-Effectiveness?: Application of Medicare Antikickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers*, 54 Food & Drug L.J. 279 (1999).

³⁵See the PhRMA NTE Submission, *supra* note 2.

³⁶*Id.*

IV. ILLUSTRATION OF INDUSTRY PRACTICES UNDER ATTACK

The PRC antibribery law leaves broad room for the government's enforcement agencies to apply it to a wide range of industry practices such as gifts and sponsorships for scientific and educational activities, payments for services (such as clinical studies), discounts other incentive arrangements, and so forth. These promotional practices are well-established and commonly employed by pharmaceutical manufacturers in the U.S. In the meantime, even in the domestic U.S. market, these practices are subject to very strict scrutiny by federal agencies (such as the Department of Health and Human Services's Office of Inspector General), and subject to self-disciplinary rules set forth by professional associations (such as American Medical Association) to prevent any abuse. In fact, while relationship between the pharmaceutical industry and the medical community has resulted in important benefits for patient care, there has been for a long time concern about the potential negative consequences of the relationship. As early as in the 1970s, following Congressional hearings on unprofessional drug promotion practices, "Examination of the Pharmaceutical Industry, 1973-74," Hearing before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare, 93rd Cong., 1st & 2nd Sess., Pt. 3(1974), the Pharmaceutical Manufacturers Association endorsed federal legislation to eliminate such practices as giving gifts to physicians to encourage them to prescribe specific drugs. "PMA's Positive Program," 36 FDC Reports ("The Pink Sheet"), no. 14, at A1 (April 8, 1974). Criticism of pharmaceutical promotional practices has not abated, however.³⁷

³⁷PETER B. HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW, 2nd Ed., 458-459 (2001).

Gifts & Sponsorships for Educational/Scientific Activities

One of the major promotional practices in question is gift-giving to physicians by pharmaceutical companies. Included in this category are personal gifts (e.g., lunches or dinners, or tickets to recreational or entertainment events), gifts that aid the physician or other health care provider in his or her practice (e.g., pens, calendars, or medical textbooks), and gifts that arguably have features of both (e.g., grants to subsidize the costs of professional education of physicians).³⁸ Many gifts serve an important and socially beneficial function; some gifts, however, may have inappropriate effects and are therefore vulnerable to attack.

Pharmaceutical companies are also active in sponsoring medical conferences that have been developed by hospitals, medical schools or professional associations. Their sponsorship often takes the form of a speaker, general support, or specific underwriting grants and includes hospitality suites, dinners, and cash payments to registrants to defray the costs of attending the conference. In some cases, companies will pay the full costs for a physician to attend a conference in another city or another country and offer to pay for additional days of vacation at the conference site. Some companies put on conferences with speakers who are selected by the company and who discuss the company's products. These conferences are typically held at attractive locations, and some physicians are flown in with their spouses for a weekend of presentations, recreation, and entertainment, all at company expense. Often, a company will direct its invitations at physicians who are viewed as leading practitioners by other physicians in their community. The companies recognize that practices adopted by these "leaders" are generally followed by their peers. Companies schedule individual speakers to speak to groups of physicians over dinner at no cost to the physicians, and some companies will

³⁸Thomas N. Buleit, Jr. and Joan H. Krause, *supra* note 33.

make cash payment to each physician who attends the dinner to compensate for the physician's time.³⁹

Gifts and sponsorships are at once the easiest and most difficult to analyze under the antibribery law. In one sense, it is easy to analyze this category under the antibribery law: because these items have economic value, plainly are intended to encourage the customer to give favorable consideration to purchasing the giver's product, they arguably would seem to violate the letter of the law. It is worthy noting that the PRC antibribery law as well as the implementation opinions issued by the relevant government agencies specifically render unlawful any payments to physicians from industry under the guise of "promotion and sponsorship."⁴⁰

On the other hand, however, the description of this category also indicates the difficulty with the area of gifts and sponsorships; obviously, long-standing sales and marketing custom both inside and outside the health care industry encourages companies to be "nice" to their customers, and surely it cannot be the case that every benefit described above is rendered unlawful by the antibribery law. Indeed, some gifts and gratuities, such as textbooks or meals with sales representatives, may benefit patient care by giving physicians the opportunity to learn more about a product and its uses.⁴¹ Furthermore, the sponsorships for scientific and educational activities provided to the medical professionals by the pharmaceutical industry are undisputedly beneficial to the development of the medical profession and therefore good to the society as a whole provided that they serve the genuine scientific and educational purposes.

Payment for Services

³⁹The Council on Ethical and Judicial Affairs of the American Medical Association, *Guidelines on Gifts to Physicians From Industry: An Update*, 56 Food & Drug L.J. 27 (2001).

⁴⁰The SAIC Commercial Bribery Provisions, art.2. Also see the 1994 and 1996 Circulars issued by the State Council, *supra* note 14, and the 2001 Opinions issued by the six government departments, *supra* note 15. Also see *Implementation Opinions on Strict Enforcement Actions Against Corrupt Practices in Purchases and Sales of Pharmaceutical Products*, issued by the Ministry of Health on June 1, 1999.

⁴¹Thomas N. Bulleit, Jr. and Joan H. Krause, *supra* note 33.

Another more controversial category of promotional practices is payment to medical professionals for their services.

In general, there are a large number of common arrangements in the health care industry pursuant to which persons in a position to make prescription or purchase decisions also might be hired to perform services for the manufacturer. Most obviously, physicians, who can prescribe the company's products, often also are hired to carry out clinical studies for the company. It also is increasingly common for payments to be made to purchase data concerning use of the company's products by the physician's patients. Moreover, doctors and others are paid for serving as consultants and members of scientific or medical advisory boards, for attending focus groups, and performing professional speaking and writing on behalf of the company. In parts of the medical device industry, it also is common for physicians to serve as preceptors to other physicians, demonstrating techniques for appropriate use of certain medical devices. All of these practices raise issues under the antibribery law when the person is paid, whether a physician, pharmacist, hospital purchasing manager, or other, is in a position to influence the purchase of the manufacturers' products.⁴²

There is the possibility that some such arrangements may be "shams," paying for services that are not needed or are not actually provided; or that although legitimate services actually are provided, the structure or amount of the compensation is such as to provide an inducement to prescribe or purchase the company's products. In fact, many services arrangements between pharmaceutical companies and prescribing physicians or purchasing medical institutions have been rendered unlawful by the Chinese government agencies based upon the above reasoning. The PRC antibribery law and the relevant ministerial implementation opinions do provide the legislative and administrative sources for these enforcement actions.⁴³

⁴²See the introductory description of the general practices in the U.S. market in Thomas N. Bulleit, Jr. and Joan H. Krause, *supra* note 33.

⁴³See *supra* note 39.

Discount & Other Incentives

One of the most problematic and complained marketing practices engaged in by some pharmaceutical companies in China is making bold cash payment to physicians or pharmacists conditional on their prescription or purchase of the company products. In China, such obviously inappropriate payments are colloquially called “prescription fees” or “entrance fees,” and as a matter of practice are usually paid under the guise of “discounts” or “rebates.”⁴⁴

Discount and other incentives such as rebates obviously are not illegal *per se* in the commercial world. The pharmaceutical industry is also not excluded by law from engaging in these business practices when dealing with its customers (i.e., the purchasing hospitals). The major problem associated with this kind of business practices is that if the discounts or incentives are properly reported, and if they are specifically designed to unduly influence the recipients’ prescribing and purchasing practices. The PRC antibribery regulations outlaw any payment to physicians or pharmacists made by pharmaceutical manufacturers “off-the-book and covertly.”⁴⁵ The appropriateness of discounts and other incentives are also dependent on whether they are provided in a manner that may induce the prescribing physicians or purchasing medical institutions to overuse or even misuse the company products at the cost of the patients.⁴⁶

⁴⁴Id.

⁴⁵See the detailed discussion on the PRC antibribery law in Section III above.

⁴⁶The Ministry of Health, Implementation Opinions, 1999, *supra* note 39.

V. THE AMA GUIDELINES AND THE IFPMA CODE

The lack of clarity of the PRC antibribery law and the likelihood of its discretionary application by the enforcement agencies require the industry take various curative actions for a less confusing and more predictable regulatory environment in which they promote their products. The established ethical rules of the medical profession and the pharmaceutical industry, both at the national and the international level, may serve as good guidelines for company conduct, safe harbors from the attack of the antibribery law, and persuasive reference for the industry's lobbying efforts towards the Chinese government. Among these ethical rules the American Medical Association (AMA)'s Guidelines on Gifts to Physicians from Industry and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA)'s Code of Pharmaceutical Marketing Practices are of the most importance and relevance.

AMA Guidelines

In December 1990, the American Medical Association's House of Delegates adopted the Guidelines on Gifts to Physicians from (the "AMA Guidelines"), which first appeared in the Code of Medical Ethics in 1992. Over the years, the AMA's Council on Ethical and Judicial Affairs has continued to provide specific answers to requests for

clarification. The purpose of the AMA Guidelines is to provide a sound framework to minimize conflict of interests and to prevent the integrity and trust in the patient/physician relationship from being compromised by promotional or marketing activities.⁴⁷

The AMA Guidelines believes that even when gifts from industry have no effect on a physician's practices, there may be a public impression of impropriety, especially if the gifts are of substantial value. The trust of the public that physicians are dedicated foremost to the welfare of their patients may be undermined when there is a possibility that the choice of a drug, device or other product is influenced by the fact that the physician had received a gift from the company that manufactures the product. For example, when companies schedule their own conferences at resorts and pay for physicians and their spouses to attend for a weekend that includes only a few hours of lectures and many hours of recreation, lavish meals and expensive entertainment, it is difficult to view the conference as serving a legitimate educational purpose.⁴⁸

The costs of gifts from industry to physicians are ultimately passed on to the public. In effect, then, patients may be paying for a benefit that in some cases is captured primarily by their physicians. Physicians should not accept inappropriate gifts because the cost is ultimately subsidized by patients.⁴⁹

The AMA Guidelines also recognizes that many gifts from industry to physicians result in significant benefits to patients. For example, books and conferences contribute to the education of physicians, and meals at medical meetings or conferences provide a forum for colleagues to exchange information. These kinds of gifts can therefore be appropriate, depending on the extent to which the gift serves a function beneficial to patient care and on whether the same benefits can be realized through less costly promotional activities.⁵⁰

Specifically, the AMA Guidelines state:⁵¹

⁴⁷See AMA Council on Ethical and Judicial Affairs, *supra* note 38.

⁴⁸*Id.*

⁴⁹*Id.*

⁵⁰*Id.*

⁵¹*Id.*

1.

Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted.

2. Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).

3. Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's sales representative may create a relationship which could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

4. Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reimbursement for reasonable travel, lodging and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging and meal expenses. Token consulting or advisory arrangements cannot be used to justify compensating physicians for their time or their travel, lodging and other out-of-pocket expenses.

5. Scholarships or other special funds to permit medical students, residents and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents or fellows who will receive the funds is made by the academic or training institution.

6.

No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physicians' prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods and materials should belong to the organizers of the conferences or lectures.

IFPMA Code

At the international level, the International Federation of Pharmaceutical Manufacturers Associations (“IFPMA”)⁵² adopted the Code of Pharmaceutical Marketing Practices (the “IFPMA Code”) in 1981. A major revision of the IFPMA Code took place in 1994, recognizing the many changes in the market environment. The IFPMA Code, summarizing the rules of conduct generally accepted by the industry worldwide, can serve as another important set of guidelines for the U.S. drug manufacturers promoting their products in China. In the meanwhile, the principles and specific provisions of the IFPMA Code may be more acceptable by the Chinese government as a reference when drafting the supplementary legislation to the current antibribery law.

The IFPMA Code acknowledges that the promotion of prescription medicines to health care professionals

⁵²IFPMA was created in 1968 as a non-profit, non-governmental organization (NGO) and has since achieved consultative status with many United Nations and other international organizations. The IFPMA was admitted into official relations with the World Health Organization (WHO) in 1971 and is also on the NGO roster for the World Intellectual Property Organization (WIPO), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Industrial Development Organization (UNIDO), the United Nations Economic and Social Council (ECOSOC), the United Nations Children's Fund (UNICEF) and the Council of Europe. The members of IFPMA are regional and national associations representing research-based pharmaceutical companies and other manufacturers of prescription medicines. The PhRMA is a member of the IFPMA representing the U.S. research-based pharmaceutical industry. See more information about the IFPMA from its official website at <http://www.ifpma.org>.

is a vital extension of the process of searching for and developing new and better means of preventing and treating illness. Promotion and the dissemination of educational information ensures that the full benefits of the years of work and enormous expenditure of skill and money will be made available promptly to the patients of the world. The voluntary adoption of the IFPMA Code in 1981 was in accordance with a key objective of the IFPMA as set out by its Founder Members in 1968 in the Statutes (Article 3) which state that one of the objects of the IFPMA is “to promote and support continuous development throughout the pharmaceutical industry of ethical principles and practices voluntarily agreed on” and “to coordinate the efforts of its members towards the realization of the above objects.”⁵³

The IFPMA Code is intended to define universally applicable baseline standards of marketing practices. A substantial proportion of the 51 member associations of IFPMA have their own Code of Practice. Some are based on the IFPMA Code, but elaborated to recognize national circumstances and conditions, while others are derived from versions which existed even before the IFPMA Code was first introduced. All, however, fully embody the principles set out in the IFPMA Code. Companies within membership of IFPMA Member Associations are also encouraged to formulate their own codes that may include more specific requirements and additional rules that must be observed by their own employees in conducting their own promotional activities.⁵⁴

Sections III and IV of the IFPMA Code, dealing with “symposia, congresses and other means of verbal communication” and “hospitality and promotional items” respectively, are of most relevance to this article. The IFPMA Code recognizes that symposia, congresses and the like are indispensable for the dissemination of knowledge and experience, and provides the following safe harbor rules for pharmaceutical companies to engage in such activities:⁵⁵

⁵³IFPMA Code: Introduction.

⁵⁴Id.

⁵⁵IFPMA Code: Section III.

1.

Objectives: scientific objectives should be the principal focus in arranging such meetings and entertainment and other hospitality shall not be inconsistent with such objectives.

2. Sponsorship: When a pharmaceutical company or association sponsors a symposium, congress or other medical/health care or educational program:

•

The fact of sponsorship by the company or association should be clearly stated in advance, at the meeting and in any proceedings. Printed, audio-visual or computer-based material arising from such meetings should accurately reflect the presentations and discussions.

• Entertainment or other hospitality and any gifts offered to members of the medical and allied professions should be secondary to the main purpose of the meeting and should be kept to a modest level.

• Any support to individual health practitioners to participate should not be conditional upon any obligation to promote any medicinal product.

• If the program is accredited for postgraduate medical education by a medical or other professional organization, responsibility for the program content remains with the organization responsible for obtaining accreditation for the meeting, and industry support should be disclosed.

•

Payments of reasonable honoraria and reimbursement of out-of-pocket expenses, including travel, for speakers/presenters are customary and

proper.

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Companies should not pay travel costs of persons accompanying invited members of the medical and allied professions.

The IFPMA Code generally prohibits inappropriate benefits provided to health care professionals, but exempts promotional items of insignificant value and educational materials from the general prohibition. Specifically, Section IV.1 provides that inappropriate financial or material benefits, including inappropriate hospitality, should not be offered to health care professionals to influence them in the prescription of pharmaceutical products.⁵⁶ Making hospitality or other benefits conditional upon past prescribing performance is also precluded.⁵⁷ Section IV. 2 provides that promotional items of insignificant value, provided free of charge, are permissible as long as they are related to the health care provider's work and/or entail a benefit to patients.⁵⁸ Section IV. 3 further provides that textbooks or reference books/information, and other educational material may be given to health care providers if they serve a genuine educational function.⁵⁹

VI. CONCLUSION

⁵⁶IFPMA Code, Section IV.1.

⁵⁷IFPMA Code, Explanatory Note to Section IV.1.

⁵⁸IFPMA Code, Section IV.2.

⁵⁹IFPMA Code, Section IV.3.

Given the facts that the health care industry of China is still under dramatic reform and restructuring, and that the PRC antibribery law and the enforcement actions taken by the government agencies are still of the developing character, in the short run the disorder and unpredictability of China's pharmaceutical market and the regulatory regime will remain. To fully tap the attractive market potentials while avoid or minimize undesirable government interruptions, the U.S. pharmaceutical manufacturers should consider designing and implementing more effective and country-specific corporate policies governing their promotional and marketing practices in China; in the meantime, continuing the lobbying efforts to urge the Chinese government to clarify the existing regulation and set forth more safe harbors to accommodate the industry's concerns.

With respect to the provision of gifts and sponsorships from the industry to medical professionals, the cautious guidelines set forth by the AMA Guidelines and IFPMA Code should be observed. In essence, the value of the gifts and sponsorships must be appropriate and consistent with the genuine scientific and/or educational purposes, and any linkage between the provision of gifts/sponsorships and the prescribing/purchasing practices must be carefully avoided.

With respect to the payment to medical professionals for services, pharmaceutical companies should demonstrate that they do have a legitimate need for the services of the physician consultant or advisor. The best evidence of such a need probably is that the company considers and acts (either favorably or unfavorably) on the recommendations of its physician consultants. Another issue should be noted is whether the physician consultants are compensated an amount that fairly reflects the value of a service that contemporaneous documentation shows they actually provided.⁶⁰

⁶⁰Thomas N. Bulleit, Jr. and Joan H. Krause, *supra* note 33.

With respect to the discounts and other incentive arrangements, the single most important guideline is to strictly abide by the relevant accounting principles and rules and have all of these arrangements duly recorded on the company's accounting books. As previously analyzed, the dividing line between lawful "discounts" and unlawful "kickbacks" is that whether they are provided "off-the-book and covertly,"⁶¹ thus good book-keeping practice and the maintenance of an easily-checkable "paper trail" of these arrangements are highly recommendable.

The U.S. pharmaceutical industry has also started to, and should continue to, engage in lobbying activities to persuade the Chinese government to change or refine the relevant rules. The PhRMA has come up with and publicized a set of detailed suggestions for substantiate and clarify the vague provisions contained in the Drug Administration Law.⁶²

In order to address the industry's concern about the potential for controversy about the intent of Articles 59, 90 and 91 of the Drug Administration Law, the PhRMA suggest that the implementation rules supplementing to the Drug Administration Law⁶³ specify as clearly as possible what conduct remains permissible. With respect to the "valuables or other material benefits" used in the second paragraph of Article 59 and the corresponding sentences of Articles 90 and 91, the PhRMA argues that the objective of the law could be achieved with minimal disruption of *bona fide* promotional activities if the implementing rules were to make clear that the prohibition on the provision or acceptance of benefits refers to "inappropriate benefits provided to influence the recipients in the purchase or prescription of pharmaceutical products of the providers," following the lines of the IFPMA Code and legislative norms of some other countries.⁶⁴

⁶¹See the detailed discussion in Section III above.

⁶²See the PhRMA NTE Submission, *supra* note 2.

⁶³The Implementation Rules for the Drug Administration Law are under the amendment process to be consistent with the recent amendments to the Drug Administration Law. The agencies charged with the drafting work are the State Drug Administration and the State Council's Office of Legal Affairs.

⁶⁴*Id.*

The PhRMA also suggests setting forth specific exemptions from the attack of Articles 59, 90 and 91 of the Drug Administration Law, which providers and recipients of benefits could readily understand. For example, the new implementing rules might expressly provide that Articles 59, 90 and 91 do not prohibit the sponsorship of attendance by health care professionals at symposia, conferences, congresses, seminars or other similar research-oriented or educational programs, publication of scientific papers and the provision of promotional items of insignificant value and educational materials.⁶⁵

PhRMA proposes that a specific exemption along the lines of the foregoing could be made even more precise by providing that permissible sponsorships and materials are those that are (a) genuine in terms of purpose; (b) not intended to induce any pharmaceutical purchase and prescription activity, (c) appropriate to the expertise of the sponsored personnel and disclosed in writing to the responsible persons within the unit of the sponsored personnel, (d) reasonable in amount to the extent of that required by the scientific and educational purposes, and (e) properly accounted for in the books and records of the sponsor.⁶⁶

⁶⁵Id.

⁶⁶Id.