TRANSPARENCY MEASURES TO CONTROL FINANCIAL INTERACTIONS BETWEEN PHYSICIANS OR HELATHCARE PROFESSIONALS AND PHARMACEUTICAL COMPANIES

BY

MISS ARIYA SUEBPHANWONGS

A THESIS SUBMITTED IN PARTIALFULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF LAWS IN BUSINESS LAW (ENGLISH PROGRAM)

FACULTY OF LAW

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was approved as partial fulfillment of the requirements for
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ABSTRACT

It is unavoidable that medicine is one of the key fundamental things for human's needs. Nevertheless, medicine has its special qualification different from other general products because it could directly cause harm and risk to health and life of consumers. In addition, it is not freely available for consumer's purchase as other consumer goods since medicine is specific, and it requires knowledge and skills of the well trained experts, in order to provide proficient and efficient diagnosis. Consequently, patients are not at the position to select their own treatment, but to lay their trust on physician or healthcare professional to perform this role for them instead. Therefore, prior to consumption of the medicines, the patients always decide to receive recommendation or diagnosis from physicians or healthcare professionals who are experts in their relevant fields, and patients dependably put their trust on them for their solution of what medications are genuinely essential for them. This is a reason why the physicians and healthcare professionals must prioritize their patients with their best attempts since most of the patients are reliant upon the physicians and healthcare professionals who are expected to put the needs of the patient as the first priority. Even consumers are confident the physicians and healthcare professionals to act in the best interests of their patients, the medicines are manufactured and sold by pharmaceutical companies similarly as other

general items in business sector, and most consumers are widely unaware of the direct and indirect influence of the pharmaceutical companies' marketing over the physicians and healthcare professionals they depend on. To stimulate their companies' sale volume, the physicians particularly are the major targets for the marketing of pharmaceutical companies due to the authorization to prescribe and a high status in society, so their decision could determines success of each product. Therefore, it is not surprising that the majority of marketing strategies spent by pharmaceutical companies go towards direct-to-physician promotion that leads to problem of conflict of interest between the physicians or healthcare professionals and the pharmaceutical companies. This relationship is very sophisticated than we have imagined since this kind of relationship comprising of useful financial support and improper financial interactions that could cause many serious results from irrational use of medicine until bribery or corruption.

From all previously mentioned, if prescriptions from physicians and healthcare professionals are truly transparent and free from any conflicts of interest with the pharmaceutical companies under monitoring and controlling by efficient measure, the ultimate interest would be with the patients, as consumers, and with the state. In this regards, this thesis focuses on transparency measures to control financial interactions between the physician or healthcare professionals and the pharmaceutical companies by studying existing measures applied in overseas and comparing with current situations of Thailand. The study will provide analysis and recommendations to enhance the effective enforcement of the transparency measure and to find out the potential results that suitable for Thailand.

Keywords: Transparency, Physician, Healthcare professional, Pharmaceutical company

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Miss Ariya Suebphanwongs
Thammasat University
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LIST OF ABBREVIATIONS

Symbols/Abbreviations	Terms
ACCC	Australian Competition & Consumer Commission
AMA	American Medical Association
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration Thailand
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
OECD	Organization for Economic Co-operation and Development
PPACA	Patient Protection and Affordable Care Act
PPCR	Physician-Pharmaceutical Company Relationship
PPR	Physician- Patient Relationship
PReMA	Pharmaceutical Research & Manufacturers Association
TGA	Therapeutic Goods Administration, Department of Health, Australian Government
WHO	World Health Organization

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CHAPTER 1
INTRODUCTION

1.1 Backgrounds and Problems

It is undeniable that medicine is one of the key factors for human life. However, medicine is a product that has unique characteristics different from other common products since medicine can cause harm and is a risk to health and life, and some kinds of medicine cannot be accessed by ordinary persons without prescription. Therefore, prior to ordering or consuming such medicines, there must be a diagnosis and a prescription from physicians or healthcare professionals who are experts in their relevant fields. Patients also always put their trust in them to make decisions on what medicines are truly suitable and necessary for them. This is a reason why physicians and healthcare professionals must have a primary obligation to take care of their patients with their best attempts since most of them have confidence in and rely on physicians and healthcare professionals who are expected to put the needs of their patients first. This obligation can be called a fiduciary duty. A fiduciary duty is a legal duty to act solely in another party's interests.[1] Therefore, according to the trust and confidence received from the patients, all physicians and healthcare professionals should behave themselves towards their patients with a duty of care and loyalty.

Although it is clear that patients trust their physicians and healthcare professionals to act in their best interests, it is also clear that the medicines are manufactured and sold by pharmaceutical companies in the same way as other general products in the market. Most consumers are generally unaware of the direct and indirect power of marketing by pharmaceutical companies on the physicians and healthcare professionals they depend on. As per business purpose and very high market value, healthcare and pharmaceutical sectors are really vulnerable to unethical practices in its system[2] especially transparency in financial interactions among people in healthcare industry since the related stakeholders are various, different, and have

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[1] Legal Information Institute, Cornell University Law School, https://www.law.cornell.edu/wex/fiduciary_duty (last visited 27 July 2016)

[2] World Health Organization, **Measuring Transparency in Medicines Registration, Selection and Procurement: Four Country Assessment Studies**, 1 (2006).

many objectives. They comprise physicians, healthcare professionals, researchers, manufacturers, distributors, wholesalers, retailers, medical representatives[3] and regulators. For this reason, non-transparent interactions between the physicians or healthcare professionals and the pharmaceutical companies can manifest themselves in many forms throughout every level of the system such as the giving and taking of gifts, unethical drug sale promotion, collusion, fraud, bribery and corruption. A report by PriceWaterhouseCoopers (hereinafter referred to as PWC) stated that bribery and corruption are the main threats, and they are the second most commonly reported type of economic crime for the pharmaceutical sector. Furthermore, the same report also shows that in recent years the pharmaceutical sector has faced criticism over how it interacts with physicians and healthcare professionals.[4] Another report from PWC also argued that too much money is spent on advertising by pharmaceutical company.[5]

As mentioned above, it can be seen that due to many factors such as high market value and various stakeholders it is very difficult to control transparency in the pharmaceutical sector especially in financial interactions between physicians or healthcare professionals and pharmaceutical companies. The physicians are the main targets for the pharmaceutical companies due to the power to prescribe and a high profile in community, and their decisions about medicines very often determine their success. Therefore, it is not shocking that the majority of marketing spent by pharmaceutical companies goes towards direct-to-physician promotion. The most effective marketing method that the pharmaceutical companies use is to try to foster a good relationship and connection with the physicians or healthcare professionals through their medical representatives.

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[3] In this Thesis, medical representative means a person who works for pharmaceutical company or its subsidiary or distributor, and he or she is a key connection between the physicians or healthcare professionals and the pharmaceutical companies with the main purpose to increase awareness of brand and use of company's product. It also known as medical sale representative, pharmaceutical sale representative or reps.

[4] Pharmaceuticals and Life Sciences Sector Analysis of PWC's 2014 Global Economic Crime Survey, PriceWaterhouseCoopers, **Pharmaceuticals and Life Sciences' fight against bribery and Corruption**, 4 (2014).

[5] PriceWaterhouseCoopers, **Pharma 2020: The vision which path will you take?**, 7 (2007).

A medical representative spends most of his or her working time on the road visiting physicians and healthcare professionals to increase the visibility of their companies' products and the volume of their sales. Many medical representatives agree that the best representatives try to make every possible effort to sell their products, and a significant proportion of their income depends on their ability to get the product into the hands of the consumers[6]. They have to visit the physicians during their working day to try to convince them about the importance of a long-term relationship. They also have to learn about the characteristics of the physicians they are in contact with to ensure that they will prescribe their products to the patients. One-to-one visits from medical representatives are proven to be the most effective way to remind and promote medicines to the physicians because they can identify the behavior and decision-making style of the person they are selling to and adapt their approach accordingly. Visits from medical representatives are often coordinated with other methods such as the giving of gifts, free samples or running advertising campaigns[7]. Nowadays, the practice of giving gifts to physicians or healthcare professionals is common; these range from small value items to expensive foreign holidays.

In addition, according to the report of Consumer International, a non-profit independent global campaigning voice for consumers with more than 220 members in 115 countries, which was entitled "Drugs, Doctors and Dinners: How drug companies influence health in the developing world", these gifts can come in various forms from small gifts (pens, tissue boxes, soaps, mouse pads, plastic folders etc.) to product samples including sponsorship by exhibition booths, textbooks, entertainment, travel expenses, meals and family-related activities. The report also shows that the physicians and healthcare professionals' belief about gifts recognizes that they do have an impact on prescribing behavior, and can increase unreasonable drug use that

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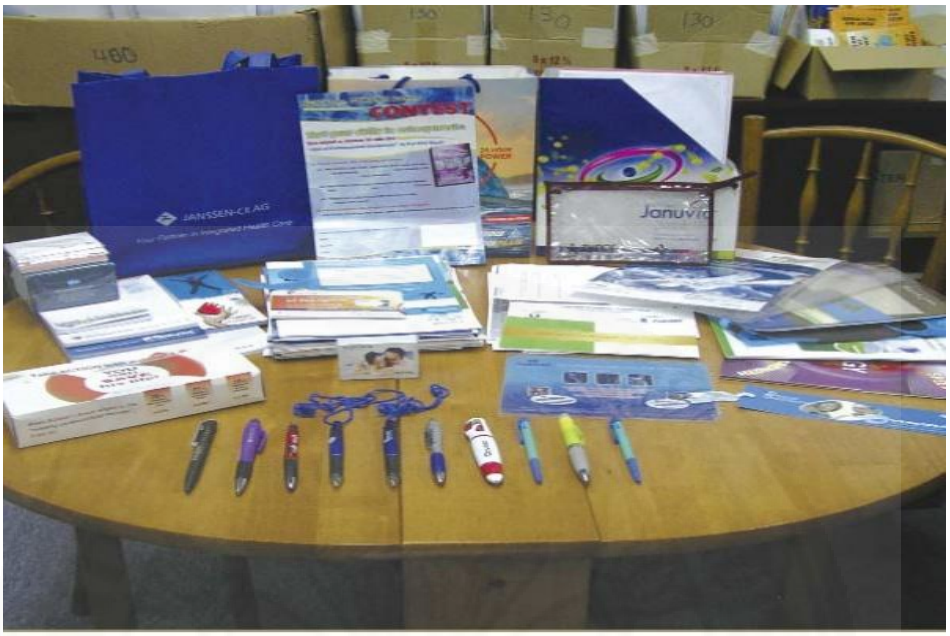
[6] The Princeton Review, *A day in the Life of a Pharmaceutical Sales Representative*, http://www.princetonreview.com/careers/110/pharmaceutical-sales-representative (last visited 27 July 2016).

[7] สุภาพร ศรีตระกูลรัตน์, **ผู้แทนยา-ปิดยอดให้ได้อะไรก็ทำได้** , ฉบับที่ 124, นิตยสารฉลาดซื้อ (มิถุนายน 2554) (Supaporn Sritrakulrat, **What does the medical representative do to close the deal?**,Volume 124, Chaladsue Magazine Volume 124 (June 2011)).

is not based on reliable data or real needs, safety, efficacy and the price of drugs but rather on the marketing tactics of individual companies.[8]



Source: Consumer International, Drugs, Doctors and Dinners: How drug companies influence health in the developing world, 6 (2007).
(The picture shows small promotional materials provided in one month by the pharmaceutical companies to a physician who is also a survey respondent)

As for academic purpose, it is obvious that the pharmaceutical companies encounter a conflict of interest in providing details of the negative impacts of their products. This represents a problem for the physicians everywhere but particularly in developing countries where they rely strongly on the drug information provided by the company and in many cases cannot access independently verified data. However, the physicians can also become part of the problem when they choose to endorse a company's marketing campaign or play the role of a seemingly independent key opinion leader to shape a positive concept of the drug among healthcare professionals.[9]

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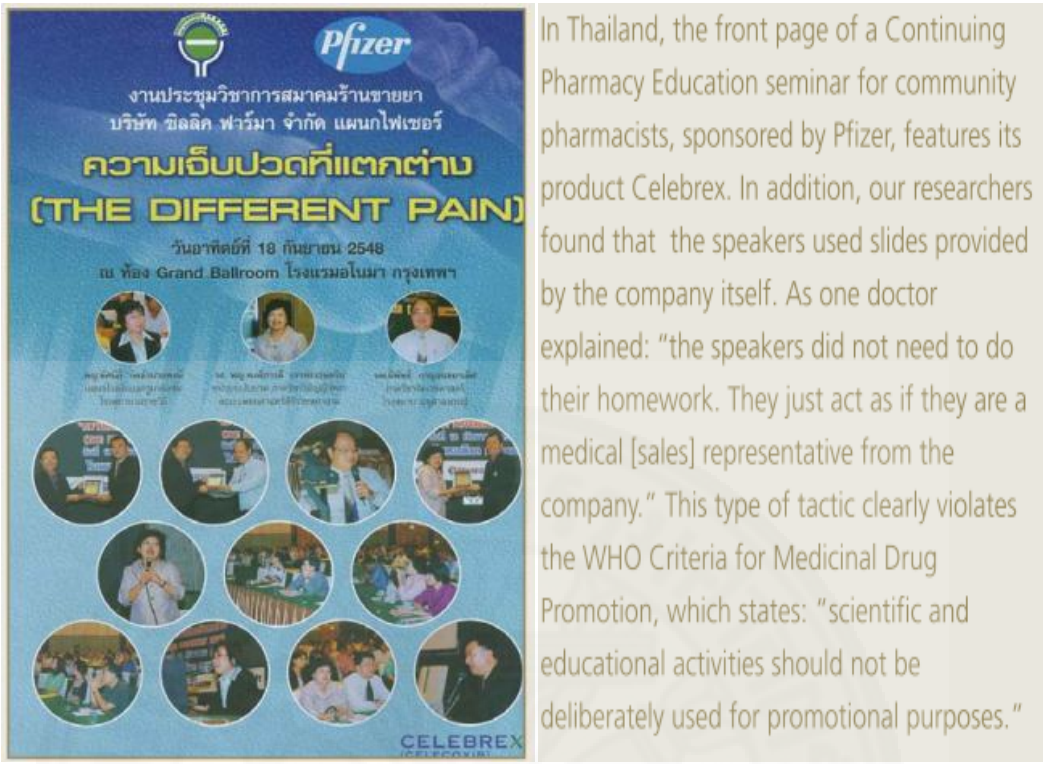
[8] Consumer International, **Drugs, Doctors and Dinners: How drug companies influence health in the developing world**, 21 (2007).
[9] *Id*. at 24.



Source: Consumer International, Drugs, Doctors and Dinners: How drug companies influence health in the developing world, 24 (2007).

(The picture represents advertising method from pharmaceutical company by sponsoring academic seminar)

All of the above raise the issue of ensuring that non-transparent financial interactions between the physicians or healthcare professionals and the pharmaceutical companies do impact on their discretion when giving a diagnosis, and procuring and dispensing medicines. For this reason, a number of countries have put in place measures to control unhealthy financial interactions between the physicians and healthcare professionals on the one side and the pharmaceutical companies on the other.

Currently, Thailand does not have legislation to control this matter directly and effectively. There is, however, an attempt to drive forward this concern including through research[10] in this area. These are reasons why it is interesting to complete a

[10] ดาราพร ถิระวัฒน์ และคณะ, **รายงานฉบับสมบูรณ์โครงการการศึกษากฎหมายควบคุมการส่งเสริมการขายยาในต่างประเทศ** , แผนงานกลไกเฝ้าระวังและพัฒนาระบบยา (2553) (Dr. Daraporn Thirawat ET AL, **Report on Study**

study on transparency measures to control financial interactions between the physicians or healthcare professionals and the pharmaceutical companies of foreign countries. Comparing the advantages and disadvantages can act as a guide for Thailand to adopt potential solutions which these solutions should cover two core principles: 1) the principle of disclosure obligation and 2) the principle of prevention of conflict of interest.

1.2 Hypothesis

The current Thai laws and regulations do not have provisions with respect to controlling transparency in financial interactions between physicians or healthcare professionals and pharmaceutical companies. Thailand should have specific laws on such matters.

1.3 Objectives of Study

i) To study the transparency measures to control financial interactions between physicians or healthcare professionals and pharmaceutical companies in selected countries;

ii) To study the situation of transparency in financial interactions between the physicians or healthcare professionals and the pharmaceutical companies in Thailand, and analyze existing provisions in connection with the situation; and

iii) To propose potential approaches based on measures applied in foreign countries in order to strengthen the current provisions against the problem of transparency in financial interactions between physicians or healthcare professionals and pharmaceutical companies in Thailand.

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on Legal Measures to Control Drug Sale Promotion in Foreign Countries, Thai Drug Watch Organization (2010)).

1.4 Scope of Study

This thesis mainly focuses on Thai transparency measures to control financial interactions between physicians or healthcare professionals[11] and pharmaceutical companies. Relevant laws and regulations will be studied, starting with the background and problems in Thailand, including the enforcement of existing laws and regulations by comparing these with the measures of selected countries. The thesis will point out the loopholes and analyze the problems thereof, and then propose potential legislative solutions.

1.5 Methodology

The method of study in this thesis is mainly based on documentary research by examining texts and documents in libraries and internet databases as source materials. Texts and documents include theses, educational institution journals, government publications, newspapers, domestic and foreign laws as well as related legislation.

1.6 Expected Results

The expected results are as follows:

i) To provide information concerning transparency in financial interactions between physicians or healthcare professionals and pharmaceutical companies in foreign countries;

[11] In this Thesis, healthcare professional means a person who may prescribe, dispense, recommend, supply drugs applied to human in Thailand as long as they hold licenses to practice their career from any other professional councils such as the Pharmacy Council of Thailand or the Physical Therapy Council.

ii) To analyze whether Thailand has problems due to the absence of transparency rules, and analyze existing laws and regulations in Thailand and whether they are sufficient to handle this issue;

iii) To raise awareness of the problems to authorities involved in dealing with this issue; and

iv) To provide appropriate recommendations and suggestions for the measures to cope with the financial interactions between physicians or healthcare professionals and pharmaceutical companies in Thailand.

CHAPTER 2
NATURE OF INTERACTIONS IN HEALTHCARE SYSTEM

2.1 Nature of Interactions between Physicians or Healthcare Professionals and Patients

Since the marketing efforts of pharmaceutical companies focus on physicians as their main target group due to their higher standing than other healthcare professionals, this chapter will only focus on the physician-patient relationship (hereinafter referred to as PPR). The area of study comprises the way their interactions are supposed to be, the way they actually are and the theories relating to such relationships.

2.1.1 Historical Nature of Interactions between Physicians and Patients

One of the oldest and most traditional guiding principles for physicians has been the obligation to work in the patient's interests. Since the Hippocratic tradition began, generations of physicians have promised to do their best to protect their patients from hazards and heal them. The physician is already accepted and acknowledged as a protector who uses his specialized knowledge to recover and benefit patients. Therefore, the relationship between the physician and the patient is compared to that of father and child, termed the "Paternalism model". Whilst this model emphasizes the protection given by the physician, at the same time it ignores the autonomy of the patient.[12]

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[12] รติกร กุลวรกุลพิทักษ์, "ความรับผิดทางแพ่งของแพทย์จากการฝ่าฝืนเจตนาปฏิเสธการรักษาล่วงหน้าของผู้ป่วยวาระสุดท้ายของชีวิต", วิทยานิพนธ์นิติศาสตร์มหาบัณฑิตสาขากฎหมายเอกชน, มหาวิทยาลัยธรรมศาสตร์, 11-12 (2557) (Ratikorn Kulvarakulpitak, "Civil liability of physicians in interference with advance directives", Master of Laws' thesis, Thammasat University, 11-12 (2014)).

2.1.2 Nature of Interactions between Physicians and Patients in the Modern World

For centuries, this model was accepted until the idea of individualism emerged. This concept does not just affect politics and religion but also influences the thinking of patients when it comes to PPR. Nowadays, the idea of patient autonomy and self-decision has emerged as the powerful ethos in the healthcare system, and the influence of the paternalism model has been slowly reduced.

The concept of patient autonomy is a combination of the patient's needs, concerns, ideas, expectations and decisions with professional recommendations from the physician, which requires a reasonable amount of mutual trust and understanding between both sides. One of the reasons why a strict paternalism model is no longer valid is the erosion of confidence in and respect for physicians by the public.

The development is demonstrated by a comparison of the ethical codes of the American Medical Association (hereinafter referred to as AMA) in two different periods of time. In the 1847 AMA ethical code, the following content was stipulated in section 6:

"The obedience of a patient to the prescriptions of his physician should be prompt and implicit. He should never permit his own crude opinion as to their fitness, to influence his attention to them. A failure in one particular may render an otherwise judicious treatment dangerous, and even fatal."

In contrast, in 1990 the AMA's opinion about the basic element of the PPR changed its position to be more individual as follows:

"The patient has the right to make decisions regarding the health care that is recommended by his or her physician. Accordingly patients may accept or refuse any recommended medical treatment."[13]

The patients can also participate more in terms of discussing risks, cost, treatment options etc as stated in the current AMA Code of Medical Ethics. The Code

[13] JJ Chin, "*Doctor-patient Relationship: from Medical Paternalism to Enhanced Autonomy*", 43(3), **Singapore Med J**, 152, 152 (2002).

goes on to say: "The patient has the right to receive information from their physicians and to have opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives, including the risks, benefits and costs of forgoing treatment. Patients should be able to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective."[14]

2.1.3 Nature of Interactions between Physicians and Patients in Thailand

Thailand has an Asian culture and has Buddhist influences. The former PPR was based on paternalism in the same way as Western culture. Thai people also gave respect to physicians due to their knowledge and high profile, and also agreed with their decisions without any comments. However, things have changed. The idea of paternalism is starting to disappear and there is a greater focus on patient autonomy and contractual model instead.[15]

2.1.4 Contractual Model of Patient-Physician Relationship

In a modern libertarian society, contractual relationships cover a wide range of human transactions which all parties agree freely to. This includes modern medicine in which the physicians are recognized as service providers of medical skills and the patients as consumers who are looking for medical products or service to serve their needs. In practice, if physicians or hospitals accept the patients, it shall be deemed that the unwritten contract is in place between them. Therefore, it is possible that the

[14] *Chapter 1: Opinions on Patient-Physician Relationships*, AMA Code of Medical Ethics, American Medical Association, http://www.ama-assn.org/ama/pub/physician resources/medical ethics/code-medical-ethics.page (last visited 21 July 2016)
[15] Kulvarakulpitak, *supra* note 12, at 12-13.

contractual model could slowly undermine and reduce the traditional paternalism model.[16]

However, the contractual model is not sufficient to explain such a sophisticated relationship as the PPR since it is complex both externally and internally. The PPR is sophisticated because the physicians and patients are not usual sellers and purchasers in general situations.

To begin with, patients do not voluntarily agree to buy healthcare products or services in the same way as buying a house. The purchase or payment for medical care is unwelcome and it always occurs in urgent situations that do not provide them enough time to consider their options carefully. In addition, the PPR is a personal and sensitive relation where one party, the patient, can be depressed, unhappy, vulnerable, sick and helpless person. In contrast, the other party, the physician, is confident, independent and equipped with knowledge. Furthermore, the physicians have an almost complete monopoly and greater bargaining power over what the patients need. Moreover, in the process of diagnosis, the patients have to disclose personal or family information to their physicians and so this relation is based on trust and confidentiality.

Lastly, the contractual model does not support medical professionalism and ethics. The contractual PPR is unprofessional and unacceptable because it assumes that physicians do not owe any duties to society and patients. The physicians, in turn, are encouraged to believe that they became physicians only because of their superior intellectual qualities, and their professional commitment to patients as practicing

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[16] อนุชา กาศลังกา, "*การศึกษาปัญหาแพทย์และบุคลากรทางการแพทย์สังกัดกระทรวงสาธารณสุขและสำนักงานปลัดกระทรวงสาธาณสุขถูกฟ้องเรื่องจากการรักษาพยาบาล* ", เล่มที่ 32, **วารสารวิชาการกรมสนับสนุนบริการสุขภาพ** , 57, 61 (2555-2556) (Anucha Kardlungka, "*The study of the doctors and medical personnel in hospitals under the Ministry of Public Health and the Office of Permanent Secretary for Public Health have been in the prosecution of the medical services purposes*", Volume 32, **Academic Journal of Department of Health Service Support**, 57, 61 (2012-2013)).

physicians is due to their personal virtues of philanthropy. They wrongly assume that their acts of healing and caring are wholly charitable.[17]

Even currently the PPR is always seen in form of the contractual model which it is expected that all parties would get into the medical agreement freely and independently. However, after considering and due to complexity of this relation, the patients still have less bargaining power than the physicians who are specialized in their relevant fields. Therefore, it is unavoidable that the physician is the person who has obligations to look after and keep in mind his patient's interest or it could be said that the physicians must remind themselves that they have a fiduciary duty.

2.1.5 Fiduciary Duty

Fiduciary duty is the highest standard of care, where one party is expected to be extremely loyal to the person to whom he owes the duty. Such a party must not profit from his position but act solely in another party's interests.[18]

A characteristic of fiduciary duty is its flexibility to accommodate new situations as they arise. From the beginning, the fiduciary doctrine was the courts' response to the absence of a remedy for a beneficiary injured by the disloyalty of a trustee.[19] Over time, the doctrine has been developed beyond the trustee-beneficiary relationship to other relationships in which one party is responsible and entrusted to act on behalf of another individual with the expectation that such a person will seek to promote the beneficiary's interest. Fiduciary relationships also have been found to exist between directors and companies, attorneys and clients, agents and principals.[20]

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[17] EC Hui, "*The Contractual Model of the Patient-Physician Relationship and the Demise of Medical Professionalism*", 11(5), **Hong Kong Med Journal**, 420, 420-422 (2005).

[18] Legal Information Institute, Cornell University Law School, *supra* note 1.

[19] Barry L. Zins, "*Trustee Liability for Breach of the Duty of Loyalty: Good Faith Inquiry and Appreciation Damages*", 49(6), **Fordham Law Review**, 1012, 1012-1037 (1981).

[20] Paul B. Miller, "*Justifying Fiduciary Duties*", 58(4), **McGill Law Journal**, 969, 969 (2012).

In the context of PPR, the fiduciary duty means that the physician must not neglect, abuse, exploit or take advantage of the vulnerable patient. This enables the patient to obtain essential help from the physicians. Therefore, the fiduciary duty of the physicians should include a responsibility to avoid placing themselves in situations where pharmaceutical companies have the potential to compromise or negotiate their medical discretion.

It can be summarized that the PPR must be conducted under the fiduciary doctrine because, when it is established, patients, implicitly or explicitly, allocate on the physicians' discretion to act on patients' behalf with respect to their health. Furthermore, the asymmetry of power and medical knowledge between patients and physicians places patients in a vulnerable position. Accordingly, in order to protect the patients, there is a heightened ethical and legal expectation that the physicians should be loyal to patients' interests, avoid acting in their self-interest, keep patients informed, and act in good faith, within the scope of authority, and with the utmost care towards patients.

2.2 Nature of Interactions between Physicians and Pharmaceutical Companies

Apart from the PPR, the nature of the physician-pharmaceutical company relationship (hereinafter referred to as PPCR) will be taken into consideration as well. The scope of study comprises the way their interactions are supposed to be and the way they really are including effects from inappropriate PPCR.

2.2.1 Nature of Interactions between Physicians and Pharmaceutical Companies

As mentioned above, the fiduciary duty is considered a priority for all physicians, and it is always seen and inserted in medical codes of conduct of professional councils.[21] However, the fiduciary duty should include a secondary

[21] The Medical Council Regulations on Medical Ethics Preservation of Thailand B.E. 2549

obligation to prevent physicians from being influenced by pharmaceutical marketing as patients' interest may be compromised inappropriately.

Generally, marketing means "the activity, set of institutions and processes for creating, communicating, delivering, and exchanging offerings that have value for customers, clients, partners, and society at large."[22] The term of marketing is broader than advertising and sale promotion; it can be said that advertising and sale promotion are component parts of marketing activities. Therefore, any transparency measure that would be effective in practical way must cover and be able to control advertising and sale promotional activities applied by the pharmaceutical companies.

Remark:

i) Advertising means "the placement of announcements and persuasive messages in time or space purchased in any of the mass media by business firms, nonprofit organizations, government agencies, and individuals who seek to inform and / or persuade members of a particular target market or audience about their products, services, organizations, or ideas."[23]

ii) Sale promotion means "those marketing activities other than personal selling, advertising, publicity, that stimulate consumer purchasing and dealer effectiveness such as display, shows and exhibitions, demonstrations and various non-recurrent selling efforts not in the ordinary routine."[24]

Given the high market value of the pharmaceutical industry, it is not surprising that pharmaceutical companies spend a lot on marketing to stimulate their sale

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Article 15 "A medical practitioner shall maintain the highest standard of medical practice in a particular setting, within the scope of competence and the limits of objectivity and circumstance surrounding."
Article 22 "A medical practitioner shall concern about patient safety."
Article 23 "A medical practitioner shall concern about patient's expense."

[22] American Marketing Association, https://www.ama.org/AboutAMA/Pages/Definition-of-Marketing.aspx (last visited 6 January 2016)

[23] American Marketing Association, https://www.ama.org/resources/Pages/Dictionary.aspx

[24] Amusat W.A, Adejumo D.A & Ajiboye F.A, "*Sale Promotion as an Antecedent of Sales Volume: A Study of Selected Manufacturing Industry in Ibadan, South Western, Nigeria*", 4 (11), **Inter Disciplinary Journal of Contemporary Research in Business**, 465, 466 (2013).

volumes. According to many surveys[25] and pieces of research,[26] the great majority of these expenditures are on medical representatives visiting the offices of physicians or contacting physicians to build a relationship and present their products. Medical representatives are primarily college-educated but those who have graduated with a science background could have more advantages in this occupation. They also have to attend training programs designed specifically to enable them to promote companies' products. This career is highly-pressured because it is commission-based. Visits from the medical representatives are always coordinated with many marketing tactics to achieve their trading purposes such as:

i) Leaving reminders such as notepads, pens and other small gifts engraved with the company logo;

ii) Leaving drugs samples;

iii) Sponsoring academic activities such as symposia, exhibition booths and paying registration fees; and

iv) Sponsoring non-academic activities such as entertainment, travel expenses, meals and family-related activities.

These create the issue of how to ensure that those unhealthy relationships will not create negative influences over medical prescriptions or lead to any conflicts of interest between the physicians or healthcare professionals and the pharmaceutical companies.

2.2.2 Corporate Social Responsibility[27]

Even though pharmaceutical companies still have as their priority to get high financial returns and have a responsibility to their shareholders regarding dividend

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[25] Consumer International, *supra* note 8, at 23.

[26] Joshua E. Perry, Dena Cox & Anthony D. Cox, "*Trust and Transparency: Patient Perceptions of Physicians' Financial Relationships with Pharmaceutical Companies*", 42(4), **Journal of Law, Medicine & Ethics**, 475, 475-477 (2014).

[27] สถาบันธุรกิจเพื่อสังคม, **ตลาดหลักทรัพย์แห่งประเทศไทย** , เข็มทิศธุรกิจเพื่อสังคม, 3-7 (2551) (Corporate Social Responsibility Institute, **Stock Exchange of Thailand**, Corporate Social Responsibility Guidelines, at 3-7 (2008).

payment, doing business requires participation and interaction with various sectors. The pharmaceutical companies should expect to be judged beyond financial results since profits alone cannot guarantee sustainable growth and development especially when the business sector ignores the impact of all relevant sectors, including social and environmental. The concept of corporate social responsibility (hereinafter referred to as CSR) is to make business, and social and environmental aspects achieve a balance in relation to integration of business purpose, ethics and good governance. The idea of CSR emerged in 1992 in the United Nations Conference on Environment and Development at Rio de Janeiro, Brazil; informally called the Earth Summit. It was announced there that a new direction was sustainable development and that social responsibility and environmental concerns should be taken into account by all organizations both in the public and private sector.

In 1999, this concept was developed further when Kofi Annan Secretary-General of the United Nations at that time issued a call to businesses around the world to show good global citizenship and he launched the United Nations Global Compact providing a framework of sustainable development for the business sector.

In compliance with CSR, there are 4 levels as follows:

i) Mandatory level means the business is obliged to comply with the related laws and regulations;

ii) Elementary level means the business must survive and could return profits to its shareholder;

iii) Preemptive level means the business can get profits reasonably in compliance with the code of conduct; and

iv) Voluntary level means doing business in parallel with the implementation of CSR practices voluntarily, without being demanded by society in any way.

As mentioned above, transparency is one of the key factors to encourage sustainable development. The business sector, especially in pharmaceutical industries, comprises various stakeholders that operate their businesses fairly and are concerned about their social impact and sustainable growth, including having a procedure to

examine transparency. This could give confidence to all stakeholders and could benefit its long-term development.

2.2.3 Impacts of Inadequate Measures to Control Transparency in Financial Interactions between Physicians and Pharmaceutical Companies

Thailand has no laws and regulations that directly regulate the transparency of financial interactions between physicians or healthcare professionals and pharmaceutical companies. This makes the issue of non-transparent financial interactions more serious, something that is reflected in a number of ways. These are given below.

a. Irrational Use of Drug

As a marketing strategy, in cultivating a gift relationship with physicians, pharmaceutical companies are trying to create a relationship of reciprocity. This means that, upon obtaining a gift, the physicians may feel obliged to give something in return. The difficulty is ensuring that such a close relationship does not have an impact on the behavior of physicians when prescribing medicine. In Thailand, it has been found that the irrational use of medicines is increasing, especially in high cost medicines such as diabetic pills and antibiotics.[28]

b. Economic System

Thailand has experienced a shortfall in its budget for medical treatment which subsidizes around 5 million civil servants. These were increasing rapidly and steadily, especially expenses for drug costs. In 2008, the expenses were double or equivalent to 54,904 million Baht while the budget for the Social Security scheme and Universal Healthcare scheme which took care of around 57 million people represented only 98,700 million Baht. This situation arose because the non-effective

[28] เอกสารหลัก มติสมัชชาสุขภาพครั้งที่ 2, **ยุติการส่งเสริมการขายยาที่ขาดจริยธรรม : เพื่อลดความสูญเสียทางเศรษฐกิจและสุขภาพของผู้ป่วย** , 4 (2552) (Main document: Resolution of National Health Assembly No. 2, **Stop Unethical Drug Sale Promotion to Decrease Economic Lost and for the Sake of Patient's Health**, at 4 (2009)).

controlling system on transparency which led to the irrational use of drugs and unethical drug sale promotion in the welfare system for civil servants.[29]

c. Corruption

The most controversial issue of corruption in 2003 was the scandal of Mr. Rakkiat Sutana, former minister of the Ministry of Public Health between November 1997 and September 1998. The Supreme Court's Criminal Division for Persons Holding Political Positions sentenced Rakkiat to 15 years in jail as per the court judgment red case no. 2/2546 dated 19 September 2003 after finding him guilty of taking bribes of the amount of 5 million Baht from 2 pharmaceutical companies, Thai Nakorn Patana Co., Ltd and TNP Healthcare Co., Ltd. In return, Rakkiat revoked a notification of the Ministry of Public Health on the average price of medicines. As a result, during the period of revocation (around one year) Thailand did not have a ceiling price for medicines so it was a channel for those two companies to make a lot of profits by selling their products to hospitals under the Ministry of Public Health which was much more expensive than usual, around 50 to 300 percent. In that situation, Rakkiat ordered people under his control to convince or instruct physicians, hospitals directors or officers involved in the procurement of medicines and medical products for the hospitals under the Ministry of Public Health to purchase the products from those two companies. Accordingly, the Ministry of Public Health lost about 180 million Baht which can be divided into direct damages to the Ministry of Public Health and damages occurred through the Government Pharmaceutical Organization.[30]

d. Moral Ethics

Financial interactions and business transactions between physicians or healthcare professionals and pharmaceutical companies are common. At the same time, these negative relationships can also create negative influences over their discretion when procuring or dispensing drugs. This unhealthy relationship can cause significant conflicts of interest. It has also become part of Thai culture that people in

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[29] *Id*. at 1.

[30] คำพิพากษาศาลฎีกาแผนกคดีอาญาของผู้ดำรงตำแหน่งทางการเมืองหมายเลขแดงที่ 2/2546 (Judgment of the Supreme Court's Criminal Division for Person Holding Political Positions Red Case No. 2/2546)

the healthcare system believe that receiving something from the pharmaceutical companies is usual or they should be treated in this way. This culture illustrates the failure of moral ethics in the healthcare sector.[31]

2.3 Meaning of Transparency in International Standard

There are many different definitions of transparency in the literature. The World Health Organization (hereinafter referred to as WHO), a specialized organization under the United Nations that is concerned with international public health, essentially defines transparency as "openness in sharing information and that information is publicly and easily accessible for those who need it."[32] Moreover, it is widely acknowledge that transparency diminishes the scope for corruption and it is major tool to promote good governance as well. Thus, the basic assumption is that the more transparent any system is, the less vulnerable to corruption it will be.

Furthermore, Transparency International, an international and non-governmental organization that cooperates with governments, businesses and citizens to stop the abuse of power and combat corruption, bribery and secret deals sees that transparency is about shedding light on rules, plans, processes and actions. Transparency ensures that public officials, civil servants, managers, board members and businesspeople act visibly and understandably, and report on their activities. It also means that the general public can hold them to account. It is the surest way of guarding against corruption, and help to increase trust in the people and institutions on which our future depends.[33]

Lastly, the Organization for Economic Co-operation and Development (hereinafter referred to as OECD), an international economic organization, defines

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[31] Resolution of National Health Assembly No. 2, *supra* note 28, at 2.

[32] Guitelle Baghdadi-Sabeti, Jillian Clare Cohen-Kohler & Eshetu Wondemagegnehu, Departments of Essential Medicines and Pharmaceutical Policies & Ethics, Equity, Trade and Human Rights , World Health Organization, **Measuring Transparency in the Public Pharmaceutical: Assessment instrumen**t, at 7 (2009).

[33] Transparency International, "*What is Transparency?*", http://www.transparency.org/what-is-corruption/#what-is-transparency (last visited 18 May 2016)

transparency as “openness about policy intentions, formulation and implementation.”, and it also sees that transparency is a necessary element of good governance.[34]

[34] Organization for Economic Co-operation and Development, **OECD Best Practices for Budget Transparency**, 7 (2002).

CHAPTER 3
FINANCIAL INTERACTIONS BETWEEN PHYSICIANS OR HEALTHCARE PROFESSIONALS AND PHARMACEUTICAL COMPANIES IN SELECTED COUNTRIES

3.1 The United States of America

Transparency has been discussed in many countries, especially in developed countries, for a long time and it is a significant concept in both public and private affairs in USA. Therefore, there are many attempts to increase transparency and accountability to ensure that all activities are conducted efficiently and effectively for their intended purpose.

3.1.1 History and Background

The US has responded to this over the decades, from enacting the Freedom of Information Act (1966) to the dominance of the internet. Similarly, the principle of transparency in medicine also has a long history. In 1974, the National Research Act led to the development of Institutional Review Boards to oversee the conduct of human experimentation and research. The Omnibus Budget Reconciliation Act of 1989 is, at its core, a statutory requirement for transparency regarding a physician's conflicts of interest. All the laws mentioned above contain principles found in the Physician Payment Sunshine Act which mandates public disclosure on various aspects that the public should know about.

As demonstrated by these examples, most transparency initiatives to date have sought to improve the quality of care that patients receive. There has always been a concern that a patient's treatment should be exclusively controlled by their particular medical condition and never influenced by financial considerations, gifts or other

monetary incentives or business decisions. The argument for transparency leading to quality improvement is a strong one.[35]

In response to those concerns, Congress passed the Patient Protection and Affordable Care Act (hereinafter referred to as PPACA) as a United States federal statute which was then signed into law by President Barack Obama on 23 March 2010 with the main objective of providing the opportunity to mandate greater transparency regarding these financial relationships by establishing a disclosure program known as the Physician Payment Sunshine Act which shifted the burden to those organizations in the pharmaceutical industries to self-report and disclose their financial relationships with physicians or healthcare professionals.

The PPACA will ensure that all Americans have access to quality, affordable healthcare and will create the transformation within the healthcare system necessary to contain costs. The Congressional Budget Office has determined that the PPACA is fully paid for, will provide coverage to more than 94% of Americans while staying under the $900 billion limit that President Obama established, bending the health care cost curve and reducing the deficit over the next ten years and beyond.[36]

The PPACA contains ten titles, each addressing an essential component of reform as follows:

i) Quality, affordable health care for all Americans

ii) The role of public programs

iii) Improving the quality and efficiency of health care

iv) Prevention of chronic disease and improving public health

v) Health care workforce

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[35] Sarah Freymann Fontenot, "**Understanding the Affordable Care Act Bit by Bit: Will Transparency and Sunshine Shrink Costs?**", 2013, http://sarahfontenot.com/wp-content/uploads/2015/04/4-Oct-2013-Sunshine-Law-Article.pdf (last visited 13 June 2016)

[36] Democratic Policy & Communications Center, The Patient Protection and Affordable Care Act Detailed Summary, http://www.dpc.senate.gov/healthreformbill/healthbill04.pdf (last visited 13 June 2016)

vi) Transparency and program integrity

vii) Improving access to innovative medical therapies

viii) Class act

ix) Revenue provisions

x) Strengthening quality, affordable health care for all Americas

Under the 6th Title, the legal measure is added to ensure the integrity of federally financed and sponsored health programs, it creates new requirements to provide information to the public on the health system and promotes a newly invigorated set of requirements to combat fraud and abuse in public and private programs.

3.1.2 Purpose

Section 6002 of the PPACA finalizes requirements for applicable manufacturers to annually report certain payments or other transfers of value to covered recipients. It gives definitions of numerous terms, such as applicable manufacturer, and covered drug, device, biological, and medical supply. In addition, it also clarifies how applicable manufacturers should report and characterize payments or other transfers of value, including rules for research payments and indirect payments provided to a covered recipient through a third party. It also finalizes which payments or other transfers of value are excluded from the reporting requirements.

3.1.3 Transparency Measure to Control Financial Interactions between Physicians or Healthcare Professionals and Pharmaceutical Companies

In order to amend the Social Security Act in the area of transparency, Section 6002 of the PPACA states that:

"Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128F the following new section:

Section1128G. TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS……..……"[37]

a. Related Parties who have disclosure obligations

An applicable manufacturer who provided a payment or other transfer of value to covered recipients shall submit a report to the Secretary annually.

It can be seen that the person who has an obligation as per this law is the manufacturer or the pharmaceutical companies and not the physicians or the healthcare professionals. The definitions according to the law are given below.

i) The term "applicable manufacturer" means a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

ii) The term "covered drug, device, biological, or medical supply" means any drug, biological product, device, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

iii) The term "manufacturer of a covered drug, device, biological, or medical supply" means any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).

iv) The term "covered recipient" means the following:

- A physician.
- A teaching hospital.

Exclusion - Such a term does not include a physician who is an employee of the applicable manufacturer that is required to submit information under subsection (a).

[37] Patient Protection and Affordable Care Act, 42 U.S.C. § 6002 (2010)

v) The term “payment or other transfer of value” means a transfer of anything of value. Such a term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.

Exclusions- An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:

- A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $100. For calendar years after 2012, the dollar amounts specified in the preceding sentence shall be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; US city average) for the 12-month period ending with June of the previous year.

- Product samples that are not intended to be sold and are intended for patient use.

- Educational materials that directly benefit patients or are intended for patient use.

- The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

- Discounts (including rebates).

- In-kind items used for the provision of charity care.

- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1877(c)).

- In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

- In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such a licensed non-medical professional.

- In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding

b. Submission Date

The first submission was on March 31, 2013, and after that within 90 days of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary of the Department of Health and Human Services (hereinafter referred to as Secretary), in such electronic form as the Secretary shall require, information regarding any payments or transfers of value with respect to the preceding calendar year.

Centers for Medicare & Medicaid Services (hereinafter referred to as CMS); an agency within the Department of Health & Human Services, has been assigned to be a specific authority responsible for monitoring and collecting the information about these financial relationships and to make them available on its website through the Open Payment system. The Open Payment system is the federally run program that collects the information about these financial transactions and operates it to available on CMS's website.

Once the data is collected by the CMS, the physicians and teaching hospitals have the opportunity to register in the Open Payments system, review payments attributed to them, and dispute any information reported about them that may be inaccurate. Then data are displayed on the searchable and public CMS website. In addition, no later than April 1 of each year beginning with 2013, the Secretary shall submit to Congress a report and annual report to Congress that will include aggregated information submitted during the previous calendar year. The table below represents numbers of reviews and disputes made by the covered recipients including the disputes that are affirmed and unresolved.

Categories	Data Published*
Number of physicians that registered in Open Payments system to review and dispute	28,000
Number of teaching hospitals that registered Open Payments system to review and dispute	450
Number of records that were disputed	25,000**
Number of unresolved disputes at the end of review period	3,700
Number of records that were affirmed	27,000***

* Rounded

** Multiple disputes on the same record may occur. As a result, there were about 30,000 total disputes initiated during review and dispute associated with about 25,000 unique payment records.

*** "Affirmed" indicator signifies that the covered recipient associated with the reported record has reviewed it and agreed with its accuracy.

Source: Centers for Medicare & Medicaid Services, Department of Health & Human Services, Annual Report to Congress on the Open Payments Program, 15 (2016).

c. Required Information

The 6 main items that must be reported are:

i) The name of the covered recipient.

ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier; a unique 10-digit identification number issued to healthcare providers in the United States, of the covered recipient.

iii) The amount of the payment or other transfer of value.

iv) The dates on which the payment or other transfer of value were provided to the covered recipient.

v) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

- Cash or a cash equivalent;
- In-kind items or services;
- Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or
- Any other form of payment or other transfer of value (as defined by the Secretary).

vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

- Consulting fees;
- Compensation for services other than consulting;
- Honoraria;
- Gift;
- Entertainment;
- Food;
- Travel (including the specified destinations);
- Education;
- Research;
- Charitable contribution;
- Royalty or license;
- Current or prospective ownership or investment interest;

- Direct compensation for serving as faculty or as a speaker for a medical education program;
- Grant; or
- Any other nature of the payment or other transfer of value (as defined by the Secretary).

3.1.4 Process for Enforcement Actions

The PPACA requires the applicable manufacturers to submit transparency reports in a timely, accurate and comprehensive way. To ensure that the applicable manufacturers are compliant with Open Payments reporting requirements, the CMS has the authority to impose civil monetary penalties for late, inaccurate, and incomplete reporting.

Depending on the situation, non-compliance with the statute's requirements could subject the applicable manufacturers to financial penalties ranging from:

i) Not less than $1,000, but not more than $10,000 for each payment or transfer of value not reported; and

ii) Not less than $10,000, but not more than $100,000 for knowingly failing to report a payment or transfer of value.

The total maximum penalty which may be imposed against an applicable manufacturer shall not exceed $1,150,000.

In 2013 as a starting year, the CMS implemented strategies to assist compliance in the Open Payments system through education activities for the manufacturers who were potentially subject to the requirements. These outreach activities educated entities about the Open Payments system in an effort to promote compliance with program requirements.

As a result of CMS' outreach efforts, a 2016 Annual Report to Congress submitted by the CMS shows that the number of transparency reports increased in

2014 compared with the past year. This indicates that the efforts by the CMS are effective and are reaching its target group.[38] The following table shows the change.

Categories	Total
Program Year 2014	
Total value	$6.49 billion*
Total number of records	11.41 million*
Total number of physicians	607,000*
Total number of teaching hospitals	1,121
Total number of applicable manufacturers and GPOs	1,444
Program Year 2013	
Value	$3.43 billion*
Number of records	4.3 million*
Number of physicians	470,000*
Number of teaching hospitals	1,019
Number of applicable manufacturers and applicable GPOs	1,347
* rounded	

Source: Centers for Medicare & Medicaid Services, Department of Health & Human Services, Annual Report to Congress on the Open Payments Program, 9 (2016).

3.1.5 Analysis

In the USA, marketing activities in the form of sale promotion and advertising have been practiced by manufacturers to achieve their sales such as discounts, premiums, giveaways etc. It can be noted that in the USA sale promotion activities can be practiced as they are considered constitutional rights.[39] According to the non-regulated marketing activities, pharmaceutical companies are able to apply and practice all complicated strategic marketing activities to stimulate their sale volumes. Consequently, a patient, in this case an end consumer, might be directly affected by the excessive consumption of an unnecessary drug. In addition, this also impacts on the burden to the state of medical care and public expenditure on drugs which would be more costly than they should be due to additional costs of promotional activities.

[38] Centers for Medicare & Medicaid Services, Department of Health & Human Services, **Annual Report to Congress on the Open Payments Program**, 9 (2016).
[39] Thirawat ET AL, *supra* note 10, at 2.

A survey[40] estimated that pharmaceutical companies spent 20.4 billion USD in 2007 and most of these expenses were from direct marketing to physicians. This information can be read with a national survey[41] which revealed that 94% of physicians had financial interactions with pharmaceutical companies. In addition, PWC report[42] also stated that over the past few years, there have been a number of high profile cases where pharmaceutical and life sciences firms have been accused paying physicians to dispense and prescribe their products.[43]

In some countries, the idea[44] has been put forward of entirely restricting any drug sale promotional activities as the best way to prevent any inappropriate relationships between the mentioned parties. In addition, others believe that a clean relationship without interest between physicians or healthcare professionals and pharmaceutical companies would enhance potential drug research and development which would result in pharmaceutical advancement in the future.

According to another survey,[45] 64% of Americans believed that it was crucial to be aware of financial interactions between physicians or healthcare professionals and pharmaceutical companies. The same survey stated that 68% of Americans would support a law that forces pharmaceutical companies to disclose any financial interaction with physicians or healthcare professionals. The survey also reveals that most Americans do not agree with gifts being given by pharmaceutical companies to those in the healthcare sector since they believe that receiving any sort of gifts would influence physicians' decision about prescription regardless of the value of the gifts.

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[40] Pew Prescription Project, "*Fact Sheet: Addressing Cost and Quality: The Physicians Payments Sunshine Act"* (2009), http://www.pewtrusts.org (last visited 11 July 2016)

[41] Eric G. Campbell, Ph.D. and team, "*A National Survey of Physician–Industry Relationships*", 356(17), **New England Journal of Medicine**, 1742, 1746 (2007).

[42] PriceWaterhouseCoopers, *supra* note 4, at 4.

[43] The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program, Annual Report for Fiscal Year 2013, https://oig.hhs.gov/publications/docs/hcfac/FY2013-hcfac.pdf (last visited 27 July 2016)

[44] Peter R Mansfield, "*Banning all drug promotion is the best option pending major reforms*", 2(2), **Journal of Bioethical Inquiry**, 75, 75-81 (2005).

[45] Pew Prescription Project, "*Consumer Survey: Disclosure of Industry Payments to Physicians*" (2008), http://www.pewtrusts.org (last visited 11 July 2016).

After having closely considered this issue, in order to have any transparency measures to control financial activities between physicians or healthcare professionals and pharmaceutical companies, such measures must include the following two principles: the principle of disclosure obligation and the principle of prevention of conflicts of interest.

Legislators decided to draft a law, namely the Physician Payment Sunshine Act, which was first introduced and supported by Senators Charles Grassley and Herb Kohl[46] and finally enacted into law in 2010 as Section 6002 of the PPACA. The cornerstone of the mentioned law is the requirement to report the expenditure of pharmaceutical companies by emphasizing disclosure to the public of any financial interactions with physicians or healthcare professionals. The objective of this law is to prevent conflicts of interest of physicians or healthcare professionals related to pharmaceutical companies. Although the PPACA does not directly stop drug sale promotional activities, the pharmaceutical companies must be very careful about what they spend on their marketing activities. Furthermore, this law creates awareness of reciprocal arrangements between physicians or healthcare professionals and pharmaceutical companies.

The distinctive point of the PPACA is a clear specification of actions within scope of financial interaction which needs to be disclosed. These cover a varied number of strategic marketing activities which are usually practiced by pharmaceutical companies. Additionally, this law also specifies which actions can be exempted from disclosure and who is responsible for disclosure obligation, including the specific responsible department to manage effective data and information compilation. Consequently, transparency is enhanced and inappropriate reciprocation between physicians or healthcare professionals and pharmaceutical companies is limited. In other words, if a company must disclose its expenditure, it will not practice any improper financial interactions with such parties. For Thailand, this principle could be used and considered as a model for the solution to the current lack of morality in pharmaceutical business issues. However, if this law is to be transferred to

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[46] Press Releases, Grassley and Kohl Urge Action on Sunshine Law, http://www.aging.senate.gov/press-releases/grassley-and-kohl-urge-action-on-sunshine-law (last visited 11 July 2016)

Thailand, there must be a consideration of the context, surroundings and issues in Thailand.

3.2 Australia

One of the first countries to move towards greater transparency was Australia. The representative pharmaceutical industry, Medicines Australia, has a self-regulatory code of conduct that all Medicines Australia member companies are required to comply with. It sets standards for the ethical marketing and promotion of prescription pharmaceutical products for its member companies.

3.2.1 History and Background

Australia does not have a specific law to control financial interactions between physicians or healthcare professionals and pharmaceutical companies directly. However, Medicines Australia, an organization whose members comprise leading companies that invent, manufacture and supply innovative medicines and vaccines to the Australian community with the mission of sustainable growth for Australian medicine industry has its self-regulation framework in the form of Medicines Australia's Code of Conduct (hereinafter referred to as Australia Code of Conduct) which has been in place since 1960. The latest edition of Australia Code of Conduct was authorized by Australian Competition and Consumer Commission (hereinafter referred to as ACCC) on 24 April 2015 with effective date on 16 May 2015.[47]

3.2.2 Purpose

The Australia Code of Conduct sets the minimum standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia. The provisions include standards for appropriate advertising, the behavior of medical

[47] Medicine Australia's Code of Conduct Edition 18

representatives and relationships between physicians or healthcare professionals and pharmaceutical companies.

Medicines Australia is a strong advocate for transparency of payments and other transfers of value provided by the Australian medicines industry to health consumer organizations and healthcare professionals. The purpose of disclosure of payments and other activities is to demonstrate ongoing financial activities between those related people. For this reason, and to ensure continued public trust in these relationships, the latest Australia Code of Conduct includes requirements for reporting of payments and benefits to healthcare professionals (e.g. speaker fees, consultant fees, and advisory board member fees) to increase and encourage confidence and trust among the governmental sector, business sector, physicians, healthcare professionals and consumers.

3.2.3 Transparency Measure to Control Financial Interactions between Physicians or Healthcare Professionals and Pharmaceuticals Companies

The Australia Code of Conduct divides its disclosure obligations into two types of reports: I) Report of Health Consumer Organization and II) Report of all other types of activities.

I. Report of Health Consumer Organization

a. Related Parties who have Disclosure Obligations

A member company must provide a report to Medicines Australia for publication on its website which lists health consumer organizations to which it provides financial support and/or significant direct/indirect non-financial support.

It is the responsibility of the member company to inform a health consumer organization that any sponsorship received by the health consumer organization from the pharmaceutical company, whether sponsorship of the organization, a specific publication, website or activity, and including the monetary value of the sponsorship,

will be publicly disclosed. Below are the definitions pursuant to the Australia Code of Conduct:

i) The term "Member Company" means an entity registered as a member of Medicine Australia.

ii) The term "Health Consumer Organization" means not-for-profit organizations that represent the interests and views of consumers of healthcare. They may range from small volunteer groups to large organizations, and generally promote views that are independent of government, the pharmaceutical industry and professional health service providers.

b. Submission Date

The report with information with respect to the previous year must be submitted to Medicines Australia within 30 April of the next calendar year.

Medicines Australia will make publicly available on its website the completed health consumer organization reports provided by each member company within two months of receiving the reports.

c. Required Information

The published report must include:

i) The name of the health consumer organization; and

ii) Description of and/or purpose of the support. A description of the nature of the support must be sufficiently complete to enable the average reader to form an understanding of the nature of the support; and

iii) Nature of support - monetary value (or equivalent) or description of non-financial support. The monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organization receives.

II) Report of All Activities

This type of report will provide transparency for consumers of payments and transfers of value to Healthcare Professionals who are participating in patient care.

a. Related Parties who have Disclosure Obligations

A member company must report on its website information regarding any payments and transfers of value to healthcare professionals who are engaged in patient care. Any payments or transfers of value to healthcare professionals that arise through employment by a member company are excluded from being reported. The definitions for these are given below:

i) The term "Member Company" means an entity registered as a member of Medicines Australia.

ii) The term "Healthcare Professional" means a healthcare professional registered to practice in Australia who in the course of their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine in Australia.

b. Submission Date

The initial reports covering the period 1 October 2015 to 30 April 2016 must be published on the websites of companies by 31 August 2016 and every 6 months thereafter. The information disclosed shall be published on there for 3 years from the date of first publication.

Then, the most senior executive officer of the company will provide to Medicines Australia a signed and dated declaration that it has published the required report on the company's website that includes all payments and transfers of value required. This declaration must be provided to Medicines Australia within seven calendar days following publication of each report.

c. Required Information

The 8 main items that must be reported are:

i) Date of the event or provision of service;

ii) Healthcare professional's name;

iii) Type of healthcare professional (i.e. medical practitioner, pharmacist, nurse practitioner);

iv) Healthcare professional's principal practice address;

v) Description of the service (i.e. speaker, advisory board member, chairperson at educational meeting etc.);

vi) Description of the event (i.e. company sponsored meeting in Australia; independent meeting held in Australia; independent meeting held overseas; etc.);

vii) The amount of the payment or transfer of value, subdivided into (where relevant) registration fees, travel and accommodation, and fees for service.

viii) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as

- Fees paid to healthcare professionals in return for speaking at an educational meeting or event.
- Sponsorship of a healthcare professional to attend an educational event in accordance with Section 9.7[48]

(Specific reportable items in regard to sponsorships are any airfare, accommodation or registration fees directly associated with the meeting whether held within or outside Australia)

- Fees paid to healthcare professional consultants in Australia, or to their employers on their behalf, for specific services rendered by them. This includes, but is not limited, to all consultancy services provided in relation to educational meetings, preparation of promotional materials or product position papers, assistance with training or any other advice to the company. This does not include payments to

[48] Section 9.7 of Medicine Australia's Code of Conduct Edition 18 "Sponsorship of Healthcare Professionals to Attend Educational Events (Australian and International)"

consultants in relation to research and development work, including the conduct of clinical trials.

(Specific reportable items include all payments in respect to consulting fees, accommodation and airfares both within and outside Australia associated with the provision of the consulting services.)

- Fees paid to healthcare professionals in their role as advisory board members in accordance with Section 9.9.[49]

(Specific reportable items include all payments in respect to advisory board sitting fees, accommodation and airfares both within and outside Australia associated with the activities of the advisory board).

- Fees paid to healthcare professionals for the purpose of market research. Such fees will be reportable for the individual healthcare professional where the identity of the healthcare professional is known to the company (reporting is not required where the company contracting the market research is not involved in the selection of participating healthcare professionals and is not aware of the identities of those participating in the market research).

- Where healthcare professionals request a payment for any of the above to be made to a third party, these payments must still be disclosed for the individual healthcare professional, however, the report should identify that payment was made to a third party.

3.2.4 Process for Enforcement Actions

To promote compliance with the Australia Code of Conduct, the Medicines Australia Monitoring Committee will proactively monitor and conduct checks on member companies on a regular and ongoing basis. The goals of monitoring are to support compliance with the Australia Code of Conduct, provide advice on compliance, and obtain and publish statistical information on the degree of compliance.[50]

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[49] Section 9.9 of Medicine Australia's Code of Conduct Edition 18 "Advisory Boards"

[50] Medicine Australia, Medicine Australia's Code of Conduct, at 63 (18th ed. 2015).

In case of failure in compliance with the Australia Code of Conduct, the first step is that Medicines Australia must receive a complaint alleging violation by a company[51]. The complaint may be lodged by the monitoring committee, member company, healthcare professional and etc.

The company that is subject to a complaint shall be given full details of the complaint lodged with Medicines Australia. Such a company will be invited to state within 10 working days whether or not it believes there is any basis to the complaint, to give any important explanation and to answer any inquiries as required.

The complaint and all supporting details including the company's feedback shall be referred to the Code Committee. In case of failure in compliance with the Code is established, the Chief Executive or his or her delegate will within 2 working days of the Committee meeting notify such company and the complainant in writing that a violation has been found and identify what section of the Australia Code of Conduct has been violated and within 10 working days of the Committee meeting provide copies of the decisions and the reasons to the company including a full explanation and form of sanctions to be applied to such a company pursuant to Section 28[52] of the Code of Conduct.

The sanctions may only be imposed on a company where breaches of the Code of Conduct have been established. The sanctions may consist of one or more of the following:

i) Cessation of conduct and withdrawal;

ii) Corrective action; and/or

iii) Monetary fine.

According to Medicines Australia Annual Report 2014-2015[53], in 2014-2015 Medicines Australia received 15 new complaints. This is an increase over 2013-2014 when 10 new complaints were received but a decrease when compared

[51] Section 20.1 of Medicine Australia's Code of Conduct Edition 18 "Acceptance of Complaints".
[52] Section 28 of Medicine Australia's Code of Conduct Edition 18 "Sanctions"
[53] Medicine Australia, **Annual Report 2014-2015**, 17 (2015).

with 2012-2013 when 18 new complaints were received. 5 of the new complaints received this year were submitted by Member Companies, another 5 complaints submitted by the Monitoring Committee, 4 complaint submitted by healthcare professionals and 1 complaint submitted by a member of the general public. Of the 15 new complaints received and finalized in 2014-2015, 6 were found not to be a breach of the Code and 9 complaints were found to be in breach of some or all aspects of the alleged breaches. However, the Annual Report does not declare what kinds of actions or what sections have been breached.

In addition, Medicines Australia has power over non-members since a complaint can also be submitted to it against them. The complaint will be forwarded to the non-member with an invitation to state whether or not the information supporting the complaint is correct and to answer required necessary inquiries. If the non-member accepts the invitation, the complaint will proceed pursuant to the provisions of the Code. On the other hand, if the non-member refuses the invitation, Medicines Australia shall have the right but not the obligation to refer this complaint together with the non-member's response to the Therapeutic Goods Administration (hereinafter referred to as TGA), Australia's regulatory authority for therapeutic goods under the Department of Health, or to the ACCC[54].

3.2.5 Analysis

The pharmaceutical industry is a significant and enormous sector of its economy and has unique nature from other businesses or industries. Traditionally, pharmaceutical companies rely upon medical representative to persuade physicians' behavior or discretion in prescribing. This relationship has been controversial issue in their negative impact on public and society.[55] The use of promotional activities in the drugs business in Australia is similar to that found in the USA in that most

[54] Section 25 of Medicine Australia's Code of Conduct Edition 18 "Complaints Against Non-Members"

[55] Magda Huynh, David Low & Geoffrey Lee, University of Western Sydney, **Relationships between Medical Sales Representatives and Physicians: An Exploratory Study**, 1 (2008), http://researchdirect.westernsydney.edu.au /islandora/object/uws:7787 (last visited 28 July 2016).

pharmaceutical companies spend a great deal of money on strategic marketing activities. The objective of these marketing activities is to stimulate sales. Research[56] conducted by the University of South Australia and La Trobe University found that the most popular way to achieve this objective was to send medical representatives to meet physicians or public healthcare professionals with the purpose of building a good relationship. Additionally, when the medical representatives make their visits, as the most common method of building influence is to offer complementary presents or free meals. Consequently, it is undeniable that this well-grounded relationship might influence physicians or healthcare professionals in making decisions on issuing prescription to their patients by favoring products from the medical representatives with whom they have close a relationship over products from other companies with similar quality drugs.

Such information is consistent with another survey[57] which reveals that 76% of patients in Australia are not aware of any financial interactions with interest related to their physicians and pharmaceutical companies. 70% wished to be able to know if their physicians were offered any financial benefits or incentives to participate in research, and 61% expressed that they would want to know if there was any sponsorship offered to physicians to attend conferences. Additionally, 79% of patients wanted to be aware of any incentives received by the physicians, and 80% revealed that they would have more confidence in their physicians' decisions if any interests related to their physicians were disclosed. Similarly, there was a statement issued by the Chairman of the ACCC on 26 July 2006[58] where he said that: "Consumers should be able to have confidence that decisions made by their doctors are made solely having regard to their best interest without any potential for influence by benefits or perks."

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[56] E.E. Roughead, K.J. Harvey & A.L. Gilbert, A. L., "*Commercial detailing techniques used by pharmaceutical representatives to influence prescribing*", 28(3), **Australian and New Zealand Journal of Medicine**, 306, 306-310 (1998).

[57] Martin H N Tattersall, Aneta Dimoska & Kevin Gan, "*Patients expect transparency in doctors' relationships with the pharmaceutical industry*", 190(2), **the Medical Journal of Australia**, 65, 66 (2009).

[58] Martin H N Tattersall & Ian H Kerridge, "*Doctors behaving badly?*", 185(6), the **Medical Journal of Australia**, 299, 299-300 (2006).

In considering the above evidence, if there is to be any transparency measures to control such activities between physicians or healthcare professionals and pharmaceutical companies then these should include the following two principles:

i) Principle of disclosure obligation; and

ii) Principle of prevention of conflicts of interest.

Accordingly, Medicines Australia adopted principle of disclosure obligation into the 18th edition of its Code of Conduct which is the latest version authorized by the ACCC in April 2015. The objective is to strengthen the pharmaceutical industry in the country by requiring pharmaceutical companies to submit a report related to any financial activities with people in the healthcare sector to Medicines Australia. This requirement highlights financial interaction disclosure of the prescription medicines companies if they are financially related to physicians or healthcare professionals in order to prevent conflicts of interest and to increase public trust and confidence.

Before the success of the 18th edition of the Code, Medicines Australia had formed its Transparency Working Group to improve policies and measures which would level up transparency of reciprocation between physicians or healthcare professionals and the drug companies. Moreover, the US Physician Payment Sunshine Act has likewise been adopted as a model for its study as well.[59] The Transparency Working Group suggested that even though financial disclosure under the US Physician Payment Sunshine was all-inclusive and broad, it should be adapted to be less complicated and to be more practical to Australia's context[60].

The core of the Code emphasizes information disclosure of prescription medicine companies by clearly indicating activities within the terms of financial interaction which covers those usually practiced by pharmaceutical companies: strategic marketing activities, exemption on such activities from disclosure,

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[59] Medicine Australia, "*Transparency Working Group, Terms of Reference*", https://medicinesaustralia.com.au/code-of-conduct/transparency-working-group/ (last visited 12 July 2016)

[60] Medicine Australia, "*Transparency Working Group, Transparency Working Group Communiqués*",https://medicinesaustralia.com.au/wp-content/uploads/sites/52 /2012/08/20121009-comm-Transparency-Working-Group-Second-Meeting.pdf (last visited 12 July 2016)

responsible parties control and information compilation. In case there are any petitions against non-members of Medicines Australia, an examination could take place if Medicines Australia receives approval from the complaint companies. However, if the accused companies refuse to cooperate in such examination, Medicines Australia has the right to submit the information to the TGA or ACCC. This principle could be used as a model to solve the unethical situations in the pharmaceutical industry in Thailand. However, if the provisions are applied to Thailand's situation, consideration of the context, environment and specific issues in Thailand need to be taken into account.

CHAPTER 4
FINANCIAL INTERACTIONS BETWEEN PHYSICIANS OR HEALTHCARE PROFESSIONALS AND PHARMACEUTICAL COMPANIES IN THAILAND

4.1 Law on Health Product

This chapter will focus on contents of Drug Act B.E. 2510 as it is one and only statue controlling over drug system in Thailand whether it is sufficient to be the transparency measures to control financial interactions among people in healthcare sector. In addition, 2 new draft drug acts will be taken into consideration as well

4.1.1 Drug Act B.E. 2510

Drug Act B.E. 2510 (hereinafter referred to as Drug Act) is the most important protection in consumer law on health products controlled by the Food and Drug Administration (hereinafter referred to as FDA), Ministry of Public Health as a governing authority.

The Drug Act only stipulates general provisions such as definitions, details and authorities of the Drug Committee, application, issuance, renewal and revocation of licenses, duties of licensees, imports of drugs etc.

However, it does not have provisions to control transparency in financial interactions between physicians or healthcare professionals and pharmaceutical companies including the protection of conflicts of interest between such people.

Furthermore, in Thailand it is found that it does not strictly prohibit drug advertising pursuant to Sections 88 to 90 Bis[61], Chapter 11. Rather, it merely prohibits

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[61] The Drug Act B.E. 2510
Section 88
"An advertisement for the sale of a drug shall :

exaggerated advertisements, and advertisements for abortion pills, false medical claims etc. Moreover, it does not define clearly an exact term of "advertisement" so the authorities have to take the Consumer Protection Act B.E. 2522 into consideration when regulating advertising practice.

The term of "advertisement" stated in Section 3 of the Consumer Protection Act B.E. 2522 is defined as "any actions which, by whatever means, cause the statement to be seen or known by an ordinary person for trading purposes." Said

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(1) not be boastful of its therapeutic properties or of its ingredients as being miraculously or completely capable of curing, mitigating, treating or preventing a disease or illness, nor shall any other wording of similar meaning be used;
(2) not falsely or exaggeratedly show its therapeutic properties;
(3) not cause to be understood that it has a substance as its chief or component ingredient, which in fact it has not or does have but less than the quantity as caused to be understood;
(4) not cause to be understood that it is an abortion pill or a strong emmenagogue;
(5) not cause to be understood that it is an aphrodisiac or a birth control drug;
(6) not show the therapeutic properties of a dangerous or a specially-controlled drug;
(7) contain no certification or laudation of its therapeutic properties by any other person;
(8) not show its therapeutic properties as being capable of curing, mitigating, treating or preventing disease or symptom thereof as notified by the Minister under Section 77.
The provisions of (5) and (6) do not apply to the statement on the label or accompanying leaflet of a drug, and those of (1), (4), (5), (6), (7) and (8) do not apply to an advertisement directed to a medical practitioner or a veterinary practitioner."
Section 88 Bis
"The advertisement to sell drugs through radio amplifier, television slides or motion picture or through printed matter must:
(1) receive permission for the text, sound or picture used in the advertisement from the licensor;
(2) follow the conditions set by the licensor."
Section 89
"No sale of drugs shall be advertised impolitely, or by means of singing and dancing, or by showing the distress or suffering of a patient."
Section 90
"No sale of drugs shall be advertised by means of a gift or lottery drawing."
Section 90 Bis
"The Secretary of the Food and Drugs Administration is empowered to issue written orders to cease any advertisement deemed to be contrary to this act."

definition is too narrow and does not cover the meaning of "pharmaceutical marketing" in the pharmaceutical industry which has a broader meaning than "advertisement". Generally, the Drug Act has been found to be out of date, ineffective and lacking in strong sanctions. Moreover, it does not tackle the problem of non-transparent interactions.

4.1.2 Draft Drug Act (Office of the Council of State Version)[62]

a. General Information

Since the Drug Act B.E. 2510 has been in force for ages, some provisions do not go well with current situations and it is inadequate to solve many concerns including problems of improper financial interactions between the physicians or healthcare professionals and the pharmaceutical companies, there have been many attempts from the governmental sector and professional councils in healthcare sector to revise the Drug Act to be more up-to-date and in compliance with ongoing circumstances. This is the reason why the Draft Drug Act (Office of the Council of State Version) has been revised many times and is now finally set to be approved by the Office of the Council of State numbered as 1017/2557 (hereinafter referred to as Draft Drug State Version).

However, at the moment the Draft Drug Act State Version is still pending because it is strongly objected by the Pharmacy Council of Thailand. The Pharmacy Council has already submitted an objection letter no. 01/01/399 dated 7 August 2014 to the National Council for Peace and Order to point out the major flaws of the Draft

[62] Draft Drug Act (Office of the Council of State Version) is publicized on website of Bureau of Drug Control, "*Food and Drug Administration Thailand*", Ministry of Public Health available at http://drug.fda.moph.go.th/zone_law/files/%E0%B8%A3%E0%B9%88%E0%B8%B2%E0%B8%87%E0%B8%9E.%E0%B8%A3.%E0%B8%9A.%E0%B8%A2%E0%B8%B2_1017_2557.pdf (last visited 15 July 2016).

Drug Act State Version.[63] In the statement, its problematic features are that the drug categories do not follow international standards and there would be no control over drug sale promotion.

b. New Provisions in the Draft Drug Act (Office of the Council of State Version)

i) Definition of Advertising and Sale Promotion

The current Drug Act does not give a definition for advertising and sale promotion. However, Section 4 of the Draft Drug Act State Version does. It defines "advertising" as any action which, by whatever means, cause the statement to be seen, heard or known by an ordinary person for trading purposes, and it also includes "sale promotion".

Section 4 also defines "sale promotion", which is to provide information, to persuade or any actions which, by whatever means, are done with the aim to increase the use of drugs for trading purposes.

ii) Members of National Drug Committee

The Draft Drug Act State Version adds new members of the National Drug Committee. This is really different from the existing law since the new additional members consist of one representative chosen internally from a business association of a manufacturer and importer of drugs and one representative chosen internally from a business association of drug stores.

It is quite surprising that members of the National Drug Committee consist of representatives from government and the private sector. From this the question arises whether members from business associations could have any impacts if the committee wished to launch rules or regulations to control transparency in financial interactions between physicians or healthcare professionals and pharmaceutical companies.

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[63] หนังสือเลขที่ 01/01/399 ลงวันที่ 7 สิงหาคม 2557 จากสภาเภสัชกรรมและองค์กรวิชาชีพเภสัชกรรมร่วมกันเสนอความเห็นแย้งเกี่ยวกับร่างพระราชบัญญัติยาเพื่อยกเลิกและทดแทนพระราชบัญญัติยา พ.ศ. 2510 (Objection Letter no. 01/01/399 dated 7 August 2014 to the National Council for Peace and Order issued by the Pharmacy Council)

iii) Roles and Responsibilities of the National Drug Committee

In Clause 4 of Section 11 of the Draft Drug Act State Version it is specified that the committee has to support the rational use of drugs. However, such content is too wide and it does not set out the exact framework what they have to take action with timeframe.

iv) Advertising Sector

Section 88 Bis of the Drug Act states that the advertising of drug sales through radio, amplifier, television, movie or printed media must be approved in terms of the text, sound or picture used in the advertising from the licensor while the Draft Drug Act State Version states in Section 141 that drug advertising must receive a license from the licensor without classification of advertising.

However, the Drug Act stipulates that the advertising should not claim the therapeutic properties of dangerous or specially-controlled drugs while the Draft Drug Act State Version excludes this content.

c. Disclosure and Transparency

Even though the Draft Drug Act State Version adds the term of advertising and sales promotion and pays attention to the rational use of drugs, it still has no mandatory disclosure obligations and does not describe what kinds of financial interactions between physicians or healthcare professionals and pharmaceutical companies must be reported in a timely and accurate way and have an easy channel of access.

d. Enforcement

There are both criminal and civil sanctions if there is a failure to comply with the Draft Drug Act State Version.

4.1.3 Draft Drug Act (Public Version)[64]

a. General Information

Draft Drug Act (Public Version) (hereinafter referred to as Public Draft Drug Act) was initiated by cooperation between the Health and Development Foundation, Health Consumer Protection Program, Chulalongkorn University, Thai Drug Watch, Chulalongkorn University and Foundation for Consumers.

The main objectives of the Public Draft Drug Act are to protect the welfare and safety of the Thai people in their use of drugs and to encourage sustainable growth and development in the pharmaceutical industry.

b. New Provisions in the Draft Drug Act (Public Version)

i) Definitions of Advertising and Sale Promotion

Section 4 of the Public Draft Drug Act defines "advertising" as any action which, by whatever means, causes the statement to be seen or known by an ordinary person for trading purposes.

Section 4 also defines "sale promotion". Its definition is to provide information, to persuade or any actions, by whatever means, with the aim to increase dispensary, procurement or use of drugs for trading purposes.

ii) Members of the National Drug Policy Committee

The National Drug Policy Committee consists of 27 committees and the Prime Minister or Deputy Prime Minister assigned by the Prime Minister as a chairman.

The 27 committees comprise representatives from the governmental sector, educational institutions, professional councils, non-profit consumer protection

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[64] Draft Drug Act (Public Version) is publicized on website of Thai Drug Watch, http://www.thaidrugwatch.org/download/draft_revise_drug_act_19-01-55.pdf (last visited 25 July 2016)

organizations, legal experts and medical or healthcare professionals. The members of the National Drug Policy Committee are different from the members of the National Drug Committee of the Draft Drug Act State Version since it has no representatives from business associations.

iii) Roles and Responsibilities of the National Drug Policy Committee

Clause 2 and Clause 7 of Section 12 of the Public Draft Drug Act states that the committee has to set out the policy and measures to protect drug consumers and generally specifies that the committee shall support the rational use of drugs. However, it does not set out the exact framework what they have to take action with timeframe.

iv) Medical Representative

Section 4 defines "Medical Representative" as a licensed person from the Pharmacy Council of Thailand who received sufficient training from the Licensee so that he could provide information of the Licensee's product accurately and completely.

Section 4 also defines "Licensee" as a licensed person who operates its business pursuant with this Act. If a licensed person is a juristic person, the licensee also includes its manager or representative.

The duties of the Medical Representative are stated in Section 64 as follows:

(1) The Medical Representative shall present information of the Licensee's product which is based on academic reference accurately and completely. Moreover, the Medical Representative shall reveal the side-effects of such products to the person who may prescribe or dispense the drugs.

(2) The Medical Representative shall not offer money, assets or any other interest to the person who may prescribe or dispense the drugs.

Furthermore, in Section 65 the Licensee shall control of the moral ethics of its Medical Representative and the Licensee shall not set the income of the Medical Representative to be commission-based.

v) Advertising and Sale Promotion Sector

Section 131 states that: “It is prohibited to do any sale promotion except direct sale promotion to the physicians or healthcare professionals in accordance with Section 132 and 133.”

Sector 132 states that “Sale promotion that is made directly to the physicians or healthcare professionals shall not be in the form of offering money, assets or any other interest except how it is given traditionally or it relates to their occupations with reasonable value not exceeding a price limited by the authorized committee”.

Section 133 states that: “The Licensee who does sale promotion directly to the physicians or healthcare professionals shall provide and present updated and accurate information and it is prohibited to do anything that leads to overuse of the drug”.

Furthermore, according to Section 134 drug advertising is allowed if it is medicine that can be accessed by ordinary people to take basic care of themselves.

c. Disclosure and Transparency

Even though the Public Draft Drug Act emphasizes the moral ethics and behavior of the medical representative, it has no mandatory disclosure obligations and does not describe what kinds of financial interactions must be disclosed on a timely basis with an easy channel of access between the physicians or healthcare professionals and the pharmaceutical companies.

d. Enforcement

In the case of a failure to comply with the Public Draft Drug Act, there are criminal and civil sanctions including administrative punishment.

4.1.4 Comparison of the Drug Act B.E. 2510, the Draft Drug Act (Office of the Council of State Version) and the Draft Drug Act (Public Version)

At present, since the Drug Act B.E. 2510 has been in force for a long time, many sectors both public and private have been trying to make an effort to revise the Drug Act to be more modern and in line with the current situation. Currently, there are 2 versions of this proposed by 2 different sectors as described above. The table below will set out how the present provisions compare with the 2 versions.

	Drug Act B.E. 2510	**Draft Drug Act (Office of the Council of State Version)**	**Draft Drug Act (Public Version)**
Status	Existing law	Draft approved by the Office of the Council of State with strong dissent from the Pharmacy Council	Draft signed by 10,565 people and proposed to the speaker of the parliament on 19 January 2012
Definition of Advertising	None	Any action which, by whatever means, causes the statement to be seen, heard or known by an ordinary person for trading purposes, and it also includes "sale promotion"	Any action which, by whatever means, causes the statement to be seen or known by an ordinary person for trading purposes.

	Drug Act B.E. 2510	Draft Drug Act (Office of the Council of State Version)	Draft Drug Act (Public Version)
Definition of Sale Promotion	None	To provide information, to persuade or any actions, by whatever means, with the aim to increase the use of drugs for trading purposes.	To provide information, to persuade or any actions, by whatever means, with the aim to increase dispensary, procurement or use of drugs for trading purposes.
Definition of Medical Representative	None	None	A licensed person from the Pharmacy Council of Thailand who received sufficient training from the Licensee so that he could provide information of the Licensee's product accurately and completely
Disclosure and Transparency	None	None	None
Moral Ethics and Income of the Medical Representative	None	None	The Licensee shall control of the moral ethics of its Medical Representative and the Licensee shall not set the income of the Medical Representative to be commission based

	Drug Act B.E. 2510	Draft Drug Act (Office of the Council of State Version)	Draft Drug Act (Public Version)
Prohibition of Offer of Gift or Transfer of Value	None	None	(1) The Medical Representative shall present information of the Licensee's product which is based on academic reference accurately and completely; and the Medical Representative shall reveal the side-effects of such products to the person who may prescribe or dispense the drugs. (2) The Medical Representative shall not offer money, assets or any other interest to the person who may prescribe or dispense the drugs.

4.2 Laws on Consumer Protection

In this part, the laws relating to consumer protections that are taken into considerations are Consumer Protection Act B.E. 2522 and Direct Selling and Direct Marketing Act B.E. 2545. However, both of them are not direct laws to control over drug system in Thailand.

4.2.1 Consumer Protection Act B.E. 2522

The protection of consumer rights in the Consumer Protection Act B.E. 2522 (hereinafter referred to as Consumer Protection Act) is divided into 5 principles as stated in Section 4,[65] such as the right to receive correct information, right of freedom to choose and right to get a fair contract. Except if there is a specific law on matter, the Consumer Protection Act can be applied to all sale or purchase of goods and services in accordance with Section 21.[66] It also includes provisions for advertisement of goods and services in accordance with Sections 22 to 29.

However, the Consumer Protection Act does not have provisions to control the transparency of interactions between physicians or healthcare professionals and pharmaceutical companies directly or indirectly for the sake of consumer rights; the protection of conflicts of interest between such people is not mentioned by this law either.

4.2.2 Direct Selling and Direct Marketing Act B.E. 2545

The Direct Selling and Direct Marketing Act B.E. 2545 (hereinafter referred to as Direct Selling Act) has the objective to control direct sales business which is goods

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[65] The Consumer Protection Act B.E. 2522
Section 4
"The consumer has the following right of protection:
(1) the right to receive correct and sufficient information and description as to the quality of goods or services;
(2) the right to enjoy freedom in the choice of goods or service;
(3) the right to receive a safety in the use of goods or services;
(3 Bis) the right to receive a fair contract;
(4) the right to have the injury considered and compensated
in accordance with the laws on such matters or with the provision of this Act."

[66] Consumer Protection Act B.E. 2522
Section 21
"In the case where any law has specifically provided for any matter, such matter shall be subject to the provisions of such law, and the provision of this Act shall apply only in so far as it is not a repetition or contrary to such provision, unless;….."

or services marketing in the manner of directly offering to the consumers at the residence or the work place of the consumer or of other person or at a place other than a regular place of business through the direct sale agent or the independent distributor on a single-level or multi-level.[67]

However, the Direct Selling Act does not have provisions to control the transparency of interactions between physicians or healthcare professionals and pharmaceutical companies directly nor provisions on the protection of conflicts of interest between such people nor provisions to control marketing activities made directly to the physicians or healthcare professionals either.

4.3 Regulations and Codes of Conduct in Healthcare Sectors

In this part, regulations from professional council and code of conduct from public sectors including code of conduct which is self-regulation from business sector will be taken into consideration whether they are sufficient or not to cope with the transparency issue.

4.3.1 The Medical Council Regulations on Medical Ethics Preservation B.E. 2519

a. General Information

By virtue of Section 21(3)(g) of the Medical Profession Act B.E. 2525, the Medical Council Regulations on Medical Ethics Preservation B.E. 2519 (hereinafter referred to as Medical Council Regulations) was issued by the Committee of the Medical Council effective from 31 November 2006.

[67] Section 3 of Direct Selling and Direct Marketing Act B.E. 2545

The purpose of the Medical Council Regulations is to encourage good practice and to act as guidelines for medical practitioners who are registered with and obtain a license to be medical practitioners from the Medical Council.[68]

The Medical Council Regulations are divided into 11 principles as follows:

i) Definitions

ii) General Principles

iii) Medical Practice Advertising

iv) Medical Practice

v) Behaviors towards Other Medical Practitioners

vi) Behaviors towards Associates

vii) Behaviors in Relation to Sanatorium

viii) Behaviors When Having Interactions with Healthcare Product Entrepreneurs

ix) Research Study and Experiments on Humans

x) Medical Profession on Organ Transplantation

xi) Medical Practice on Stem Cell Transplantation

b. Disclosure and Transparency

The Medical Council Regulations prevent conflicts of interest between physicians and pharmaceutical companies in general by setting down an anti-gift rule

[68] Article 4 of the Medical Council Regulations on Medical Ethics Preservation B.E. 2519
"Medical profession means any profession that performs to humans activities of examination, diagnosis, treatment, disease prevention, midwifery, visual correction by contact lens insertion, acupuncture for therapeutic or anaesthetic purpose, and shall include surgical act, radiation use, injection of medicine or any substance, insertion of any object into the body for birth control, beautification, and fitness."

among said people pursuant to Clauses 41-44. Nevertheless, there are no any disclosure obligations mentioned in the Medical Council Regulations except in Clause 45 as follows:

"When publicizing an opinion about any healthcare product properties by spoken, written, or other form, a medical practitioner shall also reveal his or her connection with the entrepreneur, for example, as a consultant, as a co-investor, or as a recipient of visiting, conference, or lecture subsidy."

c. Enforcement

The Medical Council Regulations are considered as secondary law issued by virtue of Section 21(3)(g) of the Medical Profession Act B.E. 2525. Any medical profession who fails to comply with shall be subject to sanctions or punishments pursuant to the Medical Profession Act BE 2525, since the Medical Council Regulations could not define sanctions or punishments into itself.[69]

4.3.2 Notification of the Ministry of Public Health on the Code of Conduct for Procurement and Sale Promotion of Drugs and Medical Supplies B.E. 2557

a. General Information

By virtue of Clause 16 of the Regulations of the Ministry of Public Health on Management of Drugs and Medical Supplies of Divisions under the Ministry of Public Health B.E. 2557, the Permanent Secretary of the Ministry of Public Health has issued the Notification of the Ministry of Public Health on the Code of Conduct for Procurement and Sale Promotion of Drugs and Medical Supplies B.E. 2557 (hereinafter referred to as Notification) effective from 30 October 2014.

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[69] ยุทธพงศ์ ภูรีเสถียร, "*กฎหมายลำดับรอง* ", เล่มที่ 20 ตอนที่ 2, **วารสารกฎหมายปกครอง** , 50, 50-51 (2544) (Yuttapong Phurisatien, "*Secondary Law*", 20(2), **Admistrative Law Journal**, 50, 50-51 (2001)).

The purposes of the Notification are to propose good governance and to act as a guideline for the medical institutions, divisions or any government sectors under the Ministry of Public Health that need to comply with it. Therefore, it is legally binding for government agencies but private entities are not legally required to abide by its requirements.

The Notification is divided into 7 principles as follows:

i) General Provision

ii) Physician or Healthcare Professional

iii) Executive

iv) Pharmacist or Other Healthcare Professionals Involving in Procurement, Dispensation and Delivery of Drug and Medical Supply

v) Pharmaceutical Company and Retailer or Sale Representative of Drug and Medical Supply

vi) Medical Institution or Division

vii) Academy

b. Disclosure and Transparency

The Notification prevents conflicts of interest between physicians and pharmaceutical companies in general. Nevertheless, no disclosure obligations are mentioned in this Notification except in Clauses 2.4 and 7.8 as follows:

Clause 2.4 “The physicians and healthcare professionals who have authorization to dispense of drugs and medical supplies shall disclose that whether they have any benefits or conflicts of interests with the pharmaceutical or medical supply companies or not when they do public opinion about such products in the way of speech, written or other methods”.

Remark: Clause 3.7 and 4.4 also require the executive, pharmacist or other healthcare professionals involved in procurement, dispensation and delivery of drug and medical supplies to comply with Clause 2.4.

Clause 7.8 “The academy shall set out the policy for their lecturers or staffs to disclose that whether they have any benefits or conflicts of interests with the pharmaceutical or medical supply companies or not when they do public opinion about such products in the way of speech, written or other methods.”

It is clear from this that the disclosure obligations stated in the Notification are too narrow and are not sufficient to create transparency between the relevant people.

c. Enforcement

The Notification is considered as secondary law issued by virtue of Clause 16 of the Regulations of the Ministry of Public Health on Management of Drugs and Medical Supplies of Divisions under the Ministry of Public Health B.E. 2557. However, both of them do not include any sanctions or punishment if there is a failure to comply with the Notification.

4.3.3 Code of Conduct for Drug Sales Promotion in Thailand

a. General Information

The Code of Conduct for Drug Sales Promotion in Thailand (hereinafter referred to as Code of Conduct) was written by the Committee of Strategic Plan for Encouragement of Ethical Practice and Stop Unethical Drug Sale Promotion appointed by the Subcommittee of Encouragement of Rational Drug Use. The Code of Conduct has been approved by National Drug System Development Commission since 9 August 2012.

The purpose of the Code of Conduct is to be used as a standard and guideline for all related sectors to apply or expand, and to encourage good governance in all

medical institutions and for the physicians, healthcare professionals, executives, pharmacists, medical institutions or other divisions, pharmaceutical companies, retailers and lecturers or students in medical academy. The main purpose of the Code of Conduct is to establish standard practices for drug sale promotion across various stakeholders.

The Code of Conduct is divided into 7 principles as follows:

i) Definition

ii) Physician and Healthcare Professional

iii) Executive

iv) Pharmacist

v) Pharmaceutical Company and Retailer of Drug

vi) Medical Institution, Pharmacy Institution or Division

vii) Academy

b. Disclosure and Transparency

Similarly to the Notification, the Code of Conduct prevents conflicts of interest between physicians or healthcare professionals and pharmaceutical companies in general by laying down an anti-gift rule among said people. Nevertheless, there are no disclosure obligations mentioned in this Code of Conduct except in Clause 2.4 and 6.3 as follows:

Clause 2.4 “The physicians and healthcare professionals who have authorization to dispense drugs and medical supplies shall disclose whether they have any benefits or conflicts of interests with the pharmaceutical or medical supply companies or not when they give a public opinion about such products for academic purposes in the way of speech, written or other methods.”

Clause 6.3 “In the case of medical institutions, pharmacy institutions or any divisions that hold a meeting supported by the pharmaceutical companies in the way

of a budget, providing a lecturer or academic information, the said institutions shall disclose to the attendants about that support."

It is obvious to see that the disclosure obligations stated in the Code of Conduct are too narrow and do not differ from the Notification.

c. Enforcement

The Code of Conduct is not considered as law since it has been issue for being a minimum standard and guideline for involved sectors in Thailand. Moreover, it does not include any sanctions or punishment if there is a failure to comply with the Code of Conduct.

4.3.4 Code of Practices 9th Edition, 2012 of Pharmaceutical Research & Manufacturers Association

a. General Information

In order to institute best practice for the private business sector, the Pharmaceutical Research & Manufacturers Association (hereinafter referred to as PReMA) issued Code of Practice 9TH Edition, 2012 (hereinafter referred to as PReMA Code) effective from 1 October 2012 in compliance with 2012 International Federation of Pharmaceutical Manufacturers & Associations Code of Practice issued by the International Federation of Pharmaceutical Manufacturers & Associations (hereinafter referred to as IFPMA) to set out high ethical standards for the Thai pharmaceutical industry.

PReMA is a non-profit organization with members who are leading companies in the research and development of new drugs to combat diseases that are untreatable and to improve on existing treatments. The key feature of the PReMA Code is that all members, comprising ordinary members, associate members and honorary members voluntarily accept to observe and adhere to the provisions of the PReMA Code as a condition of their membership with the PReMA. The PReMA Code covers a wide

range of interactions with healthcare professionals, medical institutions and patient organizations, and the promotion of pharmaceutical products. This can be divided into 19 principles as follows:

i) Scope and Definition;

ii) Principles;

iii) General Provision Applicable to All Promotional Practices;

iv) Pre-Approval Communications;

v) Printed Promotional Material, including Advertisements;

vi) Electronic Material, Audiovisuals, including Digital Media;

vii) Interactions with Healthcare Professionals;

viii) Customary Gifts, Promotional Aids, Medical Utilities;

ix) Samples;

x) Clinical Research and Transparency;

xi) Market Research;

xii) Interactions with Patient/Patient Organization;

xiii) Promotion to Non-Healthcare Professionals;

xiv) Company Procedures and Responsibilities;

xv) Medical Representatives;

xvi) Administration;

xvii) Complaint Procedure;

xviii) Sanctions; and

xix) Operative Date

b. Disclosure and Transparency

Similarly to the Notification and the Code of Conduct, the PReMA Code prevents conflicts of interest between physicians or healthcare professionals and pharmaceutical companies in general by laying down an anti-gift rule among said people. Nevertheless, there are no disclosure obligations mentioned in this PReMA Code except in Clause 10.1 as follows:

"Companies are committed to the transparency of clinical trials which they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and others. Such disclosure, however, must maintain protections for individual privacy, intellectual property and contract rights as well as conform to legislation and current national practices in patent law. Companies disclose clinical trial information as set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Database (2009) and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010) issued by the IFPMA, the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA)."

c. Enforcement

An enforcement of the PReMA Code is not very effective because it is voluntarily binding only for PReMA members –most of these are manufacturers, traders and importers of medicine in the private sector.

In addition, the PReMA Code is considered as self-regulation, and the Thai government authorities such as FDA do not have the power to give punishment or sanction if there is a failure to comply with. In case of a violation of the PReMA Code, a complaint can be submitted in writing to the PReMA CEO. Upon the decision of the Code of Practice Committee, the PReMA CEO shall apply one or more of the

following punishments to the company who was found to be in breach of the PReMA Code.

i) Refer the complaint to the IFPMA

ii) Refer the complaint and the Code of Practice Committee's finding to the headquarters or regional office of the offending company

iii) Suspend the offending company's membership for not more than 3 years

iv) Revoke the PReMA membership of the offending company

v) Issue a fine

4.3.5 Roles and Responsibilities of the Ombudsman on Code of Conduct

Over the last few years, the principle of good governance has become a big issue in Thailand, and most Thai people have started to realize that every organization, both in the public and private sectors including their staffs should perform their duties with good morals.

Most of the laws concentrate on conditions and on determining the nature of the offence, and focus on punishment or repressive measures after a fault occurs. In contrast, the code of conduct (or code of ethics or code of practices) has different characteristics. It is applied only to a particular profession, and pays attention to guidance in the practice of the profession to maintain the dignity of the profession that is worthy of the faith from the public. This is detailed differently according to each professional area and is also more subtle and delicate than the laws. Therefore, leading organizations either government agencies or the business sector have started to draft their own codes of conduct to encourage good governance within their organizations especially in professional councils.

According to Sections 36 to 39, Chapter 4 of Organic Act on Ombudsman B.E. 2552,[70] the ombudsman has the power and duty to support and examine the code

[70] The Organic Act on Ombudsman B.E. 2552
Section 36

of conduct. At the same time, government agencies, state agencies, state enterprises

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"In conducting the proceedings in relation to ethics of a person holding political position and State official, the Ombudsmen shall have the powers and duties as follows:

(1) to give advice or recommendation for the making of ethical standard or improving the code of ethics of each kind of persons holding political positions and State officials;

(2) to enhance ethical consciousness of a person holding political position and State official;

(3) to report any conduct which is in violation of the code of ethics so as to make the person responsible for the enforcement of the code of ethics to make enforcement thereof. For the execution of this Chapter, a government agency, State agency, State enterprise and local government organisation shall submitted their established code of ethics to the Office of the Ombudsmen within sixty days as from the establishment date thereof. 10"

Section 37

"If there is a complaint that a person holding political position violates or fails to comply with the ethical standard under the code of ethics, the Ombudsmen shall consider and inquire into fact. In this regard, the provisions of Chapter II Complaint and Inquiry shall apply mutatis mutandis.

If it appears, upon the completion of consideration and inquiry under paragraph one, that a person holding political position violates or fails to comply with the ethical standard under the code of ethics, the Ombudsmen shall report the National Assembly, Council of Ministers or related local assembly, as the case may be, so as to make enforcement of the code of ethics. If such conduct is serious offense, the Ombudsmen shall submit such matter to the National Counter Corruption Commission for consideration. In this case, such conduct is deemed to be a cause for removal from office under the Constitution."

Section 38

"If there is a complaint that a State official violates or fails to comply with the ethical standard under the code of ethics, the Ombudsmen shall submit such matter to the person responsible for the enforcement of the code of ethics to make enforcement thereof."

Section 39

"If the Ombudsmen is of opinion that any violation or failure to comply with the ethical standard is serious or there is a reasonable ground to believe that the proceedings conducted by the responsible person may be unfair, the Ombudsmen may conduct inquiry and disclose the result thereof to the public. An inquiry and the disclosure of the result thereof to the public under paragraph one shall be in accordance with the regulation as determined by the President of the Ombudsmen which having standard or having security of not lower than the standard or security under section 31."

and local government organizations have a responsibility to submit their codes of conduct to the Office of the Ombudsmen within sixty days as from the establishment date thereof, and if there is a complaint with regard to failure to comply with criteria of the code of conduct, the ombudsman has the power to refer such a matter to the person who is responsible for enforcement of such code of conduct to make enforcement thereof.

CHAPTER 5
ANALYSIS

5.1 Analysis of Transparency Measures to Control Financial Interactions between Physicians or Healthcare Professionals and Pharmaceutical Companies in the USA and Australia

This part will concentrate on the existing measures applied in USA and Australia. The transparency measures in both countries have the same objective which is to enhance and increase transparency in financial activities between physicians or healthcare professionals and pharmaceutical companies. In order to achieve this goal, the two main principles of disclosure of obligations and principle of preventing a conflict of interest, are adopted as key factors in their measures.

First of all, the principle of disclosure obligation has the main intention of leveraging transparency in reciprocation or interest that physicians or healthcare professionals would obtain during the commercial interactions. The measures being executed in both countries have equally defined the duties of the physician or healthcare professionals and the pharmaceutical companies. They stipulate the obligation on pharmaceutical companies to disclose their financial activities and, at the same time, assure rights to the physicians or healthcare professional s to examine, correct or appeal if the declared information which relates to them is not wrong.[71] In this aspect, it can guarantee that the disclosed financial information is justified and verifiable. Moreover, the governing authorities and each party could examine and recheck the consistency of submitted information.

Then, in order to maintain the principle of prevention of conflicts of interest, the provisions stated in the Australia Code of Conduct[72] have clearly identified what activities are allowed and those that are not allowed by considering their appropriateness and practicality. The Australian measure has directed the

[71] Section 1128G(c)(1)(c)(ix) of the Patient Protection and Affordable Care Act and Section 41.3.3 of Medicine Australia's Code of Conduct Edition 18.

[72] Section 9 of Medicine Australia's Code of Conduct Edition 18 "Relationships with Healthcare Professionals".

pharmaceutical companies to follow the identified compliance. On the other hand, the PPACA is not clearly identified in that area, only which activities could be exempted from disclosure. For example, product samples that are not intended to be sold but are solely for patient's use or educational materials that directly benefit patients would not be financially disclosed. However, both countries do not entirely prohibit interactions between physicians or healthcare professionals since they are aware of the great opportunities for physicians or healthcare professionals to advance their research. This would benefit patients and the nation, and enhance their career paths if support from pharmaceutical companies in the form of research and development funds or appliances for further medical studies were granted without hidden conditions to them – especially as governmental support might not be substantial in certain areas of study.

5.2 Analysis of Situations in Thailand

This part will analyze how much importance of transparency measure is needed in Thailand including what are the main features of such measure that are suitable for our country.

5.2.1 Necessity of Transparency Measures to Control Financial Interactions between Physicians or Healthcare Professionals and Pharmaceutical Companies in Thailand

Before touching on considerations about acquiring the measures executed in other countries, it is first necessary to analyze the level of need for these in Thailand. In general, in Thailand, consumers have convenient access to medicines through pharmacies in case they have some small illness which does not require serious diagnosis. Consumers generally receive a service from drugstores by telling the pharmacist about their symptoms, getting advice and then deciding which medicines they should consume. However, if the symptoms are severe, patients would choose to get treatment or diagnosis from physicians. Consequently, physicians or healthcare professionals are believed to be trusted by patients for recommendations or treatments

because they are qualified to do this. Those personal qualifications are directly associated with medical knowledge and skills which need to be certified by medical institutes or public healthcare departments such as the Medical Council of Thailand or the Pharmacy Council of Thailand. In other words, patients place their trust on qualified physicians to recommend, diagnose, treat and provide efficient and necessary medications for the symptoms that they are suffering from. This trust brings undeniable duties to physicians or healthcare professionals in performing their work with honesty, care and morality, by putting their patients' interests before anything.

In business terms, although medicines have been manufactured and sold for commercial purposes, similarly to other consumer goods, they are different from other products due to three particularities[73]:

(1) Medicines can be both advantageous and disadvantageous to consumers. If the latter, then the consumer's life, health and hygiene will be directly affected.

(2) Medicine is not freely available for consumers to purchase as are other consumer goods because dispensing medicine requires knowledge and skills of well-trained experts, subject to efficient diagnosis. Consequently, patients are not in the position to select their own treatment but instead place their trust on physicians or healthcare professionals to perform this role for them.

(3) Medicine is one of the fundamental essentials which concern state budgets and expenses to support people's medical expenses through governmental projects, for example, Social Security scheme or Universal Healthcare scheme.

After having reviewed these particularities of medicines, the decision to recommend or prescribe them by physicians and healthcare professionals needs to be made, unavoidably, under the following three conditions[74]:

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[73] นนทวัชร์ นวตระกูลพิสุทธิ์, "*French Sunshine Act: กฎหมายเพื่อความโปร่งใสในความเกี่ยวพันระหว่างแพทย์หรือผู้ประกอบวิชาชีพด้านสาธารณสุขกับบริษัทยา*", 43 (1), **วารสารนิติศาสตร์มหาวิทยาลัยธรรมศาสตร์** , 67, 92 (มีนาคม 2557) (Nontawat Nawatrakulpisut, "*French Sunshine Act: Bill on Promoting Transparency in Interactions between Physicians or Healthcare Professionals and Pharmaceutical Companies*", 43(1), **Thammasat Law Journal**, 67, 92 (March 2011)).

[74] *Id*. at 92.

(1) The decision needs to be made by referring to the accuracy and completeness of medicine indications and possible side-effects.

(2) The decision requires considerations on patients' personal information individually such as disease severity, age and gender.

(3) The decision needs to be made, truly without bias or any kind of influential factors such as persuasion or anything else.

After having reviewed the above and the situations concerning marketing activities on pharmaceutical products in Thailand, it can be said that the situation in Thailand is similar to the USA and Australia. From statistics, during 2006-2009, the money spent on drug advertisements reached 25,000 million Baht per year, but this only account for direct advertisements to consumers. If the advertisements to physicians and healthcare professionals were included, the value of the expense would be many times higher[75].

Speaking of direct marketing activities towards physicians and healthcare professionals, the approaches and steps are not significantly different from the ones performed in the USA and Australia. The approach is to build well-grounded relationships with physicians and healthcare professionals through the medical representatives by offering presents, complementary meals, academic seminar sponsorship or travel outside the country to encourage physicians and healthcare professionals to get acquainted with the medical representatives, thus creating conflicts of interest. Consequently, the National Health Assembly meeting reached the resolution to "Stop Unethical Drug Sale Promotion to Decrease Economic Loss and for the Sake of Patient's Health" matter, in order to drive associated sectors to learn the measures which are executed outside the countries. Therefore, all associated parties would be able to suggest adaptations of measures used abroad to Thailand's context by considering efficiency and practicality of the adapted measures, with the ultimate objective to develop and improve the situation in Thailand.

From all the above, if prescriptions from physicians and healthcare professionals are transparent without any conflicts of interest, and monitoring and

[75] Resolution of National Health Assembly No. 2, *supra* note 28, at 1.

controlling was done efficiently, the ultimate interest served would be those of patients, as consumers, and the state.

5.2.2 Transparency Measures to Control Financial Interactions between Physicians or Healthcare Professionals and Pharmaceutical Companies in Thailand

5.2.2.1 Transparency Measures for Thailand

As mention in Chapter 2, the international standard of the WHO defines transparency as openness in sharing information and that information is publicly and easily accessible for those who need it.[76] Furthermore, Transparency International also defines transparency to be about shedding light on rules, plans, processes and actions.[77]

After close reviewing of situations in Thailand, any transparency measure that will be proper and sufficient to control unhealthy activities among people in the healthcare industry in Thailand must be able to achieve the following purposes:

(1) Encourage and secure the confidence and mutual respect between public and medical practitioners;

(2) Provide openness to public examination which will reduce the perception and risk that any transactions from the pharmaceutical companies to the medical practitioners compromise the independence of their decision-making;

(3) Facilitate consumers to make well informed decisions about their healthcare options and make them take into account their healthcare providers' involvement with business enterprises; and

(4) Cover all monetary transactions and other transfers of value between a company and an individual healthcare professional.

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[76] Guitelle, Jillian & Eshetu, *supra* note 32, at 7.
[77] Transparency International, *supra* note 33.

After considering the four key purposes that the transparency measure should be able to reach, principles of disclosure obligation of financial transactions between the physicians or healthcare professionals and the pharmaceutical companies shall be a crucial tool to accomplish such purposes since its main function could provide openness to the public, thus preventing or reducing conflicts of interest among said people.

5.2.2.2 Loophole in the Principle of Disclosure Obligation

After examining the Drug Act B.E. 2510 and comparing with models used in USA and Australia, it has been found that the current law controlling the drug system in Thailand does not include principle of disclosure obligation in its contents. Sections 88 to 90 Bis under Chapter 11[78] states about drug advertising only in terms of general principles which do not cover issues of concern about improper financial transactions among people in the healthcare sector.

Since the current Drug Act has been in force for a very long time, some of the provisions no longer apply to current circumstances and it is lacking in areas including issues of inappropriate action related to collaborations between physicians or healthcare professionals and pharmaceutical companies. There have been numerous endeavors to modify the Drug Act to be more modern and consistent with continuous circumstances. Eventually, the two draft drug acts were drafted. However, neither of these incorporates disclosure concepts into their drafts.

Furthermore, even though provisions in the Medical Council Regulations on Medical Ethics Preservation B.E. 2519, the Notification of the Ministry of Public Health on the Code of Conduct for the Procurement and Sale Promotion of Drugs and Medical Supplies B.E. 2557, the Code of Conduct for Drug Sales Promotion in Thailand and the Code of Practice 9th Edition, 2012 of Pharmaceutical Research & Manufacturers Association include principles of prevention of conflicts of interest by

[78] The Drug Act B.E. 2510, *supra* note 61.

prohibiting gifting, it is found that the practice of unethical drug sale promotion through various complicated strategies is still going on in Thai culture[79].

After taking the practices applied overseas into consideration along with the resolution of the National Health Assembly to stop unethical drug sale promotion, it is undeniable that having transparency measures to control financial interactions between physicians or healthcare professionals and the pharmaceutical companies in Thailand is necessary and important. However, transparency measures are not intended to detect or specify that every relationship among said people must be inappropriate. However, if they are confident that their interactions are clean, then there is no reason not to disclose such information.

[79] Resolution of National Health Assembly No. 2, *supra* note 28, at 2.

CHAPTER 6
CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

It is clear that, by analyzing all matters involved with how to control transparency in financial interactions between physicians or healthcare professionals and the pharmaceutical companies in USA and Australia, the following summary can be given. The PPACA and the Australia Code of Conduct do not strictly prohibit financial interactions between physicians or healthcare professionals and the pharmaceutical companies and nor do they restrict sale promotions and advertising directed at the former. However, both countries also include the principle of disclosure obligation into their laws and codes of conduct respectively.

The PPACA requires applicable manufacturer who make a payment or other transfer of value to the covered recipients to submit a report to the Secretary of the Department of Health and Human Services with the main purpose of providing enhanced transparency into the relationships between physicians or healthcare professionals and commercial enterprises.

In addition to the PPACA requirement, the Australia Code of Conduct also includes the principle of disclosure obligation under Clause 41 “Transparency Reporting” by requiring the member company to report payment or other transfer of value that is made to physicians or healthcare professionals who are registered to practice in Australia.

It can be said that disclosure of the financial relationships between the pharmaceutical industry and healthcare providers is not intended to signify an improper relationship. Collaborations among the medical product industries, physicians and healthcare professionals can contribute to the design and delivery of life-saving drugs, devices and medical supplies. However, these relationships might influence research, and the discretion or decision-making of the physicians or healthcare professionals in ways that compromise them. This can also potentially cause increased healthcare costs. Whilst disclosure alone is not sufficient to separate

acceptable financial support and those that may raise conflicts of interest, disclosure and transparency have the objective of shedding light on the nature and extent of the relationships that exist and discourage development of inappropriate relationships.

In Thailand, it is clear that the Drug Act as the existing and most important law to control the drug system does not have a principle of disclosure obligation. Even the Draft Drug Act State Version and Public Draft Drug Act do not include this principle either.

6.2 Recommendations

It was a missed opportunity not to have developed a more appropriate transparency measure in Thailand, and promote such a measure by amending the existing law to tackle with such concerning issues. The process of creating a transparency measure should include a policy aspect and legal aspect in its strategy.

6.2.1 Policy Aspect

Even though the National Drug Policy B.E. 2554 and National Drug System Development Strategy B.E. 2555-2559[80] as the current national drug policy includes a strategic plan to encourage ethical practices and stop unethical drug sale promotion, it would be more progressive to incorporate the concept of transparency to control financial interactions between physicians or healthcare professionals and pharmaceutical companies, assign the related authorities to study all existing measures that there are and compare them with the foreign laws to point out loopholes in the current policies, laws and regulations to accomplish the purpose in a practical way.

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[80] นโยบายแห่งชาติด้านยา พ.ศ. 2554 และยุทธศาสตร์การพัฒนาระบบยาแห่งชาติ พ.ศ. 2555-2559 โดยคณะกรรมการระบบยาแห่งชาติ (National Drug Policy B.E. 2554 and National Drug System Development Strategy B.E. 2555-2559 by National Drug System Development Committee)

6.2.2 Legal Aspect

a. Amendment the Drug Act B.E. 2510

In terms of the legal aspect, the author would like to recommend the model law applied in the USA since it includes principle of disclosure obligation into its legislative law so it has a stronger enforcement than the self-regulation model of the Australia Code of Conduct which has power over its members only. In addition, after considering current self-regulation in Thailand, the PReMA Code, it was found that the problem of unethical drug sale promotion is still going on in Thailand. Therefore, encouraging the insertion of a transparency measure into the legislation would be more effective.

Furthermore, there should be amendments to the existing Drug Act B.E. 2510 by adding a new chapter of procedure for disclosure obligation to control financial interactions between physicians or healthcare professionals and pharmaceutical companies since it would be better to include all provisions related to the drug system into one statute to make it easier to study and comply with it.

b. Structure of the Laws

The disclosure obligation relating to all transactions of financial interactions between physicians or healthcare professionals must be included in the law by specifying who holds the disclosure obligation. The main contents of the law should include the following points to make the law more effective in practice.

i) Governing Authority

The Food and Drug Administration, Ministry of Public Health should be assigned as the direct authority to control and monitor the subject including collecting information on the financial interactions that are reported since the FDA is the agency that controls the drug system in Thailand.

ii) Terms and Definitions

The definitions of some importance words such as pharmaceutical company, physician, healthcare professional, medical representative, financial interaction, sale

promotion and advertising should be specified clearly. Definition of those words should reach international standard by comparing them with the definitions given by others organizations. For example, the author would like to give the meaning of sale promotion given by the WHO as:

"Promotion is all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs."[81]

To avoid interpretation and to act as guidelines for related persons to comply with each situation, the law must define clearly enough what kinds of actions are considered financial interactions, sale promotion or advertising by giving examples such as offering of gifts, payment, transfer of value or being sponsored for a seminar.

iii) medical representative

medical representative should be defined as "a person who works for pharmaceutical company or its subsidiary or distributor, and he or she is a key connection between the physicians or healthcare professionals and the pharmaceutical companies with the main purpose to increase awareness of brand and use of company's product" since it is possible that the pharmaceutical company may set up its subsidiary or hire distributor to distribute its products.

iv) Which party has a disclosure obligation

It should specify who has the disclosure obligation when physicians or healthcare professions have financial interactions with pharmaceutical companies, and should authorize another party to have the right to examine and correct the submitted information.

v) The kinds of transactions to be disclosed

The transactions or interactions that are required to be reported should cover all practices or marketing strategies adopted by the pharmaceutical companies when approaching physicians or healthcare professionals such as consulting fees,

[81] Ethical Criteria for Medicinal Drug Promotion, World Health Organization, 5 (1988).

compensation for services other than consulting, honoraria, gift, entertainment, meals, travel, research etc.

vi) Penalty

To make the law be efficient measure, the FDA must have the power to issue monetary sanctions to parties who fail to report each payment or transfer of value. If the person who fails to comply with the law is a juristic person, the representatives of such a company should be subject to criminal punishments as well.

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